# ETHICS APPROVALS AND RELATED DOCUMENTS

## DELIVERABLE 9.3
## DELIVERABLE 9.5

SCALING UP PSYCHOLOGICAL INTERVENTIONS WITH SYRIAN REFUGEES
STRENGTHS

This project has received funding from the European Union's Horizon 2020 Research and Innovation programme Societal Challenges under Grant Agreement No 733337.

# About this document

**Work Package in charge:** WP9 Ethics Requirements
**Delivery date of this deliverable: September 30, 2017**
**Dissemination level: CO (only for members of the Consortium including the Commission Services).**

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

**Funding organisation:** EU Horizon2020 – Research and Innovation Action

**EU Project number:** 733337

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Universität Zürich, Monique Pfaltz, Naser Morina, Ulrich Schnyder, Matthis Schick



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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 |
| IMC | International Medical Corps UK LBG |
| ISU | İstanbul Sehir Universitesi |
| KIT | Royal Tropical Institute |
| LSHTM | London School of Hygiene and Tropical Medicine |
| PM+ | Problem Management Plus |
| RCT | Randomized Control Trial |
| 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 research ethics procedures

This document provides an overview of all steps that have been taken to gain ethics approval for the STRENGTHS studies across all partners and project countries.

STRENGTHS is a multi-country project, that involves both studies in healthy volunteers (WP2 and 3), surveys in Syrian refugees (WP2) and studies evaluating the effectiveness of the implementation of the WHO scalable programmes to reduce psychological distress in Syrian refugees across Europe (the Netherlands, Turkey, Switzerland, Germany) and countries in the Middle East and north Africa hosting Syrian refugees (Jordan, Lebanon, Egypt).
Below we briefly describe the STRENGTHS studies that involve submission to ethics committees. We distinguish between (bio)medical research studies and non-medical research studies.

## 1.1. STRENGTHS medical research studies

Medical research studies[1] are studies in human participants that involve invasive assessments or imposing an intervention on participants. Securing medical ethics approval involves preparing a detailed study protocol, that includes a detailed description of the procedures, and also includes all measures, participant information leaflets, and informed consent forms. These documents must be submitted for consideration, comment, guidance and approval to the concerned independent research ethics committee before the study begins.[1] The committee must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards.[1] After submission of the study protocol to the ethics committee, it may take up to 4 months in some countries (e.g. Switzerland) after submission to receive formal ethics approval.

STRENGTHS consists of 10 medical research studies involving Syrian refugees include both quantitative as well as qualitative data collection:

- Within WP2, two population-based surveys in Syrian refugees will be carried out by LSHTM (one in Turkey, one in Germany). These studies have been approved by the ethics committee of LSHTM (United Kingdom). The survey in Turkey has been approved locally in Turkey. The survey in Germany is also submitted for local approval in Leipzig, Germany.
- Within WP4, 5 and 6 eight RCTs will be carried out to evaluate the implementation of the low intensity scalable WHO programmes in Syrian refugees with increased levels of psychologist distress. One trial and one implementation study evaluating the implementation of the adult PM+ group intervention is led by UNSW in collaboration with IMC (WP4) and will take place in Jordan. This study has been approved by the ethics review board of UNSW.
  One trial in Lebanon on the implementation of the young adolescent adaptation of PM+ will be lead by WCH (WP4) and has been submitted for ethics approval at St. Joseph University in Lebanon.
- Two trials on individual PM+ in adult refugees in the Netherlands and Switzerland (WP5) are conducted by VUA and UZH, respectively, and have been approved by the ethics review boards of the VU Medical Center (the Netherlands) and of the University Hospital Zürich (Switzerland), respectively. One trial evaluating the group version of PM+ will be carried out in Turkey (WP5), and has been approved by the ISU ethics review board.

[1] World Medical Organisation. *Declaration of Helsinki.* 2013.

- Finally, three RCTs will be carried out by FUB in Germany, Egypt and Sweden (WP6). The protocols for the three trials have been approved by the ethics review committee of FUB, where all data will be gathered and stored.

Note that in WP1 (Management and Overall Coordination), WP7 (Economic and Implementation Evaluation) and WP8 (Synthesis and Dissemination), no primary data are collected. Therefore, these WPs did not include studies that needed to be submitted for ethics review.

## 1.2. STRENGTHS non-medical research studies

In addition to studies in Syrian refugees with increased levels of distress, the STRENGTHS project also includes research interviews with healthy volunteers. These volunteers will be stakeholders in selected participating countries, such as healthy Syrian volunteers, mental health professionals, policy makers and other stakeholders. They will be asked to participate in questionnaires and interviews on cultural adaptation of the intervention package, on mental health stigma and on general access to health services for Syrian refugees.
Since non-medical research studies are conducted in healthy non-patient samples, and do not include invasive measurements, ethics approval by an accredited ethics committee is usually not required for non-medical research studies. However, most countries and institutions require that studies in healthy volunteers are submitted for ethics review to an ethics committee, to the national government for approval, or require a waiver for ethics review, depending on the country where the study is carried out. Informed consent will be asked and all data collected will be kept confidential in line with the data management procedures outlined in the Data Management Plan and Protection Plan (Deliverable 1.1).

STRENGTHS consists of the following two non-medical research studies:

- Qualitative interviews in key stakeholders (healthy volunteers) on implementation of the scalable WHO programmes across the project countries (WP2). Stakeholders such as health care professionals and policy makers in project countries (Jordan, Lebanon, the Netherlands, Turkey, Switzerland, Germany, Egypt and Sweden), will be interviewed to identify barriers and levers to implementation of the scalable WHO programmes across the project countries.
- Qualitative interviews in Syrian refugees and key informants in the Syrian refugee communities in all project countries (Jordan, Lebanon, the Netherlands, Turkey, Switzerland, Germany, Egypt and Sweden), to inform cultural adaptation of the scalable WHO programmes and training programmes (WP3).

Since the qualitative interviews for WP2 and WP3 took place in the period of May to August 2017, and partly overlapped in the sense that some participants were asked both health systems questions (WP2) as well as cultural adaptation question (WP3), STRENGTHs partners have combined the protocols of the two studies and ethics approval has been applied for the combined protocols.

## 1.3. Update status ethics approvals September 30, 2017

As per September 30, 2017, ethics approval by nationally accredited ethics review committees in all countries has been obtained for all STRENGTHS studies that are planned during STRENGTHS' lifetime. However, two secondary approvals are still underway:

- For the community-level survey in Syrian refugees located in Germany that will be carried out in WP2, ethics approval has been granted by the Observational / Interventions Research Ethics Committee of the London School of hygiene and Tropical Medicine. However, local approval of the Ethics Committee of Leipzig University was applied for in July 2017. Feedback was sent only in the week of 27 September, proposing that some very minor queries were raised by the Leipzig University Ethics Committee. These required responses of clarification only. These issues have been responded to and therefore, we expect that we will receive ethics approval shortly (early October 2017).
- For the study in WP4 in Jordan lead by the University of New South Wales (Australia), ethical approval has been granted by the University of New South Wales Human Research Ethics Committee. Local approval to conduct the research in Jordan will be obtained from the Jordanian Ministry of Health, which is currently being prepared. We expect to receive this approval by December 2017.

# 2. Overview of approvals and other documents

## 2.1. WP2 Health Systems Evaluation

| **Study 1** | **Rapid assessments of health systems responsiveness (T2.1)** |
|---|---|
| Partners involved: | LSHTM, KIT, IMC, WCH, VUA,ISU, UZH, FUB, |
| Data collected by: | 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: | **LSHTM:** Ethics approval submitted to London School of Hygiene and Tropical Medicine, (dd. September 14 2017).<br>**IMC:** Ministry of Health, Jordan, (dd. June 11, 2017).<br>**WCH:** St Joseph University, Beirut, Lebanon, (dd. March 24, 2017).<br>**VUA:** Waiver from VU Medical Center Medical Ethics Committee (dd. April 20, 2017).<br>**ISU:** Approval from ISU Research Ethics Committee (dd. April 12, 2017), The Immigration Authority of Turkey (dd. March 29, 2017)<br>**UZH:** No objection waiver by Ethics Committee of Canton Zurich KEK-ZH REQ-2017-00404 (dd. June 02, 2017).<br>**FUB:** Ethics committee of the Department of Education and Psychology at Freie Universität Berlin (dd. June 12, 2017). |

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**www.lshtm.ac.uk**

**Observational / Interventions Research Ethics Committee**

Professor Bayard Roberts
Professor Health Systems and Policy
Department of Health Services Research and Policy (HSRP)
Public Health and Policy (PHP)
LSHTM

14 September 2017

Dear Bayard

**Study Title:** STRENGTHS QUALITATIVE RESEARCH PROTOCOL FOR SYRIAN REFUGEE MENTAL HEALTH

**LSHTM Ethics Ref:** 14330

Thank you for responding to the Observational Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

**Conditions of the favourable opinion**

Approval is dependent on local ethical approval having been received, where relevant.

**Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

| Document Type | File Name | Date | Version |
|---|---|---|---|
| Protocol / Proposal | Qualitative Research Protocol_Final | 30/06/2017 | 1 |
| Protocol / Proposal | Topic Guides Interviews | 30/06/2017 | 1 |
| Investigator CV | Bayard Roberts CV June 2017 long | 30/06/2017 | 1 |
| Investigator CV | Egbert Sondorp CV 2017 | 30/06/2017 | 1 |
| Investigator CV | CV- Daniela Fuhr short | 30/06/2017 | 1 |
| Investigator CV | CV A Woodward June 2017 | 30/06/2017 | 1 |
| Advertisements | STRENGTHS WP2 qualitative recruitment | 30/06/2017 | 1 |
| Covering Letter | Qualitative research STRENGTHS ethics response letter Bayard Roberts 22 Aug 2017 | 22/08/2017 | 1 |
| Information Sheet | Revised Information Sheets and Consent Form revised 22 Aug 2017 | 22/08/2017 | 2 |

**After ethical review**

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

**Professor John DH Porter**
**Chair**

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

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**Improving health worldwide**

وزارة الصحة

نهضة

الرقم تطوير/ص/٤٤٢/١

التاريخ

الموافق ٢٠١٧/٦/١٨

**مدير صحة محافظة العاصمة**
**مدير صحة محافظة ا لزرقاء**
**مدير صحة محافظة المفـرق**
**مدير صحة محافظة الكـــرك**
**مدير صحة محافظة اربـــد**

تحية طيبة وبعد ،،،

أرفـق طيـاً صـورة عن كتـــاب مدير مستشفى البشير / رئيس لجنة أخلاقيـات البحث العلمي رقـم م ب أ / لجنة أخلاقيات /٨٢٥٥ تاريـخ ٢٠١٧/٦/١٣ بخصـــوص طلب الموافقة للهيئة الطبية الدولية على تنفيذ دراسة بعنوان :-

**( تقييم خدمات الصحة النفسية التي تقدمها الهيئة الطبية الدولية )**

وذلك من خلال المراكز الصحية المستضيفة للعيادات النفسية وتشمل الدراسة اجراء مقابلات مع مدراء المراكز الصحية وضباط ارتباط الصحة النفسية في مديريات الصحة في عمان ، الزرقاء ، المفرق ، الكرك ، اربد )

أرجو التكرم بالإيعاز لمن يلزم تسهيل مهمة اجراء البحث أعلاه .

وتفضلوا بقبول فائق الاحترام ،،،

**مدير تطوير الموارد البشرية المكلف**

**الدكتورة سوسن جباعته**

٢٠١٧/٦/١٥

وزارة الصحة

الرقم ..... م ب ا / لجنة اخلاقيات / ٨٢٥٥

التاريخ .....

الموافق ..... ١٤/٦/٢٠١٧

مدير تطوير الموارد البشرية

**تحيه طيبه وبعد ،،،**

**اشاره لكتابكم رقم تطوير/خطط/**4196تاريخ2017/6/7بخصوص الدراسة المقدمة من قبل الهيئة الطبية الاردنية.

ارفق بطيه قرار لجنة اخلاقيات البحث العلمي والمتضمن الموافقة على إجراء الدراسة العائدة للهيئة المذكورة أعلاه .

للتكرم بالاطلاع واجراءاتكم لطفا .

**واقبلوا الاحترام**

**مدير مستشفى البشير/المكلف**

**الدكتور/عمار نعيم الشرفا**

ص ب

٥١٢٠ / ٢٨٠٧٧

الصيدلية

١٤/٦/٢٠١٧

بسم الله الرحمن الرحيم

وزارة الصحة

**CODE : MOH REC 170084**

الرقم .....

التاريخ .....

الموافق .....

## قرار لجنة اخلاقيات البحث العلمي

اجتمعت لجنة اخلاقيات البحث العلمي بتاريخ2017/6/11 لمناقشة الدراسة العلمية المقدمة من قبل الهيئة الطبية الاردنية.

**بعنوان:**

***تقييم خدمات الصحة النفسية التي تقدمها الهيئة الطبية الاردنية***

وقد قررت اللجنه بالاجماع الموافقه على اجراء البحث المشار اليه اعلاه.

وعليه تم التوقيع من قبل اعضاء اللجنه حسب الاصول .

| | | |
|---|---|---|
| **عضو اللجنه**<br>**المساعد للتمريض** | **عضو اللجنه**<br>**رئيس قسم الجراحة** | **عضو اللجنه**<br>**رئيس قسم الاشعة العلاجية** |
| **الدكتور/هاني القضاه** | **الدكتور/ فايز الحمود** | **الدكتور/ رسمي مبيضين** |
| **عضو اللجنه**<br>**رئيس قسم الاطفال** | **عضو اللجنه**<br>**رئيس قسم الباطني/المكلف** | **عضو اللجنه**<br>**رئيس قسم النساءلة والتوليد** |
| **الدكتوره/باسمه مرار** | **الدكتور/عباس منصور** | **الدكتور/عبدالمانع السليمات** |

**رئيس اللجنه /**
**مدير مستشفى البشير/المكلف**

**الدكتور/عمار نعيم الشرفا**

COMITÉ D'ÉTHIQUE

Beyrouth, le 24 mars 2017

Monsieur le Docteur Rabih EL-CHAMMAY
Service de psychiatrie -HDF

**Nos réf.** : USJ -2017-24

**Titre** : Formative research to inform the evoluation of the helping young adolescents cope intervention.

Cher Collègue,

Lors de sa réunion du 21 mars, le Comité a pris acte du protocole de l'étude et du formulaire de consentement.

Après en avoir délibéré, le Comité estime à l'unanimité que ce projet ne soulève aucune objection d'ordre éthique ; il vous notifie donc bien volontiers son accord et vous autorise à utiliser le formulaire proposé.

Avec tous mes vœux pour le succès de cette recherche, je vous prie de croire, Cher collègue, en l'assurance de mes sentiments dévoués.

UNIVERSITÉ SAINT-JOSEPH USJ comité d'éthique

Pr. Michel SCHEUER
Président



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| onderwerp | ons kenmerk | datum |
|---|---|---|
| niet-WMO advies | 2017.209 | 20 april 2017 |

Geachte mevrouw Sijbrandij,

Het Dagelijks Bestuur van de Medisch Ethische Toetsingscommissie VU medisch centrum heeft uw onderzoek **Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes** besproken in de vergadering van 20/04/2017.

Het onderzoek valt niet onder de reikwijdte van de Wet Medisch-wetenschappelijk Onderzoek met mensen (WMO).

Het oordeel is gebaseerd op de volgende documenten:

| Sectie | Onderwerp | Versie |
|---|---|---|
| A1 | aanbiedingsbrief | d.d. 5-4-2017 |
| A1 | commentaar METc | d.d. 20-4-2017 |
| B25 | privacyverklaring | getekend d d. 5-4-2017 |
| C1 | onderzoeksprotocol | versie 1 d d. 5-4-2017 |
| C1 | onderzoeksprotocol | bijlage: DIME module |
| E11 | informatiebrief | behandelaren d.d. versie 1 d.d. 5-4-2017 |
| E11 | informatiebrief | beleidsmakers versie 1 d.d. 5-4-2017 |
| E11 | informatiebrief | Syrische vluchtelingen FGD versie 1 d.d. 5-4-2017 |
| E11 | informatiebrief | Syrische vluchtelingen FL versie 1 d.d. 5-4-2017 |
| E11 | informatiebrief | Syrische vluchtelingen KI versie 1 d.d 5-4-2017 |
| E2 | toestemmingsverklaring | behandelaren versie 1 d.d. 5-4-2017 |
| E2 | toestemmingsverklaring | beleidsmakers versie 1 d.d. 5-4-2017 |
| E2 | toestemmingsverklaring | Syrische vluchtelingen FGD versie 1 d.d. 5-4-2017 |
| E2 | toestemmingsverklaring | Syrische vluchtelingen FL versie 1 d.d. 5-4-2017 |
| E2 | toestemmingsverklaring | Syrische vluchtelingen KI versie 1 d.d. 5-4-2017 |
| F1 | vragenlijst | behandelaren interview versie 1 d.d. 5-4-2017 |

| | | |
|---|---|---|
| F1 | vragenlijst | beleidsmaker interview versie 1 d.d. 5-4-2017 |
| F1 | vragenlijst | free list recording form versie 1 d.d. 5-4-2017 |
| F1 | vragenlijst | KI recording form versie 1 d.d. 5-4-2017 |
| F1 | vragenlijst | Syrische vluchtelingen FGD versie 1 d d 5-4-2017 |
| F1 | vragenlijst | Syrische vluchtelingen FL interviews versie 1 d.d. 5-4-2017 |
| F1 | vragenlijst | Syrische vluchtelingen KI interviews versie 1 d.d. 5-4-2017 |

Het Dagelijks Bestuur van de Medisch Ethische Toetsingscommissie VU medisch centrum wijst u erop dat hoewel het ingediende onderzoek niet onder de reikwijdte van de WMO valt, andere wet- en regelgeving (mogelijk) wel van toepassing is, waaronder:

- WGBO (Wet Geneeskundige BehandelingsOvereenkomst);
- WBP (Wet Bescherming Persoonsgegevens), zie www.cbpweb.nl;
- Code Goed Gedrag (Gedragscode gezondheidsonderzoek: gebruik medische gegevens in wetenschappelijk onderzoek), zie www.federa org;
- Code Goed Gebruik (Gedragscode Verantwoord omgaan met lichaamsmateriaal ten behoeve van wetenschappelijk onderzoek, 2011), zie www.federa.org;
- Biobanken: Reglement toetsing biobank VUmc, zie https://www.vumc.nl/afdelingen/METc/biobank/;
- WBO (Wet Bevolkings Onderzoek), zie http://www.vumc.nl/afdelingen/METc/wetgeving/wetbevolkingsonderzoek/.

