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

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3 During 26 years of protracted internal conflict in Sri Lanka, more than 100,000 people of all
4 ethnicities are estimated to have died, and hundreds of thousands injured [4, 5]. The substantial
5 internal displacement from conflict was compounded by the 2004 tsunami [6].
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11 Although Sri Lanka has a very effective primary care system, the treatment gap for mental
12 health is extensive, especially for post-conflict populations [1, 7]. While provision of health
13 services has improved, resources are insufficient to meet population needs, especially those
14 related to severity of trauma, or to difficulties experienced in displacement or return migration
15 [8]. Primary care practitioners in the Northern Province region regularly spearhead mental
16 health care efforts, however, they do so without adequate training. Training primary care
17 practitioners to deliver mental health care at primary care level is in line with the task-shifting
18 approach in the global mental health field [2, 9-11]. A pilot feasibility study (COMGAP) to
19 explore this possibility was conducted in 2013-2014 based on a peer-reviewed protocol and is
20 reported elsewhere [8].
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35 In this context, the aim of COMGAP-S is to use a scaled-up training intervention based on the
36 World Health Organization Mental Health Gap Action Programme (WHO mhGAP 2.0) to
37 integrate mental health services into primary care by providing training to primary care
38 practitioners and public health professionals serving conflict-affected populations in primary care
39 settings in the Northern Province [12].
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46 The first phase of the study was completed in 2015-2016 and facilitated understanding of the
47 mental disorder burden and treatment gap at primary care level. Results from the cross-
48 sectional study indicate the most prevalent mental health disorders in primary care settings
49 were depression (41.1%, 95% CI: 38.7-44.5%), anxiety (46.7%, 95% CI: 41.9-51.5%), post-
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3 traumatic stress disorder (13.7%, 95% CI: 10.6-16.8%), and psychosis with hypomania (17.6%,
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5 95 CI: 13.3-21.9) [13].
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8 COMGAP-S is the first large-scale trial in the region to use mhGAP to integrate mental health
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10 services into primary care for conflict-affected populations, and is the only trial to include wider
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12 health care staff and community members as part of a long-term strategy to improve mental
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14 health awareness and stigma reduction.
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23 **METHODS AND ANALYSIS**

24 **Aims and objectives**

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26
27 The aim of COMGAP-S is to investigate if implementation of WHO mhGAP training within
28
29 primary care settings increases identification and treatment of mental disorders for post-conflict
30
31 populations in Northern Province, Sri Lanka.
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33 Primary outcomes

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36 1. 30% increase in patients identified, treated and referred to specialist care for mental disorders
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38 of interest by primary care practitioners. Measured at baseline using the pre/post-monitoring
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40 questionnaires on current practice with mental health patients and compared to post-training
41
42 practice.
43
44 2. 40% minimum concurrence between diagnoses of patients identified with mental disorders of
45
46 interest by trained primary care practitioners and psychiatrists as compared to diagnosis of
47
48 patients pre-training (baseline) measured using qualitative interviews.
49
50 3. 20% reduction in positive screening for depression and anxiety in patients pre-training and at
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52 3 and 6 months follow-up time points, measured using the Hopkins Symptom-Checklist 25.
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54 Secondary outcomes

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3 1. 20% increase between mean pre- and post-training test scores for primary care practitioners
4 using the WHO mhGAP 2.0 pre/post training test.
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- 7 2. At least 50% reduction of mental health stigma measured using AMIQ in primary care
8 practitioner, public health professional, and community representative participant groups at
9 training, and 3- and 6-month follow-up.
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- 12 3. At least 40% of primary care practitioners and public health professionals in the region will be
13 delivered training on mhGAP, and at least 2 community representatives from each facility
14 catchment areas will receive tailored training on mental health awareness and stigma reduction.
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24 **Study design**

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26 This is a randomized clinical trial using a stepped wedge cluster design [14]. This design was
27 chosen because: 1) in an intervention trying to integrate mental health services into primary
28 care for post-conflict populations it is unethical to use a parallel design which prevents equal
29 distribution of knowledge and skills; 2) the stepped wedge cluster design is more logistically
30 feasible in the post-conflict setting of Northern Sri Lanka [15].
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39 Facilities are randomized using standardized randomization techniques to allocate facilities to
40 the training sequence within the stepped wedge design. Patients and community
41 representatives were not randomized.
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47 **Setting**

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

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

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

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

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47 Primary care practitioners in each selected facility undergo one month of monitoring prior to
48 training to establish a baseline. They receive a paper booklet to record information on patients
49 identified, treated, managed, and/or referred for mental health disorders. Further, before
50 training, primary care practitioners recruit up to eight patients using provided inclusion and
51 exclusion criteria to have their diagnosis verified by a psychiatrist. Members of the research
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3 team provide patients with information sheets and obtain informed consent. Patients complete a
4 brief socio-demographic questionnaire at point of recruitment and the Hopkins Symptom
5 Checklist-25 screening questionnaire for depression and anxiety at point of recruitment, and at 3
6 and 6 months follow-up to establish a baseline, and determine if patient outcomes change after
7 training of primary care practitioners. Primary care practitioners are asked detailed questions
8 about their management and treatment of recruited patients, and patients are asked about any
9 treatments undertaken or medications prescribed to understand any intervening factors between
10 baseline, and 3 and 6 months follow-up.
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22 After the one-month monitoring period, primary care practitioners undergo a 3-day training
23 intervention delivered in their primary care facility. Trained members of the research team
24 deliver training at each selected facility to minimize disruption of work at facilities.
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30 After completion of training, monitoring of primary care practitioners continues for one month,
31 where they continue to use the paper booklet to record information on patients they identify,
32 treat, manage, and/or refer for common mental health disorders. Research team members visit
33 or telephone the primary care practitioners once a week at their facility to monitor
34 implementation of the training intervention.
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43 After the one-month monitoring period primary care practitioners continue to use paper booklets
44 to record their experience of the training implementation for six weeks. At this point (three
45 months post-training) primary care practitioners participate in a 1-day refresher course and
46 continue to use the experience of training implementation application for a further three months.
47 At six months post-training, primary care practitioners take a second 1-day refresher course
48 (Figure 1).
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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

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3 one month of monitoring and record the same information as in the pre-monitoring period to see
4 how/if practice has changed. Research team members visit or telephone once a week to
5 monitor implementation of the training intervention.
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11 After the one-month, monitoring period community representatives' record information on their
12 experience of the training intervention in paper booklets for six weeks. At this point (three
13 months post-training), community representatives participate in a half-day refresher course and
14 continue to use provided booklets to record their experience of training implementation for a
15 further three months. At six months post-training, community representatives participate in a
16 second half-day refresher course (Figure 3).
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26 **Timing of intervention delivery and follow-up**

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28 COMGAP-S runs for 7 months in each facility and catchment area. Every 2 weeks a facility is
29 enrolled in the study until all 23 have completed the study timeline. Participants discontinuing
30 engagement are not subject to follow-up. Measures are collected at six time points:
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- 34 1. Pre-training monitoring period: questionnaire to establish a baseline on current practice.
35 Primary care practitioners only: recruitment of patients for diagnosis verification.
36 Patients administered Hopkins Symptom Checklist 25 for anxiety and/or depression (baseline),
37 and at 3 and 6 months follow-up to assess change in clinical symptoms.
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- 39 2. Pre-training intervention: WHO mhGAP knowledge pre-test and AMIQ stigma questionnaire.
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- 41 3. Post-training intervention: second administration of WHO mhGAP knowledge test.
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- 43 4. Post-training monitoring period: questionnaire to establish if/how practice has changed, and
44 qualitative interviews to reflect on initial diagnosis practice.
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- 46 5. 3 months follow-up training: WHO mhGAP pre- and post- knowledge test and AMIQ stigma
47 questionnaire.
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3 6. 6 months follow-up training: WHO mhGAP pre- and post- knowledge test and AMIQ stigma
4 questionnaire.
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8 9 **Patient and Public Involvement**

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

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

42 An intention-to-treat analysis will be used. Analysis will include generalized linear regression
43 modules to adjust for repeated measures and descriptive analytics.
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49 **Sample size calculation**

50 A total of 23 primary care practitioners, 75 public health professionals, 50 community
51 representatives, and 200 patients will be recruited. Target sample sizes were calculated
52 separately for each participant group and for each outcome. Sample sizes for the first and
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3 second outcomes were calculated following methods described by Hemming and Taljaard,
4 where each outcome is considered an individually randomized trial and then multiplied by a
5 design effect to account for the stepped wedge design [17]. Sample sizes for the third and fourth
6 outcomes were calculated using formulae from the 1994 textbook “Analysis of Longitudinal
7 Data” by Diggle, Liang and Zeger [18].
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13 14 15 **Dissemination and access**

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18 Trial results and analyses will be purposefully communicated to the Provincial Department of
19 Health Service, Regional Divisional Health Secretariats in the five districts, participating
20 healthcare professionals and community representatives. Dissemination events will be held with
21 the University of Jaffna. Activities will include publications and presentations to general and
22 specialized audience by team members. The research dataset and statistical analyses will be
23 available by request from the primary investigator.
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32 33 **Trial Status**

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35 A planned pilot was completed between 24th January and 11th February 2018 in the Mullaitivu
36 district in Northern Sri Lanka. Recruitment and enrolment for the full clinical trial period
37 commenced in March 2018. Due to the COVID-19 pandemic the project has been granted a no-
38 cost extension and data collection will be completed under local health regulations. At present,
39 21 of 23 facilities have been successfully recruited.
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48 49 **Data Monitoring**

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51 The funder Centers for Disease Control and Prevention acted as a *de facto* data monitoring
52 committee as they reviewed clinical trial progress quarterly and audited progress yearly. Only
53 the Principal Investigator and select research team members will have access to interim data for
54 quality checks and data cleaning. In the unlikely event that a participant reported an adverse
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3 event, standard operating procedures as per the COMGAP-S training manual would be
4 followed.
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8 9 **Evaluation**

10 **Cost Ratio Economic Evaluation**

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

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

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

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3 region, but also improve mental health service delivery addressing the unmet needs of a
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5 vulnerable population.
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41 **Authors' contributions:** CS and SD developed the concept and design of this study with
42 contributions from GD, AE, BR, RS and MA. CS and SD wrote the manuscript with contributions
43 from GD, AE, BR, RS and MA. All authors commented on and approved the final version of this
44 manuscript.
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48

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3 of the data, preparation and review of the manuscript for publication. The Northern Ministry of
4 Health, Sri Lanka was involved in management of the data collection. The University of Jaffna,
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17 **Competing interests statement:** RS declares research support received in the last 5 years
18 from Roche, Janssen, GSK and Takeda.
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24 **Ethics approvals:** This trial has received ethical approval from the Faculty of Medical Science,
25 Anglia Ruskin University, UK (SC/jc/FMFREP/16/17 076), from the Faculty of Medicine,
26 University of Jaffna, Sri Lanka (J/ERC/17/81/NDR/0170) and non-engagement approval from
27 the funding body, the Centers for Disease Control and Prevention (2018-015). All participants
28 gave written consent.
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33
34 **Availability of data and materials:** Data presented in this paper are available from the
35 corresponding author on request.
36
37

