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Protocol of a randomized clinical trial to integrate mental health services into primary care for post-conflict populations in Northern Sri Lanka (COMGAP-S)

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Complete List of Authors:	Doherty, Shannon; Anglia Ruskin University Dass, Giselle; THEME Institute, 50, 13 Old Kesbewa Road, Nugegoda Edward, Anne; THEME Institute, 50, 13 Old Kesbewa Road, Nugegoda Stewart, Robert; King's College London, Institute of Psychiatry Roberts, Bayard; London School of Hygiene and Tropical Medicine, Abas, Melanie; Institute of Psychiatry, King's College London, Section of Epidemiology, Health Services & Population Research
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Authors: Shannon Doherty, PhD, Anglia Ruskin University, Cambridge, United Kingdom; Giselle Dass, THEME Institute, Colombo, Sri Lanka; Anne Edward, THEME Institute, Colombo, Sri Lanka; Robert Stewart, MD, King's College London, United Kingdom; Bayard Roberts, PhD, London School of Hygiene and Tropical Medicine, United Kingdom; Melanie Abas, PhD, King's College London, United Kingdom

Corresponding Author: Shannon Doherty, PhD, Anglia Ruskin University, Bishop Hall Lane, Chelmsford, UK, CM1 1SQ, shannon.doherty@anglia.ac.uk, +44 75 2212 8409

ABSTRACT

Introduction

Sri Lanka has a long history of armed conflict and natural disasters increasing risk of mental health disorders in the population. Due to a lack of specialist services, there is a treatment gap between those seeking and those able, to access mental health services. The aim of this research programme is to integrate mental health services into primary care to meet the needs of this post-conflict population.

Methods and analysis

This is a stepped wedgecluster design randomized clinical trial of the WHO mhGAP primary care mental health training intervention. We will provide a 10-day training to primary care practitioners of 23 randomly selected primary care facilities aimed at increasing their ability to identify, treat, and manage mental health disorders. Public health professionals and community representatives will receive a tailored training intervention to increase mental health awareness.. Refresher courses will occur at 3 and 6 months post-training. Supervision and monitoring will occur for one month pre- and post-training. Target sample sizes have been calculated separately for each group of participants and for each outcome.

Discussion

This clinical trial, which started in February 2018 and is still ongoing, will help build local capacity through a sustainable and culturally appropriate intervention and contribute to reduction of the mental health treatment gap for a population in need.

Trial Registration

ISRCTN registry ISRCTN62598070, 1 Sept 2017. SLCTR registration number: SLCTR/2018/008, 27 Feb 2018.

Abbreviations

WHO mhGAP - World Health Organization's mental health Gap Action Programme

LMIC - Low- and middle-income countries

Keywords

Conflict, clinical trial, health systems, mental health, mhGAP

Strengths and Limitations

- First study to culturally adapt all mhGAP materials
- Strengthened primary care system and took burden off specialized services
- Showed feasibility of mhGAP training for non-specialists
- Patients were difficult to enroll and retain which makes data limited
- COVID-19 limited ability to deliver later refresher sessions face-to-face

INTRODUCTION

Mental health disorders often present in primary care settings, especially in low- and middle-income countries (LMIC), where specialized psychiatric services may be lacking. Low- or non-detection, low referral rates for specialist care, and increased costs are all features of mental health disorders in primary care settings in LMIC. Furthermore, lack of adequate training for primary care physicians and lack of involvement of public health personnel can act as barriers to effective treatment and management of mental health disorders in primary care [1, 2]. Barriers can be compounded in post-conflict situations, as existing limited health systems may be severely affected, especially for those internally displaced. There is strong evidence that conflict-driven, internally displaced migrants have increased rates of mental health disorders [1, 3].

During 26 years of protracted internal conflict in Sri Lanka, more than 100,000 people of all ethnicities are estimated to have died, and hundreds of thousands injured [4, 5]. The substantial internal displacement from conflict was compounded by the 2004 tsunami [6].

Although Sri Lanka has a very effective primary care system, the treatment gap for mental health is extensive, especially for post-conflict populations [1, 7]. While provision of health services has improved, resources are insufficient to meet population needs, especially those related to severity of trauma, or to difficulties experienced in displacement or return migration [8]. Primary care practitioners in the Northern Province region regularly spearhead mental health care efforts, however, they do so without adequate training. Training primary care practitioners to deliver mental health care at primary care level is in line with the task-shifting approach in the global mental health field [2, 9-11]. A pilot feasibility study (COMGAP) to explore this possibility was conducted in 2013-2014 based on a peer-reviewed protocol and is reported elsewhere [8].

In this context, the aim of COMGAP-S is to use a scaled-up training intervention based on the World Health Organization Mental Health Gap Action Programme (WHO mhGAP 2.0) to integrate mental health services into primary care by providing training to primary care practitioners and public health professionals serving conflict-affected populations in primary care settings in the Northern Province [12].

The first phase of the study was completed in 2015-2016 and facilitated understanding of the mental disorder burden and treatment gap at primary care level. Results from the cross-sectional study indicate the most prevalent mental health disorders in primary care settings were depression (41.1%, 95% CI: 38.7-44.5%), anxiety (46.7%, 95% CI: 41.9-51.5%), post-

traumatic stress disorder (13.7%, 95% CI: 10.6-16.8%), and psychosis with hypomania (17.6%, 95 CI: 13.3-21.9) [13].

COMGAP-S is the first large-scale trial in the region to use mhGAP to integrate mental health services into primary care for conflict-affected populations, and is the only trial to include wider health care staff and community members as part of a long-term strategy to improve mental health awareness and stigma reduction.

METHODS AND ANALYSIS

Aims and objectives

The aim of COMGAP-S is to investigate if implementation of WHO mhGAP training within primary care settings increases identification and treatment of mental disorders for post-conflict populations in Northern Province, Sri Lanka.

Primary outcomes

1. 30% increase in patients identified, treated and referred to specialist care for mental disorders of interest by primary care practitioners. Measured at baseline using the pre/post-monitoring questionnaires on current practice with mental health patients and compared to post-training practice.

2. 40% minimum concurrence between diagnoses of patients identified with mental disorders of interest by trained primary care practitioners and psychiatrists as compared to diagnosis of patients pre-training (baseline) measured using qualitative interviews.

3. 20% reduction in positive screening for depression and anxiety in patients pre-training and at 3 and 6 months follow-up time points, measured using the Hopkins Symptom-Checklist 25.

Secondary outcomes

1. 20% increase between mean pre- and post-training test scores for primary care practitioners using the WHO mhGAP 2.0 pre/post training test.

2. At least 50% reduction of mental health stigma measured using AMIQ in primary care practitioner, public health professional, and community representative participant groups at training, and 3- and 6-month follow-up.

3. At least 40% of primary care practitioners and public health professionals in the region will be delivered training on mhGAP, and at least 2 community representatives from each facility catchment areas will receive tailored training on mental health awareness and stigma reduction.

Study design

This is a randomized clinical trial using a stepped wedge cluster design [14]. This design was chosen because: 1) in an intervention trying to integrate mental health services into primary care for post-conflict populations it is unethical to use a parallel design which prevents equal distribution of knowledge and skills; 2) the stepped wedge cluster design is more logistically feasible in the post-conflict setting of Northern Sri Lanka [15].

Facilities are randomized using standardized randomization techniques to allocate facilities to the training sequence within the stepped wedge design. Patients and community representatives were not randomized.

Setting

The study setting is 23 government primary care health facilities within the five districts of the Northern Province: Jaffna, Mannar, Kilinochchi, Vavunia, and Mullaitivu. Full list of participating sites can be obtained from the Primary Investigator or from the offices of THEME Institute, Colombo, Sri Lanka.

Inclusion criteria

Facilities are included if they indicate willingness to participate, are located in any of the five districts of Northern Province (Jaffna, Mannar, Kilinochchi, Vavunia, Mullaitivu), provide primary care services, and are either divisional hospitals of type A, B & C or primary medical care units. Facilities should also provide services to conflict-affected, previously displaced populations.

Primary care practitioners are included if they have full registration with the Sri Lankan Medical Council, have at least 6 months or more until their next transfer rotation, or 6 months to retirement. Public health professionals are included if they have at least 6 months left on their transfer rotation, or 6 months to retirement. Community representatives located within the catchment area of each selected facility are included after identification through local registration organisations. Patients are included if they are 18 years or older, attend selected facilities, and belong to internally displaced or conflict-affected populations.

Exclusion criteria

Larger facilities such as district hospitals and teaching hospitals are excluded as they are not part of the primary care system. Private facilities are excluded due to the lack of an official registry.

Primary care practitioners, public health professionals, and community representatives are excluded if they have secondary mental health training. Patients under 18 years and those diagnosed with mental disorders outside of depression and/or anxiety are excluded.

Recruitment and enrolment

Support letters from Provincial Department of Health Service, and Regional Divisional Health Secretariats in each district of Northern Province are used to approach primary care practitioners and public health professionals. Community representatives are recruited through local registration organizations. Patients are recruited by primary care practitioners. Trained research team members perform screening and enrolment procedures and gain informed consent for each participant group following established study protocols.

Ethics approvals

Ethical approval has been received from the Faculty of Health, Education, Medicine and Social Care, Anglia Ruskin University, UK (SC/jc/FMFREP/16/17 076), from the Faculty of Medicine, University of Jaffna, Sri Lanka (J/ERC/17/81/NDR/0170) and non-engagement approval from the funding body, the Centers for Disease Control and Prevention (2018-015).

Structure and delivery of the intervention

Training material was adapted for local use and included translation and cultural adaption of relevant modules of the WHO mhGAP 2.0 IG, and production of locally adapted and developed mhGAP video material for the Tamil context [16]. This was completed in collaboration with local academics, psychiatrists, primary care practitioners, Northern Province Ministry of Health, and the University of Jaffna.

Primary care practitioners and patients

Primary care practitioners in each selected facility undergo one month of monitoring prior to training to establish a baseline. They receive a paper booklet to record information on patients identified, treated, managed, and/or referred for mental health disorders. Further, before training, primary care practitioners recruit up to eight patients using provided inclusion and exclusion criteria to have their diagnosis verified by a psychiatrist. Members of the research

team provide patients with information sheets and obtain informed consent. Patients complete a brief socio-demographic questionnaire at point of recruitment and the Hopkins Symptom Checklist-25 screening questionnaire for depression and anxiety at point of recruitment, and at 3 and 6 months follow-up to establish a baseline, and determine if patient outcomes change after training of primary care practitioners. Primary care practitioners are asked detailed questions about their management and treatment of recruited patients, and patients are asked about any treatments undertaken or medications prescribed to understand any intervening factors between baseline, and 3 and 6 months follow-up.

After the one-month monitoring period, primary care practitioners undergo a 3-day training intervention delivered in their primary care facility. Trained members of the research team deliver training at each selected facility to minimize disruption of work at facilities.

After completion of training, monitoring of primary care practitioners continues for one month, where they continue to use the paper booklet to record information on patients they identify, treat, manage, and/or refer for common mental health disorders. Research team members visit or telephone the primary care practitioners once a week at their facility to monitor implementation of the training intervention.

After the one-month monitoring period primary care practitioners continue to use paper booklets to record their experience of the training implementation for six weeks. At this point (three months post-training) primary care practitioners participate in a 1-day refresher course and continue to use the experience of training implementation application for a further three months. At six months post-training, primary care practitioners take a second 1-day refresher course (Figure 1).

Public health professionals

Public health professionals in each selected facility undergo one month of monitoring prior to training to establish a baseline. Each enrolled public health professional records information in a paper booklet on facilitation of referral and follow-up practices for mental health patients, and supporting primary care practitioners with patient management activities. After the one-month monitoring period, public health professionals are provided with a tailored 3-day training programme on mental health awareness, management, referral, and stigma reduction. After training, public health professionals undergo one month of monitoring and record the same information as in the pre-monitoring period to see how/if practice has changed. Research team members visit or telephone their facility once a week to monitor implementation of the training intervention.

After the one-month, monitoring period public health professionals record information on their experience of the training intervention for six weeks. At this point (three months post-training), public health professionals participate in a 1-day refresher course and continue to use the paper booklets to record their experience of training implementation for a further three months. At six months post-training, public health professionals take a second 1-day refresher course (Figure 2).

Community representatives

Community representatives undergo one month of monitoring prior to training to establish a baseline. Each enrolled community representative records information in a paper booklet on mental health awareness raising activities undertaken, and any referrals of people they encounter with mental health issues. After the one-month monitoring period, community representatives participate in a tailored 1-day training programme on mental health awareness, stigma reduction, and finding local resources. After training, community representatives undergo

one month of monitoring and record the same information as in the pre-monitoring period to see how/if practice has changed. Research team members visit or telephone once a week to monitor implementation of the training intervention.

After the one-month, monitoring period community representatives' record information on their experience of the training intervention in paper booklets for six weeks. At this point (three months post-training), community representatives participate in a half-day refresher course and continue to use provided booklets to record their experience of training implementation for a further three months. At six months post-training, community representatives participate in a second half-day refresher course (Figure 3).

Timing of intervention delivery and follow-up

COMGAP-S runs for 7 months in each facility and catchment area. Every 2 weeks a facility is enrolled in the study until all 23 have completed the study timeline. Participants discontinuing engagement are not subject to follow-up. Measures are collected at six time points:

1. Pre-training monitoring period: questionnaire to establish a baseline on current practice. Primary care practitioners only: recruitment of patients for diagnosis verification.

Patients administered Hopkins Symptom Checklist 25 for anxiety and/or depression (baseline), and at 3 and 6 months follow-up to assess change in clinical symptoms.

2. Pre-training intervention: WHO mhGAP knowledge pre-test and AMIQ stigma questionnaire.

3. Post-training intervention: second administration of WHO mhGAP knowledge test.

4. Post-training monitoring period: questionnaire to establish if/how practice has changed, and qualitative interviews to reflect on initial diagnosis practice.

5. 3 months follow-up training: WHO mhGAP pre- and post- knowledge test and AMIQ stigma questionnaire.

6. 6 months follow-up training: WHO mhGAP pre- and post- knowledge test and AMIQ stigma questionnaire.

Patient and Public Involvement

Research materials and project aims were developed in collaboration with academic and service provider stakeholders to ensure priorities were addressed. Participants were consulted during the pilot stage to ensure research questions and materials were appropriate and relevant. Once the trial has been published, participants and the public will be informed of the results through a dedicated website (http://globalhme.org) as well as through paper leaflets, townhall discussions and social media to ensure both specialist and non-specialist audience can access study findings.

Data management

Data is collected on tablets and uploaded to a secure server. Data is cleaned and checked throughout the trial. Paper records are scanned in by local research team members and held on secure desktop computers and a password-protected hard drive. Team members and selected staff from the funding body will have access to the full dataset.

Statistical methods

An intention-to-treat analysis will be used. Analysis will include generalized linear regression modules to adjust for repeated measures and descriptive analytics.

Sample size calculation

A total of 23 primary care practitioners, 75 public health professionals, 50 community representatives, and 200 patients will be recruited. Target sample sizes were calculated separately for each participant group and for each outcome. Sample sizes for the first and

second outcomes were calculated following methods described by Hemming and Taljaard, where each outcome is considered an individually randomized trial and then multiplied by a design effect to account for the stepped wedge design [17]. Sample sizes for the third and fourth outcomes were calculated using formulae from the 1994 textbook "Analysis of Longitudinal Data" by Diggle, Liang and Zeger [18].

Dissemination and access

Trial results and analyses will be purposefully communicated to the Provincial Department of Health Service, Regional Divisional Health Secretariats in the five districts, participating healthcare professionals and community representatives. Dissemination events will be held with the University of Jaffna. Activities will include publications and presentations to general and specialized audience by team members. The research dataset and statistical analyses will be available by request from the primary investigator.

Trial Status

A planned pilot was completed between 24th January and 11th February 2018 in the Mullaitivu district in Northern Sri Lanka. Recruitment and enrolment for the full clinical trial period commenced in March 2018. Due to the COVID-19 pandemic the project has been granted a no-cost extension and data collection will be completed under local health regulations. At present, 21 of 23 facilities have been successfully recruited.

Data Monitoring

The funder Centers for Disease Control and Prevention acted as a *de facto* data monitoring committee as they reviewed clinical trial progress quarterly and audited progress yearly. Only the Principal Investigator and select research team members will have access to interim data for quality checks and data cleaning. In the unlikely event that a participant reported an adverse

event, standard operating procedures as per the COMGAP-S training manual would be followed.

Evaluation

Cost Ratio Economic Evaluation

This component will involve two evaluations. The first will evaluate the ratio between costs associated of training primary care practitioners to identify, treat and refer mental health care patients compared to costs of referral to, and treatment from, psychiatrists. Costs will be linked to the primary outcome measure to determine the extra cost of training incurred to detect one extra patient and understand economic implications of service provision to conflict-affected populations [19]. The second will evaluate the ratio between costs associated with patients receiving care from trained primary care practitioners at primary care facilities compared to costs of seeking care from specialist psychiatrists.

Process Evaluation

After initial training, 3 and 6 month refresher courses, quantitative and qualitative feedback will be collected from participants to explore how training was received. Qualitative case studies with primary health care staff, trainers, supervisors, patients will take place during post-training monitoring and evaluation periods to understand how the programme was received and implemented. Descriptive analysis will be used for quantitative data, while thematic analysis will be used for qualitative data.

Protocol amendments

Changes to the protocol will be reported by official letter to the sponsor institution, the sponsor ethics panel, the in-country ethics board, and the funder.

DISCUSSION

Due to the history of conflict and displacement in Sri Lanka, it is vital to address unmet mental health needs of the population. The completed cross-sectional survey at primary care level supports this and demonstrates prevalence and predictors of mental health disorders in the region. The WHO mhGAP IG 2.0 training programme provides a strategy to address this gap between those seeking, and those able, to access mental health services in the region. COMGAP-S will not only demonstrate the feasibility of implementing the mhGAP training programme, but ongoing monitoring activities will contribute to evaluation of both training and implementation.

Using the mhGAP guide to train on mental health services could empower primary care practitioners to effectively address mental health needs of the population in this post-conflict setting. Additionally, training public health professionals and community representatives can positively increase mental health awareness and decrease stigma in the local community. Training materials have undergone cultural adaptation to ensure training is relevant and acceptable to all participants and stakeholders. Use of a locally adapted mhGAP guide will increase acceptability and sustainability of the implementation of the clinical trial. This project includes key stakeholders from Northern Ministry of Health, University of Jaffna, Sri Lankan psychiatrists, and Sri Lankan researchers. Thus, COMGAP-S will not only contribute to the evidence base on integrating mental health services in primary care in low resource settings, it will also build local capacity, be culturally relevant, and sustainable.

COMGAP-S will be the first large-scale implementation of WHO mhGAP IG 2.0 training to improve mental health service delivery in primary care in Northern Province, Sri Lanka. Implementation of COMGAP-S aims to build capacity within the primary care system in the

region, but also improve mental health service delivery addressing the unmet needs of a vulnerable population.

Authors' contributions: CS and SD developed the concept and design of this study with contributions from GD, AE, BR, RS and MA. CS and SD wrote the manuscript with contributions from GD, AE, BR, RS and MA. All authors commented on and approved the final version of this manuscript.

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Competing interests statement: RS declares research support received in the last 5 years from Roche, Janssen, GSK and Takeda.

Ethics approvals: This trial has received ethical approval from the Faculty of Medical Science, Anglia Ruskin University, UK (SC/jc/FMFREP/16/17 076), from the Faculty of Medicine, University of Jaffna, Sri Lanka (J/ERC/17/81/NDR/0170) and non-engagement approval from the funding body, the Centers for Disease Control and Prevention (2018-015). All participants gave written consent.

Availability of data and materials: Data presented in this paper are available from the corresponding author on request.

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Protocol version: 11 November 2017, version 2

Name and contact of trial sponsor: Anglia Ruskin University, Faculty of Health, Education, Medicine, and Social Care, 4th Floor William Harvey Building, Bishop Hall Lane, Chelmsford, UK, CM11SQ

Dissemination policy: Publications, updates on social media, stakeholder meetings

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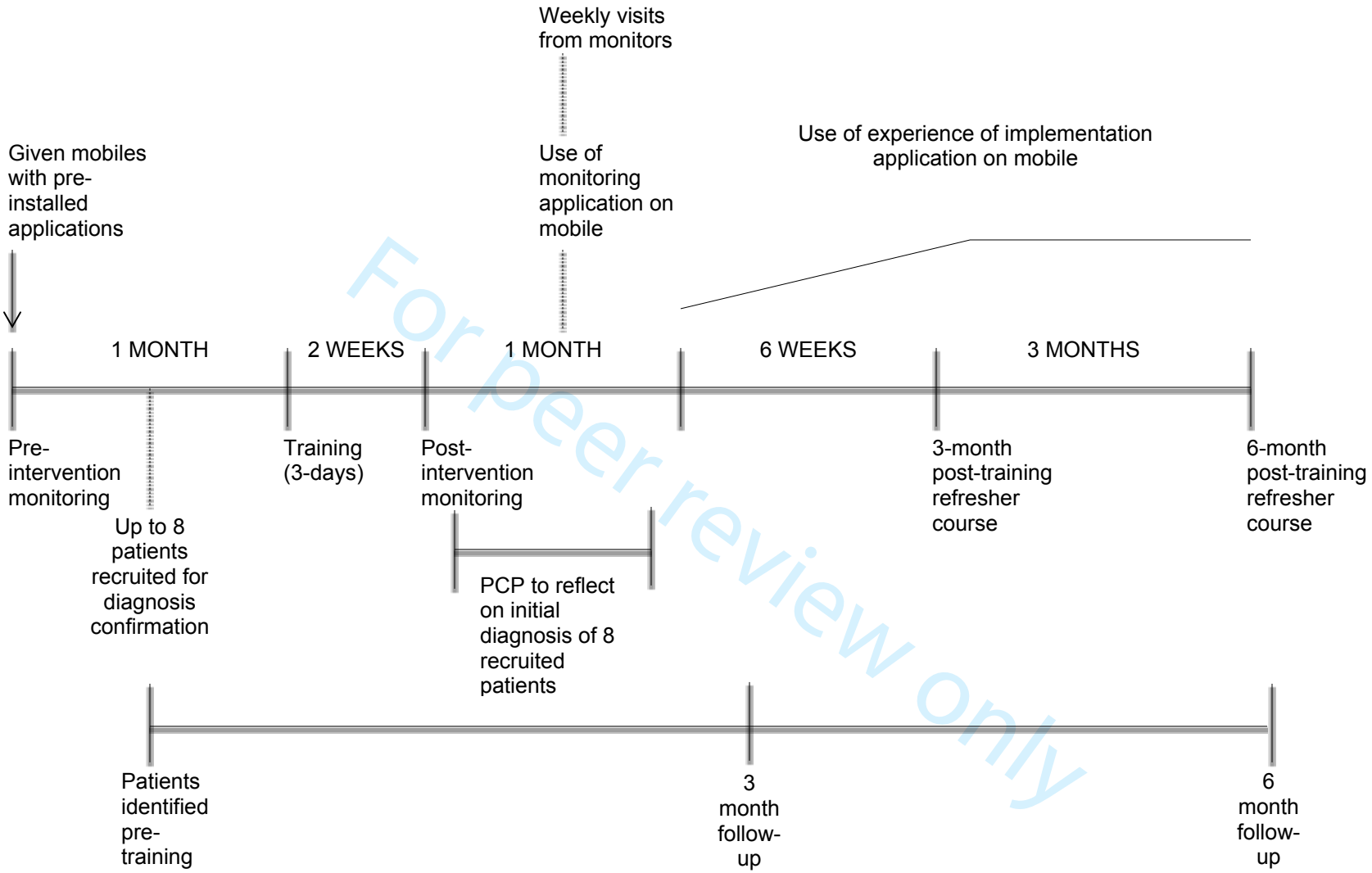

Figure 1. Primary Care Practitioner study timeline

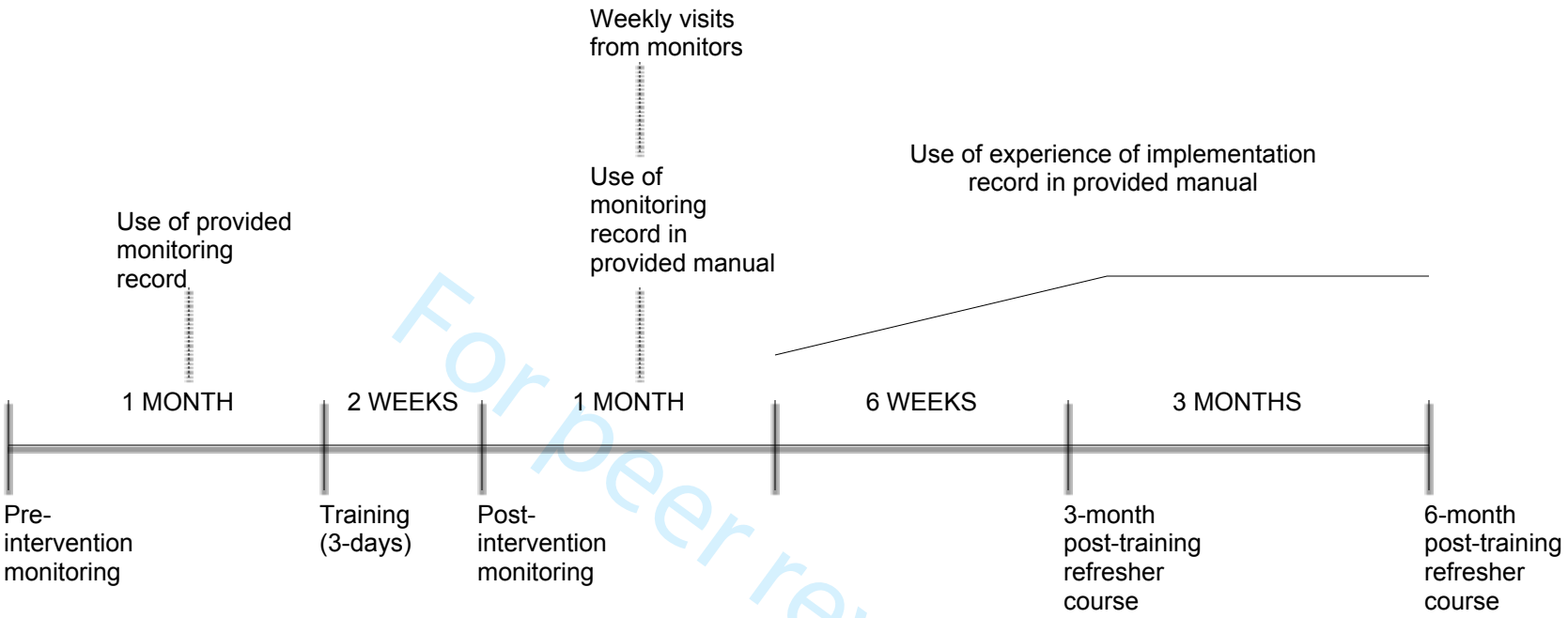

Figure 2. Public Health Professional study timeline

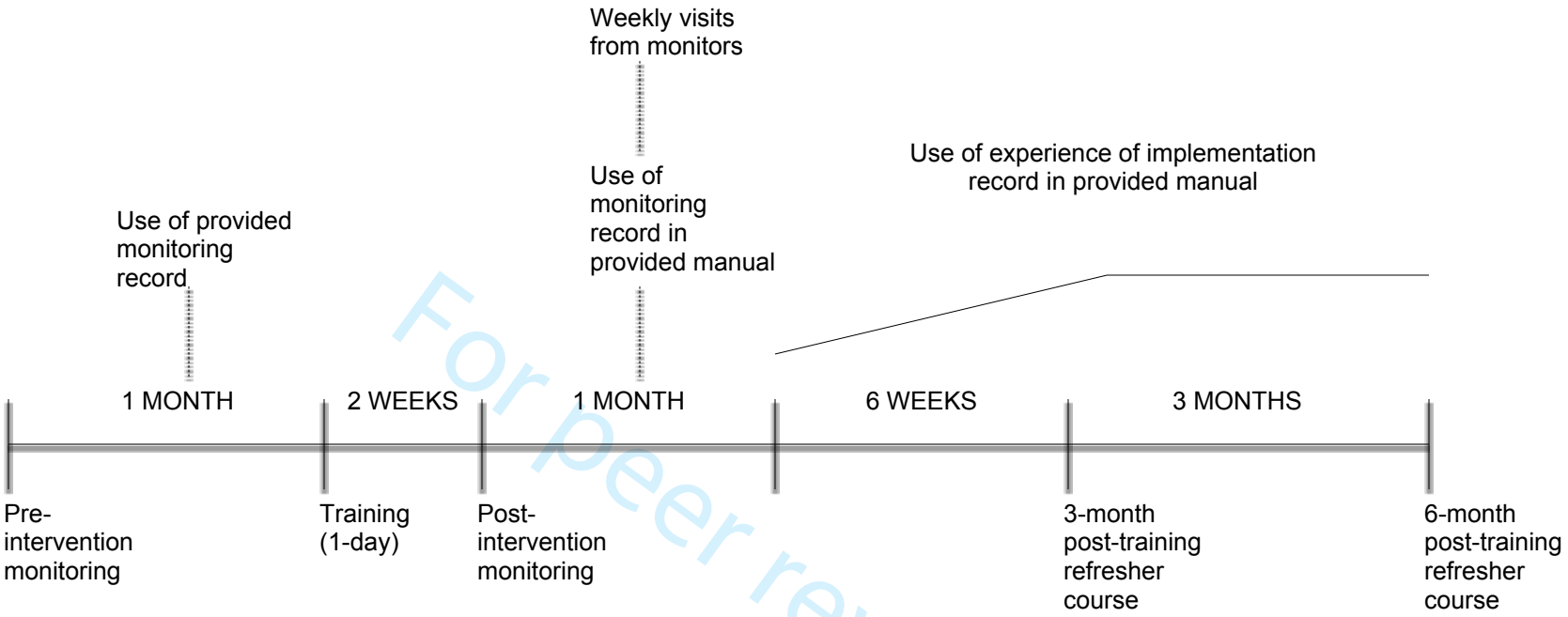

Figure 3. Community representative study timeline

Annex 1: Detailed Sample Size Procedure

Outcome 1: Patient outcomes – change in mental health symptoms

For the outcome of assessing change patient's responses to the HSCL questionnaire to assess depression and anxiety we considered this a stepped wedge design as patients will be recruited within facilities, which will be randomized into the study in a stepped-wedge manner. Using the formula for individual randomized trials with a stepped wedge design effect, we assumed an alpha of 0.5, an ICC of 0.5, 4 patients per facility and a calculated stepped-wedge design effect of 1.5. Using data from a previous study of HSCL outcomes in Sri Lanka, we assumed a mean baseline score of 22 (SD: 7.5) for depression and mean baseline score of 16 (SD: 6.5) for anxiety [Hollifield et al., 2008]. In order to detect a 25% decrease from baseline to endline, a calculated 87 patients for depression and 86 patients for anxiety would be required, resulting in 22 facilities needed per outcome. As we specify a necessary 25 facilities in the following three outcomes, we plan to include all 25 facilities in this portion as well. To account for an anticipated loss to follow up as large as 50%, the number of patients needed per facility was adjusted to 8, yielding a final total sample size of 200 patients.