To whom it may concern

We are pleased to confirm that the Medical Research Involving Human Subjects Act (WMO) does not apply to the above mentioned study and that an official approval of this study by our committee is not required.

The Medical Ethics Review Committee of VU University Medical Center is registered with the US Office for Human Research Protections (OHRP) as IRB00002991. The FWA number assigned to VU University Medical Center is FWA00017598.

Met vriendelijke groet,
namens de Medisch Ethische Toetsingscommissie VU medisch centrum,

p.o.

prof. dr. J.A. Rauwerda, voorzitter

c.c.: A.M. de Graaff / a.m.de.graaff@vu.nl

İSTANBUL ŞEHİR ÜNİVERSİTESİ

**ARAŞTIRMA ETİK KURUL KARARLARI**
**(Research Ethics Committee Decision)**

| | |
|---|---|
| **Toplantı Tarihi** | : 12.04.2017 |
| **Toplantı Sayısı** | : 10/2017 |
| **Toplantı Saati** | : 11:00 |
| **Toplantıya Katılanlar** | : Prof. Dr. Hatice AYNUR |
| | Prof. Dr. Nihat BULUT |
| | Prof. Dr. Cem BEHAR |
| | Doç. Dr. Eda YÜCESOY |
| | Yrd. Doç. Dr. Sinem ELKATİP HATİPOĞLU |
| | Yrd. Doç. Dr. Betül NİZAM |
| | Yrd. Doç. Dr. Eyyüp Said KAYA |
| | Yrd. Doç. Dr. Hızır Murat KÖSE |

**Karar No 1:**
İstanbul Şehir University Research Ethics Committee has reviewed the project named "Fostering responsive mental health systems in the Syrian refugee crisis (STRENGHTS)" Yrd. Doç. Dr. Zeynep Ceren ACARTÜRK.

According to the given information, STRENGTHS aims to provide effective community-based health care implementation strategies to scale-up the delivery and uptake of effective mental health interventions (Problem Management Plus, PM+) in different country contexts (The Netherlands, Germany, Switzerland, Egypt, Turkey, Jordan, Lebanon). The STRENGTHS project focuses on implementation of a trans-diagnostic mental health intervention related to the current Syrian refugee crisis, since the sudden increase in refugees seeking asylum in Europe and Syria's bordering countries poses a significant challenge to their health systems' responsiveness.

With **scaling-up and implementing** the low-intensity PM+ programs, we refer to their expansion of coverage, both geographically across European countries and the MENA countries and in terms of involving a new client group, namely Syrian refugees with increased psychological distress. We also refer to increasing the financial, human and capital resources required to expand this coverage.[7] The main goal of scaling-up the evidence-based low intensity PM+ programs is to reach more people who may benefit from them (**coverage**), and to attract more clients (**utilization**) in systematic ways that ensure durability of these health system changes (**sustainability**).


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The consortium, which is coordinated by Vrije Universiteit Amsterdam is composed of 15 partners, moreover 3 institutions will be supporting the 60 months project as 3rd Party.

Members of Consortium

Vrije Universiteit Amsterdam (VU)
Danish Red Cross, Denmark;
Freie Universität Berlin, Germany;
International Medical Corps, UK;
I-Psy Amsterdam, Netherlands;
The Royal Tropical Institute (KIT), Netherlands;
London School of Economics and Political Science, UK;
London School of Hygiene and Tropical Medicine, UK;
War Child Holland, Netherlands;
War Trauma Foundation, Netherlands;
Mülteciler ve Sığınmacılar Yardımlaşma ve Dayanışma Derneği, Turkey
The United Nations High Commissioner for Refugees, Switzerland;
University of New South Wales, Australia
University Hospital Zurich, Switzerland;

- İstanbul Şehir University, Turkey

Moreover, Noor Al-Hussein Foundation (Jordan), World Health Organization and Ministry of Public Health Lebanon take part as 3rd party.

Millions of Syrians had to flight from their home country and seek asylum as refugees in many different countries after the crisis that started in 2011. According to the official records published in March 2016, there are more than 2.700.000 Syrian refugees in Turkey and 500.000 of them resides in Turkey.

The current crisis has a negative effect on individual refugees' both physical health and psychological well-being. In response to this crisis, the STRENGTHS project aims to provide a framework for scaling-up the delivery and uptake of effective community-based mental health strategies to address the specific needs of refugees within and outside Europe's borders.

This study is a part of the project named STRENGHTS which is supported by EU, H2020. This study will be carried out by two partners which are Istanbul Sehir University (ISU) and Refugees and Asylum Seekers Assistance and Solidarity Association (RASASA). In the context of the participating European and LMICs in the MENA region, the objectives of STRENGTHS are:

1. To outline necessary steps needed to integrate evidence based low-intensity psychological interventions for common mental disorders (the PM+ programs) into the health systems. These include key preparatory steps in the local political, regulatory and governance processes for uptake and scaling-up of the intervention and key contextual and system-related factors for its integration. These steps will be validated for the real-life impact on the responsiveness of the system.
2. To adapt the PM+ programs and training materials to the recipients of care within the specific health systems and co-create the necessary local conditions for implementation and up-scaling, e.g. training a workforce and develop internet-delivery modality and supporting tools.
3. To *scale-up* the PM+ programs successfully in terms of health-system performance, effectiveness, affordability, and sustainability and identify barriers and facilitators to this end.
4. To determine the invested cost and effort in terms of organizational, resource and political-economic requirements relative to the reduction of economic burden of the large-scale implementation of the specific PM+ programs into the health systems in the different contexts.

5. To *disseminate* the evidence-base for *PM+ programs* as well as the validated implementation strategies and step-guides to maintain its sustainability and engage with new stakeholders and health systems to further scaling up across Europe and beyond.
6. Recent crises in the Middle East, most notably in Syria, have resulted in an unprecedented increase in the number of refugees seeking asylum in neighboring countries as well as in Europe. The refugee crisis imposes highly challenging demands on health systems in Europe and the Middle East. In 2015, over 1 million refugees have been registered entering Europe through the Mediterranean Sea (UNHCR, December 31 2015), and 4.8 million have fled to Syria's neighboring countries. Reports state that over 50% of Syrian refugees are children, in many cases unaccompanied by their family.

7. In Sultanbeyli where the RASASA is located, there are more than 20.000 registered Syrian refugees. Research indicates that the risk for mental health disorders is higher for refugees compared to host population. With this study, we aim to identify Syrian refugees who have mental health problems and deliver them an evidence based low intensity psychological intervention.

The part of the STRENGHTS project which will be implemented in Istanbul mainly consists of four stages:

1. Focus Group
2. Pilot Study for The Application of PM+ (Exploratory RCT)
3. PM+ (Problem Management Plus)
    - Pre-test
    - Identification of the participants and distributing them to groups
    - Post-test
    - Follow-up test (2-month)
4. Reporting the results

In the first stage, we will be working with focus groups. Focus group interviews will be conducted with three following different groups:

1. 6 mental health professional involved in refugee mental health care
2. 6 Syrian refugees
3. 6 local and national representatives who are working with issues involving refugees (immigration authority, municipality, etc.)

During the cognitive interviewing of the groups, interviewers will be listing all the mental health problems that the participants reported with the method called free listing.

The aim of this stage is to adapt the psychological intervention that we will be used in this study to the needs and the culture of Syrian refugees by asking them questions about their needs, problems they face with, cultural differences and their sensitivities (*see Appendix 1 for the Focus Group questions*).

The raw data that is obtained at this stage of the study will be shared with Danish Red Cross, which is one of the partners of the consortium. However, the confidentiality of the participants of our focus groups will be our primary concern and only the information will be shared, not the names of our informants.

The second stage of the study will be a pilot study with the aim of gaining information about the feasibility, safety, and delivery of the intervention (PM+); and that will identify issues around its training, supervision, and outcome measures. In this stage, which will be a randomized controlled

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study, overall 60 Syrian participants will be recruited (30 refugees in the treatment group, 30 refugees in the control group). Since this will be a trial for the main study, the research design will be similar. PM+ will be applied in group sessions and there will be three groups each consisted of 10 participants.

The third stage of the study is the main stage that the intervention will be implemented. About 1500 Syrian refugees will be expected to fill the questionnaires that are stated below:

- A Demographic Form,
- The WHODAS (WHO Disability Assessment Schedule) will measure the level of functional impairment.
- SRQ-20 (WHO_Self-Report Questionnaire-20),
- CIS-R (Clinical Interview Schedule-Revised),
- LEC (Life Events Checklist) will measure the number of adverse life events.
- PCL-5 (PTSD Checklist for DSM-5) will measure the severity of posttraumatic stress reactions.
- PHQ-9 (Patient Health Questionnaire-9) will measure the severity of depression symptoms.
- HESPER (The Humanitarian Emergency Settings Perceived Needs Scale) will measure the perceived serious needs.
- GHQ-12 (General Health Questionnaire)
- Client Satisfaction Trauma (CIS-8) To assess client satisfaction with treatment.

All instruments (see Appendix 2) will be administered by trained research staff, blind to the allocation status of the participants. As far as possible independent assessors will have prior experience of research studies. All assessors will receive a five-day training in administering the instruments, in general interview techniques, and in responding to participant distress, including, as mentioned, psychological first aid. The training will be delivered by the ISU research team.

According to the results, 354 Syrian refugees will be identified who are in need of a psychological intervention. Participant will be selected considering the following criteria:

Inclusion Criteria:

- Arabic speaking Syrians who are 18 years old and older
- > 2 GHQ-12
- > 16 WHODAS 2.0

Exclusion Criteria:

- Acute medical conditions
- Imminent risk of suicide
- Having experienced a major traumatic event during the past month (e.g., an accident, natural disaster, assault, or death of a loved one)
- Severe mental disorder (psychotic disorders, substance dependence)

Severe cognitive impairment (severe intellectual disability or dementia

The method of Randomized Controlled Trial (RCT) will be used in this study and the participants who are elected because they fit the criteria above will be randomly assigned to control and treatment groups.

Power calculations were carried out according to the previous findings. A total number of 354 participants will be included. Based on previous studies with PM+ carried out in Peshawar, Pakistan, and Nairobi Kenya, we aim for a conservatively estimated small to medium Cohen's *d* effect size of 0.4 in the PM+ group at 6 months' follow-up. Power calculations suggest a minimum sample size of 133 participants per group (power = 0.90, $\alpha$ = 0.05, two-sided). Taking into account an expected 20% attrition at 2 months' follow-up, we aim to include a total number of 354 participants (177 in the PM+ group and 177 in the care-as-usual control group -see Appendix 3).

The participants in the control group will continue with their usual treatment during the study so that the effect of PM+ can be detected. The usual treatment is consisted of the daily services that they get from the association such as psychological support.

PM+ is a manual written by Katie Dawson with the support of World Health Organization. It is a therapy that focuses on the management of problems which the treatment will group will receive it for 5 weeks. PM+ has 4 core features. It is:

1. Brief (5-sessions),
2. Delivered by paraprofessionals,
3. Transdiagnostic, addressing depression, anxiety, PTSD, stress, and problems as defined by people themselves, and
4. Designed for people in low-income country communities affected by adversity (e.g. violence).

The sessions will be given as a group therapy. There will be 18 groups and each group will consist of 8-10 participants. The groups for male and female participants will be different.

The therapies will be given by Syrians who have no background in psychology. First, PM+ specialists will have a visit to Turkey and train a group of 15-20 people who speaks Arabic on the therapy and these people will train the Syrian service providers. In this study, we will have 8 Syrian service providers and 2 Arabic speaking professional mental health workers.

At the end of the intervention, the effect of the therapy on the participants will be measured by using the questionnaires that were used before and these questionnaires will be used again after 2 months on 354 participants.

The GHQ-12 is the primary outcome measure; the WHODAS 2.0, PHQ-9, and PCL-5 are the secondary outcome measures.

Evaluations on the effectiveness of the process (adaptation, quality, dose, reach) will be made during and after the implementation. In consideration of these evaluations, it is aimed that the PM+ treatment will be more effective on the psychological problems that Syrian refugees experience. Various mediators will also be examined to understand the effect mechanism of the treatment.

a) *Does your study include elements which might be threatening for the physical/psychological well-being of the participants or might cause them stress? If yes, explain. Explain the measures that you will take to resolve or decrease the effect of these elements.*

   Traumatic memories might emerge while filling the questionnaires but the interviewers are notified about this. It is possible for the participants to get affected during the therapy as well but the field coordinator who is trained in psychological first aid and professional psychologists will be on the field of study, RASASA, to give support and help the participants who are in need.

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To reduce these factors, it is clarified on the informed consent that the participants can quit the study any time they wish to, without any sanctions.

b) *Does the information about the aim of the study will be kept completely or partially hidden from the participants? If yes, explain the reasons. State how this will be explained to the participants after the collection of the data.*
The aim of our study will be completely explained with the informed consent and the participants will be included in the study if the fill this form.

c) *Ensuring the confidentiality of participants' personal information*

This study is based on the security and the confidentiality of the participants. The name of the participants will be kept secret and the information will not be used other than research purposes. Before the interview, the participants will be assigned with a number and the link between the number and the names will only be known by the project conductor and the research assistants who are trained on data confidentiality.

After the data collection, questionnaires and the documents that include the names of the participants will be kept locked in separate places. Data management protector who is working in ISU will be responsible from the protection of the collected data.
In line with the APA (American Psychology Association) rules, the raw data will be kept in a safe place for 5 years after the research findings are published.

Followed by this information, undersigned Research Ethics Committee Members have seen no harm in view of ethics in the project entitled "'Fostering responsive mental health systems in the Syrian refugee crisis (STRENGHTS)'' Yrd. Doç. Dr. Zeynep Ceren ACARTÜRK.

Prof. Dr. Hatice AYNUR
President

Prof. Dr. Nihat BULUT
Member

Prof. Dr. Cem BEHAR
Member

Doç. Dr. Eda YÜCESOY
Member

Yrd. Doç. Dr. Hızır Murat KÖSE
Member

Yrd. Doç. Dr. Betül NİZAM
Member

Yrd. Doç. Dr. Sinem ELKATİP HATİPOĞLU
Member

Yrd. Doç. Dr. Eyyüp Said KAYA
Member

İTBF
Boyuna
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**T.C.**
**İÇİŞLERİ BAKANLIĞI**
**Göç İdaresi Genel Müdürlüğü**
**Göç Politika ve Projeleri Dairesi Başkanlığı**

**Sayı** : 62103649-604.02.02 -15143 29../..03.2017
**Konu** : Araştırma İzni

**İlgi** : 21.03.2017 tarih ve bila sayılı yazınız.

İlgi yazı eki ile "Suriye Mülteci Krizinde Hassas Ruh Sağlığını İyileştirme" isimli proje hakkında izin talep etmektedir.

Söz konusu izin talebi 6458 sayılı Yabancılar ve Uluslararası Koruma Kanunu'nun 94 üncü maddesi ile 2014/6883 karar sayılı Geçici Koruma Yönetmeliğinin 51 inci maddesinde belirtilen gizlilik ilkesine gerekli hassasiyetin gösterilmesi ve elde edilecek verilerin araştırma dışında kullanılmaması, üçüncü kişilerle paylaşılmaması, dahası çalışmaya konu kişilerden ve/veya aile üyelerinden ad, soyad, telefon, adres bilgilerinin istenmemesi ve çalışma esnasında ses ya da video kaydının alınmaması şartıyla uygun görülmüştür.

Bilgi ve gereğini rica ederim.

Sa[illegible]ih BIÇAK
Başkan a.
Genel Müdür Yardımcısı

İSTANBUL ŞEHİR ÜNİVERSİTESİ
GELEN EVRAK
Tarih 05 -04- 2017
Sayı 609

**Dağıtım:**
**Gereği:**
**İSTANBUL ŞEHİR ÜNİVERSİTESİ**

**Bilgi:**
**SAĞLIK BAKANLIĞINA**
(Türkiye Halk Sağlığı Kurumu)

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Göç Uzman Yardımcısı
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Kanton Zürich
**Kantonale Ethikkommission**

**Prof. Dr. med. Peter Meier-Abt**
Präsident

**Dr. med. Peter Kleist**
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UniversitätsSpital Zürich
Klinik für Psychiatrie und Psychohterapie
Dr. phil. Morina Naser
Culmannstrasse 8
8091 Zürich

02. Juni 2017/ ktr

**Anfrage BASEC-Nr. Req-2017-00404**
**Unbedenklichkeitserklärung**

Projekt: Cultural adaptation for the low-intensity Problem Management Plus (PM+) programmes

Sehr geehrte Frau Dr. Naser

Wir beziehen uns auf Ihre Einreichung vom 31.05.2017.
Die KEK ist nicht zuständig für die Beurteilung Ihres Projektes, da es nicht in den Geltungsbereich des Humanforschungsgesetzes fällt. Indessen wird festgestellt, dass die Durchführung dieser Studie aus ethischer Sicht unbedenklich ist.

Wir erlauben uns, für die Erteilung dieser Unbedenklichkeitserklärung den Betrag von CHF 300.- in Rechnung zu stellen.

Freundliche Grüsse

Peter Kleist

Freie Universität Berlin

Ethikkommission der Freien Universität Berlin
Habelschwerdter Allee 45, 14195 Berlin

Dipl.-Psych. Sebastian Burchert
Freie Universität Berlin
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Division of Clinical Psychological Intervention
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**Ethikkommission**
**der Freien Universität Berlin**
**Fachbereich Erziehungswissenschaft und Psychologie**

Prof. Dr. Annette Kinder
Vorsitzende der Ethikkommission
Habelschwerdter Allee 45
14195 Berlin

**Bearb.-Zeichen** 150/2017
**Bearbeiter/in** Frau Luttert

Berlin, 12.06.2017

**Beschlussmitteilung der Ethikkommission**

Die Ethikkommission der Freien Universität Berlin hat eine Neuerung des nachstehenden Projekts begutachtet:

## Cultural and mHealth adaptation of the low-intensity Problem Management Plus (PM+) program.

Die Ethikkommission kommt zu folgendem Beschluss:

Das Projekt wurde **positiv** begutachtet (die Ethikkommission hat keine Einwände erhoben).

