

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/03/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/12/2015	Condition category Other	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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).

Secondary outcome measures

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. WHO's 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).

Overall study start date

22/03/2011

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

CLINICS: 38; PATIENTS: 4598

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)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/03p74gp79>

Funder(s)

Funder type

Government

Funder Name

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	30/11/2015		Yes	No