

Integrating mental health into primary care for conflict-affected internal forced migrants in Northern Sri Lanka (COMGAP-S)

Submission date 05/01/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/01/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/05/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Since the end of conflict in 2009, Northern Sri Lanka has an increased need to rebuild the health system. Currently, there is a lack of human resources, as the amount of new healthcare professionals being trained is below that of the growing need in the region. The relative political, social and economic stability in the region is favorable to training new healthcare workers and increasing the capacity of existing health work force. The proposed project, already applied in small pilot study in the Northern Province, aims to improve the skills of existing primary care health work force by adding mental health care into primary care services (first port of call) across all districts of the province.

Who can participate?

Primary Care Practitioners (doctors), Public Health Professionals (such as nurses and health service assistants) working at participating centres for at least six months, community representatives, and adult patients attending participating centres who are from areas of conflict.

What does the study involve?

25 primary care facilities are randomly selected across all 5 districts of Northern Province. All selected facilities are monitored for a period of one month. Each facility receives training over the course of one week and then monitoring for a month, which they receive staggered one week apart. The order that facilities receive this is randomly selected. Primary care practitioners and public health professionals in primary care facilities across the Northern Province are invited to attend a three-day training, which involves role-plays, videos and seminars using material developed by the World Health Organization. Once trained, they are asked to use their training to diagnose, treat and refer patients with possible mental health problems. Patients of trained primary care practitioners are asked to answer some questions about their mental health problems and visit a psychiatrist to confirm their diagnosis and received treatment as required. Public health professionals are asked to engage activities such as stigma (negative associations) reduction, enabling referrals and follow-up and supporting community representative-led community engagement activities. Community representatives from the areas near each primary

care facility will be invited to a one-day training course and afterwards are asked to help raise awareness, find local resources and organise mental health promotional activities, such as play and group activities in their communities. There are two refresher courses for primary care practitioners, public health professionals and community representatives 3 and 6 months after the first training course.

What are the possible benefits and risks of participating?

The long-term benefits of this project will be an increase of the mental wellbeing of the population, enabling people to live happier, healthier lives and to increase knowledge, skills and education levels of the public health workforce in the Northern Province. Community awareness programmes are also part of the project, to increase mental health knowledge among the general public, students and other professionals in the region, and help to reduce stigma (negative views) around mental illnesses. There are no foreseeable risks for any participants taking part in this study.

Where is the study run from?

The study is run from the THEME Institute and takes place in 25 primary care facilities located across 5 districts of the Northern Province of Sri Lanka (Sri Lanka)

When is the study starting and how long is it expected to run for?

September 2016 to April 2021

Who is funding the study?

Centers for Disease Control and Prevention (USA)

Who is the main contact?

Ms Shannon Doherty

shannon.doherty@anglia.ac.uk

Contact information

Type(s)

Public

Contact name

Ms Shannon Doherty

ORCID ID

<http://orcid.org/0000-0002-6123-1238>

Contact details

4th Floor William Harvey Building
Faculty of Health, Education, Medicine & Social Care
Anglia Ruskin University
Bishop Hall Lane
Chelmsford
United Kingdom
CM1 1SQ
+44 845 196 3154
shannon.doherty@anglia.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

COMGAP-S/Y2, SLCTR/2018/008

Study information

Scientific Title

Integrating mental health into primary care for CONflict-affected internal forced Migrants in Northern Sri Lanka using WHO mhGAP intervention (COMGAP-S)

Acronym

COMGAP-S

Study objectives

The aim of this study is to:

1. Integrate mental health into primary care by providing training to PCP and Public Health Personnel (PHP) serving conflict-affected populations in resource-poor, primary care settings in the Northern Province via a scaled-up training intervention based on World Health Organization mental health gap programme (WHO mhGAP 2.0)
2. Enhance community awareness, reduce stigma and to improve psychosocial well-being of local communities by including community representatives (CR) in the training intervention