HSCL outcome	Baseline Mean Score	Endline Mean Score	SD	Change	Alpha	Power	n per cluster	n per cluster with 50% LTFU*	Number of steps	ICC	Individual Randomized Sample Size Needed	$DEFF_{SW}$	SW Sample Size needed	# clusters needed	Total patient sample size (accounting for 50% LTFU and 25 clusters)
Depression	22	16.5	7.5	25%	0.05	0.80	4	8	25	0.50	59	1.5	87	22	200
Anxiety	16	11.2	6.5	25%	0.05	0.80	4	8	25	0.50	58	1.5	86	22	200

*Loss to follow up

Outcome 2: Change in knowledge scores of primary care practitioners, public health professionals, community representatives

The goal of the second outcome is to assess the change in provider knowledge score from baseline to endline, considering three different groups of providers: primary care providers, public health professionals, and community representatives. Sample size was calculated for each group separately, with the assumption that each facility will have 1 primary care practitioner and 3 public health professionals, and that the catchment area will have at least 2 community representatives. The sample sizes for community representatives and public health professionals were calculated using a stepped-wedge cluster design as more than one individual per facility is being selected; however, since there is only 1 primary care practitioners per facility, this was considered a simple random sample with 26 repeated measures (25 time points plus a baseline measurement). Assuming a baseline mean score of 65 and a pooled standard deviation of 12 across all three groups [Siriwardhana et al., 2016], an ICC of 0.5, and an alpha of 0.05, using the 25 facilities needed for the first outcome will provide adequate power

Provider type	Baseline mean score	Endline mean score	Pooled SD	Difference %	Alpha	Power	Number of steps	ICC	Individual Randomized Sample Size Needed	DEF F_{SW}	SW Sample Size needed	# clusters needed
PCP	65	78	12	20%	0.05	0.80	25	0.50	27	1*	14	14
CR	65	78	12	20%	0.05	0.80	25	0.50	27	1.5	40	20
PHP	65	78	12	20%	0.05	0.80	25	0.50	27	1.5	40	14

to detect a change in score of 20% from baseline to endline in each of the three groups.

*As we only have one primary care practitioner per facility, this is regarded as a simple random sample

Outcome 3: Concurrence of diagnosis by primary care practitioners in facilities with those of specialists

For the outcome of assessing change in concurrence by primary care practitioners in facilities with those of specialist psychiatrists, sample size was calculated considering a simple random sample using the formula for binary responses proposed by Diggle et al. [1994] for repeated measures. Assuming a baseline concurrence of 0.3, an endline concurrence of 0.70, an alpha of 0.05, and 80% power, 26 repeated measures (25 steps plus a baseline measurement), an ICC of 0.5, a sample size of 25 PCPs is needed to detect a difference of 0.4 (40%) from baseline to endline.

Baseline proportion	Endline proportion	Difference	Alpha	Power	Number of repeated measures	ICC	Sample Size Needed
0.3	0.70	0.4	0.05	0.80	26	0.5	25

Outcome 4: Changes in the numbers of correct identification, treatment and referral of patients by primary care practitioners

For the outcome of assessing change in correct identification, treatment and referral of patients at the facility level, using the formula for binary responses proposed by Diggle et al. [1994] for repeated measures, 25 facilities will yield sufficient power (0.8) to detect a minimum detectible difference of 0.3 (30%) from baseline to endline assuming an alpha of 0.05, a baseline referral accuracy of 0.20, 26 repeated measures (25 steps plus a baseline measurement), and an ICC of 0.3.

Baseline proportion	Endline proportion	Difference	Alpha	Power	Number of repeated measures	ICC	Sample Size Needed
0.2	0.60	0.3	0.05	0.80	26	0.3	25

Formulae used in calculations:

1. Hemming and Taljaard [2016]

$$DEFF_{SW} = (k+1)\frac{1+\ \rho(km+m-1)}{1+\rho(\frac{1}{2}km+m-1)} * \frac{3(1-\rho)}{2(k-\frac{1}{k})}$$

where *k* = the number of steps

ρ = Intracluster Correlation Coefficient (ICC)

m = number of individuals per cluster per step

2. Diggle's formula for binary response

$$n = \frac{z_\alpha\{2\overline{p}\overline{q}(1+(r-1)\rho)\}^{1/2} * + z_Q\{(1+(r-1)\rho)(p_Aq_A+p_Bq_B)\}^{1/2} * DEFF}{rd^2}$$

where z_α = Z score for alpha, set at 0.05

z_Q = Z score for power, set at 0.80

p_A = the proportion with the outcome at baseline (and $q_A = 1 - \ p_A$)

p_B = the proportion with the outcome at endline (and $q_B = 1 - \ p_B$)

$\overline{p}$ = ($p_A + \ p_B$)/2 and $\overline{q} = 1 - \ \overline{p}$

ρ = estimated correlation among repeated observations

d = minimum detectable difference between baseline and endline (calculated as $p_B - p_A$)

$DEFF$ = Design effect

3. Diggle's formula for repeated response

$$n = \frac{2(z_\alpha + z_Q)^2 \sigma^2 \{1 + (r-1)\rho\} * DEFF}{rd^2}$$

where z_α = Z score for alpha, set at 0.05
z_Q = Z score for power, set at 0.80
σ = standard deviation of the response
r = number of repeated observations
ρ = estimated correlation among repeated observations
d = minimum detectable difference between baseline and endline
$DEFF$ = Design effect

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Protocol of a randomized clinical trial to integrate mental health services into primary care for post-conflict populations in Northern Sri Lanka (COMGAP-S)
Trial registration	2a	ISRCTN registry ISRCTN62598070, 1 Sept 2017. SLCTR registration number: SLCTR/2018/008, 27 Feb 2018.
Protocol version	3	11 November 2017, version 2
Funding	4	The research undertaken is supported by the Centers for Disease Control and Prevention, Cooperative Agreement Number, 1U01GH001654-01
Roles and responsibilities	5a	Shannon Doherty, PhD, Anglia Ruskin University, Cambridge, United Kingdom; Giselle Dass, THEME Institute, Colombo, Sri Lanka; Anne Edward, THEME Institute, Colombo, Sri Lanka; Robert Stewart, MD, King's College London, United Kingdom; Bayard Roberts, PhD, London School of Hygiene and Tropical Medicine, United Kingdom; Melanie Abas, PhD, King's College London, United Kingdom CS and SD developed the concept and design of this study with contributions from GD, AE, BR, RS and MA. CS and SD wrote the manuscript with contributions from GD, AE, BR, RS and MA. All authors commented on and approved the final version of this manuscript.
	5b	Anglia Ruskin University, Faculty of Health, Education, Medicine, and Social Care, 4th Floor William Harvey Building, Bishop Hall Lane, Chelmsford, UK, CM11SQ

	5c	The Funding organization was involved in consultations regarding the scientific validity of the design, analysis of the data, preparation and review of the manuscript for publication. The Northern Ministry of Health, Sri Lanka was involved in management of the data collection. The University of Jaffna, Sri Lanka was involved in consultations on the design of the study, collection and interpretation of data, preparation and review of the manuscript for publication.RS is part-funded by: i) the National Institute for Health Research (NIHR) Biomedical Research Centre at the South London and Maudsley NHS Foundation Trust and King's College London; ii) a Medical Research Council (MRC) Mental Health Data Pathfinder Award to King's College London; iii) an NIHR Senior Investigator Award.
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	6a	The aim of COMGAP-S is to investigate if implementation of WHO mhGAP training within primary care settings increases identification and treatment of mental disorders for post-conflict populations in Northern Province, Sri Lanka.
	6b	Facilities are randomized using standardized randomization techniques to allocate facilities to the training sequence within the stepped wedge design. The stepped wedge cluster design is more logistically feasible in the post-conflict setting of Northern Sri Lanka.
Objectives	7	The aim of COMGAP-S is to investigate if implementation of WHO mhGAP training within primary care settings increases identification and treatment of mental disorders for post-conflict populations in Northern Province, Sri Lanka.
Trial design	8	Randomised clinical trial using stepped wedge cluster design; pragmatic trial
Methods: Participants, interventions, and outcomes		
Study setting	9	23 government primary care health facilities within the five districts of the Northern Province, Sri Lanka: Jaffna, Mannar, Kilinochchi, Vavunia, and Mullaitivu Full list of participating sites can be obtained from the Primary Investigator or from the offices of THEME Institute, Colombo, Sri Lanka

Eligibility criteria	10	**Inclusion criteria** Facilities are included if they indicate willingness to participate, are located in any of the five districts of Northern Province (Jaffna, Mannar, Kilinochchi, Vavunia, Mullaitivu), provide primary care services, and are either divisional hospitals of type A, B & C or primary medical care units. Facilities should also provide services to conflict-affected, previously displaced populations. Primary care practitioners are included if they have full registration with the Sri Lankan Medical Council, have at least 6 months or more until their next transfer rotation, or 6 months to retirement. Public health professionals are included if they have at least 6 months left on their transfer rotation, or 6 months to retirement. Community representatives located within the catchment area of each selected facility are included after identification through local registration organisations. Patients are included if they are 18 years or older, attend selected facilities, and belong to internally displaced or conflict-affected populations. **Exclusion criteria** Larger facilities such as district hospitals and teaching hospitals are excluded as they are not part of the primary care system. Private facilities are excluded due to the lack of an official registry. Primary care practitioners, public health professionals, and community representatives are excluded if they have secondary mental health training. Patients under 18 years and those diagnosed with mental disorders outside of depression and/or anxiety are excluded.

Interventions	11a	Primary Care Practitioners Primary care practitioners in each selected facility undergo one month of monitoring prior to training to establish a baseline. They receive a paper booklet to record information on patients identified, treated, managed, and/or referred for mental health disorders. Further, before training, primary care practitioners recruit up to eight patients using provided inclusion and exclusion criteria to have their diagnosis verified by a psychiatrist. Members of the research team provide patients with information sheets and obtain informed consent. Patients complete a brief socio-demographic questionnaire at point of recruitment and the Hopkins Symptom Checklist-25 screening questionnaire for depression and anxiety at point of recruitment, and at 3 and 6 months follow-up to establish a baseline, and determine if patient outcomes change after training of primary care practitioners. Primary care practitioners are asked detailed questions about their management and treatment of recruited patients, and patients are asked about any treatments undertaken or medications prescribed to understand any intervening factors between baseline, and 3 and 6 months follow-up. After the one-month monitoring period, primary care practitioners undergo a 3-day training intervention delivered in their primary care facility. Trained members of the research team deliver training at each selected facility to minimize disruption of work at facilities. After the one-month monitoring period primary care practitioners continue to use paper booklets to record their experience of the training implementation for six weeks. At this point (three months post-training) primary care practitioners participate in a 1-day refresher course and continue to use the experience of training implementation application for a further three months. At six months post-training, primary care practitioners take a second 1-day refresher course. Public Health Professionals Public health professionals in each selected facility undergo one month of monitoring prior to training to establish a baseline. Each enrolled public health professional records information in a paper booklet on facilitation of referral and follow-up practices for mental health patients, and supporting primary care practitioners with patient management activities. After the one-month monitoring period, public health professionals are provided with a tailored 3-day training programme on mental health awareness, management, referral, and stigma reduction. After training, public health professionals undergo one month of monitoring and record the same information as in the pre-monitoring period to see how/if practice has changed. Research team members visit or telephone their facility once a week to monitor implementation of the training intervention. After the one-month, monitoring period public health professionals record information on their experience of the training intervention for six weeks. At this point (three months post-training), public health professionals participate in a 1-day refresher course and continue to use the paper booklets to record their experience of training implementation for a further three months. At six months post-training, public health professionals take a second 1-day refresher course After completion of training, monitoring of primary care practitioners continues for one month, where they continue to use the paper booklet to record information on patients they identify, treat, manage, and/or refer for common mental health disorders. Research team members visit or telephone the primary care practitioners once a week at their facility to monitor implementation of the training intervention. Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

Community representatives
Community representatives undergo one month of monitoring prior to training to establish a baseline. Each enrolled community representative records information in a paper booklet on mental health awareness raising activities undertaken, and any referrals of people they encounter with mental health issues. After the one-month monitoring period, community representatives participate in a tailored 1-day training programme on mental health awareness, stigma reduction, and finding local resources. After training, community representatives undergo one month of monitoring and record the same information as in the pre-monitoring period to see how/if practice has changed. Research team members visit or telephone once a week to monitor implementation of the training intervention.

After the one-month, monitoring period community representatives' record information on their experience of the training intervention in paper booklets for six weeks. At this point (three months post-training), community representatives participate in a half-day refresher course and continue to use provided booklets to record their experience of training implementation for a further three months. At six months post-training, community representatives participate in a second half-day refresher course.