Prof. Dr. Annette Kinder
(Vorsitzende der Ethikkommission)

## 2.2. WP2 Health Systems Evaluation

| **Study 2** | **Community-level surveys with refugees (T.2.2)** |
|---|---|
| Partners involved: | LSHTM, KIT, ISU |
| 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: | Overall ethics approval London School of Hygiene and Tropical Medicine received September 14 2017.<br>Local ethics approval received from Istanbul Sehir University by ISU Research Ethics Committee (dd. June 22, 2017) in Turkey and under review at Leipzig university (outcome expected early October 2017). |

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**www.lshtm.ac.uk**

**Observational / Interventions Research Ethics Committee**

Professor Bayard Roberts
Professor Health Systems and Policy
Department of Health Services Research and Policy (HSRP)
Public Health and Policy (PHP)
LSHTM

14 September 2017

Dear Bayard

**Study Title:** STRENGTHS QUALITATIVE RESEARCH PROTOCOL FOR SYRIAN REFUGEE MENTAL HEALTH

**LSHTM Ethics Ref:** 14330

Thank you for responding to the Observational Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

**Conditions of the favourable opinion**

Approval is dependent on local ethical approval having been received, where relevant.

**Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

| Document Type | File Name | Date | Version |
|---|---|---|---|
| Protocol / Proposal | Qualitative Research Protocol_Final | 30/06/2017 | 1 |
| Protocol / Proposal | Topic Guides Interviews | 30/06/2017 | 1 |
| Investigator CV | Bayard Roberts CV June 2017 long | 30/06/2017 | 1 |
| Investigator CV | Egbert Sondorp CV 2017 | 30/06/2017 | 1 |
| Investigator CV | CV- Daniela Fuhr short | 30/06/2017 | 1 |
| Investigator CV | CV A Woodward June 2017 | 30/06/2017 | 1 |
| Advertisements | STRENGTHS WP2 qualitative recruitment | 30/06/2017 | 1 |
| Covering Letter | Qualitative research STRENGTHS ethics response letter Bayard Roberts 22 Aug 2017 | 22/08/2017 | 1 |
| Information Sheet | Revised Information Sheets and Consent Form revised 22 Aug 2017 | 22/08/2017 | 2 |

**After ethical review**

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

**Professor John DH Porter**
**Chair**

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

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**Improving health worldwide**

İSTANBUL ŞEHİR ÜNİVERSİTESİ

**ARAŞTIRMA ETİK KURUL KARARLARI**
**(Research Ethics Committee Decision)**

| | |
|---|---|
| **Toplantı Tarihi** | : 22.06.2017 |
| **Toplantı Sayısı** | : 21/2017 |
| **Toplantı Saati** | : 11:00 |
| **Toplantıya Katılanlar** | : Prof. Dr. Hatice AYNUR |
| | Prof. Dr. Nihat BULUT |
| | Prof. Dr. Cem BEHAR |
| | Doç. Dr. Eda YÜCESOY |
| | Yrd. Doç. Dr. Sinem ELKATİP HATİPOĞLU |
| | Yrd. Doç. Dr. Betül NİZAM |
| | Yrd. Doç. Dr. Eyyüp Said KAYA |
| | Yrd. Doç. Dr. Hızır Murat KÖSE |

**Karar No 1:**
İstanbul Şehir University Research Ethics Committee has reviewed the project named "A cross-sectional survey on access to mental health and psychosocial support services for Syrian refugees in Turkey'' by Assist. Prof. Zeynep Ceren Acartürk

According to the given information, A cross-sectional survey on access to mental health and psychosocial support services (MHPSS) for Syrian refugees will be conducted in İstanbul with the aim of collecting scientifically rigorous evidence on MHPSS needs and access to MHPSS.

The STRENGTHS (Syrian REfuGees MeNTal HealTH Care Systems) study is a 5-year study that started in January 2017 with funding from the European Commission Horizon 2020 scheme. Istanbul Sehir University is a partner of this project. STRENGTHS aim to provide effective community-based health care implementation strategies to scale-up the delivery and uptake of effective mental health interventions in different country contexts.

STRENGTHS consist of eight Work Packages led by the different project partners. The London School of Hygiene and Tropical Medicine (LSHTM) is leading Work Package 2, collaborating with the Koninklijk Instituut voor de Tropen (KIT, Royal Tropical Institute) in the Netherlands.



Kuşbakısı Caddesi No: 27 34662 Altunizade Üsküdar İstanbul | T. 44 44 0 34 | F. 0 216 474 53 53 | www.sehir.edu.tr

The aim of the proposed project is to collect scientifically rigorous evidence on MHPSS needs and access to MHPSS care among Syrians under Temporary Protection in Turkey.

The specific objectives are to:

- Measure the prevalence of key mental health disorders.
- Examine patterns of access and utilization of MHSS services.
- To examine facilitators and barriers to accessing MHPSS services
- To draft evidence-based recommendations to help inform the STRENGTHS study and activities by relevant governmental and professional bodies in Turkey.

It is well recognized that conflict-affected populations are frequently exposed to traumatic events and war-related socio-economic stressors placing them at risk of elevated levels of mental disorders. Common mental disorders among conflict-affected populations such as depression, post-traumatic stress disorder (PTSD), and anxiety cause significant distress and reduce people's ability to function socially and economically and may impede people's ability to make the decisions needed to ensure the well-functioning of their families. Therefore, great need exists for large-scale mental health and psychosocial support (MHPSS) interventions to relieve individual suffering and to support well-being and functioning.

There are an estimated 2,992,567 Syrian refugees in Turkey, officially known by government in Turkey as persons under 'Temporary Protection'. They have experienced multiple types of trauma exposure such as forced displacement, bombardment, being caught in war fighting, injury and assault. Poverty and other socio-economic stressors for mental health are high. Mental health and psychosocial needs of refugees outstretches support and treatment capacities. A number of health system innovations have been implemented in response to this, including using Syrian medical providers, mental health and psychosocial programs have begun work with caregivers for self-care services.

Reliable epidemiological data on the burden of mental disorders and current pattern of access to MHPSS services are crucial in helping to improve access to such services. However, such data are lacking for Syrian persons under temporary protection in Turkey.

The study will use a quantitative population-level cross-sectional household survey design and will consist of three main stages:

1. Selection of the study population and sampling
2. Data collection
3. Data analysis

**1. <u>Selection of the study population and sampling:</u>**

The study will take place in Sultanbeyli in İstanbul, Turkey.

Inclusion Criteria:

- Adult (aged≥ 18 years) Syrian refugee men and women in Turkey.

Exclusion criteria:

- People deemed under the influence of alcohol or drugs during the data collection.
- Those with severe intellectual or mental impairment.

*Random sampling* will be used to select respondent as Sultanbeyli Municipality has an accurate registration system which the study applicants have access to. A total sample size of up to 2000 men and women aged ≥18 years will be included. The sample size determined by the statistical requirements of a proposed descriptive and multivariate analysis of factors associated with mental health and access to services.

**2. Data Collection:**

The questionnaires will be administered through face-to-face interviews in a private space a research office in the community center of RASASA in central Sultanbeyli. The collected data will be recorded by using tablets. Potential respondents will be approached by telephone and invited to attend the survey interview at a date convenient to them. They will be verbally provided the key information on the survey and advised on principles of informed consent (See Appendix I). Should the potential respondent agree, an interview date and time will be agreed. A small amount will be given to respondents to compensate them for their time in the form of a gift card.

All interviews will be conducted in Arabic. All data collectors will be trained on the aims of the survey, good enumeration techniques, ethical issues and quality standards, and being sensitive to respondents needs. Supervision will also be provided. Where possible, data collectors will be the same gender as respondents. The interviews will last approximately 45 minutes (depending on skip patterns).

To reduce bias, if the selected respondent does not attend the interview on the agreed date/time, they will be telephoned and encouraged to attend.

The following questionnaires will be included in the survey:

- Kessler Psychological Distress Scale (K10) to measure psychological distress,
- Hopkins Symptoms Checklist (HSCL-25) to measure depression and anxiety,
- PTSD (PCL-5),
- WHO Disability questionnaire (WHODAS-12) to measure functioning.
- HESPER
- 5 questions from CSRI
- Questions adapted from Mini Cope instrument

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A range of demographic and socio-economic characteristics will be also obtained, including: sex, age, education level, marital status, living conditions, employment status, and household economic situation (see Appendix II for the questionnaire).

The survey questionnaire will undergo a through adaptation and translation process to help ensure reliability, validity and appropriateness with the study population based on best practice procedures. Instrument translation will use standard procedures as:

- Translation from English into Arabic using professional translators.
- Independent back-translation to check for accuracy, consistency and equivalence, with adjustments made accordingly. The persons(s) doing the back translation will not have seen the original English version.
- Translations reviewed by Turkish, Syrian and international mental health experts from the study team, individually and then as an expert group, for cultural relevance, content and concept consistency, clarity and understanding.
- Piloting and field-testing to refine the instruments further.
- Conducting a test re-test mini survey to test the reliability of the psychometric measures.

**3. Data analysis:**

Data analysis will include descriptive analysis (e.g. prevalence of disorders and access to services) and simple multivariate regression analysis of factors influencing outcomes and access to services. The validity and reliability of the main mental health measures will also be analyzed and reported (e.g. Cronbach alpha test for reliability, test re-test reliability, construct validity, and known groups validity). Data analysis will be overseen by Bayard Roberts, with input from other study staff.

Data analysis will include descriptive analysis (e.g. prevalence of disorders and access to services) and simple multivariate regression analysis of factors influencing outcomes and access to services. The validity and reliability of the main mental health measures will also be analyzed and reported (e.g. Cronbach alpha test for reliability, test re-test reliability, construct validity, and known groups validity). Data analysis will be overseen by Bayard Roberts, with input from other study staff.

Followed by this information, undersigned Research Ethics Committee Members have seen no harm in view of ethics in the project entitled "A cross-sectional survey on access to mental health and psychosocial support services for Syrian refugees in Turkey" by Assist. Prof. Zeynep Ceren Acartürk

Prof. Dr. Hatice AYNUR
President

Prof. Dr. Nihat BULUT
Member

Prof. Dr. Cem BEHAR
Member

Doç. Dr. Eda YÜCESOY
Member

Yrd. Doç. Dr. Hızır Murat KÖSE
Member

Yrd. Doç. Dr. Betül NİZAM
Member

Yrd. Doç. Dr. Sinem ELKATİP HATİPOĞLU
Member

Yrd. Doç. Dr. Eyyüp Said KAYA
Member

## 2.3. WP3 Adaptation

| **Study 1** | |
|---|---|
| Partners involved: | DRC, IMC, WCH, VUA, ISU, UZH, FUB |
| Data collected by: | IMC (Jordan), WCH (Lebanon), VUA (the Netherlands), ISU (Turkey), UZH (Switzerland), FUB (Germany, Sweden and Egypt). |
| Aim of data collection: | To translate and culturally adapt the different versions of the scalable WHO programmes and training materials for use in Syrian refugees |
| Study participants: | 1. Healthy Syrians from the refugee population in all project countries (Jordan, Lebanon, the Netherlands, Turkey, Switzerland, Germany, Egypt, Sweden).<br>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: | **DRC:** Region Hovedstaden- Center for Sundhed, De Videnskabsetiske Komiteer<br>**IMC:** Jordan Ministry of Health approval (dd. June 11, 2017)<br>**WCH:** St Joseph University, Beirut, Lebanon (dd. March 24, 2017).<br>**VUA:** Waiver from VU Medical Center Medical Ethics Committee (dd. April 20, 2017).<br>**ISU:** Research Ethics Committee (dd. April 12, 2017), The Immigration Authority of Turkey (dd. March 29, 2017)<br>**UZH:** No objection waiver by Ethics Committee of Canton Zurich KEK-ZH REQ-2017-00404 (dd. June 02, 2017).<br>**FUB:** Ethics committee of the Department of Education and Psychology at Freie Universität Berlin (dd. June 12, 2017). |

Region Hovedstaden

**Center for Sundhed**

De Videnskabsetiske Komiteer

Regionsgården
Kongens Vænge 2
3400 Hillerød

**Opgang** B+D
**Telefon** 3866 6395
**Direkte** 38 66 52 08
**Mail** vek@regionh.dk

Martha Bird
International Federation of Red Cross and Red Crescent Societies
Blegdamsvej 27
2100 København Ø

Protokol nr.: 17018199

Dato: 28. juni 2017

**Røde Kors I Danmark og kulturel tilpasning af materialet til syriske flygtninge**

Du har ved mail af den 19. juni 2017 spurgt, om ovennævnte projekt skal anmeldes til det videnskabsetiske komitesystem.

Komiteen har vurderet, at der ikke er tale om et sundhedsvidenskabeligt forskningsprojekt som dette er defineret i komitélovens § 2[1]. Vi har lagt vægt på, at projektets formål er at oversætte og kulturelt tilpasse 3 WHO materialer til den arabiske kontekst. Dette gøres ved interviewundersøgelser. Der er således tale om en udvikling af kvaliteten af et påtænkt senere studie, som efter det oplyste ikke kommer til at foregå i Danmark.

Dette er ikke sundhedsvidenskabeligt forskning i komitelovens forstand. Projektet er derfor ikke anmeldelsespligtigt, jf. komitélovens § 1, stk. 4 og kan iværksættes uden tilladelse fra De Videnskabsetiske Komiteer for Region Hovedstaden.

I Danmark har det videnskabsetiske komitesystem til opgave at vurdere sundhedsvidenskabelige forskningsprojekter.

Ved et sundhedsvidenskabeligt forskningsprojekt forstås projekter, der indebærer forsøg på levendefødte menneskelige individer, menneskelige kønsceller, der agtes anvendt til befrugtning, menneskelige befrugtede æg, fosteranlæg og fostre, væv, celler og arvebestanddele fra mennesker, fostre og lign. eller afdøde. Herunder omfattes kliniske forsøg med lægemidler på mennesker og klinisk afprøvning af medicinsk udstyr.

Sundhedsvidenskabelig forskning omhandler primært forskning inden for de lægevidenskabelige fag, den kliniske og den socialmedicinsk-epidemiologiske forskning. Begrebet omfatter, udover forskning af de somatiske sygdomme, tillige de psykiatriske og de klinisk-psykologiske sygdomme og til-

[1] Lov nr. 593 af 14. juni 2011 om videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter med senere ændring.

standsformer. Herudover inddrages tilsvarende odontologisk og farmaceutisk forskning under begrebet.

Registerforskningsprojekter, interviewundersøgelser og spørgeskemaundersøgelser skal kun anmeldes, hvis der indgår menneskeligt biologisk materiale i projektet.

Undersøgelser af anonymt biologisk humant materiale skal dog ikke anmeldes til en videnskabsetisk komité, med mindre der er tale om et forskningsprojekt vedrørende befrugtede menneskelige æg samt kønsceller, jf. §§ 25 og 27, stk. 2 i lov om kunstig befrugtning i forbindelse med lægelig behandling, diagnostik og forskning m.v. Det er et krav, at materiale er fuldstændig anonymt (der må ikke være en identifikationskode til data), og at materialet er indsamlet i overensstemmelse med lovgivningen på indsamlingsstedet.

Forsøg på cellelinier eller lignende, der stammer fra et forsøg med indsamling af celler eller væv, som har opnået den nødvendige godkendelse, skal heller ikke anmeldes.

Forsøg, der alene har til formål at fastlægge et kemikaliums toksikologiske grænse i mennesket, er ikke anmeldelsespligtige. Ved et kemikalium forstås i denne forbindelse et stof, der ikke finder terapeutisk anvendelse.

Der ligger således ikke i afvisningen af at bedømme projektet nogen etisk stillingtagen eller negativ vurdering af dets indhold.

Vi gør opmærksom på, at Styrelsen for Patientsikkerhed i visse tilfælde skal godkende videregivelse af oplysninger fra patientjournaler. Nærmere oplysning kan findes på styrelsens hjemmeside.

Behandling af personhenførbare oplysninger er omfattet af persondataloven. Nærmere oplysning herom findes på Datatilsynets hjemmeside.

**Klagevejledning:**

Komitéens afgørelse kan, jf. komitélovens § 26, stk. 1, indbringes for National Videnskabsetisk Komité, senest 30 dage efter afgørelsen er modtaget. National Videnskabsetisk Komité kan, af hensyn til sikring af forsøgspersonernes rettigheder, behandle elementer af projektet, som ikke er omfattet af selve klagen.

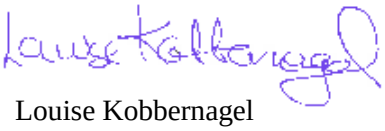
Klagen skal indbringes elektronisk og ved brug af digital signatur og kryptering, hvis protokollen indeholder fortrolige oplysninger.

Dette kan ske på adressen: dketik@dketik.dk

Klagen skal begrundes og være vedlagt kopi af Den Regionale Videnskabsetiske Komités afgørelse samt de sagsakter, som Den Regionale Videnskabsetiske Komité har truffet afgørelse på grundlag af.

