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Strengthening human resources for health through simplified clinical tools

Submission date	Recruitment status	[_] Prospectively registered
08/02/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/02/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/04/2011	Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MGC - 105989-001

Study information

Scientific Title
Strengthening human resources for health through simplified clinical tools and educational outreach: a cluster-randomised trial

Acronym
PALM PLUS

Study objectives
Our hypothesis is that the PALM-PLUS guideline/training intervention will be associated with improved staff retention and satisfaction, and better patient outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Malawi National Health Sciences Research Committee approved on the 10th December 2009 (ref: NHSRC 687)

Study design
Unblinded cluster randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Training methods in primary care centres

Interventions
The project centres on the STAT-PALM guidelines and novel training method. The STAT-PALM guidelines and training program will be developed through a review and modification of the proven PALSA-PLUS guidelines in light of Malawian national guidelines, and through consultations with the Ministry of Health, Malawian nurses and clinical officers, the Medical Council of Malawi and the Nursing and Midwifery Council of Malawi regarding content and accreditation of the training, drafting of the content, review of the content by stakeholders, and graphic design of the clinical tools (desktop maps and flipcharts) and training materials. Relevant Malawian national guidelines have been collected, and our guideline developers have been adapting and drafting specific guideline pages. These are then subjected to review in Malawi, and circulated to the appropriate Department Heads within the MoH for review and comments (e.g., National tuberculosis unit, human immunodeficiency virus [HIV] Unit, Malaria Unit, etc) as well as frontline clinicians/specialists in the district or region. The reviewers are expected to

check that the content is correct and appropriate, and to check that the algorithms flow properly and reflect available drugs/resources in Malawian Health Center settings. These comments are then transcribed and clarified if needed and discussed, then incorporated into the next draft of the guidelines, which are then returned to the same partners for review until they are accurately completed. Once the flow, content and materials have been completed, the various senior Malawi MOH Unit and Department personnel will sign off and approve them, then they will be sent to be printed and bound.

Training follows the proven innovative and evidence-based model of PALSA-PLUS, called educational outreach, a form of point-of-care training that provides case-based, onsite, training in clinical settings where primary care providers work. Trainers will be front-line healthcare workers from the MoH and other partners including the Christian Hospital Association of Malawi (CHAM) and other NGOs who will be trained to provide outreach training and support to their fellow front-line healthcare workers during focused (1 - 2 hours), intermittent, interactive sessions. A Master Trainer, already trained by the Knowledge Translation Unit (KTU) Team in Cape Town, South Africa, will be responsible for training all facility trainers. Curriculum development will also be informed by a training needs assessment during the curriculum design process. The initial facility trainer training is conducted offsite during the one week intensive course, during which the facility trainers are equipped with the necessary content, and their training skills developed and evaluated using an iterative process of training and feedback. In order to minimise travel between remote health centres, 12 facility trainers will be trained, and will conduct an average of 16 training sessions (one per health centre) each week. At health centres, integration of antiretroviral treatment (ART) into primary healthcare services will be facilitated through the training of all, rather than selected, healthcare workers at each health centre. A minimum of 6 and a maximum of 10 training sessions will occur at each health centre, over a maximum period of 16 weeks. Point-of-care guideline tools will be developed and distributed (e.g., a thin [approximately 30 pages] sturdy laminated ring binder containing the entire guideline, colourful and easy to follow algorithms designed to be on the primary care provider's desktop during each patient encounter, desk blotters with key STAT-PALM messages, laminated cards with key guideline messages on lanyards to be worn around the provider's neck). Ongoing routine training conducted by the DHO will continue in both intervention and control health centres.

The STAT-PALM training differs significantly from the current healthcare worker training in Malawi and elsewhere, which are usually didactic, taught by experts (rather than peers), and where HCWs are removed from their clinical setting for days to weeks at a time and compensated with per diems. The Master Trainer will conduct a follow-up visit with facility trainers and their trainees to assess progress and uptake. On a quarterly basis, facility trainers will meet with the Master Trainer and a high-level core trainer from Dignitas and/or the KTU to review progress, discuss challenges to implementation, and share experiences with a view to improving the quality of the trainings and subsequent versions of the guidelines. The guidelines distribution and training will occur at intervention sites only. No active distribution of the STAT-PALM materials or training sessions will occur in control facilities, however routine ongoing health centre supervision by DHO personnel and off-site DHO training courses will continue in all sites.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Health centre staffing retention: months remaining in same job post-intervention, measured at staff-person level. Can do overall and by health cadre. Denominator is staff at work at study start.
2. Staff turnover (sum of retention/recruitment/loss): Denominator to be calculated based on ideal ratio of HCWs to patient visits (e.g., no. of attendances in last year
3. Staff satisfaction: Individually scored questions from validated questionnaire

Secondary outcome measures
1. Cotrimoxazole prophylaxis among HIV+ pregnant women attending ante-natal care at health centre
2. HIV testing among pregnant women
3. Anti-retroviral treatment (ART) among HIV+ pregnant women attending ante-natal care at health centre
4. Non-ART prevention-of-mother-to-child-transmission of HIV treatment provided to HIV+ pregnant women attending ante-natal care at health centre
5. New adult ARV follow-ups at health centre
6. New adult TB follow-ups at health centre
7. New TB treatment among ART patients at health centre
8. New HIV diagnosis among TB patients at health centre
9. New ART initiations among TB patients at health centre
10. Initiation of malaria treatments at health centre
11. Immunizations (overall and measles specific) given 0 - 5 years at health centre
12. New child ART initiations at health centre
13. HIV tests in children at health centre

Overall study start date
01/02/2010

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Centres: All public primary care health centres within Zomba District (30 centres)
2. Individuals: All health professional staff (no age limit, either sex) eligible to provide clinical services within the randomised health centres

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30 health centres and approximately 200 clinical staff (in total) working in them

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/02/2010

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Canada

Malawi

Study participating centre
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Sponsor information

Organisation
International Development Research Center (IDRC) (Canada)

Sponsor details
Global Health Research Initiative
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Sponsor type
Research organisation

Website
http://www.idrc.ca/ghri/

ROR
https://ror.org/0445x0472

Funder(s)

Funder type
Research organisation

Funder Name
Global Health Research Initiative (Canada) - a research funding partnership of five agencies and departments of the Government of Canada, including the Canadian International Development Agency (CIDA), the Canadian Institutes of Health Research (CIHR), Health Canada (HC), the International Development Research Centre (IDRC), and the Public Health Agency of Canada (PHAC) (ref: MGC-105989-001)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/12/2010		Yes	No