11b Participant request, external circumstances, force majeure

11c Monitoring and supervision for healthcare professionals and community representatives

11d Healthcare professionals and community representatives - N/A
Patients - no restrictions on care, information gathered only

Outcomes 12 Primary outcomes
1. 30% increase in patients identified, treated and referred to specialist care for mental disorders of interest by primary care practitioners.
2. 40% minimum concurrence between diagnoses of patients identified with mental disorders of interest by trained primary care practitioners and psychiatrists as compared to diagnosis of patients pre-training (baseline) measured using qualitative interviews.
3. 20% reduction in positive screening for depression and anxiety in patients pre-training and at 3 and 6 months follow-up time points, measured using the Hopkins Symptom-Checklist 25.
Secondary outcomes
1. 20% increase between mean pre- and post-training test scores for primary care practitioners using the WHO mhGAP 2.0 pre/post training test.
2. At least 50% reduction of mental health stigma measured using AMIQ in primary care practitioner, public health professional, and community representative participant groups at training, and 3- and 6-month follow-up.
3. At least 40% of primary care practitioners and public health professionals in the region will be delivered training on mhGAP, and at least 2 community representatives from each facility catchment areas will receive tailored training on mental health awareness and stigma reduction.

Participant timeline	13	Figures 1, 2, 3 of the manuscript
Sample size	14	23 primary care practitioners, 75 public health professionals, 50 community representatives, and 200 patients. Target sample sizes were calculated separately for each participant group and for each outcome. Sample sizes for the first and second outcomes were calculated following methods described by Hemming and Taljaard, where each outcome is considered an individually randomized trial and then multiplied by a design effect to account for the stepped wedge design. Sample sizes for the third and fourth outcomes were calculated using formulae from the 1994 textbook "Analysis of Longitudinal Data" by Diggle, Liang and Zeger. (For full citations see manuscript references.)
Recruitment	15	Support letters from Provincial Department of Health Service, and Regional Divisional Health Secretariats in each district of Northern Province are used to approach primary care practitioners and public health professionals. Community representatives are recruited through local registration organizations. Patients are recruited by primary care practitioners.

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Facilities are randomized using standardized randomization techniques to allocate facilities to the training sequence within the stepped wedge design. Patients and community representatives were not randomized.
Allocation concealment mechanism	16b	N/A - crossover design
Implementation	16c	Team members from the THEME Institute generate allocation using a random numbers generator, approach and enrol participants
Blinding (masking)	17a	N/A - crossover design
	17b	N/A - crossover design

Methods: Data collection, management, and analysis

Data collection methods	18a	Measures are collected at six time points: 1. Pre-training monitoring period: questionnaire to establish a baseline on current practice. Primary care practitioners only: recruitment of patients for diagnosis verification. Patients administered Hopkins Symptom Checklist 25 for anxiety and/or depression (baseline), and at 3 and 6 months follow-up to assess change in clinical symptoms. 2. Pre-training intervention: WHO mhGAP knowledge pre-test and AMIQ stigma questionnaire. 3. Post-training intervention: second administration of WHO mhGAP knowledge test. 4. Post-training monitoring period: questionnaire to establish if/how practice has changed, and qualitative interviews to reflect on initial diagnosis practice. 5. 3 months follow-up training: WHO mhGAP pre- and post-knowledge test and AMIQ stigma questionnaire. 6. 6 months follow-up training: WHO mhGAP pre- and post-knowledge test and AMIQ stigma questionnaire.
	18b	N/A - discontinued participants not subject to follow-up
Data management	19	Data is collected on tablets and uploaded to a secure server. Data is cleaned and checked throughout the trial. Paper records are scanned in by local research team members and held on secure desktop computers and a password-protected hard drive.
Statistical methods	20a	An intention-to-treat analysis will be used. Analysis will include generalized linear regression modules to adjust for repeated measures and descriptive analytics.
	20b	N/A
	20c	N/A
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
	21b	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	N/A
Ethics and dissemination		

Research ethics approval	24	Ethical approval has been received from the Faculty of Health, Education, Medicine and Social Care, Anglia Ruskin University, UK (SC/jc/FMFREP/16/17 076), from the Faculty of Medicine, University of Jaffna, Sri Lanka (J/ERC/17/81/NDR/0170) and non-engagement approval from the funding body, the Centers for Disease Control and Prevention (2018-015).
Protocol amendments	25	Changes to the protocol will be reported to the sponsor institution, the sponsor ethics panel, the in-country ethics board, and the funder.
Consent or assent	26a	Trained research team members perform screening and enrolment procedures and gain informed consent for each participant group following established study protocols.
	26b	N/A
Confidentiality	27	Data is collected on tablets and uploaded to a secure server. Paper records are scanned in by local research team members and held on secure desktop computers and a password-protected hard drive.
Declaration of interests	28	No competing interests for primary investigator. RS (see authors) declares research support received in the last 5 years from Roche, Janssen, GSK and Takeda.
Access to data	29	Team members and selected staff from the funding body will have access to the full dataset.
Ancillary and post-trial care	30	N/A
Dissemination policy	31a	Trial results and analyses will be purposefully communicated to the Provincial Department of Health Service, Regional Divisional Health Secretariats in the five districts, participating healthcare professionals and community representatives. Dissemination events will be held with the University of Jaffna. Activities will include publications and presentations to general and specialized audience by team members.
	31b	N/A
	31c	The research dataset and statistical analyses will be available by request from the primary investigator.
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the

protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Protocol of a randomized clinical trial to integrate mental health services into primary care for post-conflict populations in Northern Sri Lanka (COMGAP-S)

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Title: Protocol of a randomized clinical trial to integrate mental health services into primary care for post-conflict populations in Northern Sri Lanka (COMGAP-S)

Authors: Shannon Doherty, PhD, Anglia Ruskin University, Cambridge, United Kingdom; Giselle Dass, THEME Institute, Colombo, Sri Lanka; Anne Edward, THEME Institute, Colombo, Sri Lanka; Robert Stewart, MD, King's College London, United Kingdom; Bayard Roberts, PhD, London School of Hygiene and Tropical Medicine, United Kingdom; Melanie Abas, PhD, King's College London, United Kingdom

Corresponding Author: Shannon Doherty, PhD, Anglia Ruskin University, Bishop Hall Lane, Chelmsford, UK, CM1 1SQ, shannon.doherty@anglia.ac.uk, +44 75 2212 8409

ABSTRACT

Introduction

Sri Lanka has a long history of armed conflict and natural disasters increasing risk of mental health disorders in the population. Due to a lack of specialist services, there is a treatment gap between those seeking and those able, to access mental health services. The aim of this research programme is to integrate mental health services into primary care to meet the needs of this post-conflict population.

Methods and analysis

This is a stepped wedge cluster design randomized clinical trial of the World Health Organisation mhGAP primary care mental health training intervention. We will provide a 10-day training to primary care practitioners of 23 randomly selected primary care facilities aimed at increasing their ability to identify, treat, and manage common mental health disorders. Public health professionals and community representatives will receive a tailored training intervention to increase mental health awareness. Refresher courses will occur at 3- and 6-months post-training. Supervision and monitoring will occur for one month pre- and post-training. Target sample sizes have been calculated separately for each group of participants and for each outcome.

Ethics and dissemination

This trial has received ethical approval from the Faculty of Health, Education, Medicine and Social Care, Anglia Ruskin University, UK (SC/jc/FMFREP/16/17 076), from the Faculty of Medicine, University of Jaffna, Sri Lanka (J/ERC/17/81/NDR/0170) and non-engagement approval from the funding body, the Centers for Disease Control and Prevention (2018-015). All participants gave written consent.

Dissemination of study results will be completed through publication of academic articles, conference presentations, townhall meetings, written pamphlets in plain language, reports to Ministry of Health and other government organisations, and through social media outlets.

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Trial Registration

ISRCTN registry ISRCTN62598070, 1 Sept 2017. SLCTR registration number:

SLCTR/2018/008, 27 Feb 2018.

Abbreviations

WHO mhGAP - World Health Organization's mental health Gap Action Programme

LMIC - Low- and middle-income countries

Keywords

Conflict, clinical trial, health systems, mental health, mhGAP

Strengths and limitations of this study

- First study to culturally adapt all World Health Organisation mhGAP written and video training materials
- Seeks to demonstrate feasibility of using World Health Organisation mhGAP materials to train non-specialists
- Multiple refresher sessions should increase knowledge retention among participants
- Representative sample means findings could be generalized to other areas of Northern Sri Lanka
- Limited to publicly available healthcare facilities as private facilities were excluded

Word count: 3,957

INTRODUCTION

Mental health disorders often present in primary care settings, especially in low- and middle-income countries (LMIC), where specialized psychiatric services may be lacking. Low- or non-detection, low referral rates for specialist care, and increased costs are all features of mental health disorders in primary care settings in LMIC. Furthermore, lack of adequate training for primary care physicians and lack of involvement of public health personnel can act as barriers to effective treatment and management of common mental health disorders in primary care [1, 2]. Barriers can be compounded in post-conflict situations, as existing limited health systems may be severely affected, especially for those internally displaced. There is strong evidence that conflict-driven, internally displaced migrants have increased rates of mental health disorders [1, 3].

During 26 years of protracted internal conflict in Sri Lanka, more than 100,000 people of all ethnicities are estimated to have died, and hundreds of thousands injured [4, 5]. The substantial internal displacement from conflict was compounded by the 2004 tsunami [6].

Although Sri Lanka has a very effective primary care system, the treatment gap for mental health is extensive, especially for post-conflict populations [1, 7]. While provision of health services has improved, resources are insufficient to meet population needs, especially those related to severity of trauma, or to difficulties experienced in displacement or return migration [8]. Primary care practitioners in the Northern Province region regularly spearhead mental health care efforts, however, they do so without adequate training. Training primary care practitioners to deliver mental health care at primary care level is in line with the task-shifting approach in the global mental health field [2, 9-11]. A pilot feasibility study (COMGAP) to explore this possibility was conducted in 2013-2014 based on a peer-reviewed protocol and is reported elsewhere [8].

The first phase of the study was completed in 2015-2016 and facilitated understanding of the mental disorder burden and treatment gap at primary care level. Results from the cross-sectional

study indicated the most prevalent mental health disorders in primary care settings were depression (41.1%, 95% CI: 38.7-44.5%), anxiety (46.7%, 95% CI: 41.9-51.5%), post-traumatic stress disorder (13.7%, 95% CI: 10.6-16.8%), and psychosis with hypomania (17.6%, 95 CI: 13.3-21.9) [12]. While this facilitated understanding of the underlying mental health issues within the region, the issue of unmet need was still present. In this context, the aim of Phase 2 of COMGAP-S is to use a scaled-up training intervention based on the World Health Organization Mental Health Gap Action Programme (WHO mhGAP 2.0) to integrate mental health services into primary care by providing training to primary care practitioners and public health professionals serving conflict-affected populations in primary care settings in the Northern Province [12, 13]. The second phase of the project was conducted between 2016-2021.COMGAP-S is the first large-scale trial in the region to use mhGAP to integrate mental health services into primary care for conflict-affected populations. Further, it is the only trial to include wider health care staff and community members as part of a long-term strategy to improve mental health awareness and stigma reduction.

Aims and objectives

The aim of COMGAP-S is to investigate if implementation of WHO mhGAP training within primary care settings increases identification and treatment of common mental disorders for post-conflict populations in Northern Province, Sri Lanka.

Primary outcomes

1. 30% increase in patients identified and treated for common mental health disorders, and referrals to specialist care for complex mental disorders by primary care practitioners. Measured at baseline using the pre/post-monitoring questionnaires on current practice with mental health patients and compared to post-training practice.

2. 40% minimum concurrence between diagnoses of patients identified with mental disorders of interest by trained primary care practitioners and psychiatrists as compared to diagnosis of

patients pre-training (baseline) measured using quantitative reporting forms from the consultant psychiatrist and in-depth, individual interviews with trained primary care practitioners to understand any changes in practice.

3. 20% reduction in positive screening for depression and anxiety in patients pre-training and at 3- and 6-months follow-up time points, measured using the Hopkins Symptom-Checklist 25.

Secondary outcomes

1. 20% increase between mean pre- and post-training test scores for primary care practitioners using the WHO mhGAP 2.0 pre/post training test.

2. At least 50% reduction of mental health stigma measured using Attitudes to Mental Illness Questionnaire (AMIQ) in primary care practitioner, public health professional, and community representative participant groups at training, and 3- and 6-month follow-up. Prevalence rates were based on previous mental health studies conducted within the country [1,5].

3. At least 40% of primary care practitioners and public health professionals in the region will be delivered training on mhGAP, and at least 2 community representatives from each facility catchment areas will receive tailored training on mental health awareness and stigma reduction.

METHODS AND ANALYSIS

Study design

This is a randomized clinical trial using a stepped wedge cluster design [14]. This design comprises a preliminary period where no clusters (healthcare facilities) are exposed to the intervention, then at regular intervals, one cluster is randomized to cross from control to intervention. This continues until all clusters have been exposed [14]. The stepped wedge design

is increasingly utilized as a way to evaluate interventions that involve service delivery and involves sequential and random crossover of clusters (facilities) from control (delivery of standard care) to intervention (mhGAP training) until all clusters are exposed [14]. The stepped wedge design takes into account the logistical constraints of needing to sequentially roll out the intervention by training one facility at a time enabling us to understand how this intervention can be implemented in the future on a larger scale. This design was chosen because: 1) in an intervention trying to integrate mental health services into primary care for post-conflict populations it is unethical to use a parallel design which prevents equal distribution of knowledge and skills; 2) the stepped wedge cluster design is more logistically feasible in the post-conflict setting of Northern Sri Lanka [15].

Facilities will be randomized using standardized randomization techniques to allocate facilities to the training sequence within the stepped wedge design. Patients and community representatives will not be randomized. The study team cannot be blinded to the allocation of facilities. However, the study psychiatrist will be masked to the randomization status of facilities from which patients originate. Patients will also be blinded to facility randomization status. [1]

There is a theoretical possibility of contamination due to close professional or personal networks between participant groups and geographical location of facilities. However, this is not envisaged to exert significant influence on expected outcomes due to specifics of the extensive training, requirement to carry out intensive tasks, and low risk of contamination through informal discussions [1]. Potential contamination will be observed at all stages and taken into account at the end of the study. Further, an important strength of cluster sampling is that it helps mitigate the risk of treatment contamination between intervention and control groups.

Setting

The study setting will be 23 government primary care health facilities within the five districts of the Northern Province: Jaffna, Mannar, Kilinochchi, Vavuniya, and Mullaitivu. A full list of participating sites can be obtained from the Primary Investigator or from the offices of THEME Institute, Colombo, Sri Lanka.

A list of public primary care facilities has been provided to the study team by the Northern Ministry of Health. A random number generator will be used to select 23 facilities across the 5 districts. Distribution of clusters will be allocated proportionally to the total numbers of internally displaced people in each district (districts with larger numbers were assigned more clusters). This will ensure adequate representation of conflict displacement and severity.