38
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46 Health, Sri Lanka, and the University of Jaffna, Sri Lanka.
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52 **Protocol version:** 11 November 2017, version 2
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3 **Name and contact of trial sponsor:** Anglia Ruskin University, Faculty of Health, Education,
4 Medicine, and Social Care, 4th Floor William Harvey Building, Bishop Hall Lane, Chelmsford,
5 UK, CM11SQ
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9 **Dissemination policy:** Publications, updates on social media, stakeholder meetings
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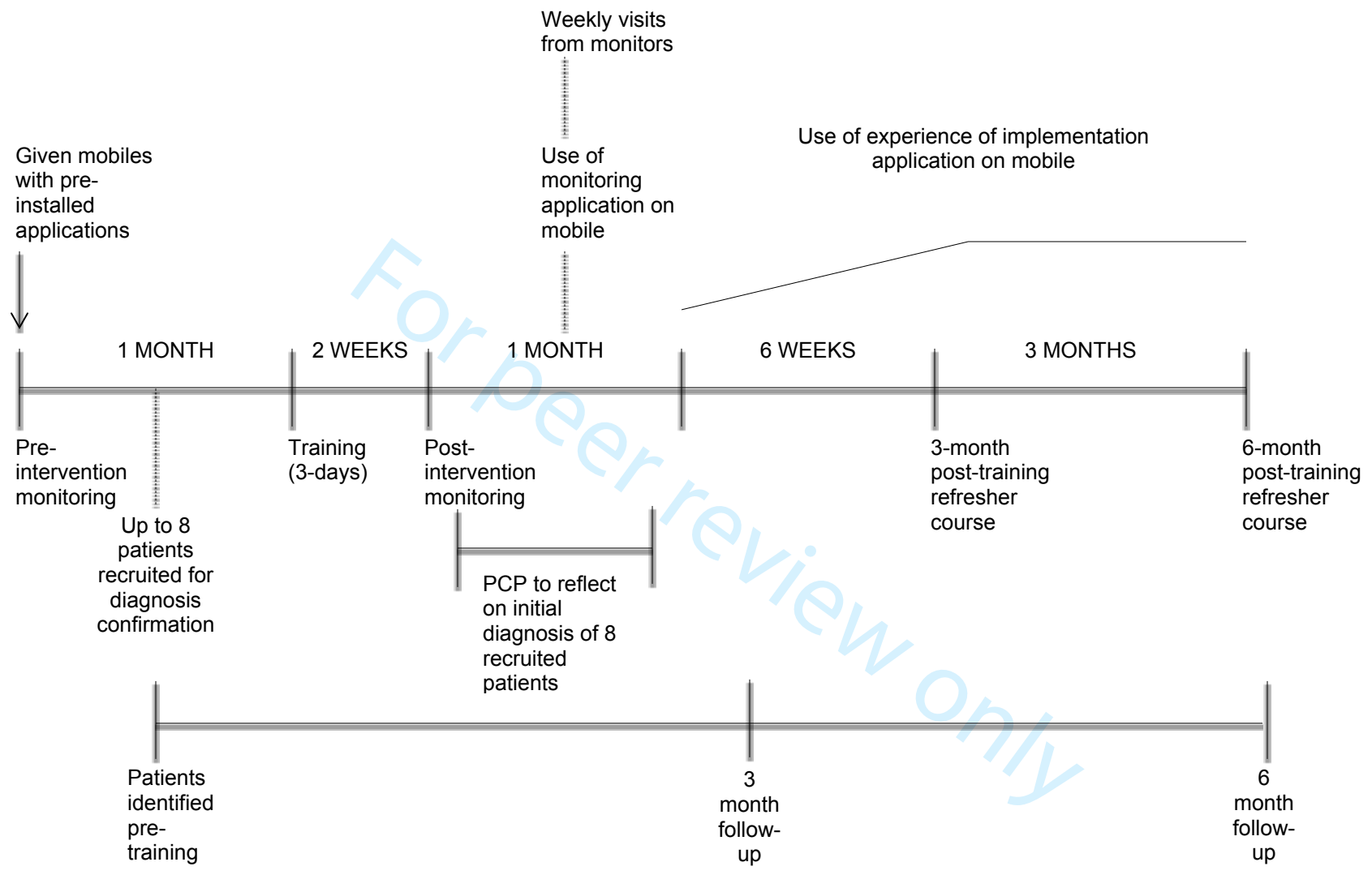


Figure 1. Primary Care Practitioner study timeline

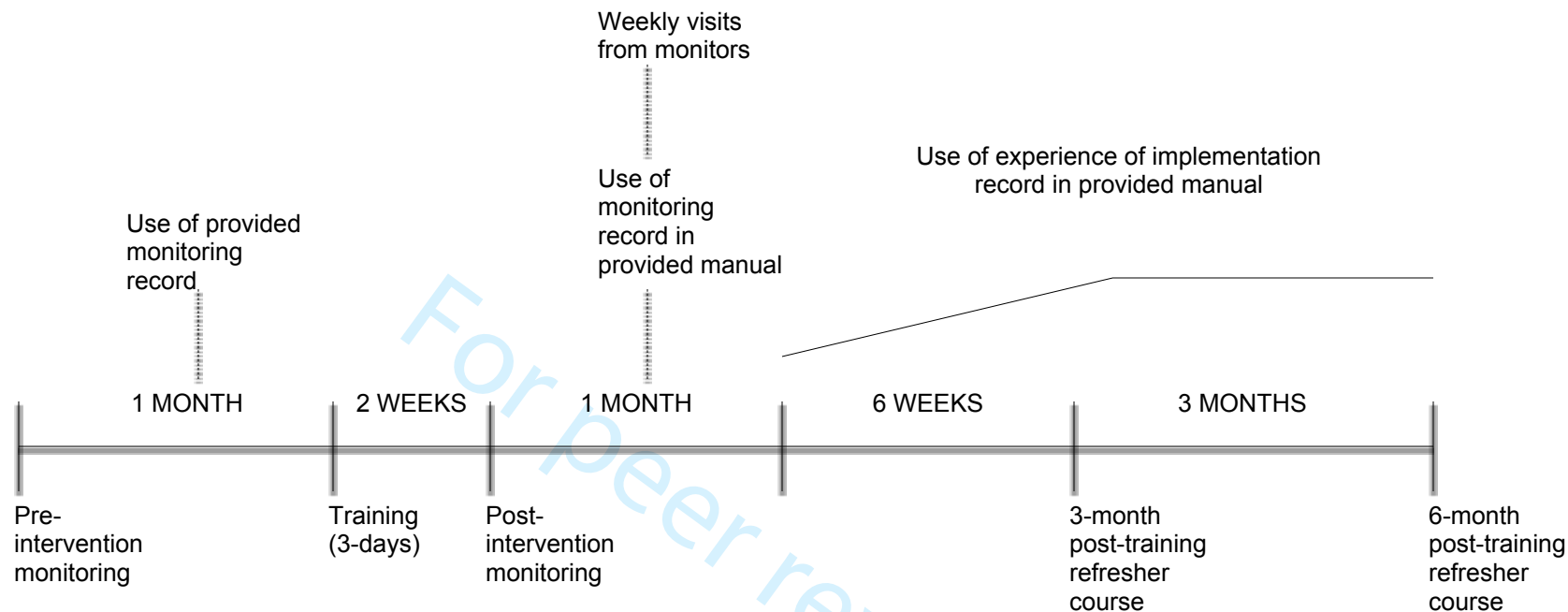


Figure 2. Public Health Professional study timeline

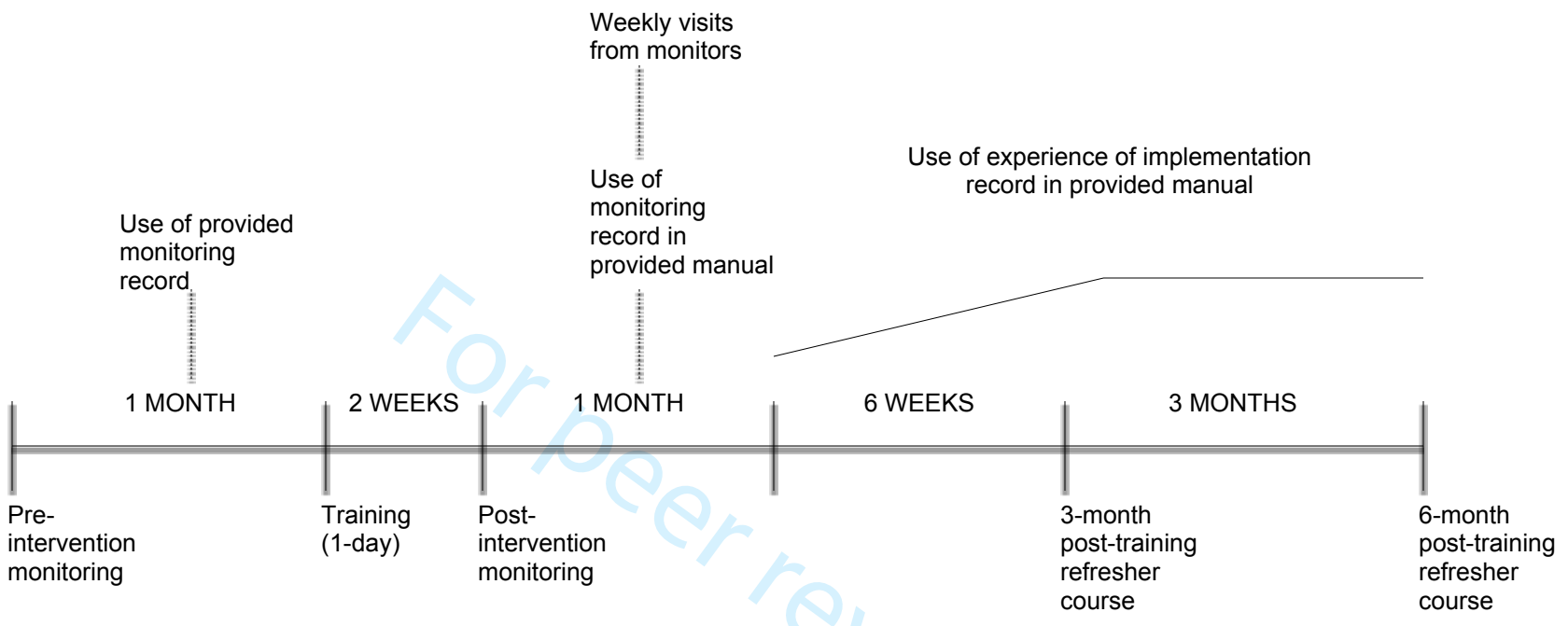


Figure 3. Community representative study timeline

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.