*NB: Der <u>må ikke</u> foretages ændringer i dokumenterne, som har været til behandling i komiteen, da sagens ellers vil blive sendt retur til komiteen.*

Med venlig hilsen



Louise Kobbernagel
Juridisk konsulent

بسم الله الرحمن الرحيم

وزارة الصحة

نهضة

الرقم تطوير/ص/٤٤٢/١

التاريخ

الموافق ٢٠١٧/٦/١٨

**مدير صحة محافظة العاصمة**
**مدير صحة محافظة ا لزرقاء**
**مدير صحة محافظة المفـرق**
**مدير صحة محافظة الكـــرك**
**مدير صحة محافظة اربـــد**

تحية طيبة وبعد ،،،

أرفـق طيـاً صـورة عن كتـــاب مدير مستشفى البشير / رئيس لجنة أخلاقيـات البحث العلمي رقـم م ب أ / لجنة أخلاقيات /٨٢٥٥ تاريـخ ٢٠١٧/٦/١٣ بخصـــوص طلب الموافقة للهيئة الطبية الدولية على تنفيذ دراسة بعنوان :-

**( تقييم خدمات الصحة النفسية التي تقدمها الهيئة الطبية الدولية )**

وذلك من خلال المراكز الصحية المستضيفة للعيادات النفسية وتشمل الدراسة اجراء مقابلات مع مدراء المراكز الصحية وضباط ارتباط الصحة النفسية في مديريات الصحة في عمان ، الزرقاء ، المفرق ، الكرك ، اربد )

أرجو التكرم بالإيعاز لمن يلزم تسهيل مهمة اجراء البحث أعلاه .

وتفضلوا بقبول فائق الاحترام ،،،

**مدير تطوير الموارد البشرية المكلف**

**الدكتورة سوسن جباعته**

٢٠١٧/٦/١٥

وزارة الصحة

الرقم ..... م ب ا / لجنة اخلاقيات / ٨٢٥٥

التاريخ .....

الموافق ..... ١٤/٦/٢٠١٧

مدير تطوير الموارد البشرية

تحيه طيبه وبعد ،،،

اشاره لكتابكم رقم تطوير/خطط/4196تاريخ2017/6/7بخصوص الدراسة المقدمة من قبل الهيئة الطبية الاردنية.

ارفق بطيه قرار لجنة اخلاقيات البحث العلمي والمتضمن الموافقة على إجراء الدراسة العائدة للهيئة المذكورة أعلاه .

للتكرم بالاطلاع واجراءاتكم لطفا .

واقبلوا الاحترام

مدير مستشفى البشير/المكلف

الدكتور/عمار نعيم الشرفا

ص ب

٥١٢٠ / ٢٨٠٧٧

الصفوط

١٤/٦/٢٠١٧

بسم الله الرحمن الرحيم

وزارة الصحة

**CODE : MOH REC 170084**

الرقم .....

التاريخ .....

الموافق .....

## قرار لجنة اخلاقيات البحث العلمي

اجتمعت لجنة اخلاقيات البحث العلمي بتاريخ2017/6/11 لمناقشة الدراسة العلمية المقدمة من قبل الهيئة الطبية الاردنية.

**بعنوان:**

***تقييم خدمات الصحة النفسية التي تقدمها الهيئة الطبية الاردنية***

وقد قررت اللجنه بالاجماع الموافقه على اجراء البحث المشار اليه اعلاه.

وعليه تم التوقيع من قبل اعضاء اللجنه حسب الاصول .

| | | |
|---|---|---|
| **عضو اللجنه**<br>**المساعد للتمريض** | **عضو اللجنه**<br>**رئيس قسم الجراحة** | **عضو اللجنه**<br>**رئيس قسم الاشعة العلاجية** |
| **الدكتور/هاني القضاه** | **الدكتور/ فايز الحمود** | **الدكتور/ رسمي مبيضين** |
| **عضو اللجنه**<br>**رئيس قسم الاطفال** | **عضو اللجنه**<br>**رئيس قسم الباطني/المكلف** | **عضو اللجنه**<br>**رئيس قسم النساءلة والتوليد** |
| **الدكتوره/باسمه مرار** | **الدكتور/عباس منصور** | **الدكتور/عبدالمانع السليمات** |

**رئيس اللجنه /**
**مدير مستشفى البشير/المكلف**

**الدكتور/عمار نعيم الشرفا**

نهضة

وزارة الصحة

الرقم ٤١٩٦/ط ص/ سلوى
التاريخ
الموافق ٢٠١٧/٦/٧

**مدير مستشفى البشير**
**رئيس لجنة اخلاقيات البحث العلمي**

تحية طيبة وبعد ،،،

ارفق طيا صورة عن كتاب مدير ادارة التخطيط رقم ١ص/IMC/٦/١٥٨تاريخ ٢٠١٧/٥/٣١ ومرفقه كتاب الهيئة الطبية الدولية رقم 2017/432/MHPSS/IMS بخصوص طلب الهيئة اجراء دراسة بعنوان :

**"تقييم خدمات الصحة النفسية التي تقدمها الهيئة الطبية الدولية "**

وذلك من خلال المراكز الصحية المستضيفة للعيادات النفسية وتشمل الدراسة اجراء مقابلات مع مدراء المراكز الصحية وضباط ارتباط الصحة النفسية في مديريات الصحة في عمان ، الزرقاء ، المفرق ، الكرك ، اربد .

ارجو التكرم بالاطلاع واعلامي رأيكم حول امكانية الموافقة على اجراء الدراسة اعلاه .

وتفضلوا بقبول فائق الاحترام ،،،

**مدير تطوير الموارد البشرية المكلف**

**الدكتورة سوسن جباعته**

المملكة الأردنية الهاشمية
وزارة الصحة
11 JUN 2017
الديوان
وارد:


المملكة الأردنية الهاشمية
هاتف: ٦٥٢٠٠٢٣٠ ٩٦٢+ فاكس: ٦٥٦٨٨٣٧٣ ٩٦٢+ ص.ب: ٨٦ عمان ١١١١٨ الأردن الموقع الإلكتروني: www.moh.gov.jo

COMITÉ D'ÉTHIQUE

Beyrouth, le 24 mars 2017

Monsieur le Docteur Rabih EL-CHAMMAY
Service de psychiatrie -HDF

**Nos réf.** : USJ -2017-24

**Titre** : Formative research to inform the evoluation of the helping young adolescents cope intervention.

Cher Collègue,

Lors de sa réunion du 21 mars, le Comité a pris acte du protocole de l'étude et du formulaire de consentement.

Après en avoir délibéré, le Comité estime à l'unanimité que ce projet ne soulève aucune objection d'ordre éthique ; il vous notifie donc bien volontiers son accord et vous autorise à utiliser le formulaire proposé.

Avec tous mes vœux pour le succès de cette recherche, je vous prie de croire, Cher collègue, en l'assurance de mes sentiments dévoués.

UNIVERSITÉ SAINT-JOSEPH USJ comité d'éthique

Pr. Michel SCHEUER
Président



Centre universitaire d'éthique, Campus des sciences médicales, rue de Damas
B.P. 11-5076 Riad el Solh, Beyrouth 1107 2180 - Liban
Tél : 961-1-421229, Email : cue@usj.edu.lb

Van der Boechorststraat 7
postbus 7057
1007 MB Amsterdam

telefoon 020 444 5585
kamer H-565

www.vumc.nl/METc
METc@vumc.nl

dr. E.M. Sijbrandij
FPP, afdeling klinische psychologie
BS 1 KAMER 3F-71

VUmc

| onderwerp | ons kenmerk | datum |
|---|---|---|
| niet-WMO advies | 2017.209 | 20 april 2017 |

Geachte mevrouw Sijbrandij,

Het Dagelijks Bestuur van de Medisch Ethische Toetsingscommissie VU medisch centrum heeft uw onderzoek **Cultural adaptation of the low-intensity Problem Management Plus (PM+) programmes** besproken in de vergadering van 20/04/2017.

Het onderzoek valt niet onder de reikwijdte van de Wet Medisch-wetenschappelijk Onderzoek met mensen (WMO).

Het oordeel is gebaseerd op de volgende documenten:

| Sectie | Onderwerp | Versie |
|---|---|---|
| A1 | aanbiedingsbrief | d.d. 5-4-2017 |
| A1 | commentaar METc | d.d. 20-4-2017 |
| B25 | privacyverklaring | getekend d d. 5-4-2017 |
| C1 | onderzoeksprotocol | versie 1 d d. 5-4-2017 |
| C1 | onderzoeksprotocol | bijlage: DIME module |
| E11 | informatiebrief | behandelaren d.d. versie 1 d.d. 5-4-2017 |
| E11 | informatiebrief | beleidsmakers versie 1 d.d. 5-4-2017 |
| E11 | informatiebrief | Syrische vluchtelingen FGD versie 1 d.d. 5-4-2017 |
| E11 | informatiebrief | Syrische vluchtelingen FL versie 1 d.d. 5-4-2017 |
| E11 | informatiebrief | Syrische vluchtelingen KI versie 1 d.d 5-4-2017 |
| E2 | toestemmingsverklaring | behandelaren versie 1 d.d. 5-4-2017 |
| E2 | toestemmingsverklaring | beleidsmakers versie 1 d.d. 5-4-2017 |
| E2 | toestemmingsverklaring | Syrische vluchtelingen FGD versie 1 d.d. 5-4-2017 |
| E2 | toestemmingsverklaring | Syrische vluchtelingen FL versie 1 d.d. 5-4-2017 |
| E2 | toestemmingsverklaring | Syrische vluchtelingen KI versie 1 d.d. 5-4-2017 |
| F1 | vragenlijst | behandelaren interview versie 1 d.d. 5-4-2017 |

| | | |
|---|---|---|
| F1 | vragenlijst | beleidsmaker interview versie 1 d.d. 5-4-2017 |
| F1 | vragenlijst | free list recording form versie 1 d.d. 5-4-2017 |
| F1 | vragenlijst | KI recording form versie 1 d.d. 5-4-2017 |
| F1 | vragenlijst | Syrische vluchtelingen FGD versie 1 d d 5-4-2017 |
| F1 | vragenlijst | Syrische vluchtelingen FL interviews versie 1 d.d. 5-4-2017 |
| F1 | vragenlijst | Syrische vluchtelingen KI interviews versie 1 d.d. 5-4-2017 |

Het Dagelijks Bestuur van de Medisch Ethische Toetsingscommissie VU medisch centrum wijst u erop dat hoewel het ingediende onderzoek niet onder de reikwijdte van de WMO valt, andere wet- en regelgeving (mogelijk) wel van toepassing is, waaronder:

- WGBO (Wet Geneeskundige BehandelingsOvereenkomst);
- WBP (Wet Bescherming Persoonsgegevens), zie www.cbpweb.nl;
- Code Goed Gedrag (Gedragscode gezondheidsonderzoek: gebruik medische gegevens in wetenschappelijk onderzoek), zie www.federa org;
- Code Goed Gebruik (Gedragscode Verantwoord omgaan met lichaamsmateriaal ten behoeve van wetenschappelijk onderzoek, 2011), zie www.federa.org;
- Biobanken: Reglement toetsing biobank VUmc, zie https://www.vumc.nl/afdelingen/METc/biobank/;
- WBO (Wet Bevolkings Onderzoek), zie http://www.vumc.nl/afdelingen/METc/wetgeving/wetbevolkingsonderzoek/.

To whom it may concern

We are pleased to confirm that the Medical Research Involving Human Subjects Act (WMO) does not apply to the above mentioned study and that an official approval of this study by our committee is not required.

The Medical Ethics Review Committee of VU University Medical Center is registered with the US Office for Human Research Protections (OHRP) as IRB00002991. The FWA number assigned to VU University Medical Center is FWA00017598.

Met vriendelijke groet,
namens de Medisch Ethische Toetsingscommissie VU medisch centrum,

p.o.

prof. dr. J.A. Rauwerda, voorzitter

c.c.: A.M. de Graaff / a.m.de.graaff@vu.nl

İSTANBUL
ŞEHİR
ÜNİVERSİTESİ

**ARAŞTIRMA ETİK KURUL KARARLARI**
**(Research Ethics Committee Decision)**

| | |
|---|---|
| **Toplantı Tarihi** | : 12.04.2017 |
| **Toplantı Sayısı** | : 10/2017 |
| **Toplantı Saati** | : 11:00 |
| **Toplantıya Katılanlar** | : Prof. Dr. Hatice AYNUR |
| | Prof. Dr. Nihat BULUT |
| | Prof. Dr. Cem BEHAR |
| | Doç. Dr. Eda YÜCESOY |
| | Yrd. Doç. Dr. Sinem ELKATİP HATİPOĞLU |
| | Yrd. Doç. Dr. Betül NİZAM |
| | Yrd. Doç. Dr. Eyyüp Said KAYA |
| | Yrd. Doç. Dr. Hızır Murat KÖSE |

**Karar No 1:**
İstanbul Şehir University Research Ethics Committee has reviewed the project named "Fostering responsive mental health systems in the Syrian refugee crisis (STRENGHTS)" Yrd. Doç. Dr. Zeynep Ceren ACARTÜRK.

According to the given information, STRENGTHS aims to provide effective community-based health care implementation strategies to scale-up the delivery and uptake of effective mental health interventions (Problem Management Plus, PM+) in different country contexts (The Netherlands, Germany, Switzerland, Egypt, Turkey, Jordan, Lebanon). The STRENGTHS project focuses on implementation of a trans-diagnostic mental health intervention related to the current Syrian refugee crisis, since the sudden increase in refugees seeking asylum in Europe and Syria's bordering countries poses a significant challenge to their health systems' responsiveness.

With **scaling-up and implementing** the low-intensity PM+ programs, we refer to their expansion of coverage, both geographically across European countries and the MENA countries and in terms of involving a new client group, namely Syrian refugees with increased psychological distress. We also refer to increasing the financial, human and capital resources required to expand this coverage.[7] The main goal of scaling-up the evidence-based low intensity PM+ programs is to reach more people who may benefit from them (**coverage**), and to attract more clients (**utilization**) in systematic ways that ensure durability of these health system changes (**sustainability**).


Kuşbakışı Caddesi No: 27 34662 Altunizade Üsküdar İstanbul | T 44 44 0 34 | F 0 216 474 53 53 | www.sehir.edu.tr

The consortium, which is coordinated by Vrije Universiteit Amsterdam is composed of 15 partners, moreover 3 institutions will be supporting the 60 months project as 3rd Party.

Members of Consortium

Vrije Universiteit Amsterdam (VU)
Danish Red Cross, Denmark;
Freie Universität Berlin, Germany;
International Medical Corps, UK;
I-Psy Amsterdam, Netherlands;
The Royal Tropical Institute (KIT), Netherlands;
London School of Economics and Political Science, UK;
London School of Hygiene and Tropical Medicine, UK;
War Child Holland, Netherlands;
War Trauma Foundation, Netherlands;
Mülteciler ve Sığınmacılar Yardımlaşma ve Dayanışma Derneği, Turkey
The United Nations High Commissioner for Refugees, Switzerland;
University of New South Wales, Australia
University Hospital Zurich, Switzerland;

- İstanbul Şehir University, Turkey

Moreover, Noor Al-Hussein Foundation (Jordan), World Health Organization and Ministry of Public Health Lebanon take part as 3rd party.

Millions of Syrians had to flight from their home country and seek asylum as refugees in many different countries after the crisis that started in 2011. According to the official records published in March 2016, there are more than 2.700.000 Syrian refugees in Turkey and 500.000 of them resides in Turkey.

The current crisis has a negative effect on individual refugees' both physical health and psychological well-being. In response to this crisis, the STRENGTHS project aims to provide a framework for scaling-up the delivery and uptake of effective community-based mental health strategies to address the specific needs of refugees within and outside Europe's borders.

This study is a part of the project named STRENGHTS which is supported by EU, H2020. This study will be carried out by two partners which are Istanbul Sehir University (ISU) and Refugees and Asylum Seekers Assistance and Solidarity Association (RASASA). In the context of the participating European and LMICs in the MENA region, the objectives of STRENGTHS are:

1. To outline necessary steps needed to integrate evidence based low-intensity psychological interventions for common mental disorders (the PM+ programs) into the health systems. These include key preparatory steps in the local political, regulatory and governance processes for uptake and scaling-up of the intervention and key contextual and system-related factors for its integration. These steps will be validated for the real-life impact on the responsiveness of the system.
2. To adapt the PM+ programs and training materials to the recipients of care within the specific health systems and co-create the necessary local conditions for implementation and up-scaling, e.g. training a workforce and develop internet-delivery modality and supporting tools.
3. To *scale-up* the PM+ programs successfully in terms of health-system performance, effectiveness, affordability, and sustainability and identify barriers and facilitators to this end.
4. To determine the invested cost and effort in terms of organizational, resource and political-economic requirements relative to the reduction of economic burden of the large-scale implementation of the specific PM+ programs into the health systems in the different contexts.

5. To *disseminate* the evidence-base for *PM+ programs* as well as the validated implementation strategies and step-guides to maintain its sustainability and engage with new stakeholders and health systems to further scaling up across Europe and beyond.
6. Recent crises in the Middle East, most notably in Syria, have resulted in an unprecedented increase in the number of refugees seeking asylum in neighboring countries as well as in Europe. The refugee crisis imposes highly challenging demands on health systems in Europe and the Middle East. In 2015, over 1 million refugees have been registered entering Europe through the Mediterranean Sea (UNHCR, December 31 2015), and 4.8 million have fled to Syria's neighboring countries. Reports state that over 50% of Syrian refugees are children, in many cases unaccompanied by their family.

7. In Sultanbeyli where the RASASA is located, there are more than 20.000 registered Syrian refugees. Research indicates that the risk for mental health disorders is higher for refugees compared to host population. With this study, we aim to identify Syrian refugees who have mental health problems and deliver them an evidence based low intensity psychological intervention.

The part of the STRENGHTS project which will be implemented in Istanbul mainly consists of four stages:

1. Focus Group
2. Pilot Study for The Application of PM+ (Exploratory RCT)
3. PM+ (Problem Management Plus)
    - Pre-test
    - Identification of the participants and distributing them to groups
    - Post-test
    - Follow-up test (2-month)
4. Reporting the results

In the first stage, we will be working with focus groups. Focus group interviews will be conducted with three following different groups:

1. 6 mental health professional involved in refugee mental health care
2. 6 Syrian refugees
3. 6 local and national representatives who are working with issues involving refugees (immigration authority, municipality, etc.)

During the cognitive interviewing of the groups, interviewers will be listing all the mental health problems that the participants reported with the method called free listing.

The aim of this stage is to adapt the psychological intervention that we will be used in this study to the needs and the culture of Syrian refugees by asking them questions about their needs, problems they face with, cultural differences and their sensitivities (*see Appendix 1 for the Focus Group questions*).