Inclusion criteria

Facilities will be included if they indicate willingness to participate, are located in any of the five districts of Northern Province (Jaffna, Mannar, Kilinochchi, Vavuniya, Mullaitivu), provide primary care services, and are either divisional hospitals of type A, B & C or primary medical care units. Facilities should also provide services to conflict-affected, previously displaced populations.

Primary care practitioners will be included if they have full registration with the Sri Lankan Medical Council, have at least 6 months or more until their next transfer rotation, or 6 months to retirement. Public health professionals will be included if they have at least 6 months left on their transfer rotation, or 6 months to retirement. Community representatives located within the catchment area of each selected facility will be included after identification through local registration organisations. Patients will be included if they are 18 years or older, attend selected facilities, and belong to internally displaced or conflict-affected populations.

Exclusion criteria

Larger facilities such as district hospitals and teaching hospitals will be excluded as they are not part of the primary care system. Private facilities will be excluded due to the lack of an official registry.

Primary care practitioners, public health professionals, and community representatives will be excluded if they have secondary mental health training. Patients under 18 years and those diagnosed with mental disorders outside of depression and/or anxiety will be excluded.

Recruitment and enrolment

Support letters from Provincial Department of Health Service, and Regional Divisional Health Secretariats in each district of Northern Province will be used to approach primary care practitioners and public health professionals. Community representatives will be recruited through local registration organizations. Patients will be recruited by primary care practitioners. Trained research team members will perform screening and enrolment procedures and gain informed consent for each participant group following established study protocols.

Structure and delivery of the intervention

Training material was adapted for local use and included translation and cultural adaption of relevant modules of the WHO mhGAP 2.0 IG, and production of locally adapted and developed mhGAP video material for the Tamil context [16]. This was completed in collaboration with local academics, psychiatrists, primary care practitioners, Northern Province Ministry of Health, and the University of Jaffna.

Training will consist of delivery of written materials, role plays, and training videos. All training material was developed in collaboration with Sri Lankan researchers, local psychiatrists and

community physicians. All material was translated, back translated, and piloted for cultural appropriateness prior to administration in the full project.

Almost all the instruments used in the study had been previously applied in epidemiological studies within Sri Lanka and are available in Tamil, Sinhala, and English languages. New instruments were translated, back translated and adapted for cultural appropriateness in collaboration with the Sri Lankan research team. Further, the entire set of measures was field tested in a pilot study prior to the full study commencing. This pilot study examined if measures were understood by participants, culturally acceptable, and to ensure translations were correct.

To ensure safety of all participants, a local psychiatrist will be involved throughout the study to provide free mental health care if required.

Primary care practitioners and patients

Primary care practitioners (general physicians practicing in selected facilities) will undergo one month of monitoring prior to training to establish a baseline. Primary care practitioners will be trained using the mhGAP manual to recognize common mental health disorders using screening procedures, delivery brief psychosocial interventions (psychoeducation, Motivational Interviewing), and referral procedures for complex cases. They will receive a paper booklet to record information on patients identified, treated, managed, and/or referred for mental health disorders. Further, before training, primary care practitioners will be asked to recruit up to eight patients using provided inclusion and exclusion criteria to have anxiety and/or depression diagnoses verified by a psychiatrist. Members of the research team will provide patients with information sheets and consent forms available in all 3 official languages (English, Tamil, Sinhala) and obtain informed consent. Patients will complete a brief socio-demographic questionnaire at point of recruitment and the Hopkins Symptom Checklist-25 screening questionnaire for depression and anxiety at point of recruitment, and at 3- and 6-months follow-up to establish a baseline, and determine if patient outcomes change after training of primary care practitioners.

Primary care practitioners will be asked detailed questions about their management and treatment of recruited patients, and patients will be asked about any treatments undertaken or medications prescribed to understand any intervening factors between baseline, and 3- and 6-months follow-up.

After the one-month monitoring period, primary care practitioners will undergo a 3-day training intervention delivered in their primary care facility. Trained members of the research team will deliver training at each selected facility to minimize disruption of work at facilities.

After completion of training, monitoring of primary care practitioners will continue for one month, where they will continue to use the paper booklet to record information on patients they identify, treat, manage, for common mental health disorders and any cases they refer to specialized care Research team members will visit or telephone the primary care practitioners once a week at their facility to monitor implementation of the training intervention.

After the one-month monitoring period primary care practitioners will continue to use paper booklets to record their experience of the training implementation for six weeks. At this point (three months post-training) primary care practitioners will participate in a 1-day refresher course and continue to use the experience of training implementation application for a further three months. At six months post-training, primary care practitioners will take a second 1-day refresher course (Figure 1).

Supervision at all time points will be provided by research assistants who previously delivered training sessions. Supervision will consist of phone calls or visits to the clinics to understand if and how training is being utilised by participants.

Public health professionals

Public health professionals (nurse attendants, midwives) in each selected facility will undergo one month of monitoring prior to training to establish a baseline. Public health professionals will be trained using adapted written materials from the mhGAP training to recognize signs of common mental health issues, provide basic psychosocial care (education) and refer onwards if needed. Each enrolled public health professional will record information in a paper booklet on facilitation of referral and follow-up practices for mental health patients, and support primary care practitioners with patient management activities. After the one-month monitoring period, public health professionals will be provided with a tailored 3-day training programme on mental health awareness, management, referral, and stigma reduction. After training, public health professionals will undergo one month of monitoring and record the same information as in the pre-monitoring period to see how/if practice has changed. Research team members will visit or telephone their facility once a week to monitor implementation of the training intervention.

After the one-month, monitoring period public health professionals will record information on their experience of the training intervention for six weeks. At this point (three months post-training), public health professionals will participate in a 1-day refresher course and continue to use the paper booklets to record their experience of training implementation for a further three months. At six months post-training, public health professionals will take a second 1-day refresher course (Figure 2).

Supervision at all time points will be provided by research assistants who delivered previous training sessions. Supervision will consist of phone calls or visits to the clinics to understand if and how training was being utilised by participants.

Community representatives

Community representatives (teachers, social workers) will undergo one month of monitoring prior to training to establish a baseline. Community representatives will be trained using adapted

materials from the mhGAP training material to recognize signs of common mental illness, delivery basic psychosocial education and learn referral pathways and where to seek providers. Each enrolled community representative will record information in a paper booklet on mental health awareness raising activities undertaken, and any referrals of people they encounter with mental health issues. After the one-month monitoring period, community representatives will participate in a tailored 1-day training programme on mental health awareness, stigma reduction, and finding local resources. After training, community representatives will undergo one month of monitoring and record the same information as in the pre-monitoring period to see how/if practice has changed. Research team members will visit or telephone once a week to monitor implementation of the training intervention.

After the one-month, monitoring period community representatives' will record information on their experience of the training intervention in paper booklets for six weeks. At this point (three months post-training), community representatives will participate in a half-day refresher course and continue to use provided booklets to record their experience of training implementation for a further three months. At six months post-training, community representatives will participate in a second half-day refresher course (Figure 3).

Supervision at all time points will be provided by research assistants who delivered previous training sessions. Supervision will consist of phone calls or visits to the clinics to understand if and how training was being utilised by participants.

Timing of intervention delivery and follow-up

COMGAP-S will run for 7 months in each facility and catchment area. Every 2 weeks a facility will be enrolled in the study until all 23 have completed the study timeline. Participants discontinuing engagement will not be subject to follow-up. Measures will be collected at six time points:

1. Pre-training monitoring period: questionnaire to establish a baseline on current practice. Primary care practitioners only: recruitment of patients for diagnosis verification.

Patients administered Hopkins Symptom Checklist 25 for anxiety and/or depression (baseline), and at 3- and 6-months follow-up to assess change in clinical symptoms.

2. Pre-training intervention: WHO mhGAP knowledge pre-test and AMIQ stigma questionnaire.

3. Post-training intervention: second administration of WHO mhGAP knowledge test.

4. Post-training monitoring period: questionnaire to establish if/how practice has changed, and qualitative interviews to reflect on initial diagnosis practice.

5. 3 months follow-up training: WHO mhGAP pre- and post- knowledge test and AMIQ stigma questionnaire.

6. 6 months follow-up training: WHO mhGAP pre- and post- knowledge test and AMIQ stigma questionnaire.

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Statistical methods

The primary unit of analysis (i.e., where the intervention is carried out) is the healthcare facility, and data collected from the individual participants will include: sociodemographic information, conflict and displacement experience, mhGAP knowledge test scores, AMIQ stigma scores, and pre- and post- monitoring questionnaires. Descriptive statistics will be used to summarize observations using means, standard deviations, and proportions where appropriate.

An intention-to-treat analysis will be used to analyze the effect of the intervention. In the stepped wedge design, similar information will be collected repeatedly on individuals within facilities; we will therefore utilize statistical models that can adjust for repeat measures and clustering of

participants within facilities (in the case of PHPs and CRs). In particular, for the analysis of mhGAP knowledge test scores and AMIQ stigma scores as outcomes of interest among participants, we plan to use generalized linear mixed models that include random intercepts for individuals (to account for repeat measurements), random intercepts for facilities (to account for the correlation among individuals within the same facility), and adjustments for covariates. Statistical analysis will be carefully conducted as repeated time measures over a 7-month time period will mean missing data points and shifted timelines due to external circumstances. Subgroup analysis will be conducted to understand differences between clusters and well as within clusters.

For qualitative data, interviews with primary care practitioners will continue until saturation has been met and thematic analysis will be used to analyse results.

Fidelity checks will be included in the study through the utilization of feedback forms after the end of each training session to investigate if any major concerns have arisen that could be addressed before subsequent sessions. Further, a process evaluation will be conducted to understand if the study adhered to protocol, and how the intervention was received by participants.

Sample size calculation

A total of 23 primary care practitioners, 75 public health professionals, 50 community representatives, and 200 patients will be recruited. Target sample sizes were calculated separately for each participant group and for each outcome. Sample sizes for the first and second outcomes were calculated following methods described by Hemming and Taljaard, where each outcome is considered an individually randomized trial and then multiplied by a design effect to account for the stepped wedge design [17]. Sample sizes for the third and fourth outcomes were calculated using formulae from the 1994 textbook “Analysis of Longitudinal Data” by Diggle, Liang and Zeger [18].

Ethics and Dissemination

Ethical approval has been received from the Faculty of Health, Education, Medicine and Social Care, Anglia Ruskin University, UK (SC/jc/FMFREP/16/17 076), from the Faculty of Medicine, University of Jaffna, Sri Lanka (J/ERC/17/81/NDR/0170) and non-engagement approval from the funding body, the Centers for Disease Control and Prevention (2018-015). Trial results and analyses will be purposefully communicated to the Provincial Department of Health Service, Regional Divisional Health Secretariats in all five districts of Northern Province, participating healthcare professionals and community representatives. Dissemination events will be held with the University of Jaffna. Activities will include publications and presentations to general and specialized audience by team members. The research dataset and statistical analyses will be available by request from the primary investigator.

Evaluation

Cost Ratio Economic Evaluation

This component will involve two evaluations. The first will evaluate the ratio between costs associated of training primary care practitioners to identify, treat and refer mental health care patients compared to costs of referral to, and treatment from, psychiatrists. Costs will be linked to the primary outcome measure to determine the extra cost of training incurred to detect one extra patient and understand economic implications of service provision to conflict-affected populations [19]. The second will evaluate the ratio between costs associated with patients receiving care from trained primary care practitioners at primary care facilities compared to costs of seeking care from specialist psychiatrists.

Process Evaluation

After initial training, 3- and 6-month refresher courses, quantitative and qualitative feedback will be collected from participants to explore how training was received. Qualitative case studies with primary health care staff, trainers, supervisors, patients will take place during post-training monitoring and evaluation periods to understand how the programme was received and implemented. Descriptive analysis will be used for quantitative data, while thematic analysis will be used for qualitative data.

DISCUSSION

Due to the history of conflict and displacement in Sri Lanka, it is vital to address unmet mental health needs of the population. The completed cross-sectional survey at primary care level (Phase 1) supports this and demonstrates prevalence and predictors of mental health disorders in the region. The WHO mhGAP IG 2.0 training programme provides a strategy to address this gap between those seeking, and those able, to access mental health services in the region (Phase 2). COMGAP-S will not only demonstrate the feasibility of implementing the mhGAP training programme, but ongoing monitoring activities will contribute to evaluation of both training and implementation.

Using the mhGAP guide to train participants on how to identify and treat common mental health disorders could empower primary care practitioners to effectively address mental health needs of the population in this post-conflict setting. This will also take pressure of limited specialized psychiatry services in the region. Additionally, training public health professionals and community representatives can positively increase mental health awareness and decrease stigma in the local community. Training materials have undergone cultural adaptation to ensure training is relevant and acceptable to all participants and stakeholders. Use of a locally adapted mhGAP guide will increase acceptability and sustainability of the implementation of the clinical trial. This project

includes key stakeholders from Northern Ministry of Health, University of Jaffna, Sri Lankan psychiatrists, and Sri Lankan researchers. Thus, COMGAP-S will not only contribute to the evidence base on integrating mental health services in primary care in low resource settings, it will also build local capacity, be culturally relevant, and sustainable.

COMGAP-S will be the first large-scale implementation of WHO mhGAP IG 2.0 training to improve mental health service delivery in primary care in Northern Province, Sri Lanka. Implementation of COMGAP-S aims to build capacity within the primary care system in the region, but also improve mental health service delivery addressing the unmet needs of a vulnerable population.

Figure 1. Primary Care Practitioner study timeline

Figure 2. Public Health Professional study timeline

Figure 3. Community representative study timeline

Authors' contributions: SD developed the concept and design of this study with contributions from GD, AE, BR, RS and MA. SD wrote the manuscript with contributions from GD, AE, BR, RS and MA. All authors commented on and approved the final version of this manuscript.

Data sharing statement

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.

Patient and Public Involvement

Research materials and project aims were developed in collaboration with academic and service provider stakeholders to ensure priorities were addressed. Participants were consulted during the pilot stage to ensure research questions and materials were appropriate and relevant. Once the trial has been published, participants and the public will be informed of the results through a dedicated website (http://globalhme.org) as well as through paper leaflets, townhall discussions and social media to ensure both specialist and non-specialist audience can access study findings.