HSC L 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 _s	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 detectable 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

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

where z_{α} = Z score for alpha, set at 0.05

z_{β} = 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 $q_B = 1 - p_B$)

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

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

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

where z_{α} = Z score for alpha, set at 0.05

z_{β} = 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

For peer review only



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, 4 th Floor William Harvey Building, Bishop Hall Lane, Chelmsford, UK, CM11SQ

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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.

view only

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

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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.

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2	Participant	13	Figures 1, 2, 3 of the manuscript
3	timeline		
4			
5	Sample size	14	23 primary care practitioners, 75 public health professionals, 50
6			community representatives, and 200 patients. Target sample sizes
7			were calculated separately for each participant group and for each
8			outcome. Sample sizes for the first and second outcomes were
9			calculated following methods described by Hemming and Taljaard,
10			where each outcome is considered an individually randomized trial
11			and then multiplied by a design effect to account for the stepped
12			wedge design. Sample sizes for the third and fourth outcomes were
13			calculated using formulae from the 1994 textbook "Analysis of
14			Longitudinal Data" by Diggle, Liang and Zeger. (For full citations see
15			manuscript references.)
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19	Recruitment	15	Support letters from Provincial Department of Health Service, and
20			Regional Divisional Health Secretariats in each district of Northern
21			Province are used to approach primary care practitioners and public
22			health professionals. Community representatives are recruited
23			through local registration organizations. Patients are recruited by
24			primary care practitioners.
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Methods: Assignment of interventions (for controlled trials)

Allocation:

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32	Sequence	16a	Facilities are randomized using standardized randomization
33	generation		techniques to allocate facilities to the training sequence within the
34			stepped wedge design. Patients and community representatives were
35			not randomized.
36			
37	Allocation	16b	N/A - crossover design
38	concealment		
39	mechanism		
40			
41			
42	Implementation	16c	Team members from the THEME Institute generate allocation using a
43			random numbers generator, approach and enrol participants
44			
45	Blinding	17a	N/A - crossover design
46	(masking)		
47			
48		17b	N/A - crossover design
49			

Methods: Data collection, management, and analysis

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2	Data collection	18a	Measures are collected at six time points:
3	methods		1. Pre-training monitoring period: questionnaire to establish a baseline
4			on current practice. Primary care practitioners only: recruitment of
5			patients for diagnosis verification.
6			Patients administered Hopkins Symptom Checklist 25 for anxiety
7			and/or depression (baseline), and at 3 and 6 months follow-up to
8			assess change in clinical symptoms.
9			2. Pre-training intervention: WHO mhGAP knowledge pre-test and
10			AMIQ stigma questionnaire.
11			3. Post-training intervention: second administration of WHO mhGAP
12			knowledge test.
13			4. Post-training monitoring period: questionnaire to establish if/how
14			practice has changed, and qualitative interviews to reflect on initial
15			diagnosis practice.
16			5. 3 months follow-up training: WHO mhGAP pre- and post-
17			knowledge test and AMIQ stigma questionnaire.
18			6. 6 months follow-up training: WHO mhGAP pre- and post-
19			knowledge test and AMIQ stigma questionnaire.
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24		18b	N/A - discontinued participants not subject to follow-up
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26	Data	19	Data is collected on tablets and uploaded to a secure server. Data is
27	management		cleaned and checked throughout the trial. Paper records are scanned
28			in by local research team members and held on secure desktop
29			computers and a password-protected hard drive.
30			
31			
32	Statistical	20a	An intention-to-treat analysis will be used. Analysis will include
33	methods		generalized linear regression modules to adjust for repeated
34			measures and descriptive analytics.
35			
36		20b	N/A
37			
38		20c	N/A
39			
40	Methods: Monitoring		
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42	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role
43			and reporting structure; statement of whether it is independent from
44			the sponsor and competing interests; and reference to where further
45			details about its charter can be found, if not in the protocol.
46			Alternatively, an explanation of why a DMC is not needed
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49		21b	N/A
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52	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and
53			spontaneously reported adverse events and other unintended effects
54			of trial interventions or trial conduct
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56	Auditing	23	N/A
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58	Ethics and dissemination		
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2	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).
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10	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.
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14	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.
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19		26b	N/A
20	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.
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24			
25	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.
26			
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28			
29	Access to data	29	Team members and selected staff from the funding body will have access to the full dataset.
30			
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33	Ancillary and post-trial care	30	N/A
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35			
36	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.
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45		31b	N/A
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47		31c	The research dataset and statistical analyses will be available by request from the primary investigator.
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Appendices

52	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
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56	Biological specimens	33	N/A
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*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

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For peer review only

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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3 **Title:** Protocol of a randomized clinical trial to integrate mental health services into primary care
4
5 for post-conflict populations in Northern Sri Lanka (COMGAP-S)
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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.

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

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3 Mental health disorders often present in primary care settings, especially in low- and middle-
4 income countries (LMIC), where specialized psychiatric services may be lacking. Low- or non-
5 detection, low referral rates for specialist care, and increased costs are all features of mental
6 health disorders in primary care settings in LMIC. Furthermore, lack of adequate training for
7 primary care physicians and lack of involvement of public health personnel can act as barriers to
8 effective treatment and management of common mental health disorders in primary care [1, 2].
9
10 Barriers can be compounded in post-conflict situations, as existing limited health systems may be
11 severely affected, especially for those internally displaced. There is strong evidence that conflict-
12 driven, internally displaced migrants have increased rates of mental health disorders [1, 3].
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24 During 26 years of protracted internal conflict in Sri Lanka, more than 100,000 people of all
25 ethnicities are estimated to have died, and hundreds of thousands injured [4, 5]. The substantial
26 internal displacement from conflict was compounded by the 2004 tsunami [6].
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32 Although Sri Lanka has a very effective primary care system, the treatment gap for mental health
33 is extensive, especially for post-conflict populations [1, 7]. While provision of health services has
34 improved, resources are insufficient to meet population needs, especially those related to severity
35 of trauma, or to difficulties experienced in displacement or return migration [8]. Primary care
36 practitioners in the Northern Province region regularly spearhead mental health care efforts,
37 however, they do so without adequate training. Training primary care practitioners to deliver
38 mental health care at primary care level is in line with the task-shifting approach in the global
39 mental health field [2, 9-11]. A pilot feasibility study (COMGAP) to explore this possibility was
40 conducted in 2013-2014 based on a peer-reviewed protocol and is reported elsewhere [8].
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54 The first phase of the study was completed in 2015-2016 and facilitated understanding of the
55 mental disorder burden and treatment gap at primary care level. Results from the cross-sectional
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3 study indicated the most prevalent mental health disorders in primary care settings were
4 depression (41.1%, 95% CI: 38.7-44.5%), anxiety (46.7%, 95% CI: 41.9-51.5%), post-traumatic
5 stress disorder (13.7%, 95% CI: 10.6-16.8%), and psychosis with hypomania (17.6%, 95 CI: 13.3-
6 21.9) [12]. While this facilitated understanding of the underlying mental health issues within the
7 region, the issue of unmet need was still present. In this context, the aim of Phase 2 of COMGAP-
8 S is to use a scaled-up training intervention based on the World Health Organization Mental
9 Health Gap Action Programme (WHO mhGAP 2.0) to integrate mental health services into
10 primary care by providing training to primary care practitioners and public health professionals
11 serving conflict-affected populations in primary care settings in the Northern Province [12, 13].
12 The second phase of the project was conducted between 2016-2021. COMGAP-S is the first
13 large-scale trial in the region to use mhGAP to integrate mental health services into primary care
14 for conflict-affected populations. Further, it is the only trial to include wider health care staff and
15 community members as part of a long-term strategy to improve mental health awareness and
16 stigma reduction.
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35 **Aims and objectives**

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

- 44
45 1. 30% increase in patients identified and treated for common mental health disorders, and
46 referrals to specialist care for complex mental disorders by primary care practitioners. Measured
47 at baseline using the pre/post-monitoring questionnaires on current practice with mental health
48 patients and compared to post-training practice.
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- 50
51 2. 40% minimum concurrence between diagnoses of patients identified with mental disorders of
52 interest by trained primary care practitioners and psychiatrists as compared to diagnosis of
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3 patients pre-training (baseline) measured using quantitative reporting forms from the consultant
4 psychiatrist and in-depth, individual interviews with trained primary care practitioners to
5 understand any changes in practice.
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9 3. 20% reduction in positive screening for depression and anxiety in patients pre-training and at
10 3- and 6-months follow-up time points, measured using the Hopkins Symptom-Checklist 25.
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13 Secondary outcomes

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15 1. 20% increase between mean pre- and post-training test scores for primary care practitioners
16 using the WHO mhGAP 2.0 pre/post training test.
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19 2. At least 50% reduction of mental health stigma measured using Attitudes to Mental Illness
20 Questionnaire (AMIQ) in primary care practitioner, public health professional, and community
21 representative participant groups at training, and 3- and 6-month follow-up. Prevalence rates were
22 based on previous mental health studies conducted within the country [1,5].
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27 3. At least 40% of primary care practitioners and public health professionals in the region will be
28 delivered training on mhGAP, and at least 2 community representatives from each facility
29 catchment areas will receive tailored training on mental health awareness and stigma reduction.
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41 METHODS AND ANALYSIS

42 Study design

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44 This is a randomized clinical trial using a stepped wedge cluster design [14]. This design
45 comprises a preliminary period where no clusters (healthcare facilities) are exposed to the
46 intervention, then at regular intervals, one cluster is randomized to cross from control to
47 intervention. This continues until all clusters have been exposed [14]. The stepped wedge design
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3 is increasingly utilized as a way to evaluate interventions that involve service delivery and involves
4 sequential and random crossover of clusters (facilities) from control (delivery of standard care) to
5 intervention (mhGAP training) until all clusters are exposed [14]. The stepped wedge design takes
6 into account the logistical constraints of needing to sequentially roll out the intervention by training
7 one facility at a time enabling us to understand how this intervention can be implemented in the
8 future on a larger scale. This design was chosen because: 1) in an intervention trying to integrate
9 mental health services into primary care for post-conflict populations it is unethical to use a parallel
10 design which prevents equal distribution of knowledge and skills; 2) the stepped wedge cluster
11 design is more logistically feasible in the post-conflict setting of Northern Sri Lanka [15].
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24 Facilities will be randomized using standardized randomization techniques to allocate facilities to
25 the training sequence within the stepped wedge design. Patients and community representatives
26 will not be randomized. The study team cannot be blinded to the allocation of facilities. However,
27 the study psychiatrist will be masked to the randomization status of facilities from which patients
28 originate. Patients will also be blinded to facility randomization status. [1]
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37 There is a theoretical possibility of contamination due to close professional or personal networks
38 between participant groups and geographical location of facilities. However, this is not envisaged
39 to exert significant influence on expected outcomes due to specifics of the extensive training,
40 requirement to carry out intensive tasks, and low risk of contamination through informal
41 discussions [1]. Potential contamination will be observed at all stages and taken into account at
42 the end of the study. Further, an important strength of cluster sampling is that it helps mitigate the
43 risk of treatment contamination between intervention and control groups.
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54 **Setting**

