A cluster randomised control trial to evaluate the effectiveness of a community based programme to improve tuberculosis control in the agricultural sector of the Winelands Health District, South Africa

A research proposal
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SUMMARY

1. Introduction

An innovative primary health care (PHC) project was recently developed in a high tuberculosis (TB) prevalence, rural area of the Western Cape. The project consisted of a strategy to introduce community based health care onto farms by training selected farm workers to work as community health workers (CHWs). As TB is a priority health problem in the area, the programme emphased strategies for TB case detection and case-holding.

The pilot project was evaluated by the Medical Research Council during 1996. It was described as a well designed, expertly managed primary health care intervention which significantly improved treatment outcomes. *Dick J, Clarke M, Tibbs, J. Combating tuberculosis – lessons learnt from a rural community project in the Klein Drakenstein area of the Western Cape. S Afr Med J 1997; 87: 1042-1047.* The health services are keen to replicate the model in the Winelands Health District and need to ascertain whether the intervention will be a cost-effective. This proposal is designed to evaluate the effectiveness of the intervention on TB case detection, case-holding and cure rates.

An independent economic evaluation will be undertaken by the South African Network for Economic Research in order to assess the costs, savings and benefits of the intervention compared to existing practices.

2. Background and statement of the problem

TB is a global emergency and responsible for a large burden of disease in Africa. South Africa notified 108 382 TB cases during 1998, with only 60% of the positive sputum smear patients in this cohort reported as cured at the end of their treatment period. The 18% treatment interruption rate is the main reason for the poor performance of the South African TB Control Programme. TB incidence worsens in selected rural areas with the agricultural area of Wellington reporting 1035 cases per 100 000 during 1998.

South Africa adopted the revised directly observed therapy, short-course (DOTS) strategy in 1996. Experts claim that successful implementation of the DOTS policy has the potential to reduce the incidence of tuberculosis by 8% per year. The success of DOTS depends upon 85% of smear positive TB patients being ´cured`. The cure of a TB patient depends upon the conscientious adherence to the prescribed anti-tuberculosis therapy.

The problem of patient non-adherence to treatment has been well researched. Successful interventions include a multi-faceted approach which simultaneously improves the quality of patient – health provider interaction, increases the convenience of obtaining treatment and provides psycho-social support to the patient. Patient-centered strategies are difficult to implement in the current era of cost containment. Farms which were previously visited fortnightly by PHC mobile clinics have had these services reduced so that farm workers now have to walk up to five kilometers to attend a PHC facility.

The pilot study illustrated that the introduction of trained CHWs have the potential to significantly improve TB control on farms. The educational process, disseminated by the CHWs,

appeared to enhance a positive cycle of social development amongst these underpriviledged communities.

Study aim
To assess the effectiveness of a CHW programme, designed to focus on PHC, in improving the case detection, case-holding and cure rates of tuberculosis in an agricultural setting.

Objectives
- To perform a systematic review, in association with the South African Cochrane Collaboration, on the evidence linking the effectiveness of CHWs in improving TB treatment outcomes.
- To design a two armed cluster randomised trial to test the relative effectiveness of CHWs in improving the case detection, case-holding and cure rates of TB in the Winelands Health District, South Africa.
- To make recommendations to the South African TB Control Programme and the Department of Agriculture, based on the results, regarding strategies to improve case detection, case-holding and cure rates of TB in an agricultural setting.

Study setting
The study will be conducted on 240 farms in Winelands Health District, Western Cape. The study setting has a population of approximately 16 090. It is an agricultural area mainly producing grapes and fruit for export. Each farm employs between 20 to 50 permanent workers with their families who live in closed micro-communities on the farms on which they are employed. The major health problems of the farm workers in this region are TB, sexually transmitted diseases and substance abuse. The farm workers access to health care is limited by their social and economic dependence on their employers.

Design of the intervention study
The study will be an unblinded two-armed cluster randomised controlled trial with before and after data on TB case detection and patient outcomes on 240 farms. 120 farms will be allocated to receive the CHW intervention, the balance being control units who will continue with existing practices. Prospective patient data will be collected from the TB register, laboratory register, individual patient folders and CHW record cards. Qualitative data will be collected in order to ascertain the acceptabilty of the intervention to participants.