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. UK: Faculty Research Ethics Panel Faculty of Medical Science Anglia Ruskin University, 19/01/2017, ref: SC/jc/FMSFREP/16/17076
2. Sri Lanka: Ethics Review Committee Faculty of Medicine University of Jaffna, 04/01/2018, ref: J/ERC/17/81/NDR/0170

Study design

Multi-centre stepped wedge cluster randomised trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Mental disorders

Interventions

Primary Care Practitioners (PCP) at randomly selected facilities will be monitored for 1 month prior to commencement of training. In two week intervals PCPs will then receive a 3-day training intervention based on the World Health Organization mhGAP 2.0 training module. Key modules informed by previous work on depression, stress related disorders, medically unexplained symptoms, alcohol/drug use disorder, and others will be used. All materials will be locally translated and adapted. Training will occur in selected primary care facilities located across the Northern Province. Once training is completed, PCPs will use the mhGAP guide to diagnose, treat and refer primary care patients with possible mental health problems. Those who haven't yet received training will act as controls and will continue treatment as usual. Pre- and post-knowledge tests will be carried out at 3 and 6 months after initial training. After training is completed PCPs will be monitored for a period of 1 year. Standardized randomization techniques will be used to randomize facilities to the sequence of receiving training within the stepped wedge design.

Public Health Professionals (PHP) at randomly selected facilities will be monitored for 1 month prior to commencement of training. In two week intervals PCPs will then receive a 3-day training intervention based on the World Health Organization mhGAP 2.0 training module. Key modules informed by previous work on depression, stress related disorders, medically unexplained symptoms, alcohol/drug use disorder, and others will be used. All materials will be locally translated and adapted. Once training is completed, PHPs will engage in specific activities outlined during their training with the patient population attending their respective facilities. Those who haven't yet received training will act as controls and will continue treatment as usual. Pre- and post-knowledge tests will be carried out at 3 and 6 months after initial training. After training is completed PHPs will be monitored for a period of 1 year. Standardized randomization techniques will be used to randomize facilities to the sequence of receiving training within the stepped wedge design.

Community Representatives (CR) will not be randomized. CR within the catchment area of each randomly selected primary care facility will be identified and approached for inclusion. CR will receive a 1-day training intervention based on the World Health Organization mhGAP 2.0 training module. Key modules informed by previous work on depression, stress related disorders, medically unexplained symptoms, alcohol/drug use disorder, and others will be used. All materials will be locally translated and adapted. Once training is completed, CRs will engage in specific activities outlined in their training within their respective communities such as creating awareness, finding local resources and organizing mental health promotional activities. Pre- and post-knowledge tests will be carried out at 3 and 6 months after initial training. After training is completed CRs will be monitored for a period of 1 year.

Patients attending primary care facilities who are identified by mhGAP trained primary care practitioners will be asked to answer a brief socio-demographic questionnaire at point of

recruitment along with the Hopkins Symptoms Checklist and the Harvard Trauma Questionnaire at point of recruitment and at 3 and 6 months follow up. They will also be re-examined by a psychiatrist to confirm the primary care practitioner diagnosis.

Intervention Type

Other

Primary outcome measure

Successful uptake of mhGAP 2.0 training is measured using minimum 40% concurrence increase of primary care practitioners who correctly diagnose patients with common mental disorders as verified by specialist psychiatrists at 1 year.

Secondary outcome measures

Successful integration of mental health services into primary care is measured by reaching a 40% rate of mhGAP 2.0 trained primary care practitioners in the Northern Province at 1 year.

Overall study start date

01/09/2016

Completion date

30/04/2021

Eligibility**Key inclusion criteria**

Primary Care Practitioners (PCP)

1. Full registration with the Sri Lankan Medical Council
2. At least 6 months or more until their next transfer rotation (this applies only for PCP working in government facilities) or 6 months to retirement

Public Health Personnel (PHP)

1. Nurse, attendant or health service assistant within each facility
2. At least 6 months left on their transfer rotation (this applies only for PHP working in government facilities) or 6 months to retirement

Community Representatives (CR)

1. Located within the catchment area of each selected facility

Patients

1. Aged 18 years or older
2. Attend selected facilities
3. Belong to IDP or post-conflict populations

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

25 facilities (cluster): 25 PCPs total, 1 in each cluster; 75 PHPs total, 3 in each cluster; 50 CRs total, 2 in each cluster; 325 patients total, 13 in each facility

Total final enrolment

146

Key exclusion criteria

Primary Care Practitioners (PCP)

Those who have secondary mental health training.

Public Health Personnel (PHP)

Those who have secondary mental health training.

Community Representatives (CR)

Those who have secondary mental health training.

Patients

1. Aged under 18 years

2. Diagnosed with serious mental disorders (e.g. schizophrenia, bipolar disorder)

Date of first enrolment

14/03/2018

Date of final enrolment

31/05/2020

Locations

Countries of recruitment

Sri Lanka

Study participating centre

THEME Institute

No. 190, Galle Road

Colombo

Sri Lanka

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Sponsor information

Organisation

Anglia Ruskin University

Sponsor details

Research and Innovation Development Office
2nd Floor, Abbeygate House
Anglia Ruskin University
Bishop Hall Lane
Chelmsford
England
United Kingdom
CM1 1SQ
+44 (0)1245 684204
Michael.millan@aru.ac.uk

Sponsor type

University/education

Website

<http://www.anglia.ac.uk/medical-science>

ROR

<https://ror.org/0009t4v78>

Funder(s)**Funder type**

Government

Funder Name

Centers for Disease Control and Prevention

Alternative Name(s)

United States Centers for Disease Control and Prevention, Centros para el Control y la Prevención de Enfermedades, Centers for Disease Control, U.S. Centers for Disease Control and Prevention, CDC, U.S. CDC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Results and Publications

Publication and dissemination plan

Protocols, results and other data from the proposed project will result in manuscripts that will be made publicly available on PubMed Central (PMC) and OpenAccess journals to ensure widespread dissemination of material. All epidemiological data including datasets and digitally recorded factual material will be shared and/or released as defined by the CDC Data Policy. Data can then be disseminated, subject to confidentiality, technology, data quality, resources and limits imposed by law. Files deemed public use may be deposited in appropriate repositories while restricted use files may only be released to appropriate secure data centers.

All data will be released and/or shared in such a way as to maximize public access without charge and to ensure data is readily available to qualified individuals in the scientific communities for research purposes. Data will also be disseminated through the research project team at international conferences and networking meetings as well as through preliminary results reports disseminated to participants at the conclusion of the study.

Intention to publish date

31/05/2022

Individual participant data (IPD) sharing plan

Added 17/08/2021):

Individual participant data that underlie the results after deidentification (texts, tables, figures, and appendices), along with the study protocol can be shared immediately following publication, with no end date, to researchers who provide a methodologically sound proposal and/or to achieve aims in the approved proposal. Proposals should be directed to shannon.doherty@anglia.ac.uk. To gain access, data requestors will need to sign a data access agreement.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	qualitative analysis	13/02/2020	24/02/2020	Yes	No
Protocol article		31/01/2022	25/04/2022	Yes	No
Results article	Challenges and lessons learned in re-filming the WHO mhGAP training videos for Sri Lankan context - a qualitative study	13/02/2020	10/05/2022	Yes	No
Results article	Characteristics and Influencing Factors of Healthcare Utilization in Post-conflict Primary Care Attendees in Northern Sri Lanka	28/01/2022	10/05/2022	Yes	No
Results article	Prevalence of mental disorders and epidemiological associations in post-conflict primary care attendees: a cross-sectional study in the Northern Province of Sri Lanka	04/03/2019	10/05/2022	Yes	No