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3 The study setting will be 23 government primary care health facilities within the five districts of the
4 Northern Province: Jaffna, Mannar, Kilinochchi, Vavuniya, and Mullaitivu. A full list of participating
5 sites can be obtained from the Primary Investigator or from the offices of THEME Institute,
6 Colombo, Sri Lanka.
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11 A list of public primary care facilities has been provided to the study team by the Northern Ministry
12 of Health. A random number generator will be used to select 23 facilities across the 5 districts.
13 Distribution of clusters will be allocated proportionally to the total numbers of internally displaced
14 people in each district (districts with larger numbers were assigned more clusters). This will ensure
15 adequate representation of conflict displacement and severity.
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24 **Inclusion criteria**

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

54 **Exclusion criteria**

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3 Larger facilities such as district hospitals and teaching hospitals will be excluded as they are not
4 part of the primary care system. Private facilities will be excluded due to the lack of an official
5 registry.
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11 Primary care practitioners, public health professionals, and community representatives will be
12 excluded if they have secondary mental health training. Patients under 18 years and those
13 diagnosed with mental disorders outside of depression and/or anxiety will be excluded.
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18 19 20 **Recruitment and enrolment**

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

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41 Training material was adapted for local use and included translation and cultural adaption of
42 relevant modules of the WHO mhGAP 2.0 IG, and production of locally adapted and developed
43 mhGAP video material for the Tamil context [16]. This was completed in collaboration with local
44 academics, psychiatrists, primary care practitioners, Northern Province Ministry of Health, and
45 the University of Jaffna.
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51 Training will consist of delivery of written materials, role plays, and training videos. All training
52 material was developed in collaboration with Sri Lankan researchers, local psychiatrists and
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3 community physicians. All material was translated, back translated, and piloted for cultural
4 appropriateness prior to administration in the full project.
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7 Almost all the instruments used in the study had been previously applied in epidemiological
8 studies within Sri Lanka and are available in Tamil, Sinhala, and English languages. New
9 instruments were translated, back translated and adapted for cultural appropriateness in
10 collaboration with the Sri Lankan research team. Further, the entire set of measures was field
11 tested in a pilot study prior to the full study commencing. This pilot study examined if measures
12 were understood by participants, culturally acceptable, and to ensure translations were correct.
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14 To ensure safety of all participants, a local psychiatrist will be involved throughout the study to
15 provide free mental health care if required.
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26 Primary care practitioners and patients

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28 Primary care practitioners (general physicians practicing in selected facilities) will undergo one
29 month of monitoring prior to training to establish a baseline. Primary care practitioners will be
30 trained using the mhGAP manual to recognize common mental health disorders using screening
31 procedures, delivery brief psychosocial interventions (psychoeducation, Motivational
32 Interviewing), and referral procedures for complex cases. They will receive a paper booklet to
33 record information on patients identified, treated, managed, and/or referred for mental health
34 disorders. Further, before training, primary care practitioners will be asked to recruit up to eight
35 patients using provided inclusion and exclusion criteria to have anxiety and/or depression
36 diagnoses verified by a psychiatrist. Members of the research team will provide patients with
37 information sheets and consent forms available in all 3 official languages (English, Tamil, Sinhala)
38 and obtain informed consent. Patients will complete a brief socio-demographic questionnaire at
39 point of recruitment and the Hopkins Symptom Checklist-25 screening questionnaire for
40 depression and anxiety at point of recruitment, and at 3- and 6-months follow-up to establish a
41 baseline, and determine if patient outcomes change after training of primary care practitioners.
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3 Primary care practitioners will be asked detailed questions about their management and treatment
4 of recruited patients, and patients will be asked about any treatments undertaken or medications
5 prescribed to understand any intervening factors between baseline, and 3- and 6-months follow-
6 up.
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13 After the one-month monitoring period, primary care practitioners will undergo a 3-day training
14 intervention delivered in their primary care facility. Trained members of the research team will
15 deliver training at each selected facility to minimize disruption of work at facilities.
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22 After completion of training, monitoring of primary care practitioners will continue for one month,
23 where they will continue to use the paper booklet to record information on patients they identify,
24 treat, manage, for common mental health disorders and any cases they refer to specialized care
25 Research team members will visit or telephone the primary care practitioners once a week at their
26 facility to monitor implementation of the training intervention.
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34 After the one-month monitoring period primary care practitioners will continue to use paper
35 booklets to record their experience of the training implementation for six weeks. At this point (three
36 months post-training) primary care practitioners will participate in a 1-day refresher course and
37 continue to use the experience of training implementation application for a further three months.
38 At six months post-training, primary care practitioners will take a second 1-day refresher course
39 (Figure 1).
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47 Supervision at all time points will be provided by research assistants who previously delivered
48 training sessions. Supervision will consist of phone calls or visits to the clinics to understand if
49 and how training is being utilised by participants.
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56 Public health professionals
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3 Public health professionals (nurse attendants, midwives) in each selected facility will undergo one
4 month of monitoring prior to training to establish a baseline. Public health professionals will be
5 trained using adapted written materials from the mhGAP training to recognize signs of common
6 mental health issues, provide basic psychosocial care (education) and refer onwards if needed.
7 Each enrolled public health professional will record information in a paper booklet on facilitation
8 of referral and follow-up practices for mental health patients, and support primary care
9 practitioners with patient management activities. After the one-month monitoring period, public
10 health professionals will be provided with a tailored 3-day training programme on mental health
11 awareness, management, referral, and stigma reduction. After training, public health
12 professionals will undergo one month of monitoring and record the same information as in the
13 pre-monitoring period to see how/if practice has changed. Research team members will visit or
14 telephone their facility once a week to monitor implementation of the training intervention.

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

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

51 Community representatives

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

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3 materials from the mhGAP training material to recognize signs of common mental illness, delivery
4 basic psychosocial education and learn referral pathways and where to seek providers. Each
5 enrolled community representative will record information in a paper booklet on mental health
6 awareness raising activities undertaken, and any referrals of people they encounter with mental
7 health issues. After the one-month monitoring period, community representatives will participate
8 in a tailored 1-day training programme on mental health awareness, stigma reduction, and finding
9 local resources. After training, community representatives will undergo one month of monitoring
10 and record the same information as in the pre-monitoring period to see how/if practice has
11 changed. Research team members will visit or telephone once a week to monitor implementation
12 of the training intervention.
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26 After the one-month, monitoring period community representatives' will record information on their
27 experience of the training intervention in paper booklets for six weeks. At this point (three months
28 post-training), community representatives will participate in a half-day refresher course and
29 continue to use provided booklets to record their experience of training implementation for a
30 further three months. At six months post-training, community representatives will participate in a
31 second half-day refresher course (Figure 3).
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39 Supervision at all time points will be provided by research assistants who delivered previous
40 training sessions. Supervision will consist of phone calls or visits to the clinics to understand if
41 and how training was being utilised by participants.
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47 **Timing of intervention delivery and follow-up**

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49 COMGAP-S will run for 7 months in each facility and catchment area. Every 2 weeks a facility will
50 be enrolled in the study until all 23 have completed the study timeline. Participants discontinuing
51 engagement will not be subject to follow-up. Measures will be collected at six time points:
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3 1. Pre-training monitoring period: questionnaire to establish a baseline on current practice.
4
5 Primary care practitioners only: recruitment of patients for diagnosis verification.
6
7 Patients administered Hopkins Symptom Checklist 25 for anxiety and/or depression (baseline),
8
9 and at 3- and 6-months follow-up to assess change in clinical symptoms.
10
11 2. Pre-training intervention: WHO mhGAP knowledge pre-test and AMIQ stigma questionnaire.
12
13 3. Post-training intervention: second administration of WHO mhGAP knowledge test.
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15 4. Post-training monitoring period: questionnaire to establish if/how practice has changed, and
16
17 qualitative interviews to reflect on initial diagnosis practice.
18
19 5. 3 months follow-up training: WHO mhGAP pre- and post- knowledge test and AMIQ stigma
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21 questionnaire.
22
23 6. 6 months follow-up training: WHO mhGAP pre- and post- knowledge test and AMIQ stigma
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25 questionnaire.
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37 **Statistical methods**

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41 The primary unit of analysis (i.e., where the intervention is carried out) is the healthcare facility,
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43 and data collected from the individual participants will include: sociodemographic information,
44
45 conflict and displacement experience, mhGAP knowledge test scores, AMIQ stigma scores, and
46
47 pre- and post- monitoring questionnaires. Descriptive statistics will be used to summarize
48
49 observations using means, standard deviations, and proportions where appropriate.
50

51 An intention-to-treat analysis will be used to analyze the effect of the intervention. In the stepped
52
53 wedge design, similar information will be collected repeatedly on individuals within facilities; we
54
55 will therefore utilize statistical models that can adjust for repeat measures and clustering of
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3 participants within facilities (in the case of PHPs and CRs). In particular, for the analysis of mhGAP
4 knowledge test scores and AMIQ stigma scores as outcomes of interest among participants, we
5 plan to use generalized linear mixed models that include random intercepts for individuals (to
6 account for repeat measurements), random intercepts for facilities (to account for the correlation
7 among individuals within the same facility), and adjustments for covariates. Statistical analysis
8 will be carefully conducted as repeated time measures over a 7-month time period will mean
9 missing data points and shifted timelines due to external circumstances. Subgroup analysis will
10 be conducted to understand differences between clusters and well as within clusters.

11
12 For qualitative data, interviews with primary care practitioners will continue until saturation has
13 been met and thematic analysis will be used to analyse results.