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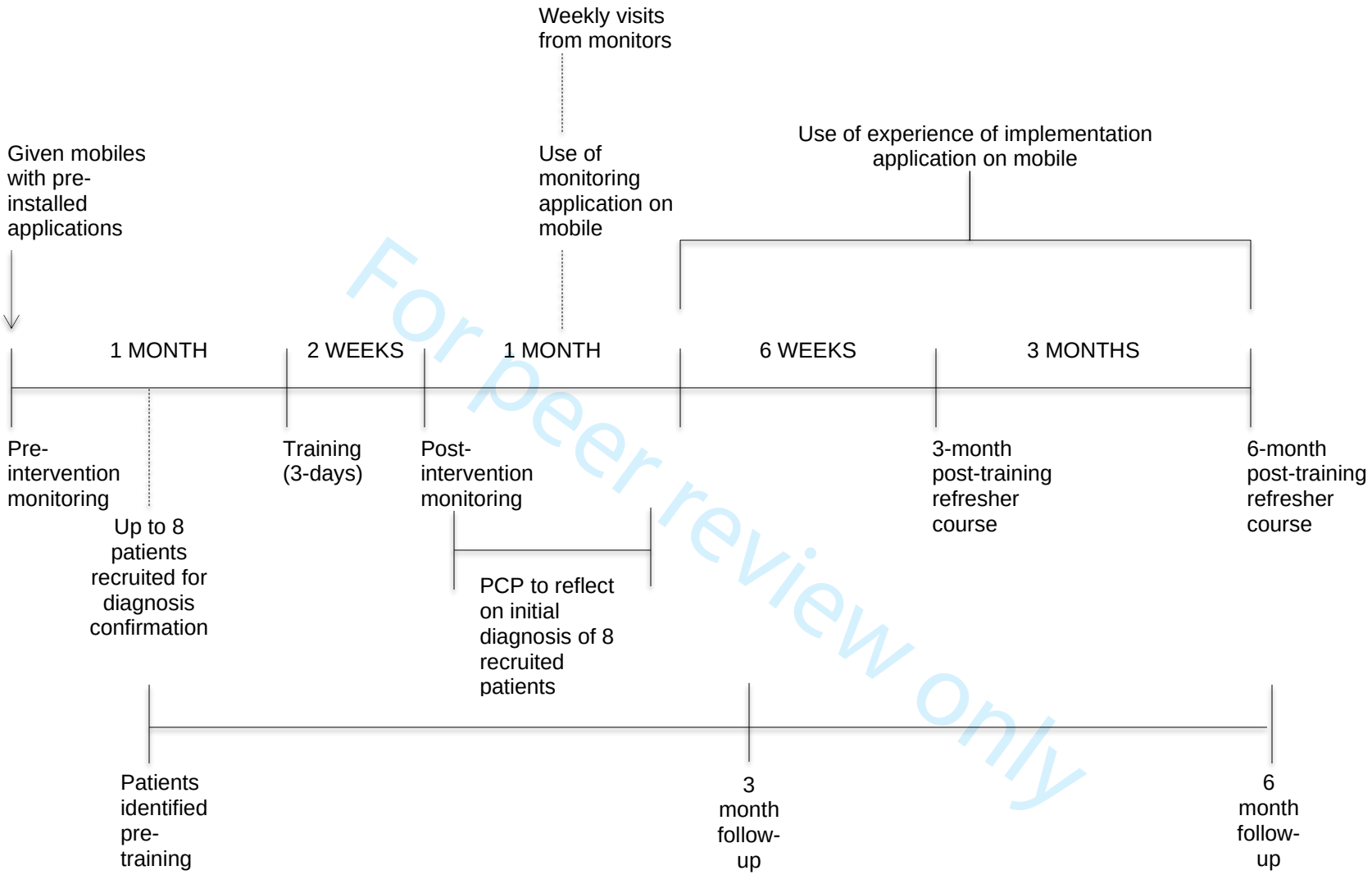

Figure 1. Primary Care Practitioner study timeline

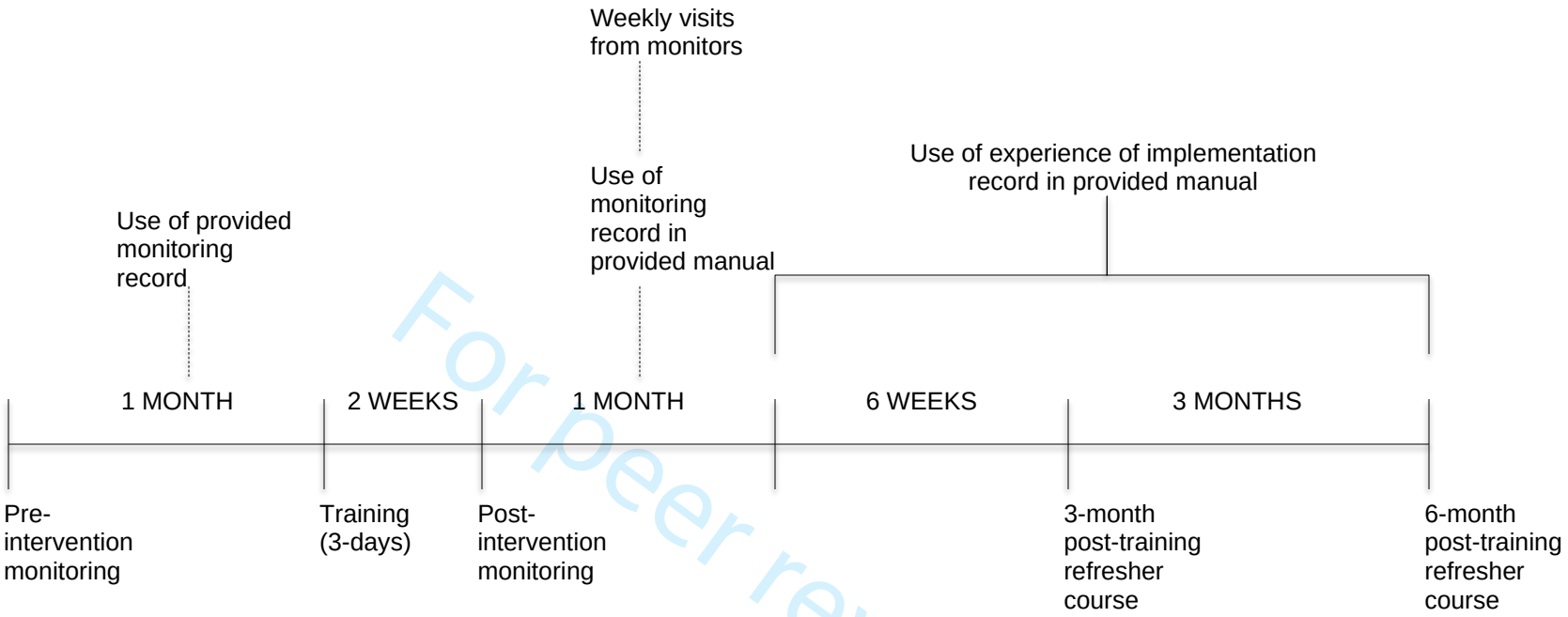

Figure 2. Public Health Professional study timeline

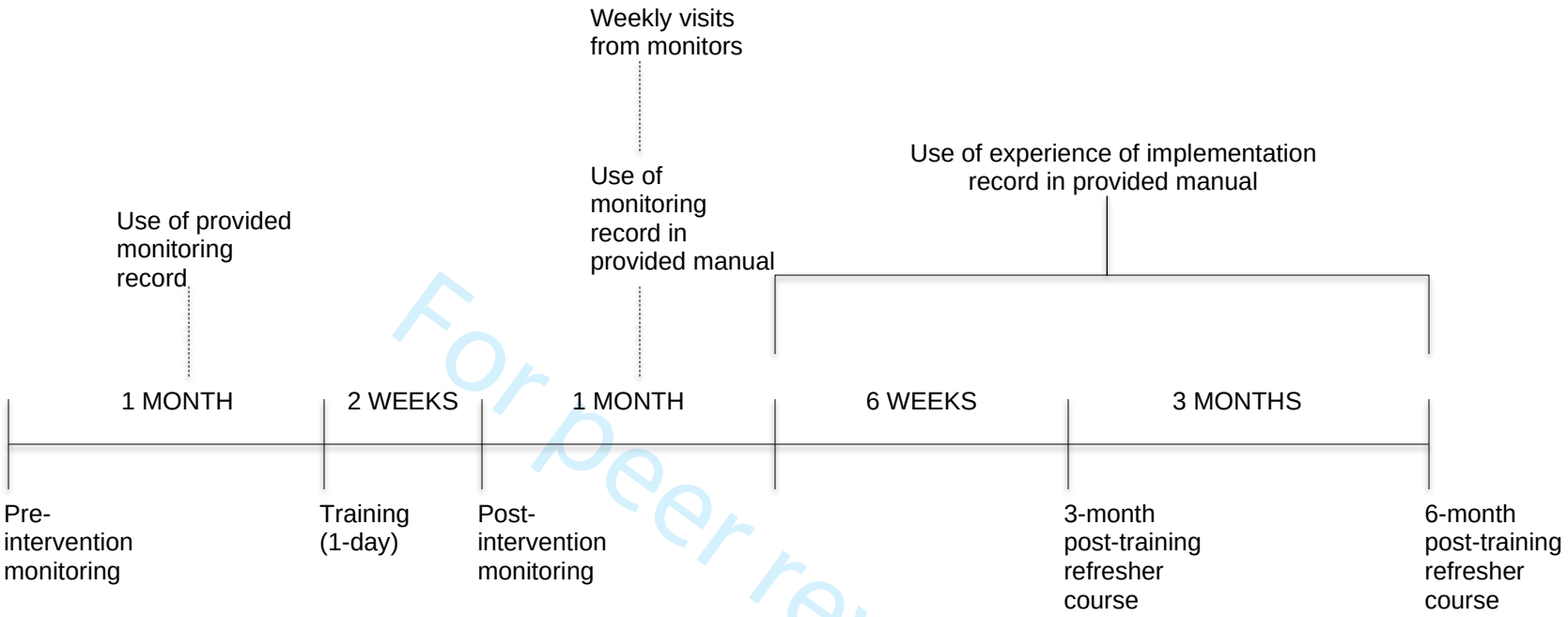

Figure 3. Community representative study timeline

BMJ Open

Protocol of a randomized clinical trial to integrate mental health services into primary care for post-conflict populations in Northern Sri Lanka (COMGAP-S)

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Title: Protocol of a randomized clinical trial to integrate mental health services into primary care for post-conflict populations in Northern Sri Lanka (COMGAP-S)

Authors: Shannon Doherty, PhD, Anglia Ruskin University, Cambridge, United Kingdom; Giselle Dass, THEME Institute, Colombo, Sri Lanka; Anne Edward, THEME Institute, Colombo, Sri Lanka; Robert Stewart, MD, King's College London, United Kingdom; Bayard Roberts, PhD, London School of Hygiene and Tropical Medicine, United Kingdom; Melanie Abas, PhD, King's College London, United Kingdom

Corresponding Author: Shannon Doherty, PhD, Anglia Ruskin University, Bishop Hall Lane, Chelmsford, UK, CM1 1SQ, shannon.doherty@anglia.ac.uk, +44 75 2212 8409

ABSTRACT

Introduction

Sri Lanka has a long history of armed conflict and natural disasters increasing risk of mental health disorders in the population. Due to a lack of specialist services, there is a treatment gap between those seeking and those able, to access mental health services. The aim of this research programme is to integrate mental health services into primary care to meet the needs of this post-conflict population.

Methods and analysis

This is a stepped wedge cluster design randomized clinical trial of the World Health Organisation mhGAP primary care mental health training intervention. We will provide a 10-day training to primary care practitioners of 23 randomly selected primary care facilities aimed at increasing their ability to identify, treat, and manage common mental health disorders. Public health professionals and community representatives will receive a tailored training intervention to increase mental health awareness. Refresher courses will occur at 3- and 6-months post-training. Supervision and monitoring will occur for one month pre- and post-training. Target sample sizes have been calculated separately for each group of participants and for each outcome.

Ethics and dissemination

This trial has received ethical approval from the Faculty of Health, Education, Medicine and Social Care, Anglia Ruskin University, UK (SC/jc/FMFREP/16/17 076), from the Faculty of Medicine, University of Jaffna, Sri Lanka (J/ERC/17/81/NDR/0170) and non-engagement approval from the funding body, the Centers for Disease Control and Prevention (2018-015). All participants gave written consent.

Dissemination of study results will be completed through publication of academic articles, conference presentations, townhall meetings, written pamphlets in plain language, reports to Ministry of Health and other government organisations, and through social media outlets.

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Trial Registration

ISRCTN registry ISRCTN62598070, 1 Sept 2017. SLCTR registration number:

SLCTR/2018/008, 27 Feb 2018.

Abbreviations

WHO mhGAP - World Health Organization's mental health Gap Action Programme

LMIC - Low- and middle-income countries

Keywords

Conflict, clinical trial, health systems, mental health, mhGAP

Strengths and limitations of this study

- First study to culturally adapt all World Health Organisation mhGAP written and video training materials
- Seeks to demonstrate feasibility of using World Health Organisation mhGAP materials to train non-specialists
- Multiple refresher sessions should increase knowledge retention among participants
- Representative sample means findings could be generalized to other areas of Northern Sri Lanka
- Limited to publicly available healthcare facilities as private facilities were excluded

Word count: 3,999

INTRODUCTION

Mental health disorders often present in primary care settings, especially in low- and middle-income countries (LMIC), where specialized psychiatric services may be lacking. Low- or non-detection, low referral rates for specialist care, and increased costs are all features of mental health disorders in primary care settings in LMIC. Furthermore, lack of adequate training for primary care physicians and lack of involvement of public health personnel can act as barriers to effective treatment and management of common mental health disorders in primary care [1, 2]. Barriers can be compounded in post-conflict situations, as existing limited health systems may be severely affected, especially for those internally displaced. There is strong evidence that conflict-driven, internally displaced migrants have increased rates of mental health disorders [1, 3].

During 26 years of protracted internal conflict in Sri Lanka, more than 100,000 people of all ethnicities are estimated to have died, and hundreds of thousands injured [4, 5]. Substantial internal displacement from conflict was compounded by the 2004 tsunami [6].

Although Sri Lanka has an effective primary care system, the treatment gap for mental health is extensive, especially for post-conflict populations [1, 7]. While provision of health services has improved, resources are insufficient to meet population needs, especially those related to severity of trauma, or to difficulties experienced in displacement or return migration [8]. Primary care practitioners in the Northern Province region regularly spearhead mental health care efforts, however, they do so without adequate training. Training primary care practitioners to deliver mental health care at primary care level is in line with the task-shifting approach in the global mental health field [2, 9-11]. A pilot feasibility study (COMGAP) to explore this possibility was conducted in 2013-2014 based on a peer-reviewed protocol and is reported elsewhere [8].