Patient recruitment
All new and retreatment pulmonary TB patients notified in the Health Areas 10 and 11 from the 1 January 2000 to the 31 December 2000 will be included in the study.

Outcome measures
Cure
A patient who has been bacteriologically confirmed as having TB, has completed a course of TB treatment, and who has two negative smears at the end of treatment.
Case-holding (adherence to treatment)
Percentage total TB treatment doses taken by the patient. For new patients this total is130 doses and for retreatment cases is 160 doses. (Continuous variable)

Analysis of data
The analysis will compare the profiles of the intervention and control farms using individual patient data.

Ethics
The research protocol will be submitted to the Nordic School of Public Health for ethical approval.

Introduction

South Africa is categorised by the World Health Organisation (WHO) as one of 16 countries hampering global efforts to control TB. [1]

Historical neglect of the TB epidemic, a fragmented health service due to the apartheid system and poor management of TB have left a legacy characterised by high incidence rates of the disease. TB is a disease associated with poverty, and the problem of TB Control is wider than the technical issues associated with the management of the disease. Health care, to be effective in underpriviledged communities, must be combined with the process of social development. Thus the control of TB requires a dynamic approach involving socio-economic advancement to reduce the rate of infection and reactivation caused by the stresses of poverty, while concurrently strengthening the case detection and case-holding functions of the TB Control Programme.

These principles have been applied in an innovative primary health care (PHC) project recently implemented in a high TB prevalence area of the Western Cape. The project consisted of a comprehensive strategy to introduce community based health care onto the farms by training farm workers, selected by their communities, as community health workers (CHWs). The pilot project was evaluated by the Medical Research Council and the study illustrated that the introduction of trained CHWs significantly improved TB control on farms. The health promotion process, disseminated by the CHWs, appeared to enhance a positive cycle of social development amongst the under-priviledged community.[2]

The principles underpinning the pilot project were described as:

- a high level of community awareness
- ongoing good relationships with the formal health sector, tuberculosis patients, their families and the employers
- a supportive health promotion package
- advocacy amongst employer peer groups
- ongoing evaluation
- integrated health care

The health services are now keen to replicate the model more widely. They would like to ascertain whether the intervention will have a similar impact on TB case detection and patient adherence to anti-tuberculosis medication in the Wellington area. Non randomised evaluations over-estimate the benefits of the intervention through the selection of `promising`sites, so they have requested a more rigorous study design. An independent evaluation will be undertaken by the South African Network for Economic Research to assess the costs, savings and benefits of the intervention compared to existing practices.

Background and statement of the problem

Tuberculosis as a priority health problem

TB is a global emergency and responsible for a large burden of disease in Africa. South Africa notified 108 382 TB cases during 1998 with only 60% of the positive sputum smear patients

diagnosed in this cohort reported as cured at the end of their treatment period. The 18% treatment interruption rate is the main reason for the poor performance of the South African TB Control Programme. [3] Approximately 31% of this caseload emanates from the Western Cape despite relatively low rates of HIV infection and multi-drug resistant strains of TB in this Province. [4-6] The TB incidence worsens in selected rural areas of this Province; the agricultural area of Wellington reporting 1035 cases per 100 000 during 1998. (Personal communication with Sandra Theron, Acting-Head of Winelands District Health Council, March 1999.)

Adoption of the DOTS Strategy

South Africa adopted the revised directly observed therapy, short-course (DOTS) strategy in November 1996. Experts claim that successful implementation of the DOTS policy has the potential to reduce the incidence of tuberculosis by 8% per year. The success of DOTS depends upon 85% of smear positive TB patients being ´cured`. The patients are treated on standardised drug regimens with close adherence to the protocols of assessing sputum conversion at 2-3 months and at the end of treatment. All drugs are issued free to the patient and a regular supply of drugs is maintained. A TB register is kept at the health centre to audit the the effects of the TB Control Programme. Each patient is treated on a directly observed therapy (DOT) basis, with supervisors being health providers, the employer or a family member. The cure of a TB patient depends upon the concientious adherence to the prescribed anti-tuberculosis therapy.[7, 8]

The problem of non-adherence to anti-tuberculosis treatment

The problem of patient non-adherence to treatment has been well researched.[9,10] Successful interventions include multi-faceted strategies which increase the quality of patient-health provider interaction, improve the convenience of TB care and provide psycho-social support to the patient. These patient-centred strategies are difficult to implement in the current era of cost containment in the South African health care.