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

18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 **Sample size calculation**

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

44 45 46 47 48 49 50 51 52 53 54 55 56 **Ethics and Dissemination**

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

31 **Cost Ratio Economic Evaluation**

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33 This component will involve two evaluations. The first will evaluate the ratio between costs
34 associated of training primary care practitioners to identify, treat and refer mental health care
35 patients compared to costs of referral to, and treatment from, psychiatrists. Costs will be linked to
36 the primary outcome measure to determine the extra cost of training incurred to detect one extra
37 patient and understand economic implications of service provision to conflict-affected populations
38 [19]. The second will evaluate the ratio between costs associated with patients receiving care
39 from trained primary care practitioners at primary care facilities compared to costs of seeking care
40 from specialist psychiatrists.
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54 **Process Evaluation**

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

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22 Due to the history of conflict and displacement in Sri Lanka, it is vital to address unmet mental
23 health needs of the population. The completed cross-sectional survey at primary care level
24 (Phase 1) supports this and demonstrates prevalence and predictors of mental health disorders
25 in the region. The WHO mhGAP IG 2.0 training programme provides a strategy to address this
26 gap between those seeking, and those able, to access mental health services in the region (Phase
27 2). COMGAP-S will not only demonstrate the feasibility of implementing the mhGAP training
28 programme, but ongoing monitoring activities will contribute to evaluation of both training and
29 implementation.
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41 Using the mhGAP guide to train participants on how to identify and treat common mental health
42 disorders could empower primary care practitioners to effectively address mental health needs of
43 the population in this post-conflict setting. This will also take pressure of limited specialized
44 psychiatry services in the region. Additionally, training public health professionals and community
45 representatives can positively increase mental health awareness and decrease stigma in the local
46 community. Training materials have undergone cultural adaptation to ensure training is relevant
47 and acceptable to all participants and stakeholders. Use of a locally adapted mhGAP guide will
48 increase acceptability and sustainability of the implementation of the clinical trial. This project
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3 includes key stakeholders from Northern Ministry of Health, University of Jaffna, Sri Lankan
4 psychiatrists, and Sri Lankan researchers. Thus, COMGAP-S will not only contribute to the
5 evidence base on integrating mental health services in primary care in low resource settings, it
6 will also build local capacity, be culturally relevant, and sustainable.
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13 COMGAP-S will be the first large-scale implementation of WHO mhGAP IG 2.0 training to improve
14 mental health service delivery in primary care in Northern Province, Sri Lanka. Implementation of
15 COMGAP-S aims to build capacity within the primary care system in the region, but also improve
16 mental health service delivery addressing the unmet needs of a vulnerable population.
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27 **Figure 1.** Primary Care Practitioner study timeline

28 **Figure 2.** Public Health Professional study timeline

29 **Figure 3.** Community representative study timeline
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3 **Authors' contributions:** SD developed the concept and design of this study with contributions
4 from GD, AE, BR, RS and MA. SD wrote the manuscript with contributions from GD, AE, BR,
5 RS and MA. All authors commented on and approved the final version of this manuscript.
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8 9 **Data sharing statement**

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

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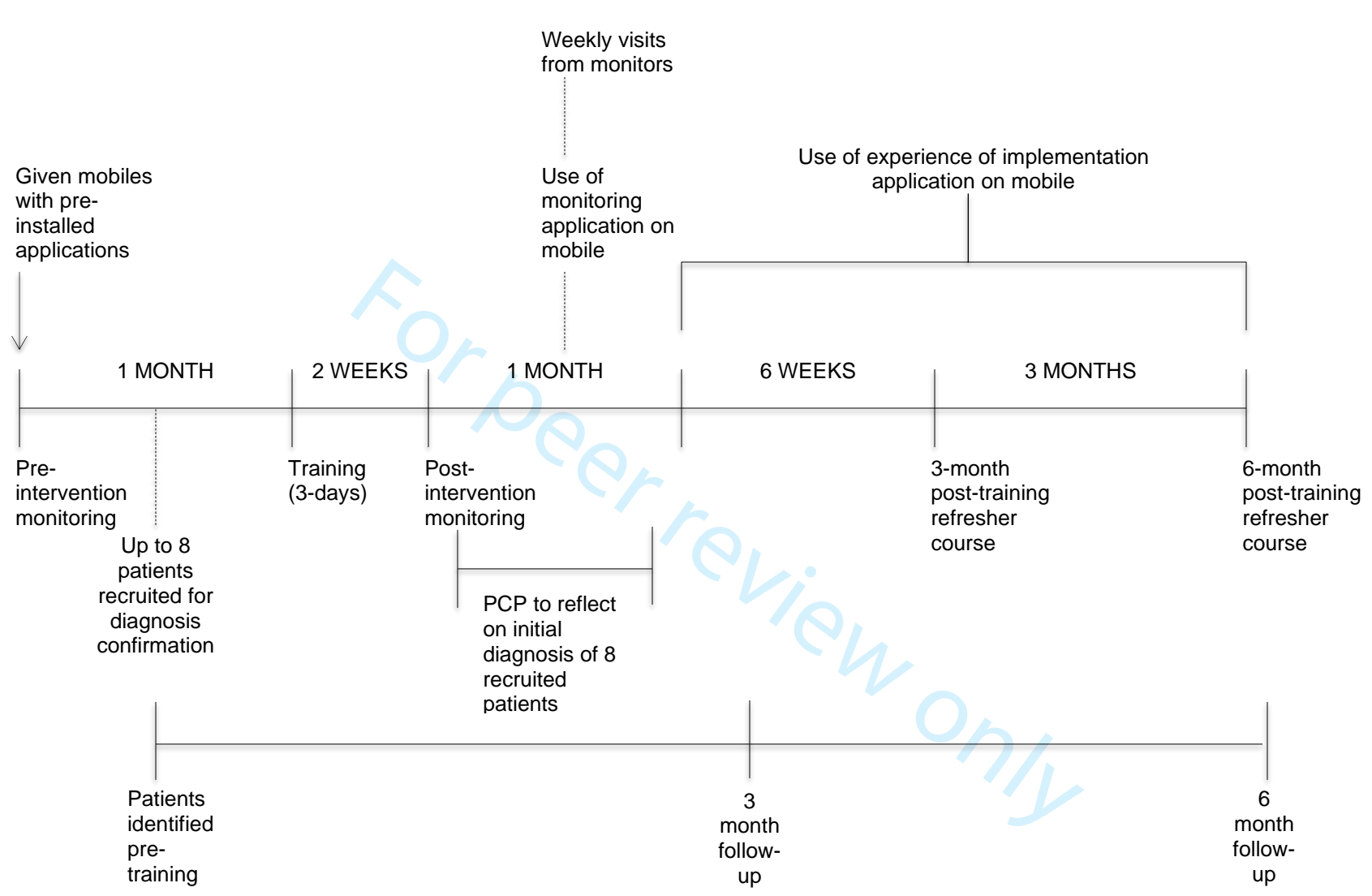


Figure 1. Primary Care Practitioner study timeline

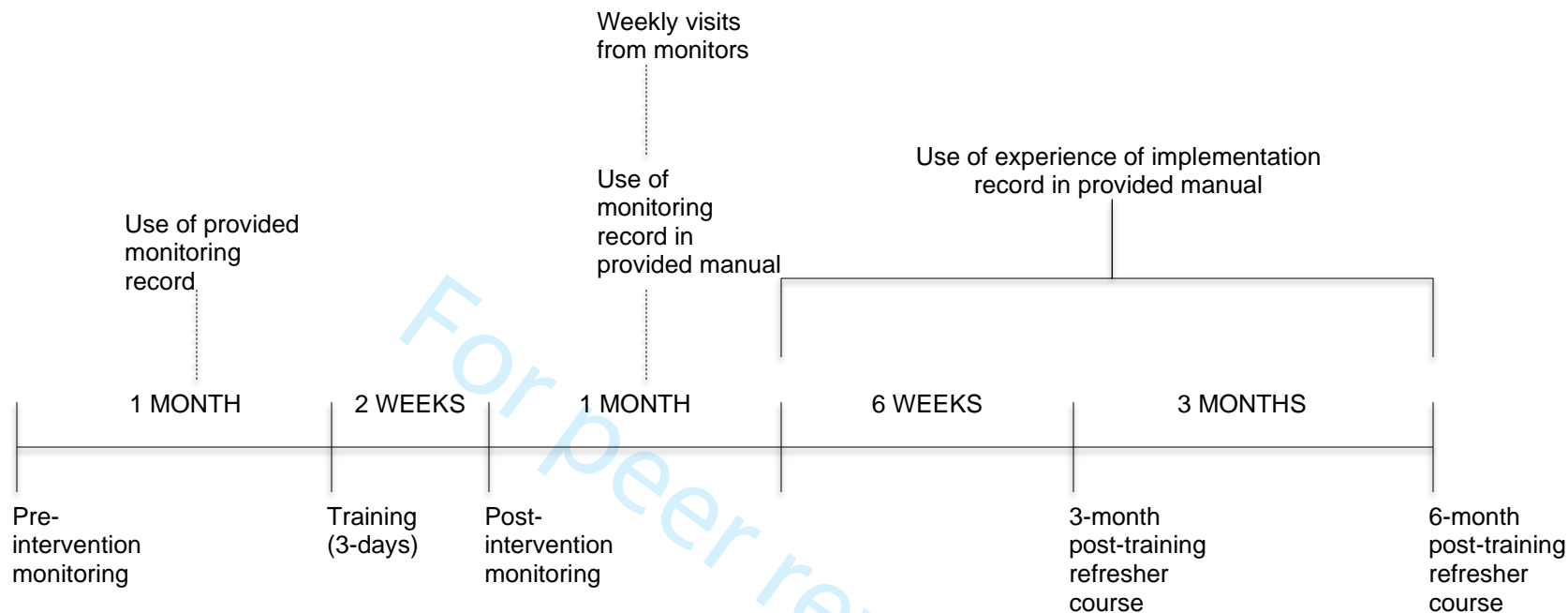


Figure 2. Public Health Professional study timeline

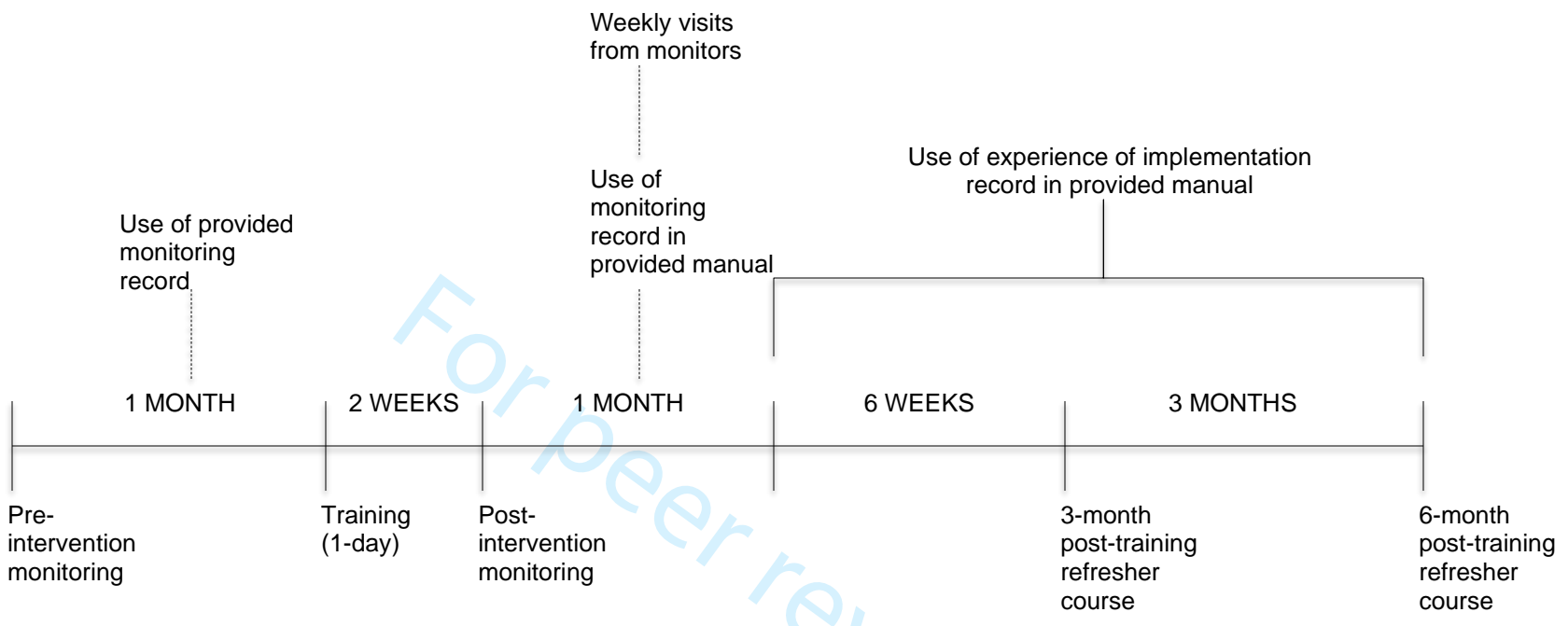


Figure 3. Community representative study timeline

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)