The first phase of the study was completed in 2015-2016 and facilitated understanding of mental disorder burden and treatment gap at primary care level. Results from the cross-sectional study

indicated the most prevalent mental health disorders in primary care settings were depression (41.1%, 95% CI: 38.7-44.5%), anxiety (46.7%, 95% CI: 41.9-51.5%), post-traumatic stress disorder (13.7%, 95% CI: 10.6-16.8%), and psychosis with hypomania (17.6%, 95 CI: 13.3-21.9) [12]. While this facilitated understanding of the underlying mental health issues within the region, the issue of unmet need was still present. In this context, the aim of Phase 2 of COMGAP-S is to use a scaled-up training intervention based on the World Health Organization Mental Health Gap Action Programme (WHO mhGAP 2.0) to integrate mental health services into primary care by providing training to primary care practitioners and public health professionals serving conflict-affected populations in primary care settings in Northern Province [12, 13]. The second phase of the project was conducted between 2016-2021. COMGAP-S is the first large-scale trial in the region to use mhGAP to integrate mental health services into primary care for conflict-affected populations. Further, it is the only trial to include wider health care staff and community members as part of a long-term strategy to improve mental health awareness and stigma reduction.

Aims and objectives

The aim of COMGAP-S is to investigate if implementation of WHO mhGAP training within primary care settings increases identification and treatment of common mental disorders for post-conflict populations in Northern Province, Sri Lanka.

Primary outcomes

1. 30% increase in patients identified and treated for common mental health disorders, and referrals to specialist care for complex mental disorders by primary care practitioners. Measured at baseline using the pre/post-monitoring questionnaires on current practice with mental health patients and compared to post-training practice.

2. 40% minimum concurrence between diagnoses of patients identified with mental disorders of interest by trained primary care practitioners and psychiatrists as compared to diagnosis of patients pre-training (baseline) measured using quantitative reporting forms from the consultant

psychiatrist and in-depth, individual interviews with trained primary care practitioners to understand any changes in practice.

3. 20% reduction in positive screening for depression and anxiety in patients pre-training and at 3- and 6-months follow-up time points, measured using the Hopkins Symptom-Checklist 25.

Secondary outcomes

1. 20% increase between mean pre- and post-training test scores for primary care practitioners using the WHO mhGAP 2.0 pre/post training test.

2. At least 50% reduction of mental health stigma measured using Attitudes to Mental Illness Questionnaire (AMIQ) in primary care practitioner, public health professional, and community representative participant groups at training, and 3- and 6-month follow-up. Prevalence rates were based on previous mental health studies conducted within the country [1,5].

3. At least 40% of primary care practitioners and public health professionals in the region will be delivered training on mhGAP, and at least 2 community representatives from each facility catchment areas will receive tailored training on mental health awareness and stigma reduction.

METHODS AND ANALYSIS

Study design

This is a randomized clinical trial using a stepped wedge cluster design [14]. This design comprises a preliminary period where no clusters (healthcare facilities) are exposed to the intervention, then at regular intervals, one cluster is randomized to cross from control to intervention. This continues until all clusters have been exposed [14]. The stepped wedge design is increasingly utilized to evaluate interventions that involve service delivery and involves sequential and random crossover of clusters (facilities) from control (delivery of standard care) to intervention (mhGAP training) until all clusters are exposed [14]. The stepped wedge design takes

into account logistical constraints to sequentially roll out the intervention by training one facility at a time enabling us to understand how this intervention can be implemented in the future on a larger scale. This design was chosen because: 1) in an intervention trying to integrate mental health services into primary care for post-conflict populations it is unethical to use a parallel design which prevents equal distribution of knowledge and skills; 2) the stepped wedge cluster design is more logistically feasible in the post-conflict setting of Northern Sri Lanka [15].

Facilities will be randomized using standardized randomization techniques to allocate facilities to the training sequence within the stepped wedge design. Patients and community representatives will not be randomized. The study team cannot be blinded to the allocation of facilities. The study psychiatrist will be masked to randomization status of facilities from which patients originate. Patients will also be blinded to facility randomization status. [1]

There is a theoretical possibility of contamination due to close professional or personal networks between participant groups and geographical location of facilities. However, this is not envisaged to exert significant influence on expected outcomes due to specifics of the extensive training, requirement to carry out intensive tasks, and low risk of contamination through informal discussions [1]. Potential contamination will be observed at all stages and taken into account at the end of the study. Further, an important strength of cluster sampling is that it helps mitigate the risk of treatment contamination between intervention and control groups.

Setting

The study setting will be 23 government primary care health facilities within the five districts of the Northern Province: Jaffna, Mannar, Kilinochchi, Vavuniya, and Mullaitivu. A full list of participating sites can be obtained from the Primary Investigator..

A list of public primary care facilities was provided to the study team by Northern Ministry of Health. A random number generator will be used to select 23 facilities across 5 districts. Distribution of clusters will be allocated proportionally to total numbers of internally displaced people in each district (districts with larger numbers were assigned more clusters). This will ensure adequate representation of conflict displacement and severity.

Inclusion criteria

Facilities will be included if they indicate willingness to participate, are located in any of the five districts of Northern Province (Jaffna, Mannar, Kilinochchi, Vavuniya, Mullaitivu), provide primary care services, and are either divisional hospitals of type A, B & C or primary medical care units. Facilities should also provide services to conflict-affected, previously displaced populations.

Primary care practitioners will be included if they have full registration with the Sri Lankan Medical Council, have at least 6 months or more until their next transfer rotation, or 6 months to retirement. Public health professionals will be included if they have at least 6 months left on their transfer rotation, or 6 months to retirement. Community representatives located within catchment areas of each selected facility will be included after identification through local registration organisations. Patients will be included if they are 18 years or older, attend selected facilities, and belong to internally displaced or conflict-affected populations.

Exclusion criteria

Larger facilities such as district hospitals and teaching hospitals will be excluded as they are not part of the primary care system. Private facilities will be excluded due to lack of an official registry.

Primary care practitioners, public health professionals, and community representatives will be excluded if they have secondary mental health training. Patients under 18 years and those diagnosed with mental disorders outside of depression and/or anxiety will be excluded.

Recruitment and enrolment

Support letters from Provincial Department of Health Service, and Regional Divisional Health Secretariats in each district of Northern Province will be used to approach primary care practitioners and public health professionals. Community representatives will be recruited through local registration organizations. Patients will be recruited by primary care practitioners. Trained research team members will perform screening and enrolment procedures and gain informed consent for each participant group following established study protocols.

Structure and delivery of the intervention

Training material was adapted for local use and included translation and cultural adaption of relevant modules of the WHO mhGAP 2.0 IG, and production of locally developed mhGAP video material for the Tamil context [16]. This was completed in collaboration with local academics, psychiatrists, primary care practitioners, Northern Province Ministry of Health, and the University of Jaffna.

Training will consist of delivery of written materials, role plays, and training videos. All training material was developed in collaboration with Sri Lankan researchers, local psychiatrists and community physicians. All material was translated, back translated, and piloted for cultural appropriateness prior to the full project.

Almost all instruments used in the study had been previously applied in epidemiological studies within Sri Lanka and are available in Tamil, Sinhala, and English languages. New instruments were translated, back translated and adapted for cultural appropriateness in collaboration with

the Sri Lankan research team. Further, the entire set of measures was field tested in a pilot study prior to the full study commencing. This pilot study examined if measures were understood by participants, culturally acceptable, and translations correct.

To ensure safety of participants, a local psychiatrist will be involved throughout the study to provide free mental health care if required.

Primary care practitioners and patients

Primary care practitioners (general physicians practicing in selected facilities) will undergo one month of monitoring prior to training to establish a baseline. Primary care practitioners will be trained using the mhGAP manual to recognize common mental health disorders using screening procedures, delivery brief psychosocial interventions (psychoeducation, Motivational Interviewing), and referral procedures for complex cases. They will receive a paper booklet to record information on patients identified, treated, managed, and/or referred for mental health disorders. Further, before training, primary care practitioners will be asked to recruit up to eight patients using provided inclusion and exclusion criteria to have anxiety and/or depression diagnoses verified by a psychiatrist. Members of the research team will provide patients with information sheets and consent forms available in all 3 official languages (English, Tamil, Sinhala) and obtain informed consent. Patients will complete a brief socio-demographic questionnaire at point of recruitment and the Hopkins Symptom Checklist-25 screening questionnaire for depression and anxiety at point of recruitment, and at 3- and 6-months follow-up to establish a baseline, and determine if patient outcomes change after training of primary care practitioners. Primary care practitioners will be asked detailed questions about their management and treatment of recruited patients, and patients will be asked about any treatments undertaken or medications prescribed to understand any intervening factors between baseline, and 3- and 6-months follow-up.

After the one-month monitoring period, primary care practitioners will undergo a 3-day training intervention delivered in their primary care facility. Trained members of the research team will deliver training at each selected facility to minimize disruption of work at facilities. PCP trainers have Masters degrees in psychology and global mental health, and have successfully completed the WHO mhGAP train-the-trainers program.

After completion of training, monitoring of primary care practitioners will continue for one month, where they will continue to use the paper booklet to record information on patients they identify, treat, manage, for common mental health disorders and any cases they refer to specialized care Research team members will visit or telephone the primary care practitioners once a week at their facility to monitor implementation of the training intervention.

After the one-month monitoring period primary care practitioners will continue to use paper booklets to record their experience of the training implementation for six weeks. At this point (three months post-training) primary care practitioners will participate in a 1-day refresher course and continue to use the experience of training implementation application for a further three months. At six months post-training, primary care practitioners will take a second 1-day refresher course (Figure 1).

Non-clinical supervision at all time points will be provided by research assistants who previously delivered training sessions. Supervision will consist of phone calls or visits to the clinics to understand if and how training is being utilised by participants. Supervision is meant to understand if and how trained participants utilise mhGAP, accurate delivery of interviewing or diagnostic skills were not evaluated.

Public health professionals

Public health professionals (nurse attendants, midwives) in each selected facility will undergo one month of monitoring prior to training to establish a baseline. Public health professionals will be trained using adapted written materials from the mhGAP training to recognize signs of common mental health issues, provide basic psychosocial care (education) and refer onwards if needed. PHP trainers hold Bachelors' degrees in psychology and have undergone 7 days training with senior members of the research team. Each enrolled public health professional will record information in a paper booklet on facilitation of referral and follow-up practices for mental health patients, and support primary care practitioners with patient management activities. After the one-month monitoring period, public health professionals will be provided with a tailored 3-day training programme on mental health awareness, management, referral, and stigma reduction. After training, public health professionals will undergo one month of monitoring and record the same information as in the pre-monitoring period to see how/if practice has changed. Research team members will visit or telephone their facility once a week to monitor implementation of the training intervention.

After the one-month, monitoring period public health professionals will record information on their experience of the training intervention for six weeks. At this point (three months post-training), public health professionals will participate in a 1-day refresher course and continue to use the paper booklets to record their experience of training implementation for a further three months. At six months post-training, public health professionals will take a second 1-day refresher course (Figure 2).

Non-clinical supervision at all time points will be provided by research assistants who delivered previous training sessions. Supervision will consist of phone calls or visits to the clinics to understand if and how training was being utilised by participants.

Community representatives

Community representatives (teachers, social workers) will undergo one month of monitoring prior to training to establish a baseline. Community representatives will be trained using adapted materials from the mhGAP training material to recognize signs of common mental illness, delivery basic psychosocial education and learn referral pathways and where to seek providers. CR trainers hold Bachelors' degrees in psychology and have undergone 7 days training with senior members of the research team. Each enrolled community representative will record information in a paper booklet on mental health awareness raising activities undertaken, and any referrals of people they encounter with mental health issues. After the one-month monitoring period, community representatives will participate in a tailored 1-day training programme on mental health awareness, stigma reduction, and finding local resources. After training, community representatives will undergo one month of monitoring and record the same information as in the pre-monitoring period to see how/if practice has changed. Research team members will visit or telephone once a week to monitor implementation of the training intervention.

After the one-month, monitoring period community representatives' will record information on their experience of the training intervention in paper booklets for six weeks. At this point (three months post-training), community representatives will participate in a half-day refresher course and continue to use provided booklets to record their experience of training implementation for a further three months. At six months post-training, community representatives will participate in a second half-day refresher course (Figure 3).

Non-clinical supervision at all time points will be provided by research assistants who delivered previous training sessions. Supervision will consist of phone calls or visits to the clinics to understand if and how training was being utilised by participants.

Timing of intervention delivery and follow-up

COMGAP-S will run for 7 months in each facility and catchment area. Every 2 weeks a facility will be enrolled in the study until all 23 have completed the study timeline. Participants discontinuing engagement will not be subject to follow-up. Measures will be collected at six time points:

1. Pre-training monitoring period: questionnaire to establish baseline on current practice. Primary care practitioners only: recruitment of patients for diagnosis verification.

Patients administered Hopkins Symptom Checklist 25 for anxiety and/or depression (baseline), and at 3- and 6-months follow-up to assess change in clinical symptoms.

2. Pre-training intervention: WHO mhGAP knowledge pre-test and AMIQ stigma questionnaire.

3. Post-training intervention: second administration of WHO mhGAP knowledge test.

4. Post-training monitoring period: questionnaire to establish if/how practice has changed, and qualitative interviews to reflect on initial diagnosis practice.

5. 3 months follow-up training: WHO mhGAP pre- and post- knowledge test and AMIQ stigma questionnaire.

6. 6 months follow-up training: WHO mhGAP pre- and post- knowledge test and AMIQ stigma questionnaire.

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Statistical methods

The primary unit of analysis (i.e., where the intervention is carried out) is the healthcare facility, and data collected from individual participants will include: sociodemographic information, conflict and displacement experience, mhGAP knowledge test scores, AMIQ stigma scores, and pre- and post- monitoring questionnaires. Descriptive statistics will be used to summarize observations

using means, standard deviations, and proportions where appropriate. Data analysis will be conducted using SAS version 9.4M7 [17].

An intention-to-treat analysis will be used to analyze the effect of the intervention. In the stepped wedge design, similar information will be collected repeatedly on individuals within facilities; we will therefore utilize statistical models that can adjust for repeat measures and clustering of participants within facilities (in the case of PHPs and CRs). In particular, for the analysis of mhGAP knowledge test scores and AMIQ stigma scores as outcomes of interest among participants, we plan to use generalized linear mixed models that include random intercepts for individuals (to account for repeat measurements), random intercepts for facilities (to account for the correlation among individuals within the same facility), and adjustments for covariates. Statistical analysis will be carefully conducted as repeated time measures over a 7-month time period will mean missing data points and shifted timelines due to external circumstances. Subgroup analysis will be conducted to understand differences between clusters and well as within clusters. Planned subgroup analysis will investigate possible differences between clusters (for example, differences between PHPs across facilities)

For qualitative data, interviews with primary care practitioners will continue until saturation has been met and thematic analysis will be used..

Fidelity checks will be included through utilization of feedback forms after the end of each training session to investigate if any major concerns have arisen that could be addressed before subsequent sessions. Further, a process evaluation will be conducted to understand if the study adhered to protocol, and how the intervention was received by participants.

