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Effectiveness of an integrated care guideline training programme (Primary Care 101) on the processes and outcomes of non-communicable chronic diseases compared with usual training and support in primary care in South Africa

Submission date
16/02/2011

Recruitment status
No longer recruiting

Registration date
24/03/2011

Overall study status
Completed

Last Edited
21/12/2015

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effectiveness of an integrated care guideline training programme (Primary Care 101) on the processes and outcomes of non-communicable chronic diseases compared with usual training and support in primary care in South Africa: a pragmatic cluster randomised controlled trial

Acronym
PC 101

Study objectives
Equipping nurse middle managers as outreach trainers to train primary care staff in integrated adult case management based on a simplified short (101 page), syndromic guideline, can simultaneously improve the quality of care for chronic diseases, chronic respiratory disease and mental health, in resource-constrained non-physician led primary care services.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Cape Town Human Research Ethics Committee approved on 1st February 2011, (HREC REF 119/2010)

Study design
Pragmatic two-arm stratified cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes, hypertension, depression, chronic respiratory disease-Primary care management

Interventions
Intervention group:Primary care 101

Integrated care guideline
1. Training of existing PALSA PLUS trainers as outreach trainers for expanded guideline (one 5 day training)
2. Outreach training of all primary care staff in intervention clinics (estimated 6 sessions per clinic)
3. Expanded prescribing provisions for professional nurses trained in 101 at intervention clinics for the duration of the trial. These provisions would make the following seven drugs available for PN prescription:
3.1. Enalapril 10mg daily for hypertension (HPT)
3.2. Amlodipine 5mg daily for HPT where enalapril is contra-indicated
3.3. Glibenclamide up to 5mg bd for diabetes
3.4. Glicazide up to 40mg two times a day (bd) for diabetes where glibenclamide is contra-

indicated
3.5. Simvastatin 10mg daily for diabetes or cardiovascular disease risk > 20%
3.6. Budesonide up to 200mcg bd for asthma
3.7. Prednisone 20-40mg daily for maximum 7 days for acute exacerbations of asthma/COPD
PALSA PLUS maintenance training to continue in intervention group

Control group:
1. Passive dissemination of integrated care guideline
2. PALSA PLUS training and guideline

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Based on target chronic condition.
1. Hypertension:Treatment intensification defined as
1.1. Increase in dose of antihypertensive medication or
1.2. Addition of new antihypertensive or
1.3. Addition of aspirin or
1.4. Addition/ increase in dose of statin
2. Diabetes: Treatment intensification defined as
2.1. Increase in dose of oral hypoglycaemic/ insulin or
2.2. Addition of new oral hypoglycaemic / insulin or
2.3. Addition/ increase in dose of angiotensin-converting enzyme (ACE) inhibitor or
2.4. Addition of aspirin or
2.5. Addition/ increase in dose of statin
3. Chronic respiratory disease: Treatment intensification defined as
3.1. Addition of beta-agonist or
3.2. Addition of ipratropium bromide or
3.3. Addition of oral theophylline or
3.4. Addition/ increase in dose of inhaled corticosteroid
4. Depression:Case detection defined as
4.1. Started on antidepressant medication or
4.2. Referred for counselling or
4.3. Referred to psychiatric services

All outcomes will be measured 14 months after recruitment (12-14 months after the intervention has started in intervention clinics).

Key secondary outcome(s))
Process outcomes
1. Breakdown of treatment intensification and test-ordering outcome by components
2. Appropriate prescribing for cardiovascular disease risk indicated by:
2.1. Proportion receiving aspirin
2.2. Proportion receiving simvastatin
2.3. Proportion receiving ACE inhibitor
3. Appropriate prescribing for obstructive lung disease indicated by:
3.1. Proportion receiving an inhaled corticosteroid

3.2. Ratio of beta-agonist to inhaled corticosteroid
4. Appropriate screening for complications:
4.1. Proportion reporting dilated eye exam
4.2. Proportion reporting foot exam
5. Smoking endpoints:
5.1. Proportion receiving smoking cessation advice
5.2. Proportion who quit
5.3. Number of units smoked per day
5.4. Readiness to quit smoking (Prochaska and DiClemente model)
6. Proportion of prescriptions filled (as proxy of adherence)

Intermediate outcomes
1. Cardiovascular disease risk
2. Systolic BP
3. HbA1C
10. Waist circumference
11. Body mass index (BMI)

Health outcomes
1. Cardiovascular (CVS) event (acute myocardial infarction (MI) and/or stroke and/or death)
2. Mortality
3. HRQoL (EuroQol 5D, St Georges Respiratory Questionnaire, CESD-10)

Economic
1. WHOs Disability Assessment Schedule II
2. Income and changes due to illness
3. Admissions
4. Inpatient days
5. Clinic visits

All outcomes will be measured 14 months after recruitment (12-14 months after the intervention has started in intervention clinics).

Completion date
30/11/2012

Eligibility

Key inclusion criteria
1.Clinics: Nurse-led fixed primary care clinics in the Eden and Overberg districts of the Western Cape province, South Africa (all clinics service around or more than 10,000 attendances per year)
2. Patients -Age more than 18 years and written consent to participate in the study
3. Four cohorts are defined. Patients may fulfill inclusion criteria for more than one cohort. Inclusion criteria based on four target chronic diseases:
3.1. Hypertension: self-reported hypertension on medication
3.2. Diabetes: self-reported diabetes on medication
3.3. Chronic respiratory disease: self-reported asthma/ chronic obstructive pulmonary disease (COPD) / chronic bronchitis/ emphysema or cough and/or difficult breathing for more than 2 weeks (not on TB treatment in the past 3 months)
3.4. Depression: CES-D 10 (Centre for Epidemiologic Studies Depression Scale) score of 10 or more

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Clinics:
1.1. Clinics with less than 9,000 attendances in the year preceding randomisation
1.2. Satellite and mobile clinics
1.3. Clinics providing exclusive antiretroviral treatment services
1.4. Clinics where chronic disease care is shared with large referral centres (to limit contamination)
2. Patients:
2.1. Inability to meet the inclusion criteria
2.2. Acute and/or terminal condition precluding participation such as acquired immune deficiency syndrome (AIDS) or cancer
2.3. Psychiatric diagnoses precluding participation such as schizophrenia, dementia and other cognitive impairment measured by self report or medical history
2.4. For chronic respiratory disease: patients receiving TB treatment in the past 3 months will be excluded

Date of first enrolment
22/03/2011

Date of final enrolment
30/11/2012

Locations

Countries of recruitment
South Africa

Study participating centre
Knowledge Translation Unit
Cape Town
South Africa
7700

Sponsor information

Organisation
University of Cape Town (South Africa)

ROR
https://ror.org/03p74gp79

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health - National Heart, Lund and Blood institute (USA) (NHLBI-HV-09-12)

Results and Publications

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	30/11/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes