

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	☒ Prospectively registered ☒ Protocol
Registration date 09/01/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/05/2022	Condition category Mental and Behavioural Disorders	☐ 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

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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Protocol serial number

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/FMSFREPP/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

Study type(s)

Other

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Results and Publications

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?
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
Protocol article		31/01/2022	25/04/2022	Yes	No
Other publications	qualitative analysis	13/02/2020	24/02/2020	Yes	No