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-051441.R2
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Primary Subject Heading:	Global health
Secondary Subject Heading:	Health services research, Mental health
Keywords:	MENTAL HEALTH, PRIMARY CARE, PSYCHIATRY

SCHOLARONE™
Manuscripts

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

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

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3 Mental health disorders often present in primary care settings, especially in low- and middle-
4 income countries (LMIC), where specialized psychiatric services may be lacking. Low- or non-
5 detection, low referral rates for specialist care, and increased costs are all features of mental
6 health disorders in primary care settings in LMIC. Furthermore, lack of adequate training for
7 primary care physicians and lack of involvement of public health personnel can act as barriers to
8 effective treatment and management of common mental health disorders in primary care [1, 2].
9
10 Barriers can be compounded in post-conflict situations, as existing limited health systems may be
11 severely affected, especially for those internally displaced. There is strong evidence that conflict-
12 driven, internally displaced migrants have increased rates of mental health disorders [1, 3].
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24 During 26 years of protracted internal conflict in Sri Lanka, more than 100,000 people of all
25 ethnicities are estimated to have died, and hundreds of thousands injured [4, 5]. Substantial
26 internal displacement from conflict was compounded by the 2004 tsunami [6].
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32 Although Sri Lanka has an effective primary care system, the treatment gap for mental health is
33 extensive, especially for post-conflict populations [1, 7]. While provision of health services has
34 improved, resources are insufficient to meet population needs, especially those related to severity
35 of trauma, or to difficulties experienced in displacement or return migration [8]. Primary care
36 practitioners in the Northern Province region regularly spearhead mental health care efforts,
37 however, they do so without adequate training. Training primary care practitioners to deliver
38 mental health care at primary care level is in line with the task-shifting approach in the global
39 mental health field [2, 9-11]. A pilot feasibility study (COMGAP) to explore this possibility was
40 conducted in 2013-2014 based on a peer-reviewed protocol and is reported elsewhere [8].
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54 The first phase of the study was completed in 2015-2016 and facilitated understanding of mental
55 disorder burden and treatment gap at primary care level. Results from the cross-sectional study
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3 indicated the most prevalent mental health disorders in primary care settings were depression
4 (41.1%, 95% CI: 38.7-44.5%), anxiety (46.7%, 95% CI: 41.9-51.5%), post-traumatic stress
5 disorder (13.7%, 95% CI: 10.6-16.8%), and psychosis with hypomania (17.6%, 95 CI: 13.3-21.9)
6 [12]. While this facilitated understanding of the underlying mental health issues within the region,
7 the issue of unmet need was still present. In this context, the aim of Phase 2 of COMGAP-S is to
8 use a scaled-up training intervention based on the World Health Organization Mental Health Gap
9 Action Programme (WHO mhGAP 2.0) to integrate mental health services into primary care by
10 providing training to primary care practitioners and public health professionals serving conflict-
11 affected populations in primary care settings in Northern Province [12, 13]. The second phase of
12 the project was conducted between 2016-2021. COMGAP-S is the first large-scale trial in the
13 region to use mhGAP to integrate mental health services into primary care for conflict-affected
14 populations. Further, it is the only trial to include wider health care staff and community members
15 as part of a long-term strategy to improve mental health awareness and stigma reduction.
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33 **Aims and objectives**

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

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43 1. 30% increase in patients identified and treated for common mental health disorders, and
44 referrals to specialist care for complex mental disorders by primary care practitioners. Measured
45 at baseline using the pre/post-monitoring questionnaires on current practice with mental health
46 patients and compared to post-training practice.
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50 2. 40% minimum concurrence between diagnoses of patients identified with mental disorders of
51 interest by trained primary care practitioners and psychiatrists as compared to diagnosis of
52 patients pre-training (baseline) measured using quantitative reporting forms from the consultant
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3 psychiatrist and in-depth, individual interviews with trained primary care practitioners to
4 understand any changes in practice.

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7 3. 20% reduction in positive screening for depression and anxiety in patients pre-training and at
8 3- and 6-months follow-up time points, measured using the Hopkins Symptom-Checklist 25.

11 Secondary outcomes

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13 1. 20% increase between mean pre- and post-training test scores for primary care practitioners
14 using the WHO mhGAP 2.0 pre/post training test.

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

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

34 METHODS AND ANALYSIS

41 Study design

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

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3 into account logistical constraints to sequentially roll out the intervention by training one facility at
4 a time enabling us to understand how this intervention can be implemented in the future on a
5 larger scale. This design was chosen because: 1) in an intervention trying to integrate mental
6 health services into primary care for post-conflict populations it is unethical to use a parallel design
7 which prevents equal distribution of knowledge and skills; 2) the stepped wedge cluster design is
8 more logistically feasible in the post-conflict setting of Northern Sri Lanka [15].
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18 Facilities will be randomized using standardized randomization techniques to allocate facilities to
19 the training sequence within the stepped wedge design. Patients and community representatives
20 will not be randomized. The study team cannot be blinded to the allocation of facilities. The study
21 psychiatrist will be masked to randomization status of facilities from which patients originate.
22 Patients will also be blinded to facility randomization status. [1]
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31 There is a theoretical possibility of contamination due to close professional or personal networks
32 between participant groups and geographical location of facilities. However, this is not envisaged
33 to exert significant influence on expected outcomes due to specifics of the extensive training,
34 requirement to carry out intensive tasks, and low risk of contamination through informal
35 discussions [1]. Potential contamination will be observed at all stages and taken into account at
36 the end of the study. Further, an important strength of cluster sampling is that it helps mitigate the
37 risk of treatment contamination between intervention and control groups.
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47 **Setting**

48 The study setting will be 23 government primary care health facilities within the five districts of the
49 Northern Province: Jaffna, Mannar, Kilinochchi, Vavuniya, and Mullaitivu. A full list of participating
50 sites can be obtained from the Primary Investigator..
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3 A list of public primary care facilities was provided to the study team by Northern Ministry of
4 Health. A random number generator will be used to select 23 facilities across 5 districts.
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6 Distribution of clusters will be allocated proportionally to total numbers of internally displaced
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8 people in each district (districts with larger numbers were assigned more clusters). This will ensure
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10 adequate representation of conflict displacement and severity.
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16 **Inclusion criteria**

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18 Facilities will be included if they indicate willingness to participate, are located in any of the five
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20 districts of Northern Province (Jaffna, Mannar, Kilinochchi, Vavuniya, Mullaitivu), provide primary
21
22 care services, and are either divisional hospitals of type A, B & C or primary medical care units.
23
24 Facilities should also provide services to conflict-affected, previously displaced populations.
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28 Primary care practitioners will be included if they have full registration with the Sri Lankan Medical
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30 Council, have at least 6 months or more until their next transfer rotation, or 6 months to retirement.
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32 Public health professionals will be included if they have at least 6 months left on their transfer
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34 rotation, or 6 months to retirement. Community representatives located within catchment areas
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36 of each selected facility will be included after identification through local registration organisations.
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38 Patients will be included if they are 18 years or older, attend selected facilities, and belong to
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40 internally displaced or conflict-affected populations.
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45 **Exclusion criteria**

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47 Larger facilities such as district hospitals and teaching hospitals will be excluded as they are not
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49 part of the primary care system. Private facilities will be excluded due to lack of an official registry.
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3 Primary care practitioners, public health professionals, and community representatives will be
4 excluded if they have secondary mental health training. Patients under 18 years and those
5 diagnosed with mental disorders outside of depression and/or anxiety will be excluded.
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10 11 **Recruitment and enrolment**

12 Support letters from Provincial Department of Health Service, and Regional Divisional Health
13 Secretariats in each district of Northern Province will be used to approach primary care
14 practitioners and public health professionals. Community representatives will be recruited through
15 local registration organizations. Patients will be recruited by primary care practitioners. Trained
16 research team members will perform screening and enrolment procedures and gain informed
17 consent for each participant group following established study protocols.
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30 31 **Structure and delivery of the intervention**

32 Training material was adapted for local use and included translation and cultural adaption of
33 relevant modules of the WHO mhGAP 2.0 IG, and production of locally developed mhGAP video
34 material for the Tamil context [16]. This was completed in collaboration with local academics,
35 psychiatrists, primary care practitioners, Northern Province Ministry of Health, and the University
36 of Jaffna.
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43 Training will consist of delivery of written materials, role plays, and training videos. All training
44 material was developed in collaboration with Sri Lankan researchers, local psychiatrists and
45 community physicians. All material was translated, back translated, and piloted for cultural
46 appropriateness prior to the full project.
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51 Almost all instruments used in the study had been previously applied in epidemiological studies
52 within Sri Lanka and are available in Tamil, Sinhala, and English languages. New instruments
53 were translated, back translated and adapted for cultural appropriateness in collaboration with
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3 the Sri Lankan research team. Further, the entire set of measures was field tested in a pilot study
4 prior to the full study commencing. This pilot study examined if measures were understood by
5 participants, culturally acceptable, and translations correct.
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9 To ensure safety of participants, a local psychiatrist will be involved throughout the study to
10 provide free mental health care if required.
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14 15 16 Primary care practitioners and patients