The raw data that is obtained at this stage of the study will be shared with Danish Red Cross, which is one of the partners of the consortium. However, the confidentiality of the participants of our focus groups will be our primary concern and only the information will be shared, not the names of our informants.

The second stage of the study will be a pilot study with the aim of gaining information about the feasibility, safety, and delivery of the intervention (PM+); and that will identify issues around its training, supervision, and outcome measures. In this stage, which will be a randomized controlled

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study, overall 60 Syrian participants will be recruited (30 refugees in the treatment group, 30 refugees in the control group). Since this will be a trial for the main study, the research design will be similar. PM+ will be applied in group sessions and there will be three groups each consisted of 10 participants.

The third stage of the study is the main stage that the intervention will be implemented. About 1500 Syrian refugees will be expected to fill the questionnaires that are stated below:

- A Demographic Form,
- The WHODAS (WHO Disability Assessment Schedule) will measure the level of functional impairment.
- SRQ-20 (WHO_Self-Report Questionnaire-20),
- CIS-R (Clinical Interview Schedule-Revised),
- LEC (Life Events Checklist) will measure the number of adverse life events.
- PCL-5 (PTSD Checklist for DSM-5) will measure the severity of posttraumatic stress reactions.
- PHQ-9 (Patient Health Questionnaire-9) will measure the severity of depression symptoms.
- HESPER (The Humanitarian Emergency Settings Perceived Needs Scale) will measure the perceived serious needs.
- GHQ-12 (General Health Questionnaire)
- Client Satisfaction Trauma (CIS-8) To assess client satisfaction with treatment.

All instruments (see Appendix 2) will be administered by trained research staff, blind to the allocation status of the participants. As far as possible independent assessors will have prior experience of research studies. All assessors will receive a five-day training in administering the instruments, in general interview techniques, and in responding to participant distress, including, as mentioned, psychological first aid. The training will be delivered by the ISU research team.

According to the results, 354 Syrian refugees will be identified who are in need of a psychological intervention. Participant will be selected considering the following criteria:

Inclusion Criteria:

- Arabic speaking Syrians who are 18 years old and older
- > 2 GHQ-12
- > 16 WHODAS 2.0

Exclusion Criteria:

- Acute medical conditions
- Imminent risk of suicide
- Having experienced a major traumatic event during the past month (e.g., an accident, natural disaster, assault, or death of a loved one)
- Severe mental disorder (psychotic disorders, substance dependence)

Severe cognitive impairment (severe intellectual disability or dementia

The method of Randomized Controlled Trial (RCT) will be used in this study and the participants who are elected because they fit the criteria above will be randomly assigned to control and treatment groups.

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Power calculations were carried out according to the previous findings. A total number of 354 participants will be included. Based on previous studies with PM+ carried out in Peshawar, Pakistan, and Nairobi Kenya, we aim for a conservatively estimated small to medium Cohen's *d* effect size of 0.4 in the PM+ group at 6 months' follow-up. Power calculations suggest a minimum sample size of 133 participants per group (power = 0.90, $\alpha$ = 0.05, two-sided). Taking into account an expected 20% attrition at 2 months' follow-up, we aim to include a total number of 354 participants (177 in the PM+ group and 177 in the care-as-usual control group -see Appendix 3).

The participants in the control group will continue with their usual treatment during the study so that the effect of PM+ can be detected. The usual treatment is consisted of the daily services that they get from the association such as psychological support.

PM+ is a manual written by Katie Dawson with the support of World Health Organization. It is a therapy that focuses on the management of problems which the treatment will group will receive it for 5 weeks. PM+ has 4 core features. It is:

1. Brief (5-sessions),
2. Delivered by paraprofessionals,
3. Transdiagnostic, addressing depression, anxiety, PTSD, stress, and problems as defined by people themselves, and
4. Designed for people in low-income country communities affected by adversity (e.g. violence).

The sessions will be given as a group therapy. There will be 18 groups and each group will consist of 8-10 participants. The groups for male and female participants will be different.

The therapies will be given by Syrians who have no background in psychology. First, PM+ specialists will have a visit to Turkey and train a group of 15-20 people who speaks Arabic on the therapy and these people will train the Syrian service providers. In this study, we will have 8 Syrian service providers and 2 Arabic speaking professional mental health workers.

At the end of the intervention, the effect of the therapy on the participants will be measured by using the questionnaires that were used before and these questionnaires will be used again after 2 months on 354 participants.

The GHQ-12 is the primary outcome measure; the WHODAS 2.0, PHQ-9, and PCL-5 are the secondary outcome measures.

Evaluations on the effectiveness of the process (adaptation, quality, dose, reach) will be made during and after the implementation. In consideration of these evaluations, it is aimed that the PM+ treatment will be more effective on the psychological problems that Syrian refugees experience. Various mediators will also be examined to understand the effect mechanism of the treatment.

a) *Does your study include elements which might be threatening for the physical/psychological well-being of the participants or might cause them stress? If yes, explain. Explain the measures that you will take to resolve or decrease the effect of these elements.*

   Traumatic memories might emerge while filling the questionnaires but the interviewers are notified about this. It is possible for the participants to get affected during the therapy as well but the field coordinator who is trained in psychological first aid and professional psychologists will be on the field of study, RASASA, to give support and help the participants who are in need.

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To reduce these factors, it is clarified on the informed consent that the participants can quit the study any time they wish to, without any sanctions.

b) *Does the information about the aim of the study will be kept completely or partially hidden from the participants? If yes, explain the reasons. State how this will be explained to the participants after the collection of the data.*
The aim of our study will be completely explained with the informed consent and the participants will be included in the study if the fill this form.

c) *Ensuring the confidentiality of participants' personal information*

This study is based on the security and the confidentiality of the participants. The name of the participants will be kept secret and the information will not be used other than research purposes. Before the interview, the participants will be assigned with a number and the link between the number and the names will only be known by the project conductor and the research assistants who are trained on data confidentiality.

After the data collection, questionnaires and the documents that include the names of the participants will be kept locked in separate places. Data management protector who is working in ISU will be responsible from the protection of the collected data.
In line with the APA (American Psychology Association) rules, the raw data will be kept in a safe place for 5 years after the research findings are published.

Followed by this information, undersigned Research Ethics Committee Members have seen no harm in view of ethics in the project entitled "'Fostering responsive mental health systems in the Syrian refugee crisis (STRENGHTS)'' Yrd. Doç. Dr. Zeynep Ceren ACARTÜRK.

Prof. Dr. Hatice AYNUR
President

Prof. Dr. Nihat BULUT
Member

Prof. Dr. Cem BEHAR
Member

Doç. Dr. Eda YÜCESOY
Member

Yrd. Doç. Dr. Hızır Murat KÖSE
Member

Yrd. Doç. Dr. Betül NİZAM
Member

Yrd. Doç. Dr. Sinem ELKATİP HATİPOĞLU
Member

Yrd. Doç. Dr. Eyyüp Said KAYA
Member

İTBF
Boyuna
77

**T.C.**
**İÇİŞLERİ BAKANLIĞI**
**Göç İdaresi Genel Müdürlüğü**
**Göç Politika ve Projeleri Dairesi Başkanlığı**

**Sayı** : 62103649-604.02.02 -15143 29../..03.2017
**Konu** : Araştırma İzni

**İlgi** : 21.03.2017 tarih ve bila sayılı yazınız.

İlgi yazı eki ile "Suriye Mülteci Krizinde Hassas Ruh Sağlığını İyileştirme" isimli proje hakkında izin talep etmektedir.

Söz konusu izin talebi 6458 sayılı Yabancılar ve Uluslararası Koruma Kanunu'nun 94 üncü maddesi ile 2014/6883 karar sayılı Geçici Koruma Yönetmeliğinin 51 inci maddesinde belirtilen gizlilik ilkesine gerekli hassasiyetin gösterilmesi ve elde edilecek verilerin araştırma dışında kullanılmaması, üçüncü kişilerle paylaşılmaması, dahası çalışmaya konu kişilerden ve/veya aile üyelerinden ad, soyad, telefon, adres bilgilerinin istenmemesi ve çalışma esnasında ses ya da video kaydının alınmaması şartıyla uygun görülmüştür.

Bilgi ve gereğini rica ederim.

Sa[illegible]ih BIÇAK
Başkan a.
Genel Müdür Yardımcısı

İSTANBUL ŞEHİR ÜNİVERSİTESİ
GELEN EVRAK
Tarih 05 -04- 2017
Sayı 609

**Dağıtım:**
**Gereği:**
**İSTANBUL ŞEHİR ÜNİVERSİTESİ**

**Bilgi:**
**SAĞLIK BAKANLIĞINA**
(Türkiye Halk Sağlığı Kurumu)

Lalegül Çamlıca Mahallesi 122. Sokak No:4 - 06370 Yenimahalle/Ankara
Telefon:0 (312) 422 05 00 Faks:0 (312) 422 09 00
e-posta: gocpolitikalari@goc.gov.tr / Elektronik Ağ: www.goc.gov.tr

Bilgi için: Gizem GÖZALICI
Göç Uzman Yardımcısı
Telefon:0 (312) 422 07 55

Kanton Zürich
**Kantonale Ethikkommission**

**Prof. Dr. med. Peter Meier-Abt**
Präsident

**Dr. med. Peter Kleist**
Geschäftsführer
Stampfenbachstrasse 121
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UniversitätsSpital Zürich
Klinik für Psychiatrie und Psychohterapie
Dr. phil. Morina Naser
Culmannstrasse 8
8091 Zürich

02. Juni 2017/ ktr

**Anfrage BASEC-Nr. Req-2017-00404**
**Unbedenklichkeitserklärung**

Projekt: Cultural adaptation for the low-intensity Problem Management Plus (PM+) programmes

Sehr geehrte Frau Dr. Naser

Wir beziehen uns auf Ihre Einreichung vom 31.05.2017.
Die KEK ist nicht zuständig für die Beurteilung Ihres Projektes, da es nicht in den Geltungsbereich des Humanforschungsgesetzes fällt. Indessen wird festgestellt, dass die Durchführung dieser Studie aus ethischer Sicht unbedenklich ist.

Wir erlauben uns, für die Erteilung dieser Unbedenklichkeitserklärung den Betrag von CHF 300.- in Rechnung zu stellen.

Freundliche Grüsse

Peter Kleist

Freie Universität Berlin

Ethikkommission der Freien Universität Berlin
Habelschwerdter Allee 45, 14195 Berlin

Dipl.-Psych. Sebastian Burchert
Freie Universität Berlin
Department of Education and Psychology
Division of Clinical Psychological Intervention
Habelschwerdter Allee 45, 14195 Berlin
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email: s.burchert@fu-berlin.de

**Ethikkommission**
**der Freien Universität Berlin**
**Fachbereich Erziehungswissenschaft und Psychologie**

Prof. Dr. Annette Kinder
Vorsitzende der Ethikkommission
Habelschwerdter Allee 45
14195 Berlin

**Bearb.-Zeichen** 150/2017
**Bearbeiter/in** Frau Luttert

Berlin, 12.06.2017

**Beschlussmitteilung der Ethikkommission**

Die Ethikkommission der Freien Universität Berlin hat eine Neuerung des nachstehenden Projekts begutachtet:

## Cultural and mHealth adaptation of the low-intensity Problem Management Plus (PM+) program.

Die Ethikkommission kommt zu folgendem Beschluss:

Das Projekt wurde **positiv** begutachtet (die Ethikkommission hat keine Einwände erhoben).

Prof. Dr. Annette Kinder
(Vorsitzende der Ethikkommission)

## 2.4. WP4 Refugee Settlement and Camp Implementation

| **Study 1** | **Jordan** |
|---|---|
| Partners involved: | UNSW, IMC |
| 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). |

| **Study 2** | **Lebanon** |
|---|---|
| Partners involved: | WCH |
| 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: | Saint Joseph University, Beirut, Lebanon, (dd. September 25, 2017). |

27-Jul-2017

Dear Scientia Professor Richard Bryant,

| | |
|---|---|
| **Project Title** | Improving Mental Health of Syrian Refugees in Jordan |
| **HC No** | HC17520 |
| **Re** | HC17520 Notification of Ethics Approval |
| **Approval Period** | 27-Jul-2017 - 26-Jul-2022 |

Thank you for submitting the above research project to the **HREC Executive** for ethical review. This project was considered by the **HREC Executive** at its meeting on **25-Jul-2017**.

I am pleased to advise you that the **HREC Executive** has granted ethical approval of this research project. The following condition(s) must be met before data collection commences:

**Conditions of Approval:**
A copy of the in-country ethics approval must be provided to the HREC before data collection commences.

**Conditions of Approval - All Projects:**

- The Chief Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Chief Investigator will seek approval from the **HREC Executive** for any modifications to the protocol or other project documents.
- The Chief Investigator will notify the **HREC Executive** immediately of any protocol deviation or adverse events or safety events related to the project.
- The Chief Investigator will report to the **HREC Executive** annually in the specified format and notify the **HREC Executive** when the project is completed at all sites.
- The Chief Investigator will notify the **HREC Executive** if the project is discontinued before the expected completion date, with reasons provided.
- The Chief Investigator will notify the **HREC Executive** of his or her inability to continue as Coordinating Chief Investigator including the name of and contact information for a replacement.

The **HREC Executive** Terms of Reference, Standard Operating Procedures, membership and standard forms are available from https://research.unsw.edu.au/research-ethics-and-compliance-support-recs.

If you would like any assistance, or further information, please contact the ethics office on:
P: +61 2 9385 6222, + 61 2 9385 7257 or + 61 2 9385 7007
E: humanethics@unsw.edu.au

Kind Regards,

A/Prof John Hunt
HREC Presiding Chairperson

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007).* The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

Beyrouth, le 25 septembre 2017

Monsieur le Docteur Rabih EL-CHAMMAY
Service de psychiatrie -HDF

**Nos réf. :** USJ -2017-24

**Titre** : Formative research to inform the evaluation of the helping young adolescents cope intervention.

Cher Collègue,

Lors de sa réunion du 19 septembre, le Comité a pris acte de votre courrier daté du 11 août ; ce courrier était accompagné du protocole de cette étude pour les phases 2-5.

Après en avoir délibéré, le Comité estime à l'unanimité que le projet de cette nouvelle étape ne soulève aucune objection d'ordre éthique ; il vous notifie donc bien volontiers son accord. Par ailleurs, je vous invite à faire parvenir en temps utile au secrétariat du Comité les documents complémentaires dans leur version arabe.

Veuillez agréer, Cher collègue, l'assurance de mes sentiments dévoués.

UNIVERSITÉ SAINT-JOSEPH USJ comité d'éthique

Pr. Michel SCHEUER
Président

## 2.5. WP5 Community Implementation

| **Study 1** | **The Netherlands** |
|---|---|
| Partners involved: | VUA, IPSY |
| 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 (dd. September 06, 2017). |

| **Study 2** | **Turkey** |
|---|---|
| Partners involved: | ISU, RASASA |
| 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) |

| **Study 3** | **Switzerland** |
|---|---|
| Partners involved: | UZH |
| 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). |

Van der Boechorststraat 7
postbus 7057
1007 MB Amsterdam

telefoon 020 444 5585
kamer H-565

www.vumc.nl/METc
METc@vumc.nl

dr. E.M. Sijbrandij
FPP, afdeling klinische psychologie
BS 1 KAMER 3F-71

VUmc

onderwerp
positief oordeel

ons kenmerk
2017.320
NL61361.029.17

datum
Amsterdam, 6 september 2017

Geachte mevrouw Sijbrandij,

De Medisch Ethische Toetsingscommissie VU medisch centrum (bevoegd tot oordelen op grond van art. 2.2.a WMO) **oordeelt positief over de uitvoering van het onderzoek** met titel:

**Implementation of Problem Management Plus in Syrian refugees**

Aanvrager van het onderzoek: dr. E.M. Sijbrandij
Verrichter: VU te Amsterdam
METc VUmc registratienummer: 2017.320

De goedkeuring van het protocol is gebaseerd op de documenten die in bijlage 1 zijn opgenomen.

Wij wijzen u erop dat **alle** onderzoekers die betrokken zijn bij de uitvoering van de studie (ook de onderzoekers in de deelnemende instellingen) op de hoogte moeten zijn van de laatste aanpassingen in het onderzoeksprotocol en eventuele appendices. Hiervan moet schriftelijk bewijs aanwezig zijn bij de onderzoeksdocumentatie.

**Deelnemende centra**
De commissie heeft de in bijlage 1 vermelde onderzoeksverklaring(en) bekeken. Zij heeft geconstateerd dat is voldaan aan de voorwaarden in artikel 3, onderdeel e en k, van de WMO.

De goedkeuring betreft de uitvoering in:

| Onderzoekscentra | Lokale hoofdonderzoeker |
|---|---|
| i-psy | Mw. Y. van Son |
| VU | Mw. Dr. M. Sijbrandij |

Het bestuur of directie van deze instelling(en) dient toestemming te geven voor de uitvoering van het onderzoek in de eigen instelling. Pas na het verkrijgen van deze toestemming kan het onderzoek in het desbetreffende centrum starten.

Indien het onderzoek ook in een of meerdere Nederlandse instellingen dan bovengenoemd zal worden uitgevoerd, dient de coördinator van het onderzoek hiervoor een onderzoeksverklaring in te dienen, op grond waarvan de METc VUmc een nader oordeel zal uitspreken over de participatie van die instellingen.

**Vergadering en documenten**
Op 09/06/2017 is het onderzoeksdossier compleet verklaard en bij de METc VUmc in behandeling genomen. Het onderzoeksdossier - gebaseerd op de documenten die in bijlage 1 zijn vermeld - is besproken in de vergaderingen van 22/06/2017 en 17/08/2017. De samenstelling van de commissieleden is in bijlage 2 opgenomen.

**Motivering**
De commissie is van oordeel dat het onderzoek voldoet aan het bepaalde in de van toepassing zijnde wet- en regelgeving, met name de WMO en, voor zover relevant, het ICH/GCP richtsnoer.

De commissie is van oordeel dat het onderzoeksprotocol in een toestemmingsprocedure voorziet die overeenstemt met artikel 6, eerste lid, van de WMO.