Sample size calculation

A total of 23 primary care practitioners, 75 public health professionals, 50 community representatives, and 200 patients will be recruited. Target sample sizes were calculated separately for each participant group and for each outcome. Sample sizes for the first and second

outcomes were calculated following methods described by Hemming and Taljaard, where each outcome is considered an individually randomized trial and then multiplied by a design effect to account for the stepped wedge design [18]. Sample sizes for the third and fourth outcomes were calculated using formulae from the 1994 textbook "Analysis of Longitudinal Data" by Diggle, Liang and Zeger [19].

Ethics and Dissemination

Ethical approval has been received from the Faculty of Health, Education, Medicine and Social Care, Anglia Ruskin University, UK (SC/jc/FMFREP/16/17 076), the Faculty of Medicine, University of Jaffna, Sri Lanka (J/ERC/17/81/NDR/0170) and non-engagement approval from the funding body, the Centers for Disease Control and Prevention (2018-015). Trial results and analyses will be purposefully communicated to the Provincial Department of Health Service, Regional Divisional Health Secretariats in all five districts of Northern Province, participating healthcare professionals and community representatives. Dissemination events will be held with the University of Jaffna. Activities will include publications and presentations to general and specialized audience by team members. The research dataset and statistical analyses will be available by request from the primary investigator.

Evaluation

Cost Ratio Economic Evaluation

This component will involve two evaluations. The first will evaluate the ratio between costs associated of training primary care practitioners to identify, treat and refer mental health care patients compared to costs of referral to, and treatment from, psychiatrists. Costs will be linked to the primary outcome measure to determine the extra cost of training incurred to detect one extra

patient and understand economic implications of service provision to conflict-affected populations [20]. The second will evaluate the ratio between costs associated with patients receiving care from trained primary care practitioners at primary care facilities compared to costs of seeking care from specialist psychiatrists.

Process Evaluation

After initial training, 3- and 6-month refresher courses, quantitative and qualitative feedback will be collected from participants to explore how training was received. Qualitative case studies with primary health care staff, trainers, supervisors, patients will take place during post-training monitoring and evaluation periods to understand how the programme was received and implemented. Descriptive analysis will be used for quantitative data, while thematic analysis will be used for qualitative data.

DISCUSSION

Due to the history of conflict and displacement in Sri Lanka, it is vital to address unmet mental health needs.. The completed cross-sectional survey at primary care level (Phase 1) supports this and demonstrates prevalence and predictors of mental health disorders in the region. The WHO mhGAP IG 2.0 training programme provides a strategy to address this gap between those seeking, and those able, to access mental health services in the region (Phase 2). COMGAP-S will not only demonstrate the feasibility of implementing the mhGAP training programme, but ongoing monitoring activities will contribute to evaluation of both training and implementation.

Using the mhGAP guide to train participants to identify and treat common mental health disorders could empower primary care practitioners to effectively address mental health needs of the population in this post-conflict setting. This will also take pressure off limited specialized

psychiatry services in the region. Additionally, training public health professionals and community representatives can positively increase mental health awareness and decrease stigma in the local community. Use of a locally adapted mhGAP guide will increase acceptability and sustainability of the implementation of the clinical trial. This project includes key stakeholders from Northern Ministry of Health, University of Jaffna, Sri Lankan psychiatrists, and Sri Lankan researchers. Thus, COMGAP-S will not only contribute to the evidence base on integrating mental health services in primary care in low resource settings, it will also build local capacity, be culturally relevant, and sustainable.

COMGAP-S will be the first large-scale implementation of WHO mhGAP IG 2.0 training to improve mental health service delivery in primary care in Northern Province, Sri Lanka. Implementation of COMGAP-S aims to build capacity within the primary care system in the region, but also improve mental health service delivery addressing the unmet needs of a vulnerable population.

Figure 1. Primary Care Practitioner study timeline

Figure 2. Public Health Professional study timeline

Figure 3. Community representative study timeline

Authors' contributions: SD developed the concept and design of this study with contributions from GD, AE, BR, RS and MA. SD wrote the manuscript with contributions from GD, AE, BR, RS and MA. All authors commented on and approved the final version of this manuscript.

Data sharing statement

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.

Patient and Public Involvement

Research materials and project aims were developed in collaboration with academic and service provider stakeholders to ensure priorities were addressed. Participants were consulted during the pilot stage to ensure research questions and materials were appropriate and relevant. Once the trial has been published, participants and the public will be informed of the results through a dedicated website (http://globalhme.org) as well as through paper leaflets, townhall discussions and social media to ensure both specialist and non-specialist audience can access study findings.

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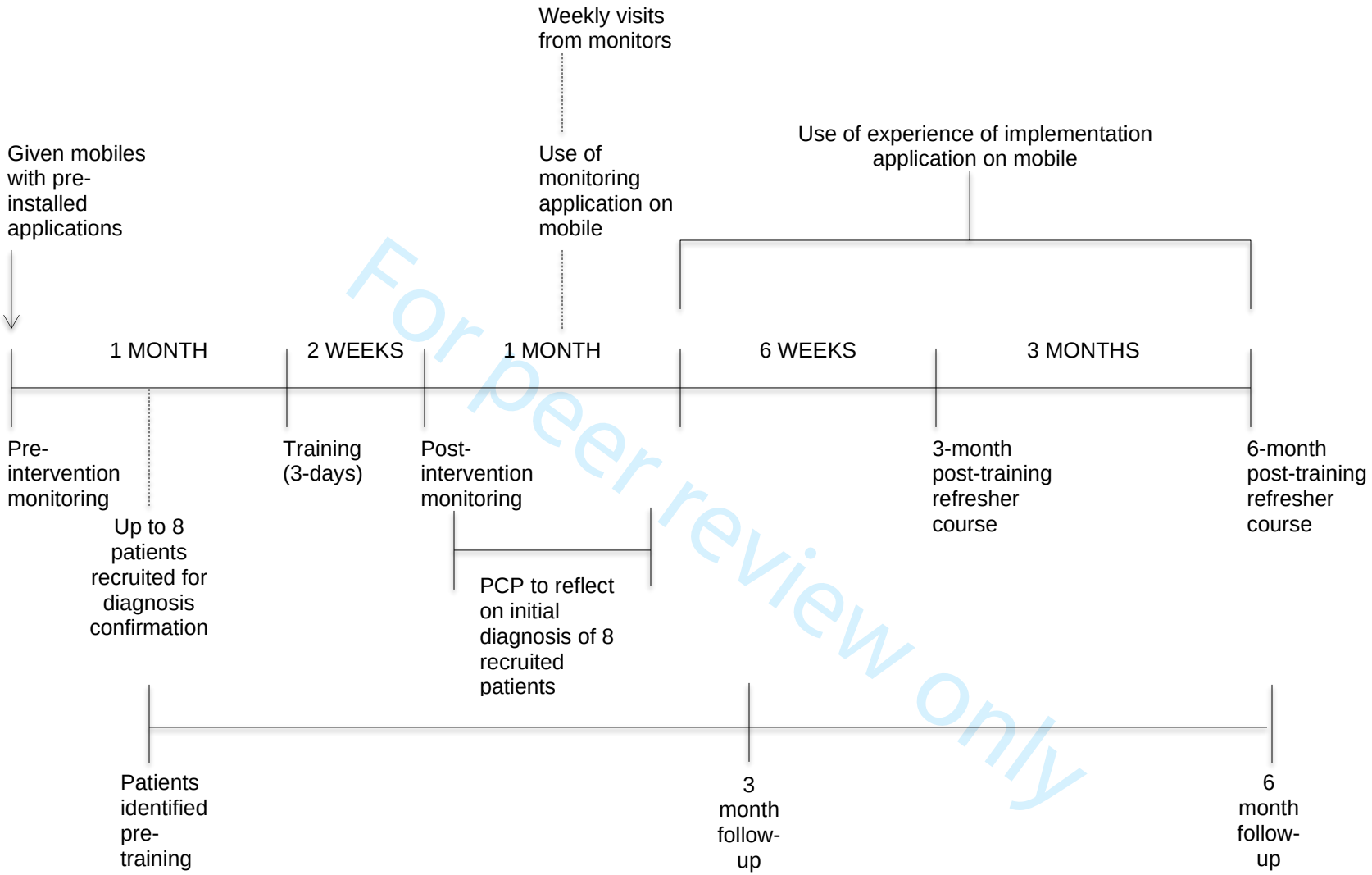

Figure 1. Primary Care Practitioner study timeline

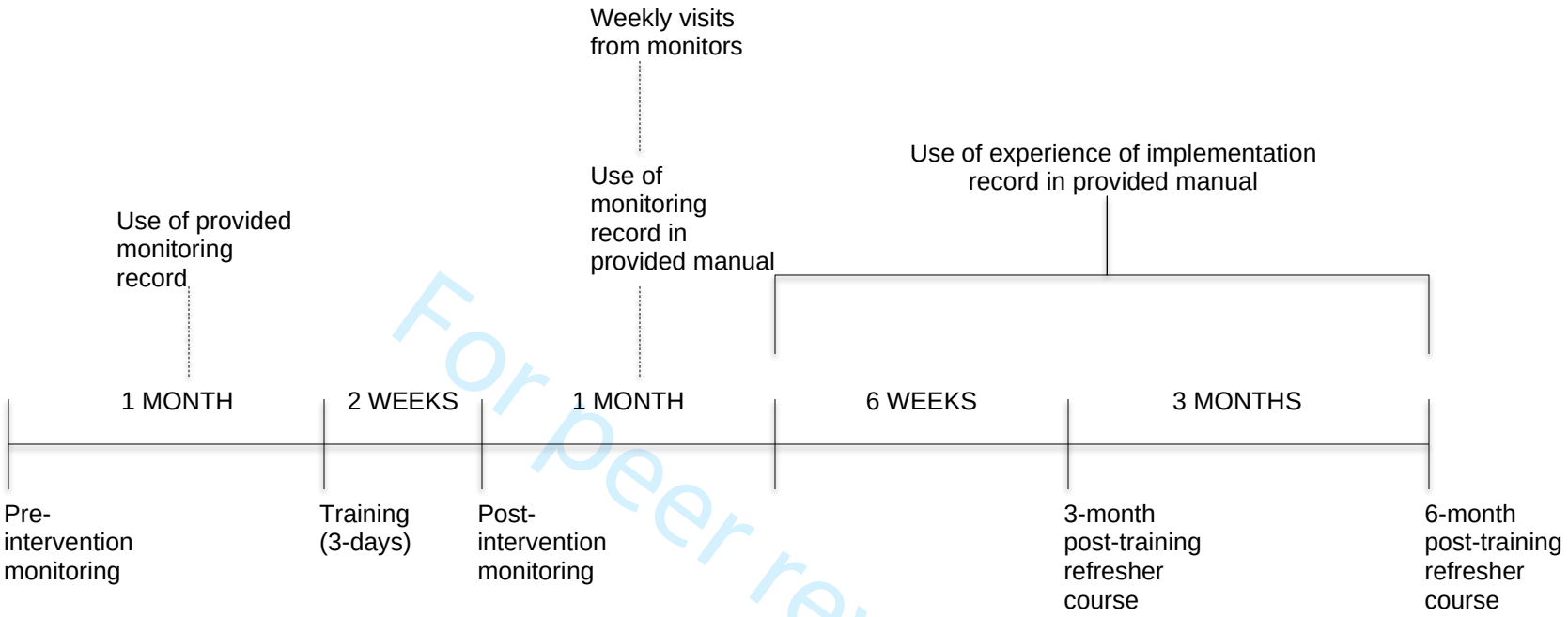

Figure 2. Public Health Professional study timeline

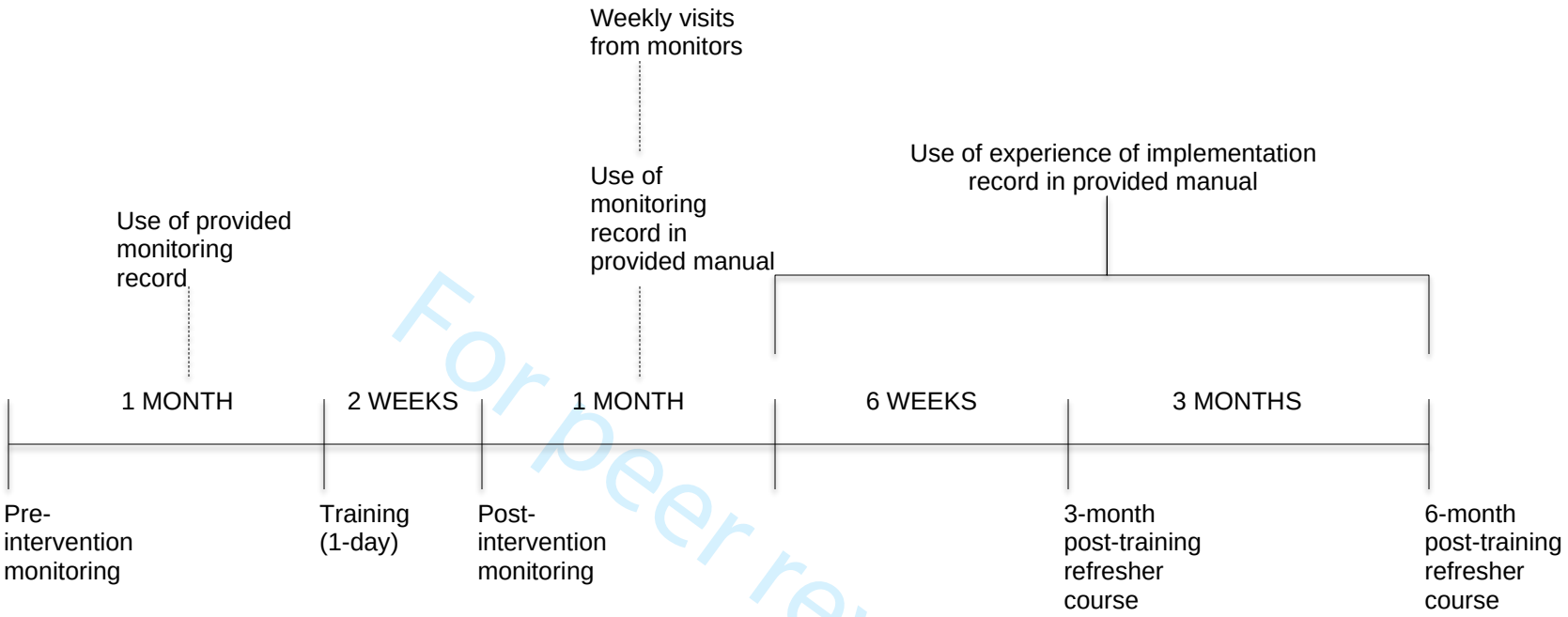

Figure 3. Community representative study timeline