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18 Primary care practitioners (general physicians practicing in selected facilities) will undergo one
19 month of monitoring prior to training to establish a baseline. Primary care practitioners will be
20 trained using the mhGAP manual to recognize common mental health disorders using screening
21 procedures, delivery brief psychosocial interventions (psychoeducation, Motivational
22 Interviewing), and referral procedures for complex cases. They will receive a paper booklet to
23 record information on patients identified, treated, managed, and/or referred for mental health
24 disorders. Further, before training, primary care practitioners will be asked to recruit up to eight
25 patients using provided inclusion and exclusion criteria to have anxiety and/or depression
26 diagnoses verified by a psychiatrist. Members of the research team will provide patients with
27 information sheets and consent forms available in all 3 official languages (English, Tamil, Sinhala)
28 and obtain informed consent. Patients will complete a brief socio-demographic questionnaire at
29 point of recruitment and the Hopkins Symptom Checklist-25 screening questionnaire for
30 depression and anxiety at point of recruitment, and at 3- and 6-months follow-up to establish a
31 baseline, and determine if patient outcomes change after training of primary care practitioners.
32 Primary care practitioners will be asked detailed questions about their management and treatment
33 of recruited patients, and patients will be asked about any treatments undertaken or medications
34 prescribed to understand any intervening factors between baseline, and 3- and 6-months follow-
35 up.
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3 After the one-month monitoring period, primary care practitioners will undergo a 3-day training
4 intervention delivered in their primary care facility. Trained members of the research team will
5 deliver training at each selected facility to minimize disruption of work at facilities. PCP trainers
6 have Masters degrees in psychology and global mental health, and have successfully completed
7 the WHO mhGAP train-the-trainers program.
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15 After completion of training, monitoring of primary care practitioners will continue for one month,
16 where they will continue to use the paper booklet to record information on patients they identify,
17 treat, manage, for common mental health disorders and any cases they refer to specialized care
18 Research team members will visit or telephone the primary care practitioners once a week at their
19 facility to monitor implementation of the training intervention.
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28 After the one-month monitoring period primary care practitioners will continue to use paper
29 booklets to record their experience of the training implementation for six weeks. At this point (three
30 months post-training) primary care practitioners will participate in a 1-day refresher course and
31 continue to use the experience of training implementation application for a further three months.
32 At six months post-training, primary care practitioners will take a second 1-day refresher course
33 (Figure 1).
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41 Non-clinical supervision at all time points will be provided by research assistants who previously
42 delivered training sessions. Supervision will consist of phone calls or visits to the clinics to
43 understand if and how training is being utilised by participants. Supervision is meant to understand
44 if and how trained participants utilise mhGAP, accurate delivery of interviewing or diagnostic skills
45 were not evaluated.
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54 Public health professionals
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3 Public health professionals (nurse attendants, midwives) in each selected facility will undergo one
4 month of monitoring prior to training to establish a baseline. Public health professionals will be
5 trained using adapted written materials from the mhGAP training to recognize signs of common
6 mental health issues, provide basic psychosocial care (education) and refer onwards if needed.
7
8 PHP trainers hold Bachelors' degrees in psychology and have undergone 7 days training with
9 senior members of the research team. Each enrolled public health professional will record
10 information in a paper booklet on facilitation of referral and follow-up practices for mental health
11 patients, and support primary care practitioners with patient management activities. After the one-
12 month monitoring period, public health professionals will be provided with a tailored 3-day training
13 programme on mental health awareness, management, referral, and stigma reduction. After
14 training, public health professionals will undergo one month of monitoring and record the same
15 information as in the pre-monitoring period to see how/if practice has changed. Research team
16 members will visit or telephone their facility once a week to monitor implementation of the training
17 intervention.

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

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47 Non-clinical supervision at all time points will be provided by research assistants who delivered
48 previous training sessions. Supervision will consist of phone calls or visits to the clinics to
49 understand if and how training was being utilised by participants.
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56 Community representatives
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3 Community representatives (teachers, social workers) will undergo one month of monitoring prior
4 to training to establish a baseline. Community representatives will be trained using adapted
5 materials from the mhGAP training material to recognize signs of common mental illness, delivery
6 basic psychosocial education and learn referral pathways and where to seek providers. CR
7 trainers hold Bachelors' degrees in psychology and have undergone 7 days training with senior
8 members of the research team. Each enrolled community representative will record information
9 in a paper booklet on mental health awareness raising activities undertaken, and any referrals of
10 people they encounter with mental health issues. After the one-month monitoring period,
11 community representatives will participate in a tailored 1-day training programme on mental health
12 awareness, stigma reduction, and finding local resources. After training, community
13 representatives will undergo one month of monitoring and record the same information as in the
14 pre-monitoring period to see how/if practice has changed. Research team members will visit or
15 telephone once a week to monitor implementation of the training intervention.
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32 After the one-month, monitoring period community representatives' will record information on their
33 experience of the training intervention in paper booklets for six weeks. At this point (three months
34 post-training), community representatives will participate in a half-day refresher course and
35 continue to use provided booklets to record their experience of training implementation for a
36 further three months. At six months post-training, community representatives will participate in a
37 second half-day refresher course (Figure 3).
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45 Non-clinical supervision at all time points will be provided by research assistants who delivered
46 previous training sessions. Supervision will consist of phone calls or visits to the clinics to
47 understand if and how training was being utilised by participants.
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54 **Timing of intervention delivery and follow-up**

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3 COMGAP-S will run for 7 months in each facility and catchment area. Every 2 weeks a facility will
4 be enrolled in the study until all 23 have completed the study timeline. Participants discontinuing
5 engagement will not be subject to follow-up. Measures will be collected at six time points:
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9 1. Pre-training monitoring period: questionnaire to establish baseline on current practice. Primary
10 care practitioners only: recruitment of patients for diagnosis verification.
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12 Patients administered Hopkins Symptom Checklist 25 for anxiety and/or depression (baseline),
13 and at 3- and 6-months follow-up to assess change in clinical symptoms.
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16 2. Pre-training intervention: WHO mhGAP knowledge pre-test and AMIQ stigma questionnaire.
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19 3. Post-training intervention: second administration of WHO mhGAP knowledge test.
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22 4. Post-training monitoring period: questionnaire to establish if/how practice has changed, and
23 qualitative interviews to reflect on initial diagnosis practice.
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26 5. 3 months follow-up training: WHO mhGAP pre- and post- knowledge test and AMIQ stigma
27 questionnaire.
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30 6. 6 months follow-up training: WHO mhGAP pre- and post- knowledge test and AMIQ stigma
31 questionnaire.
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43 **Statistical methods**

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47 The primary unit of analysis (i.e., where the intervention is carried out) is the healthcare facility,
48 and data collected from individual participants will include: sociodemographic information, conflict
49 and displacement experience, mhGAP knowledge test scores, AMIQ stigma scores, and pre- and
50 post- monitoring questionnaires. Descriptive statistics will be used to summarize observations
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3 using means, standard deviations, and proportions where appropriate. Data analysis will be
4 conducted using SAS version 9.4M7 [17].
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7 An intention-to-treat analysis will be used to analyze the effect of the intervention. In the stepped
8 wedge design, similar information will be collected repeatedly on individuals within facilities; we
9 will therefore utilize statistical models that can adjust for repeat measures and clustering of
10 participants within facilities (in the case of PHPs and CRs). In particular, for the analysis of mhGAP
11 knowledge test scores and AMIQ stigma scores as outcomes of interest among participants, we
12 plan to use generalized linear mixed models that include random intercepts for individuals (to
13 account for repeat measurements), random intercepts for facilities (to account for the correlation
14 among individuals within the same facility), and adjustments for covariates. Statistical analysis
15 will be carefully conducted as repeated time measures over a 7-month time period will mean
16 missing data points and shifted timelines due to external circumstances. Subgroup analysis will
17 be conducted to understand differences between clusters and well as within clusters. Planned
18 subgroup analysis will investigate possible differences between clusters (for example, differences
19 between PHPs across facilities)
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34 For qualitative data, interviews with primary care practitioners will continue until saturation has
35 been met and thematic analysis will be used..
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38 Fidelity checks will be included through utilization of feedback forms after the end of each training
39 session to investigate if any major concerns have arisen that could be addressed before
40 subsequent sessions. Further, a process evaluation will be conducted to understand if the study
41 adhered to protocol, and how the intervention was received by participants.
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49 **Sample size calculation**

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51 A total of 23 primary care practitioners, 75 public health professionals, 50 community
52 representatives, and 200 patients will be recruited. Target sample sizes were calculated
53 separately for each participant group and for each outcome. Sample sizes for the first and second
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3 outcomes were calculated following methods described by Hemming and Taljaard, where each
4 outcome is considered an individually randomized trial and then multiplied by a design effect to
5 account for the stepped wedge design [18]. Sample sizes for the third and fourth outcomes were
6 calculated using formulae from the 1994 textbook “Analysis of Longitudinal Data” by Diggle, Liang
7 and Zeger [19].
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13 14 15 16 **Ethics and Dissemination**

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

46 **Cost Ratio Economic Evaluation**

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48 This component will involve two evaluations. The first will evaluate the ratio between costs
49 associated of training primary care practitioners to identify, treat and refer mental health care
50 patients compared to costs of referral to, and treatment from, psychiatrists. Costs will be linked to
51 the primary outcome measure to determine the extra cost of training incurred to detect one extra
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3 patient and understand economic implications of service provision to conflict-affected populations
4 [20]. The second will evaluate the ratio between costs associated with patients receiving care
5 from trained primary care practitioners at primary care facilities compared to costs of seeking care
6 from specialist psychiatrists.
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11 12 13 14 Process Evaluation

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

34 Due to the history of conflict and displacement in Sri Lanka, it is vital to address unmet mental
35 health needs.. The completed cross-sectional survey at primary care level (Phase 1) supports this
36 and demonstrates prevalence and predictors of mental health disorders in the region. The WHO
37 mhGAP IG 2.0 training programme provides a strategy to address this gap between those
38 seeking, and those able, to access mental health services in the region (Phase 2). COMGAP-S
39 will not only demonstrate the feasibility of implementing the mhGAP training programme, but
40 ongoing monitoring activities will contribute to evaluation of both training and implementation.
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51 Using the mhGAP guide to train participants to identify and treat common mental health disorders
52 could empower primary care practitioners to effectively address mental health needs of the
53 population in this post-conflict setting. This will also take pressure off limited specialized
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3 psychiatry services in the region. Additionally, training public health professionals and community
4 representatives can positively increase mental health awareness and decrease stigma in the local
5 community. Use of a locally adapted mhGAP guide will increase acceptability and sustainability
6 of the implementation of the clinical trial. This project includes key stakeholders from Northern
7 Ministry of Health, University of Jaffna, Sri Lankan psychiatrists, and Sri Lankan researchers.
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9 Thus, COMGAP-S will not only contribute to the evidence base on integrating mental health
10 services in primary care in low resource settings, it will also build local capacity, be culturally
11 relevant, and sustainable.
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22 COMGAP-S will be the first large-scale implementation of WHO mhGAP IG 2.0 training to improve
23 mental health service delivery in primary care in Northern Province, Sri Lanka. Implementation of
24 COMGAP-S aims to build capacity within the primary care system in the region, but also improve
25 mental health service delivery addressing the unmet needs of a vulnerable population.
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36 **Figure 1.** Primary Care Practitioner study timeline