De commissie is van mening dat is voldaan aan de voorwaarden in artikel 6, vijfde t/m negende lid, van de WMO. De proefpersonen (en/of degenen die mede/in hun plaats bevoegd zijn tot het geven van toestemming voor deelname aan het onderzoek) worden op gepaste, volledige en begrijpelijke wijze schriftelijk over het onderzoek geïnformeerd.

**Verzekeringen**
De METc VUmc heeft vastgesteld dat op correcte wijze uitvoering is gegeven aan de verzekeringsplicht in artikel 7, eerste lid, van de WMO, en zoals nader uitgewerkt in het *Besluit verplichte verzekering bij medisch-wetenschappelijk onderzoek met mensen 2015* (Besluit van 24 november 2014). Naar het oordeel van de commissie gaat het onderzoek gepaard met risico.

Het onderzoek valt onder de proefpersonenverzekering van de VU.

De commissie heeft geconstateerd dat een aansprakelijkheidsverzekering is afgesloten zoals bepaald in artikel 7, negende lid, van de WMO.

**Voorwaarden en verplichtingen**
De METc VUmc wijst u op de voorwaarden en verplichtingen die in bijlage 3 zijn vermeld. De commissie heeft de bevoegdheid haar positieve oordeel in te trekken als vaststaat dat de uitvoering van het onderzoek ernstig tekort schiet.

Het voorliggend oordeel verliest zijn geldigheid indien de start van het onderzoek (inclusie van de eerste proefpersoon) niet binnen één jaar nadat dit besluit is genomen heeft plaatsgevonden.

**Administratief beroep**
Tegen dit besluit kan een belanghebbende op grond van artikel 23 WMO binnen zes weken na de dag waarop het besluit is bekend gemaakt, administratief beroep instellen bij de Centrale Commissie Mensgebonden Onderzoek (CCMO). Het beroepschrift dient u te adresseren aan: CCMO, Postbus 16302, 2500 BH Den Haag.

Met vriendelijke groet,
namens de Medisch Ethische Toetsingscommissie,
i/o

prof. dr. J.A. Rauwerda, voorzitter

Dhr. dr. D.I. Dower, secretaris

Bijlage 1: Documentenlijst
Bijlage 2: Samenstelling METc VUmc
Bijlage 3: Voorwaarden en verplichtingen
Bijlage 4: IRB approval

c.c.: Centrale Commissie Mensgebonden Onderzoek te Den Haag (CCMO) - *digitaal uploaden*
c.c.: a.m.de.graaff@vu.nl

## Bijlage 1 - Documentenlijst

| Sectie | Onderwerp | Versie |
|---|---|---|
| A1 | aanbiedingsbrief | bijlage: overzicht aanwezige documenten |
| A1 | aanbiedingsbrief | d.d. 6-6-2017 |
| A1 | commentaar METc | d.d. 3-7-2017; d.d. 19-8-2017 |
| A1 | reactie op commentaar METc | d.d. 2-8-2017; d.d. 22-8-2017 |
| B1 | ABR-formulier | versie 3 d.d. 22-8-2017 |
| B21 | goedkeuring CWO | d.d. 26-4-2017 |
| B22 | begroting/begrotingsverklaring | d.d. 3-3-2017 |
| B24 | risicoclassificatie | versie 1 d.d. 31-5-2017 (verwaarloosbaar) |
| C1 | onderzoeksprotocol | versie 3 d.d. 22-8-2017 (TC) |
| E11 | informatiefolder | Brochure Medisch-wetenschappelijk onderzoek d.d. maart 2017 |
| E12 | informatiebrief incl. toestemmingsverklaring | audio opnames PM+ versie 1 d.d. 1-8-2017 |
| E12 | informatiebrief incl. toestemmingsverklaring | familie/kennissen fase 3 en 5 versie 2 d.d. 1-8-2017 (TC) |
| E12 | informatiebrief incl. toestemmingsverklaring | fase 2 versie 2 d.d. 1-8-2017 (TC) |
| E12 | informatiebrief incl. toestemmingsverklaring | fase 3 en 5 medewerkers versie 2 d.d. 1-8-2017 (TC) |
| E12 | informatiebrief incl. toestemmingsverklaring | fase 4 versie 2 d.d. 1-8-2017 (TC) |
| E12 | informatiebrief incl. toestemmingsverklaring | PM+ behandelaren fase 3 en 5 versie 2 d.d. 1-8-2017 (TC) |
| E12 | informatiebrief incl. toestemmingsverklaring | PM+ deelnemers fase 3 en 5 versie 2 d.d. 1-8-2017 (TC) |
| F1 | vragenlijst | CSSRI-EU d.d. 15-9-1997 |
| F1 | vragenlijst | Health Service Access |
| F1 | vragenlijst | HSCL-25 |
| F1 | vragenlijst | K10 |
| F1 | vragenlijst | Living Difficulties PMLD-CL |
| F1 | vragenlijst | PCL-5 d.d. 14-8-2013 |
| F1 | vragenlijst | PCL-5 with LEC-5 and Criterion A d.d. 14-8-2013 |
| F1 | vragenlijst | PSYCHLOPS Post-Therapy versie 5 d.d. 2010 |
| F1 | vragenlijst | PSYCHLOPS Pre-Therapy versie 5 d.d. 2010 |
| F1 | vragenlijst | Study phase 3 and 5 - Interview guides qualitative evaluation PM+ program |
| F1 | vragenlijst | WHODAS 2.0 d.d. 2012 |
| G1 | WMO proefpersonenverzekering | CNA t.b.v. VU d.d. 22-2-2017 |
| G2 | aansprakelijkheidsverzekering | Willis t.b.v. VU d.d. 9-1-2017 |
| H1 | CV onafhankelijk deskundige | M.J.H. Huibers |
| H2 | CV coördinerend onderzoeker | M. Sijbrandij d.d. mei 2017 |
| I1 | lijst deelnemende centra | |
| I2 | onderzoeksverklaring | i-psy (Parnassia Groep) t.b.v. van Son d.d. 7-6-2017 |
| I32 | CV uitvoerend onderzoeker | A.M. de Graaff |
| I4 | CV lokale onderzoeker | Y. van Son (i-psy) |
| K4 | wetenschappelijke publicatie (sectie K) | Dawson et al., 2015 |

| | | |
|---|---|---|
| K4 | wetenschappelijke publicatie (sectie K) | Nadkarni et al., 2015 |
| K4 | wetenschappelijke publicatie (sectie K) | Rahman et al., 2016 |
| K4 | wetenschappelijke publicatie (sectie K) | Rahman et al., 2016 |
| K4 | wetenschappelijke publicatie (sectie K) | Sijbrandij et al., 2015 |
| K6 | overig sectie K | PM+ manual versie 1 d.d. 2016 |
| P1a | niet-WMO advies | METc VUmc d.d. 20-4-2017 |

## Bijlage 2: Samenstelling METc VUmc

| | |
|---|---|
| dhr. prof. dr. J.A. Rauwerda | voorzitter, chirurg |
| mevr. prof. dr. C. Boer | vice-voorzitter, biomedicus |
| mevr. E.A. Aarsman-Voorbij | researchverpleegkundige |
| dhr. drs. P.M. Bet | ziekenhuisapotheker-klinisch farmacoloog (plv.) |
| mevr. mr. L. Brakel | jurist |
| mevr. dr. M.A. Bremmer | psychiater |
| dhr. dr. J. Buter | internist-oncoloog |
| dhr. dr. B. Drukarch | arts-farmacoloog |
| dhr. dr. ir. ing. Th.J.C. Faes | klinisch fysicus (plv.) |
| dhr. dr. M.J.J. Finken | kinderarts (plv.) |
| dhr. dr. E.G. Haarman | kinderarts |
| dhr. dr. A.W.J. Hoksbergen | chirurg (plv.) |
| dhr. dr. M.J.P.A. Janssens | medisch ethicus |
| Mevr. K. Kersbergen-de Lange | Verpleegkundige (plv.) |
| dhr. prof. dr. M. Klein | neuropsycholoog |
| mevr. dr. M. Kouwenhoven | neuroloog (plv.) |
| dhr. dr. M.D. Lagerweij | tandarts |
| mevr. L. Muter | proefpersonenlid (plv.) |
| mevr. G. Nijman | proefpersonenlid |
| dhr. dr. B.W. van Oosten | neuroloog |
| dhr. prof.dr. G. Ossenkoppele | internist-hematoloog |
| mevr. dr. A.F.W. van der Steeg | chirurg |
| mevr. dr. C.B. Terwee | methodoloog (plv.) |
| dhr. dr. ir. P. van de Ven | methodoloog |
| dhr. ing. S.W. Vianen | stralingsdeskundige |
| mevr. dr. C. Widdershoven | medisch ethicus (plv.) |
| mevr. mr. M. Wildenbeest | jurist (plv.) |
| dhr. drs. A.J. Wilhelm | ziekenhuisapotheker-klinisch farmacoloog |

## Bijlage 3 - Voorwaarden en verplichtingen

**Geldigheid oordeel**
Het positieve oordeel verliest zijn geldigheid als de inclusie van de eerste proefpersoon niet heeft plaatsgevonden binnen een jaar nadat dit besluit is genomen.

**Geldigheid verzekering**
In het geval het verzekeringscertificaat tijdens de voortgang van het onderzoek zijn geldigheid verliest, dient aan de METc VUmc tijdig een afschrift van een nieuw geldig certificaat te worden toegestuurd.

**Amendementen**
Amendementen dienen ter beoordeling aan de METc VUmc te worden voorgelegd.

**Startdatum onderzoek**
De METc VUmc dient op de hoogte te worden gesteld van de definitieve startdatum van het onderzoek. Dat is de datum waarop de inclusie van de eerste proefpersoon plaatsvindt.

**Voortgangsrapportage**
Eén jaar na datum van het oordeel, en ieder jaar daaropvolgend, dient de METC op de hoogte te worden gebracht van de voortgang van de studie middels het formulier Voortgangsrapportage.

**Melding SAE's**
SAE's dienen aan de METc VUmc te worden gemeld

**Melding (voortijdige) beëindiging en opschorting**
(Voortijdige) beëindiging en opschorting van het onderzoek dient, met redenen omkleed, te worden gemeld aan de METc VUmc.

**Eindrapportage**
De METc VUmc dient op de hoogte te worden gebracht van de resultaten van het onderzoek middels een eindrapport.

*Termijnen en overige uitleg ten aanzien van de indiening van de verschillende documenten aan de* METc VUmc *vindt u op de website (www.vumc.nl/afdelingen/METc/).*

# Bijlage 4 - IRB approval

dr. E.M. Sijbrandij
FPP, afdeling klinische psychologie
BS 1 KAMER 3F-71

Medical Ethics Review Committee
VU University Medical Center
chairman: prof. dr. J.A. Rauwerda
internal post address: BS7, kamer H-565
telephone: (+31) (0)20 - 44 45585
e-mail: metc@vumc.nl
website: www.vumc.nl/metc

| subject | our reference | date |
|---|---|---|
| IRB approval | 2017.320 | Amsterdam, 6 september 2017 |
| multicenter study | NL61361.029.17 | |

Dear dr. Sijbrandij,

The Institutional Review Board of VU University Medical Center (hereafter: METc VUmc) in Amsterdam, competent to review in accordance with section 2.1a of the Medical Research Involving Human Subjects Act (WMO), gives approval for the study with the title:

**Implementation of Problem Management Plus in Syrian refugees**

Submitting party: dr. E.M. Sijbrandij
Sponsor: VU, Amsterdam
METc VUmc registration number: 2017.320

**Participating centers**
The approval concerns execution of the research protocol to be performed in the Netherlands in the following centre(s):

| | |
|---|---|
| i-psy | Y. van Son |
| VU | dr. M. Sijbrandij |

**Committee meetings and documents**
The research documents were discussed during the plenary meetings which took place on 22/06/2017 and 17/8/2017. The approval is based on the following documents:

- the research protocol d.d. 22/8/2017 version 3
- written information and consent statement to be used d.d. 1/8/2017 version 2

With regard to the other documents approved, we refer to appendix 1 (bijlage 1) of the original decision in Dutch.

**Motivation**
The committee is of the opinion that the study is in compliance with all current legislation, mainly the WMO and, if relevant, the ICH/GCP.
The METc VUmc is registered with the US Office for Human Research Protections (OHRP) as IRB00002991. The FWA number assigned to VU University Medical Center is FWA00017598.

İSTANBUL
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ÜNİVERSİTESİ

**ARAŞTIRMA ETİK KURUL KARARLARI**
**(Research Ethics Committee Decision)**

| | |
|---|---|
| **Toplantı Tarihi** | : 12.04.2017 |
| **Toplantı Sayısı** | : 10/2017 |
| **Toplantı Saati** | : 11:00 |
| **Toplantıya Katılanlar** | : Prof. Dr. Hatice AYNUR |
| | Prof. Dr. Nihat BULUT |
| | Prof. Dr. Cem BEHAR |
| | Doç. Dr. Eda YÜCESOY |
| | Yrd. Doç. Dr. Sinem ELKATİP HATİPOĞLU |
| | Yrd. Doç. Dr. Betül NİZAM |
| | Yrd. Doç. Dr. Eyyüp Said KAYA |
| | Yrd. Doç. Dr. Hızır Murat KÖSE |

**Karar No 1:**
İstanbul Şehir University Research Ethics Committee has reviewed the project named "Fostering responsive mental health systems in the Syrian refugee crisis (STRENGHTS)" Yrd. Doç. Dr. Zeynep Ceren ACARTÜRK.

According to the given information, STRENGTHS aims to provide effective community-based health care implementation strategies to scale-up the delivery and uptake of effective mental health interventions (Problem Management Plus, PM+) in different country contexts (The Netherlands, Germany, Switzerland, Egypt, Turkey, Jordan, Lebanon). The STRENGTHS project focuses on implementation of a trans-diagnostic mental health intervention related to the current Syrian refugee crisis, since the sudden increase in refugees seeking asylum in Europe and Syria's bordering countries poses a significant challenge to their health systems' responsiveness.

With **scaling-up and implementing** the low-intensity PM+ programs, we refer to their expansion of coverage, both geographically across European countries and the MENA countries and in terms of involving a new client group, namely Syrian refugees with increased psychological distress. We also refer to increasing the financial, human and capital resources required to expand this coverage.[7] The main goal of scaling-up the evidence-based low intensity PM+ programs is to reach more people who may benefit from them (**coverage**), and to attract more clients (**utilization**) in systematic ways that ensure durability of these health system changes (**sustainability**).


Kuşbakışı Caddesi No: 27 34662 Altunizade Üsküdar İstanbul | T 44 44 0 34 | F 0 216 474 53 53 | www.sehir.edu.tr

The consortium, which is coordinated by Vrije Universiteit Amsterdam is composed of 15 partners, moreover 3 institutions will be supporting the 60 months project as 3rd Party.

Members of Consortium

Vrije Universiteit Amsterdam (VU)
Danish Red Cross, Denmark;
Freie Universität Berlin, Germany;
International Medical Corps, UK;
I-Psy Amsterdam, Netherlands;
The Royal Tropical Institute (KIT), Netherlands;
London School of Economics and Political Science, UK;
London School of Hygiene and Tropical Medicine, UK;
War Child Holland, Netherlands;
War Trauma Foundation, Netherlands;
Mülteciler ve Sığınmacılar Yardımlaşma ve Dayanışma Derneği, Turkey
The United Nations High Commissioner for Refugees, Switzerland;
University of New South Wales, Australia
University Hospital Zurich, Switzerland;

- İstanbul Şehir University, Turkey

Moreover, Noor Al-Hussein Foundation (Jordan), World Health Organization and Ministry of Public Health Lebanon take part as 3rd party.

Millions of Syrians had to flight from their home country and seek asylum as refugees in many different countries after the crisis that started in 2011. According to the official records published in March 2016, there are more than 2.700.000 Syrian refugees in Turkey and 500.000 of them resides in Turkey.

The current crisis has a negative effect on individual refugees' both physical health and psychological well-being. In response to this crisis, the STRENGTHS project aims to provide a framework for scaling-up the delivery and uptake of effective community-based mental health strategies to address the specific needs of refugees within and outside Europe's borders.

This study is a part of the project named STRENGHTS which is supported by EU, H2020. This study will be carried out by two partners which are Istanbul Sehir University (ISU) and Refugees and Asylum Seekers Assistance and Solidarity Association (RASASA). In the context of the participating European and LMICs in the MENA region, the objectives of STRENGTHS are:

1. To outline necessary steps needed to integrate evidence based low-intensity psychological interventions for common mental disorders (the PM+ programs) into the health systems. These include key preparatory steps in the local political, regulatory and governance processes for uptake and scaling-up of the intervention and key contextual and system-related factors for its integration. These steps will be validated for the real-life impact on the responsiveness of the system.
2. To adapt the PM+ programs and training materials to the recipients of care within the specific health systems and co-create the necessary local conditions for implementation and up-scaling, e.g. training a workforce and develop internet-delivery modality and supporting tools.
3. To *scale-up* the PM+ programs successfully in terms of health-system performance, effectiveness, affordability, and sustainability and identify barriers and facilitators to this end.
4. To determine the invested cost and effort in terms of organizational, resource and political-economic requirements relative to the reduction of economic burden of the large-scale implementation of the specific PM+ programs into the health systems in the different contexts.

5. To *disseminate* the evidence-base for *PM+ programs* as well as the validated implementation strategies and step-guides to maintain its sustainability and engage with new stakeholders and health systems to further scaling up across Europe and beyond.
6. Recent crises in the Middle East, most notably in Syria, have resulted in an unprecedented increase in the number of refugees seeking asylum in neighboring countries as well as in Europe. The refugee crisis imposes highly challenging demands on health systems in Europe and the Middle East. In 2015, over 1 million refugees have been registered entering Europe through the Mediterranean Sea (UNHCR, December 31 2015), and 4.8 million have fled to Syria's neighboring countries. Reports state that over 50% of Syrian refugees are children, in many cases unaccompanied by their family.

7. In Sultanbeyli where the RASASA is located, there are more than 20.000 registered Syrian refugees. Research indicates that the risk for mental health disorders is higher for refugees compared to host population. With this study, we aim to identify Syrian refugees who have mental health problems and deliver them an evidence based low intensity psychological intervention.

The part of the STRENGHTS project which will be implemented in Istanbul mainly consists of four stages:

1. Focus Group
2. Pilot Study for The Application of PM+ (Exploratory RCT)
3. PM+ (Problem Management Plus)
    - Pre-test
    - Identification of the participants and distributing them to groups
    - Post-test
    - Follow-up test (2-month)
4. Reporting the results

In the first stage, we will be working with focus groups. Focus group interviews will be conducted with three following different groups:

1. 6 mental health professional involved in refugee mental health care
2. 6 Syrian refugees
3. 6 local and national representatives who are working with issues involving refugees (immigration authority, municipality, etc.)

During the cognitive interviewing of the groups, interviewers will be listing all the mental health problems that the participants reported with the method called free listing.

The aim of this stage is to adapt the psychological intervention that we will be used in this study to the needs and the culture of Syrian refugees by asking them questions about their needs, problems they face with, cultural differences and their sensitivities (*see Appendix 1 for the Focus Group questions*).

The raw data that is obtained at this stage of the study will be shared with Danish Red Cross, which is one of the partners of the consortium. However, the confidentiality of the participants of our focus groups will be our primary concern and only the information will be shared, not the names of our informants.

The second stage of the study will be a pilot study with the aim of gaining information about the feasibility, safety, and delivery of the intervention (PM+); and that will identify issues around its training, supervision, and outcome measures. In this stage, which will be a randomized controlled

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study, overall 60 Syrian participants will be recruited (30 refugees in the treatment group, 30 refugees in the control group). Since this will be a trial for the main study, the research design will be similar. PM+ will be applied in group sessions and there will be three groups each consisted of 10 participants.

The third stage of the study is the main stage that the intervention will be implemented. About 1500 Syrian refugees will be expected to fill the questionnaires that are stated below:

- A Demographic Form,
- The WHODAS (WHO Disability Assessment Schedule) will measure the level of functional impairment.
- SRQ-20 (WHO_Self-Report Questionnaire-20),
- CIS-R (Clinical Interview Schedule-Revised),
- LEC (Life Events Checklist) will measure the number of adverse life events.
- PCL-5 (PTSD Checklist for DSM-5) will measure the severity of posttraumatic stress reactions.
- PHQ-9 (Patient Health Questionnaire-9) will measure the severity of depression symptoms.
- HESPER (The Humanitarian Emergency Settings Perceived Needs Scale) will measure the perceived serious needs.
- GHQ-12 (General Health Questionnaire)
- Client Satisfaction Trauma (CIS-8) To assess client satisfaction with treatment.

All instruments (see Appendix 2) will be administered by trained research staff, blind to the allocation status of the participants. As far as possible independent assessors will have prior experience of research studies. All assessors will receive a five-day training in administering the instruments, in general interview techniques, and in responding to participant distress, including, as mentioned, psychological first aid. The training will be delivered by the ISU research team.

According to the results, 354 Syrian refugees will be identified who are in need of a psychological intervention. Participant will be selected considering the following criteria:

Inclusion Criteria:

- Arabic speaking Syrians who are 18 years old and older
- > 2 GHQ-12
- > 16 WHODAS 2.0

Exclusion Criteria:

- Acute medical conditions
- Imminent risk of suicide
- Having experienced a major traumatic event during the past month (e.g., an accident, natural disaster, assault, or death of a loved one)
- Severe mental disorder (psychotic disorders, substance dependence)

Severe cognitive impairment (severe intellectual disability or dementia

The method of Randomized Controlled Trial (RCT) will be used in this study and the participants who are elected because they fit the criteria above will be randomly assigned to control and treatment groups.

Power calculations were carried out according to the previous findings. A total number of 354 participants will be included. Based on previous studies with PM+ carried out in Peshawar, Pakistan, and Nairobi Kenya, we aim for a conservatively estimated small to medium Cohen's *d* effect size of 0.4 in the PM+ group at 6 months' follow-up. Power calculations suggest a minimum sample size of 133 participants per group (power = 0.90, $\alpha$ = 0.05, two-sided). Taking into account an expected 20% attrition at 2 months' follow-up, we aim to include a total number of 354 participants (177 in the PM+ group and 177 in the care-as-usual control group -see Appendix 3).

The participants in the control group will continue with their usual treatment during the study so that the effect of PM+ can be detected. The usual treatment is consisted of the daily services that they get from the association such as psychological support.

PM+ is a manual written by Katie Dawson with the support of World Health Organization. It is a therapy that focuses on the management of problems which the treatment will group will receive it for 5 weeks. PM+ has 4 core features. It is:

1. Brief (5-sessions),
2. Delivered by paraprofessionals,
3. Transdiagnostic, addressing depression, anxiety, PTSD, stress, and problems as defined by people themselves, and
4. Designed for people in low-income country communities affected by adversity (e.g. violence).

The sessions will be given as a group therapy. There will be 18 groups and each group will consist of 8-10 participants. The groups for male and female participants will be different.

The therapies will be given by Syrians who have no background in psychology. First, PM+ specialists will have a visit to Turkey and train a group of 15-20 people who speaks Arabic on the therapy and these people will train the Syrian service providers. In this study, we will have 8 Syrian service providers and 2 Arabic speaking professional mental health workers.

At the end of the intervention, the effect of the therapy on the participants will be measured by using the questionnaires that were used before and these questionnaires will be used again after 2 months on 354 participants.

The GHQ-12 is the primary outcome measure; the WHODAS 2.0, PHQ-9, and PCL-5 are the secondary outcome measures.

Evaluations on the effectiveness of the process (adaptation, quality, dose, reach) will be made during and after the implementation. In consideration of these evaluations, it is aimed that the PM+ treatment will be more effective on the psychological problems that Syrian refugees experience. Various mediators will also be examined to understand the effect mechanism of the treatment.

a) *Does your study include elements which might be threatening for the physical/psychological well-being of the participants or might cause them stress? If yes, explain. Explain the measures that you will take to resolve or decrease the effect of these elements.*

Traumatic memories might emerge while filling the questionnaires but the interviewers are notified about this. It is possible for the participants to get affected during the therapy as well but the field coordinator who is trained in psychological first aid and professional psychologists will be on the field of study, RASASA, to give support and help the participants who are in need.

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To reduce these factors, it is clarified on the informed consent that the participants can quit the study any time they wish to, without any sanctions.

b) *Does the information about the aim of the study will be kept completely or partially hidden from the participants? If yes, explain the reasons. State how this will be explained to the participants after the collection of the data.*
The aim of our study will be completely explained with the informed consent and the participants will be included in the study if the fill this form.

c) *Ensuring the confidentiality of participants' personal information*

This study is based on the security and the confidentiality of the participants. The name of the participants will be kept secret and the information will not be used other than research purposes. Before the interview, the participants will be assigned with a number and the link between the number and the names will only be known by the project conductor and the research assistants who are trained on data confidentiality.

After the data collection, questionnaires and the documents that include the names of the participants will be kept locked in separate places. Data management protector who is working in ISU will be responsible from the protection of the collected data.
In line with the APA (American Psychology Association) rules, the raw data will be kept in a safe place for 5 years after the research findings are published.

Followed by this information, undersigned Research Ethics Committee Members have seen no harm in view of ethics in the project entitled "'Fostering responsive mental health systems in the Syrian refugee crisis (STRENGHTS)'' Yrd. Doç. Dr. Zeynep Ceren ACARTÜRK.

Prof. Dr. Hatice AYNUR
President

Prof. Dr. Nihat BULUT
Member

Prof. Dr. Cem BEHAR
Member

Doç. Dr. Eda YÜCESOY
Member

Yrd. Doç. Dr. Hızır Murat KÖSE
Member

Yrd. Doç. Dr. Betül NİZAM
Member

Yrd. Doç. Dr. Sinem ELKATİP HATİPOĞLU
Member

Yrd. Doç. Dr. Eyyüp Said KAYA
Member

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Boyutsuz
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**T.C.**
**İÇİŞLERİ BAKANLIĞI**
**Göç İdaresi Genel Müdürlüğü**
**Göç Politika ve Projeleri Dairesi Başkanlığı**

**Sayı** : 62103649-604.02.02 -15143
**Konu** : Araştırma İzni

29../..03.2017

**İlgi** : 21.03.2017 tarih ve bila sayılı yazınız.

İlgi yazı eki ile "Suriye Mülteci Krizinde Hassas Ruh Sağlığını İyileştirme" isimli proje hakkında izin talep etmektedir.

Söz konusu izin talebi 6458 sayılı Yabancılar ve Uluslararası Koruma Kanunu'nun 94 üncü maddesi ile 2014/6883 karar sayılı Geçici Koruma Yönetmeliğinin 51 inci maddesinde belirtilen gizlilik ilkesine gerekli hassasiyetin gösterilmesi ve elde edilecek verilerin araştırma dışında kullanılmaması, üçüncü kişilerle paylaşılmaması, dahası çalışmaya konu kişilerden ve/veya aile üyelerinden ad, soyad, telefon, adres bilgilerinin istenmemesi ve çalışma esnasında ses ya da video kaydının alınmaması şartıyla uygun görülmüştür.

Bilgi ve gereğini rica ederim.

Sa[illegible]ih BIÇAK
Başkan a.
Genel Müdür Yardımcısı

İSTANBUL ŞEHİR ÜNİVERSİTESİ
GELEN EVRAK
Tarih 05-04-2017
Sayı 609

**Dağıtım:**
**Gereği:**
**İSTANBUL ŞEHİR ÜNİVERSİTESİ**

**Bilgi:**
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**Kantonale Ethikkommission**

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Präsident

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Dr. phil. Morina Naser
Culmannstrasse 8
8091 Zürich

08. September 2017 / bfe

**Beschlussmitteilung der Kantonalen Ethikkommission Zürich**

**Gesuch BASEC-Nr. 2017-01175**
**STRENGTHS - Scaling-up psychological interventions with Syrian refugees**

**Gesuchsteller** Dr. phil. Morina Naser, Klinik für Psychiatrie und Psychotherapie

**Zentren** Dr. phil. Morina Naser, Klinik für Psychiatrie und Psychotherapie

## I. Verfahren

☐ ordentliches Verfahren ☐ vereinfachtes Verfahren ☒ präsidiales Verfahren

## II. Entscheid

☒ **Die Bewilligung wird erteilt**

Bedeutet: Das Vorhaben gemäss bewilligtem Forschungsplan kann gestartet und im Rahmen der anwendbaren rechtlichen Bestimmungen durchgeführt werden.

Bewilligungen für **klinische Versuche der Kategorie B und C** stehen unter dem **Vorbehalt**, dass

1. allfällig durch die zuständige eidgenössische Zulassungsbehörde (Swissmedic/BAG) festgestellte Mängel keine Änderungen der von der Ethikkommission evaluierten Unterlagen erfordern, und dass

2. die Bewilligung der eidgenössischen Zulassungsbehörde (Swissmedic/BAG) vorliegt.

☐ **Die Bewilligung wird mit Auflagen erteilt**

Bedeutet: Das Vorhaben gemäss bewilligtem Forschungsplan:

**kann gestartet** und im Rahmen der anwendbaren rechtlichen Bestimmungen durchgeführt werden.

Die Auflagen sind innert angemessener Frist zu erfüllen. Die revidierten Dokumente werden nach Einreichung im präsidialen Verfahren geprüft.

Folgende Auflagen müssen erfüllt werden:

Kontaktperson:

☐ **Gegenwärtig kann die Bewilligung noch nicht erteilt werden**

Bedeutet: Das Vorhaben kann **noch nicht** gestartet werden. Die nachfolgenden Bedingungen sind zu erfüllen. Die revidierten Dokumente werden nach Einreichung von der Ethikkommission geprüft.

Folgende Bedingungen müssen für alle Zentren erfüllt werden:

Kontaktperson:

☐ **Die Bewilligung wird nicht erteilt**

Bedeutet: Das Vorhaben kann in der vorliegenden Form nicht durchgeführt werden. Eine Neueinreichung ist möglich.

☐ **Auf das Gesuch wird nicht eingetreten**

Bedeutet: Die Ethikkommission ist für die Beurteilung rechtlich nicht zuständig (entweder ist eine andere Stelle für die Bewilligung zuständig, oder das Vorhaben kann ohne Bewilligung durchgeführt werden). Oder: Das Gesuch ist nicht vollständig.

☐ **Das Verfahren wird infolge Gegenstandslosigkeit abgeschrieben**

Bedeutet: Das Verfahren wird wegen Rückzugs des Gesuchs oder anderen Gründen gegenstandslos.

☐ **Das Verfahren wird sistiert**

☐ **Die Bewilligung wird entzogen**

## III. Einteilung

☒ **Das Vorhaben gilt als klinischer Versuch gemäss KlinV**

☒ Kategorie ☒ A ☐ B ☐ C

☐ mit Arzneimitteln

☐ mit Medizinprodukten

☐ mit Transplantatprodukten

☐ der Gentherapie

☐ mit gentechnisch veränderten oder pathogenen Organismen

☐ der Transplantation

☒ anderer klinischer Versuch gemäss 4. Kapitel KlinV

☐ Umkategorisierung gemäss Art. 71 Abs. 3 KlinV, Kategorie ☐A ☐B ☐C

☐ mit Strahlenquellen

☐ **Das Vorhaben gilt als Forschungsprojekt gemäss HFV**

☐ Forschung mit Personen, Kategorie ☐A ☐B

☐ Umkategorisierung gemäss Art. 48 Abs. 2 HFV, Risiko-Kategorie ☐A ☐B

☐ mit Strahlenquellen

☐ Weiterverwendung biologischen Materials und/oder gesundheitsbezogener Personendaten

☐ Forschung mit verstorbenen Personen

☐ Forschung an Embryonen und Föten einschliesslich Totgeburten

☐ **Weiterverwendung ohne vorbestehende Einwilligung (Art. 34 HFG, Art. 37-40 HFV)**

a. Verwendungszweck

b. Bezeichnung des biologischen Materials/Personendaten

c. zur Weitergabe berechtigter Personenkreis

d. zur Entgegennahme berechtigter Personenkreis

☐ **Multizentrisches Forschungsprojekt**

☐BE ☐NZ ☐GE ☐OS ☐ TI ☐VD ☐ZH

## IV. Begründung

Die Ethikkommission stützt ihre Begründung auf die Unterlagen, wie sie aufgeführt sind:

☒ in der submission summary vom 04.09.2017

☐ in der /den Stellungnahme/n der Kantonalen Ethikkommission/en:

☒ im Beschluss der Kantonalen Ethikkommission Zürich vom 07.08.2017

☐ sowie auf

☐ Wir bitten Sie, die geänderten Unterlagen im BASEC hochzuladen.

## V. Kosten

Die Gebühren wurden bereits in Rechnung gestellt.
Gemäss der geltenden Gebührenordnung von swissethics.

## VI. Rechtsmittelbelehrung

Gegen diesen Beschluss kann innert 30 Tagen, von der Mitteilung an gerechnet, beim Regierungsrat des Kantons Zürich schriftlich Rekurs eingereicht werden. Die Rekursschrift muss einen Antrag und dessen Begründung enthalten. Der angefochtene Entscheid ist beizulegen oder genau zu bezeichnen. Die angerufenen Beweismittel sind genau zu bezeichnen und soweit möglich beizulegen.

## VII. Mitteilung an den Gesuchsteller

und in Kopie an:

☐ **Sponsor**

☐ **Swissmedic**

☐ **BAG**

☐ **beteiligte, lokale EKs (multizentrische Studien)**

☐ **Behörden:**

☐ **andere:**

## VIII. Zusammensetzung der am Entscheid beteiligten Kommission

| | | | | | am Beschluss beteiligt | | |
|---|---|---|---|---|---|---|---|
| | | | | | ja | nein | |
| | Name, Vorname | Berufliche Stellung / Titel | m | f | | abwesend | In Ausstand |
| **Vorsitz** | Meier-Abt Peter | Prof. Dr. med. | ☒ | ☐ | ☒ | ☐ | ☐ |
| **Mitglieder** | Baumann-Hölzle Ruth | Dr. theol. | ☐ | ☒ | ☐ | ☐ | ☐ |
| | Betschart Cornelia | PD Dr. med. | ☐ | ☒ | ☐ | ☐ | ☐ |
| | Bloch E. Konrad | Prof. Dr. med. | ☒ | ☐ | ☐ | ☐ | ☐ |
| | Geschwindner Heike | PhD MNSc Pflegewissenschaft | ☐ | ☒ | ☐ | ☐ | ☐ |
| | Haug Achim | Prof. Dr.med. | ☒ | ☐ | ☐ | ☐ | ☐ |
| | Hess Christian | Dr. med. | ☒ | ☐ | ☐ | ☐ | ☐ |
| | Jetter Alexander | PD Dr. med. | ☒ | ☐ | ☐ | ☐ | ☐ |
| | Jokeit Hennric* | Prof. Dr. rer. nat. Dipl.-Psych. | ☒ | ☐ | ☐ | ☐ | ☐ |
| | Kapossy Katrin | Fürsprecherin | ☐ | ☒ | ☐ | ☐ | ☐ |
| | Keller-Senn Anita | Pflegefachfrau MScN | ☐ | ☒ | ☐ | ☐ | ☐ |
| | Künig Gabriella | PD Dr. med. | ☐ | ☒ | ☐ | ☐ | ☐ |
| | Lütolf Urs M. | Prof. em. Dr. med. | ☒ | ☐ | ☐ | ☐ | ☐ |
| | Mausbach, Julian | Dr. iur. RA | ☒ | ☐ | ☐ | ☐ | ☐ |
| | Metzger Urs | Prof. Dr. med. | ☒ | ☐ | ☐ | ☐ | ☐ |
| | Nadal David | Prof. Dr. med. | ☒ | ☐ | ☐ | ☐ | ☐ |
| | Ramel Urs | Dr. med. dent. | ☒ | ☐ | ☐ | ☐ | ☐ |
| | Siegrist Michael | Prof. Dr. phil. | ☒ | ☐ | ☐ | ☐ | ☐ |
| für Biometrie zuständiges Mitglied* | Stocker Reto | Prof. Dr. med. | ☒ | ☐ | ☐ | ☐ | ☐ |
| | Ziltener Erika | Lic. phil. I, Patientenstelle | ☐ | ☒ | ☐ | ☐ | ☐ |

Peter Meier-Abt

Peter Kleist

## Bemerkungen

### Registrierungspflicht

Der Sponsor muss – falls es sich um einen klinischen Versuch handelt – diesen in einem WHO-Primärregister oder im Register der Nationalen Medizinbibliothek der USA (clinicaltrials.gov) erfassen und anschliessend diese Nummer im BASEC-Portal eingeben. Die Übertragung der erforderlichen Daten in das Swiss National Clinical Trials Portal (SNCTP) kann nach Bewilligung der Ethikkommission und Zustimmung des Gesuchstellers automatisch erfolgen. Die Informationen über den klinischen Versuch sind in beiden Registern öffentlich zugänglich. Zusätzlich veröffentlicht swissethics wenige Informationen wie Titel, Projekttyp oder Leit-Ethikkommission aller durch die kantonalen Ethikkommissionen bewilligten Gesuche auf swissethics.ch (ausser Phase-I-Studien).