37 **Figure 2.** Public Health Professional study timeline

38 **Figure 3.** Community representative study timeline
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10 **Authors' contributions:** SD developed the concept and design of this study with contributions
11 from GD, AE, BR, RS and MA. SD wrote the manuscript with contributions from GD, AE, BR,
12 RS and MA. All authors commented on and approved the final version of this manuscript.
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15 **Data sharing statement**

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

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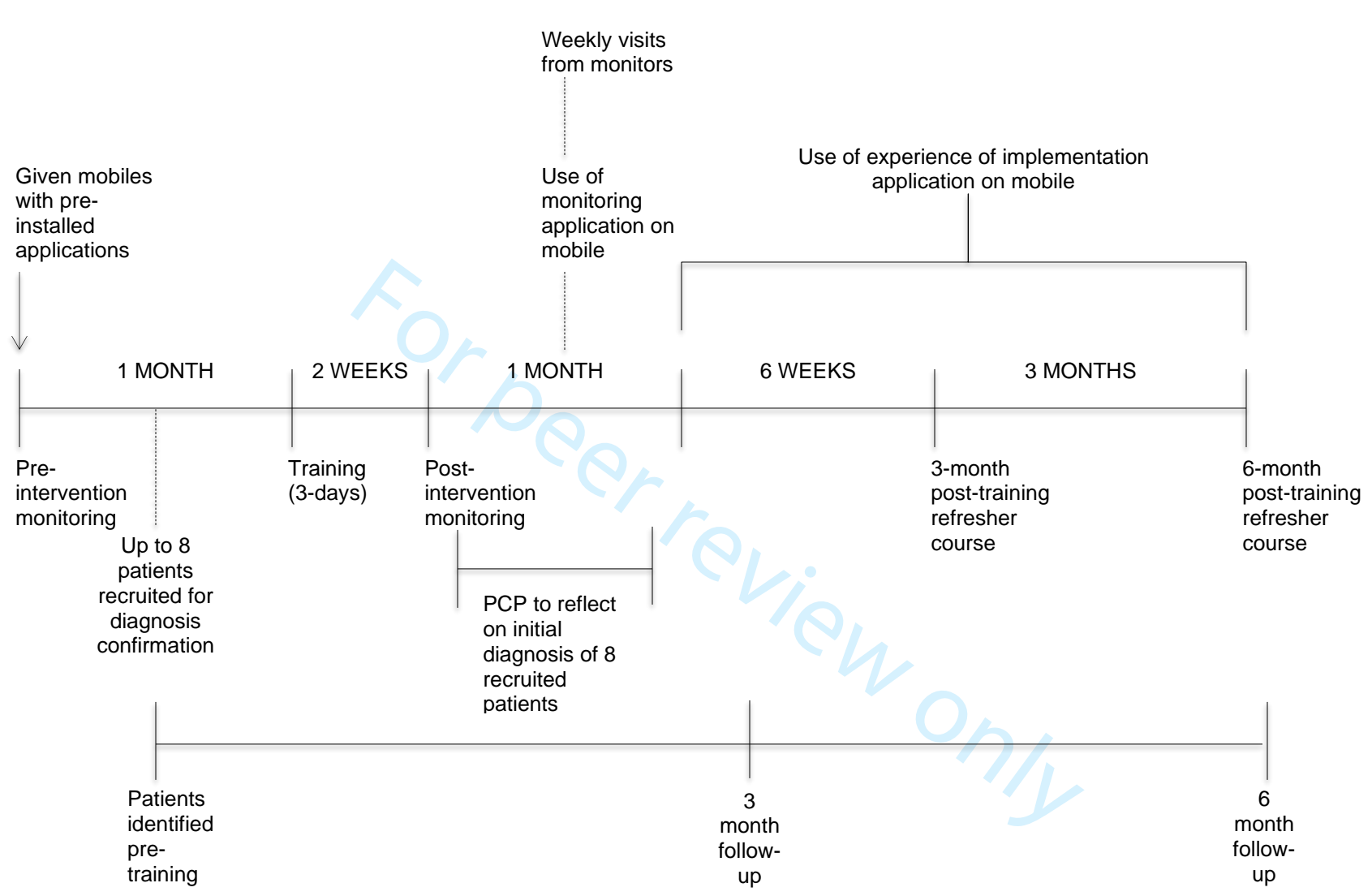


Figure 1. Primary Care Practitioner study timeline

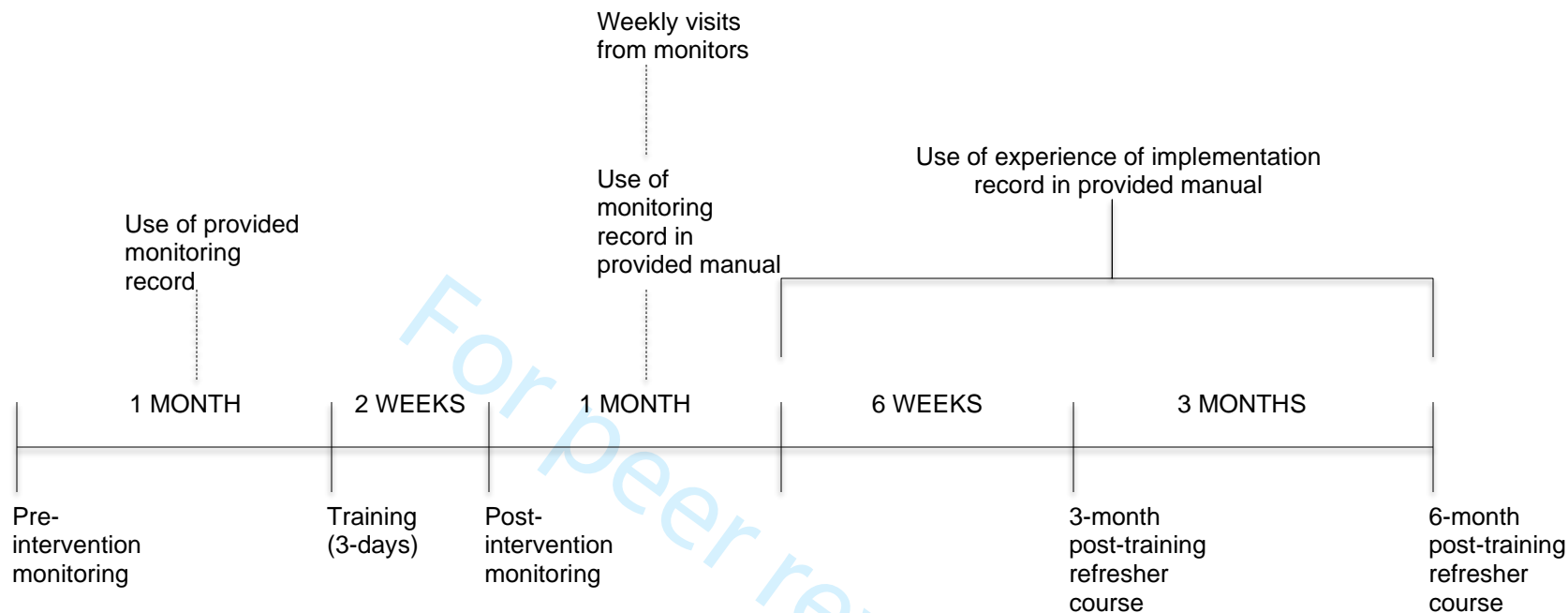


Figure 2. Public Health Professional study timeline

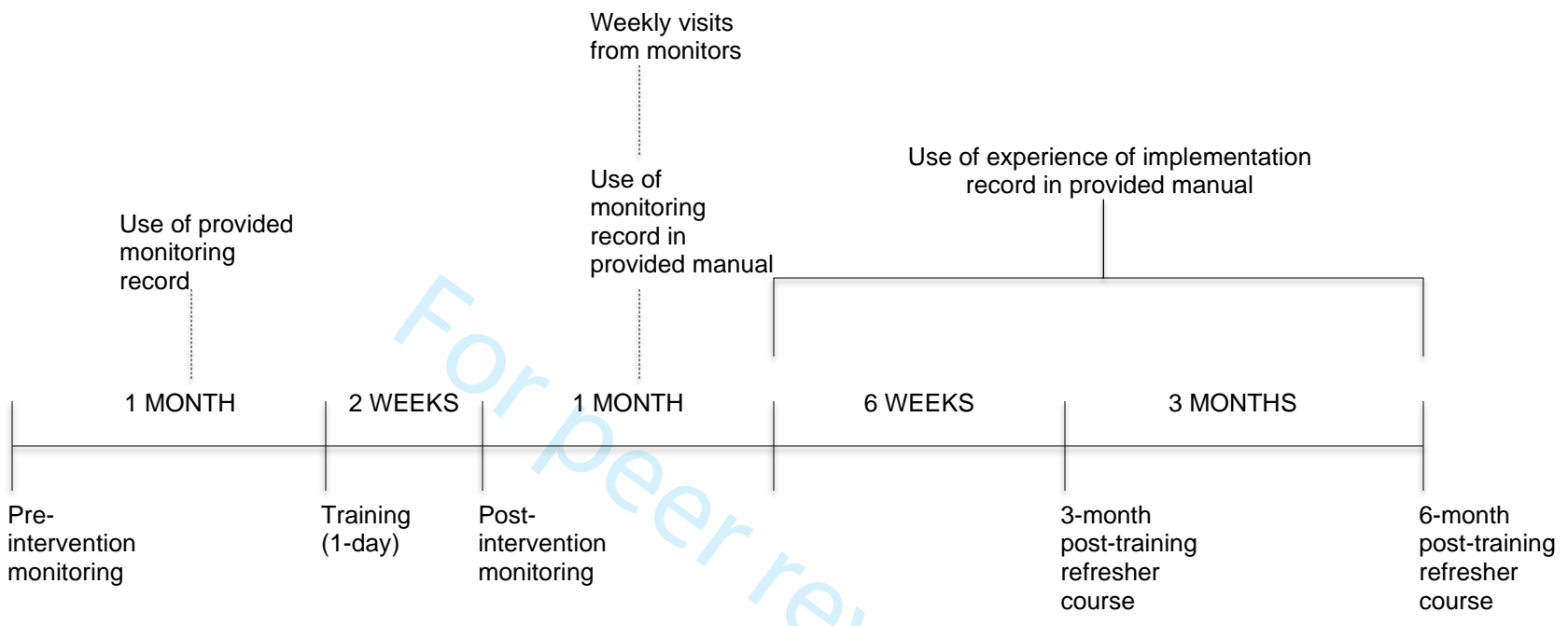


Figure 3. Community representative study timeline