Die Kantonale Ethikkommission Zürich bestätigt, dass sie nach ICH-GCP arbeitet.

### Vorgehen zur Einreichung revidierter Dokumente

- Revidierte Unterlagen sind der Ethikkommission über BASEC zuzustellen.
- Die Änderungen sind in den revidierten Dokumenten zu markieren.
- Die revidierten Dokumente sind auch weiteren involvierten Zulassungsbehörden zuzustellen, sofern sie von diesen für die Bewilligung benötigt werden.

### Meldungen und Berichterstattung an die Ethikkommission siehe Anhang 1 und Anhang 2

## Anhang 1
## Meldungen und Berichterstattung an die Ethikkommission ab 1. Januar 2014 für klinische Versuche (KlinV)

### Meldung von Sicherheits- und Schutzmassnahmen
siehe Art. 37 KlinV:
Meldung an die EK innerhalb von 7 Tagen
Versuche mit Medizinprodukten: innerhalb von 2 Tagen

### Abschluss, Abbruch oder Unterbruch des klinischen Versuchs
siehe Art. 38 KlinV:
Abschlussmeldung an die EK innerhalb von 90 Tagen
Abbruch- oder Unterbruchmeldung an die EK innerhalb von 15 Tagen
Schlussbericht an die EK: innerhalb 1 Jahres nach Abschluss/Abbruch

### Schwerwiegende unerwünschte Ereignisse (Serious Adverse Events, SAE) bei klinischen Versuchen mit Arzneimitteln
Siehe Art. 40 KlinV:
Falls gemäss Protokoll nicht anders vorgesehen SAE mit Todesfolge innerhalb von 7 Tagen (an lokale EK nur lokale Ereignisse, an Leit-EK alle Ereignisse in der CH).

### Verdacht auf eine unerwartete schwerwiegende Arzneimittelwirkung (Suspected Unexpected Serious Adverse Reaction, SUSAR)
Siehe Art. 41 KlinV:
SUSAR mit Todesfolge innerhalb von 7 Tagen, sonstige SUSARs innerhalb von 15 Tagen (an lokale EK nur lokale Ereignisse, an Leit-EK alle Ereignisse in der CH).

### Schwerwiegende unerwünschte Ereignisse (Serious Adverse Events, SAE) bei klinischen Versuchen mit Medizinprodukten
Siehe Art. 42 KlinV:
Bei Versuchen der Kategorie C SAE bei Verdacht auf Zusammenhang mit Prüfprodukt oder erfolgtem Eingriff innerhalb von 7 Tagen (an lokale EK nur lokale Ereignisse, an Leit-EK alle Ereignisse in der CH).

### Schwerwiegende unerwünschte Ereignisse (Serious Adverse Events, SAE) mit möglichem Zusammenhang zu untersuchter Intervention bei übrigen klinischen Versuchen
Siehe Art. 63 KlinV:
Meldung an EK innerhalb von 15 Tagen.

### Berichterstattung über die Sicherheit der teilnehmenden Personen
Siehe Art. 43 KlinV:
1 mal jährlich Auflistung der Ereignisse weltweit (Annual Safety Report)

Mit dem jährlichen Sicherheitsbericht sind der EK auch alle Änderungen zu melden, die nicht bewilligungspflichtig sind (d.h. alle Änderungen, die gemäss Art. 29 KlinV nicht als wesentliche gelten).

## Anhang 2
## Meldungen und Berichterstattung an die Ethikkommission ab 1. Januar 2014 für Forschungsprojekte mit Ausnahme der klinischen Versuche (HFV)

### Forschung mit Personen, die mit Massnahmen zur Entnahme biologischen Materials oder zur Erhebung gesundheitsbezogener Personendaten verbunden

Sicherheits- und Schutzmassnahmen siehe Art. 20 HFV
Meldung an die EK innerhalb von 7 Tagen

Schwerwiegende Ereignisse siehe Art. 21 HFV
Meldung innerhalb von 7 Tagen (an lokale EK nur lokale Ereignisse, an Leit-EK alle Ereignisse in der CH) und Unterbruch des Forschungsprojektes.

Abschluss und Abbruch des Forschungsprojekts siehe Art. 22 HFV
Meldung an die EK innerhalb von 90 Tagen

### Weiterverwendung biologischen Materials und gesundheitsbezogener Personendaten für die Forschung

Siehe Art. 36 HFV:
Wechsel Projektleitung: Meldung an die EK: vorgängig

Abschluss und Abbruch des Forschungsprojekts
Meldung an die EK innerhalb von 90 Tagen

### Weiterverwendung biologischen Materials und gesundheitsbezogener Personendaten für die Forschung bei fehlender Einwilligung und Information nach Artikel 34 HFG

Siehe Art. 40 HFV:
Änderungen der in der Bewilligung genannten Angaben
Meldung an die EK (vorgängig)

Abschluss oder Abbruch des Forschungsprojekts
Meldung an die EK innerhalb von 90 Tagen

### Forschung an verstorbenen Personen (Art. 43 HFV)

Siehe Art. 43 HFV:
Wechsel der Projektleitung: Meldung an die EK (vorgängig)

Bei Forschungsprojekten mit verstorbenen Personen, die künstlich beatmet werden
Wesentliche Änderungen des Forschungsplans
Meldung an die EK (vorgängig)

Abschluss oder Abbruch des Forschungsprojekts
Meldung an die EK innerhalb von 90 Tagen

# STRENGTHS - Scaling-up psychological interventions with Syrian refugees

## Universitätsspital Zürich

### Basic project info and funding

**Your application concerns**
A clinical trial

**Title**
STRENGTHS - Scaling-up psychological interventions with Syrian refugees

**Short title**
Project STRENGTHS

**Acronym**
STRENGTHS

**Ethics Committee**
Kantonale Ethikkommission Zürich

**How many research sites in Switzerland are involved in the project?**
one site in Switzerland

**Who initiated the project?**
investigator

**Is this research project solely or principally designed to obtain a degree? (Master/PhD/other)**
no

Information on Financing
**Comments about the financing of your project**
The present study is funded by the State Secretariat for Education, Research and Innovation (SERI), Switzerland.

**Source(s)**
1

Source #1
**Type**
public, other

**Name**
SBFI

**Amount (in CHF)**
663000 CHF

**Is the project taking place in other countries than Switzerland ?**
no

### Project details

**Type of clinical trial**
other clinical trials

**Risk category**
A

**Primary area of research**
treatment

**Interventions**
PM+ is a new, brief, psychological intervention program based on CBT techniques that are empirically supported and formally recommended by the WHO. The manual involves the following empirically supported elements: problem solving plus stress management, behavioural activation, facing fears, and accessing social support.
We aim to evaluate the effect of PM+ in the reducing of psychological distress level.

The control group will receive enhanced treatment as usual (ETAU). ETAU means that the research team will advise the participants to contact their doctor in case of physical or mental health problems. Adequate treatment will be provided by this physician, usually a general practitioner.

**Allocation**
randomised controlled trial

**Masking technique**
single-blind

**Type of control**
none

**Arms/distribution**
parallel groups

**Primary outcome / endpoint**
The reduction in psychological distress as measured by the Hopkins Symptom Checklist (HSCL-25) (baseline, i.e., before PM+, to 3-months follow-up)

**Secondary outcomes /endpoints**
Beneficiary-related health outcomes include reductions in symptoms (baseline, i.e., before PM+, to 3-months follow-up): Symptoms of posttraumatic stress disorder during the past month will be measured using the PTSD Checklist for DSM-5. In addition, improvements in functional disability will be assessed by the WHODAS 2.0 .

**Target sample size in Switzerland**
406

**Key inclusion criteria**
- Male and female Syrian refugees or asylum seekers who entered Switzerland after the beginning of SCW in March 2011
- ? 18 years of age
- Arabic-speaking
- Signed Informed Consent after being informed
- Increased psychological distress (K10 > 15.9)
- Reduced psychological functioning (WHODAS 2.0 > 16)

**Key exclusion criteria**
- Inability to follow the procedures of the study
- Previous enrolment into the current study,
- Participants under tutelage
- Acute or severe psychiatric (e.g. schizophrenia) or neurological illness (e.g. dementia)
- Imminent suicide risk

**Vulnerable persons**
healthy volunteers

**Start date**
2018/06/30

**End date**
2021/08/31

**Does your study involve ionising radiation?**
no

## SNCTP

**Language used for SNCTP**
German

**Laientitel / Titre public / Titolo per non esperti**
Testung einer psychologischen Intervention bei syrischen Flüchtlingen

**Untersuchte Krankheit, Gesundheitsstatus / Maladie ou état de santé étudié / Malattia studiata, condizioni di salute**
Menschen, welche traumatische Erlebnisse gehabt haben. Psychische Belastungen wie z.B. Depressivität, Angststörungen, Posttraumatische Belastungsstörungen.

**Zusammenfassung / Résumé / Sintesi**
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 psychologischen Behandlung von Schwierigkeiten. 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, an der Studie teilzunehmen. Ziel dieser Studie ist, eine neue, von der WHO entwickelte psychologische Kurzin-tervention (Problem Management Plus, PM+) bei traumatisierten syrischen Flüchtlingen in Bezug auf Anwendbarkeit und Wirksamkeit zu prüfen.

**Untersuchte Intervention / Intervention étudiée / Interventi esaminati**
Problem Management Plus (PM+) wird von ausgebildeten Laien aus dem gleichen Kulturkreis durchgeführt und besteht aus fünf Sitzungen mit folgenden Inhalten:
a) Problemlösungsstrategien
b) Stressmanagement
c) Verhaltensaktivierung
d) Soziale Unterstützung

**Einschlusskriterien / Critères d'inclusion / Criteri di inclusione**
- Syrische Geflüchtete
- Männer und Frauen
- Eingereist nach dem Beginn des syrischen Bürgerkriegs
- Volljährig
- Arabischsprechend
- Unterzeichnete Einwilligungserklärung
- Psychisch belastet (gemessen mit K10; K10>15.9)
- Erhöhte Beeinträchtigung (gemessen mit WHODAS 2.0; WHODAS 2.0 > 16)

**Ausschlusskriterien / Critères d'exclusion / Criteri di esclusione**
- Unfähigkeit der Behandlung zu folgen
- Wiederholte Teilnahme an der Studie
- Vormundschaft
- Vorliegen einer akuten oder schweren psychiatrischen Störung (Schizophrenie) resp. neurologischen Erkrankung (z.B. Demenz)
- Erhöhte Suizidgefahr

**Durchführungsorte / Lieux de déroulement / Luoghi di svolgimento dello studio**
Zürich

Contact for further information? *
**Full name**
Dr. Naser Morina

**Telephone**
+41 44 255 50 20

**Email**
naser.morina@usz.ch

**Name of Primary Registry**
ClinicalTrials.gov

Disease under investigation

Select keywords (click to expand)
Mental and Behavioural diseases

**Investigation of a rare disease?**
no

Agreement on automatic data transfer *
Please wait with the automatic transfer, I will agree to the transfer later *

## Addresses

Applicant («Gesuchsteller», «Requérant», «Richiedente») *
Principal Investigator (PI) / Coordinating Investigator in Switzerland

Applicant's address *
**Ms/Mr**
Mr

**Title**
Dr. phil.

**First Name**
Naser

**Last Name**
Morina

**Organisation**
UniversitätsSpital Zürich

**Address Lines**
Klinik für Psychiatrie und Psychotherapie
Culmannstrasse 8

**Zip Code**
8091

**City**
Zürich

**Email**
naser.morina@usz.ch

**Telephone**
+41 44 255 51 21

Sponsor *
The Principal Investigator (PI) acts as the Sponsor

Sponsor's representative in Switzerland *
The Sponsor or the organisation/person acting as Sponsor is headquartered in Switzerland

CRO (Contract Research Organisation) *
There is no CRO in this project

Billing address *
**For billing use the address of the**
Applicant

**Additional billing instructions**
please add "Project STRENGTHS" as a comment at your invoice

## Lead EC: General and main site's documents

Dr. Naser Morina

Department for Psychiatry and Psychotherapy, University Hospital Zurich

Zurich

1. Cover Letter *
**Upload**

- Begleitbrief_KEK-MORINAN.pdf

**Date of doc.**
2017/06/30

**Upload**

- Stellungnahme KEK.pdf

**Date of doc.**
2017/09/04

2. Synopsis of the study plan *
**Can this information be found in another document you are uploading?**
Yes

**Document (category) number**
4

**Page number / reference information**
Page number 6

3. Participant information sheet and informed consent (ICF) *
**Upload**

- IC screening_revised mit korrekturen.pdf

**Date of doc.**
2017/09/04

**Version of doc.**
1

**Upload**

- IC screening_revised.pdf

**Date of doc.**
2017/09/04

**Version of doc.**
1

**Upload**

- ic intervention_rev...it korrekturen.pdf

**Date of doc.**
2017/09/04

**Version of doc.**
1



**Upload**

- ic intervention_revised.pdf

**Date of doc.**
2017/09/04

**Version of doc.**
1

4. Study plan (protocol), signed and dated *
**Upload**

- Clinical Study Protocol_STRENGTHS.pdf

**Date of doc.**
2017/06/30

**Version of doc.**
1

4a. Monitoring plan *
**Can this information be found in another document you are uploading?**
Yes

**Document (category) number**
39

**Page number / reference information**
Monitoring & Data Management Plan

5. CRF (Case Report Form) *
**Upload**

- Liste mit zu erhebe...tern_STRENGTHS.pdf

**Date of doc.**
2017/06/30

**Version of doc.**
1

6. Investigator's / Project Leader's CV, dated *
**Upload**

- CV_Morina_short version.pdf

**Date of doc.**
2017/06/20

7. Investigator's proof of GCP training *
**Upload**

- GCP Morina.pdf

**Date of doc.**
2014/06/02

8. Details on infrastructure suitability and availability at the location where the trial is executed
**Upload**

- QualifikationPruefort_d.pdf

**Date of doc.**

2017/06/30

9. Agreement between sponsor/commissioned institution / grant provider or other third parties and the investigator (*)
**Upload**

- Strengths_Subventionsvertrag.pdf

**Date of doc.**
2017/01/05

10. Insurance
**Can this information be found in another document you are uploading?**
Yes

**Document (category) number**
4

**Page number / reference information**
Page number 49

11. Other documents handed over to study participants *
**Are there other documents handed over to study participants?**
Yes

**Upload**

- Flyer_revised_mit korrekturen.pdf

**Date of doc.**
2017/09/04

**Version of doc.**
1

**Upload**

- Flyer_revised.pdf

**Date of doc.**
2017/09/04

**Version of doc.**
1

12. Details on nature and scope/value of compensation for participants *
The Patient Information Form (Document no. 3) contains details on compensation

13. Staff list
**Upload**

- Staff_List_e.pdf

**Date of doc.**
2017/06/30

14. Information on secure handling of biological material and personal data, and in particular on the storage thereof *
**Can this information be found in another document you are uploading?**
Yes

**Document (category) number**
4

**Page number / reference information**
42

39. Miscellaneous / Varia

**Upload**

- Schnittstelle_AW_E...en Ethikantrag.pdf

**Date of doc.**
2017/07/03

**Version of doc.**
1

**Upload**

- Vereinbarung_Monito..._CTC_STRENGTHS.pdf

**Date of doc.**
2017/06/29

**Version of doc.**
1

**Upload**

- Vereinbarung_Data_M..._CTC_STRENGTHS.pdf

**Date of doc.**
2017/08/22

**Version of doc.**
1

## Submission Summary

**I am submitting:**
Follow-up to charges/conditions

**Comment**
Please see cover letter in this regard.

4.9.2017
Kantonale Ethikkommission Zürich
Stampfenbachstrasse 121
8090 Zürich

## 2.6. WP6 Online Implementation

| **Study 1**<br>**Study 2**<br>**Study 3** | **Germany**<br>**Egypt**<br>**Sweden** |
|---|---|
| Partners involved: | 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 (dd. August 16, 2017) |

Ethikkommission der Freien Universität Berlin
Habelschwerdter Allee 45, 14195 Berlin

Dipl.-Psych. Sebastian Burchert
Research assistant – STRENGTHS project
Freie Universität Berlin, Department of
Education and Psychology, Division of Clinical
Psychological Intervention
Habelschwerdter Allee 45
14195 Berlin

**Ethikkommission**
**der Freien Universität Berlin**
**Fachbereich Erziehungswissenschaft**
**und Psychologie**

Prof. Dr. Annette Kinder
Vorsitzende der Ethikkommission
Habelschwerdter Allee 45
14195 Berlin

**Bearb.-Zeichen** 161/2017
**Bearbeiter/in** Daniel Herbstreit

Berlin, 16.08.2017

## Beschlussmitteilung der Ethikkommission

Die Ethikkommission der Freien Universität Berlin hat das nachstehende Forschungsprojekt begutachtet:

**Implementation and evaluation of a mHealth version of the low-intensity Problem Management Plus (PM+) program for Syrian refugees in Germany, Sweden and Egypt**

Die Ethikkommission kommt zu folgendem Beschluss:

Das Projekt wurde **positiv** begutachtet (die Ethikkommission hat keine Einwände erhoben).

Prof. Dr. Annette Kinder
(Vorsitzende der Ethikkommission)