Since the political dispensation in 1994, South Africa has been in a process of radical social, economic and political reform. While faced with the challenge of implementing a comprehensive district system, health administrators are frequently unable to focus on the specialised aspects of TB Control.[11,12]

The development of effective DOTS programmes in high TB prevalence areas is labour-intensive and becomes expensive in rural, sparsely populated areas. The systematic withdrawal of health care resources during the process of restructuring the health system is having a negative impact on the quality of the delivery of care in many agricultural areas. Farms which were previously visited fortnightly by PHC mobile clinics have had these services reduced so that farm workers now have to walk up to five kilometers to attend a PHC facility.

The intervention is designed to introduce PHC trained CHWs onto the farms in order to counter the effects of the withdrawal of services. The CHWs will initally focus on tasks associated with TB case detection and case-holding, but will also be encouraged to develop wider skills in providing PHC. The CHW training process will be tailored to the needs of the participants and will emphasise issues leading to improved self efficacy and gender empowerment.

Study aim

To assess the effectiveness of a community health worker programme designed to focus on primary health care in improving the case detection and case-holding rates of tuberculosis in an agricultural setting.

Main objectives

- To perform a systematic review, in collaboration with the South African Cochrane Collaboration, of the evidence linking the effectiveness of community health workers to improving TB treatment outcomes
- To design a two armed cluster randomised trial to test the relative effectiveness of community health workers in improving the case detection, case-holding and cure rates of tuberculosis in an agricultural setting of Wellington, South Africa
- To make recommendations to the National TB Control Programme and the Department of Agriculture based on the results regarding strategies to improve case detection, case-holding and cure rates of tuberculosis in an agricultural setting

Specific objectives

- To conduct a situational analysis to describe the current practices in TB management and case detection, case-holding and cure rates of tuberculosis patients in the Winelands area of the Western Cape, South Africa
- To collect data required for the sampling process
- To request permission from the community to conduct the study on the240 farms in theWinelands area
- To empower 120 farm communities to select, appoint and manage peers as community health workers
- To equip the staff members of the Formal Health Sector with the skills required to develop, implement and maintain a community health worker (CHW) programme
- To train selected community health workers in tuberculosis and primary health care skills
- To facilitate and support the process of implementation of the strategy
- To monitor the community health worker adherence to the detailed tuberculosis case detection and case-holding strategies
- To evaluate the effectiveness of the community health worker strategy in tuberculosis case detection, case-holding and cure rates

Study setting

The study will be conducted in the Winelands Health District situated north west of the metropolitan area of Cape Town. The area is primarily an agricultural area consisting of farm units conducting vineculture and fruit orchards. Each farm employs between 20 to 50 permanent workers. Seasonal workers are recruited during harvest season from adjacent communities to work on specific farms. There is no movement of the pickers from farm to farm to harvest. Traditionally farm workers live in closed micro-communities on the farms on which they are employed. The farm workers access to health care is limited by their social and economic dependence on their employers. The major health problems of the farm workers in the area of Wellington are tuberculosis, sexually transmitted diseases and substance abuse.

The intervention

The intervention is a comprehensive strategy to introduce community-based health care onto farms by training selected farm labourers as community health workers. The thrust of the intervention focuses on the early detection and treatment of tuberculosis, but the long-term plan involves a more general promotion of health of farm workers.

In each of the participating farms the community health nurse arranges a meeting with the farm workers in which the extent of the tuberculosis problem, the pathophysiology and treatment of the disease is explained. The aims of of the proposed intervention are explained to each group of farm workers. A volunteer is then selected by the farm worker community to be trained as a CHW.

The primary function of the CHWs is to weigh and sceen the farm workers each month for clinical features suggestive of tuberculosis. The results are routinely documented, and all those with suspected disease are referred to the nearby primary health care clinic for further diagnostic tests. The CHWs provide an extra resource for administrating anti-tuberculosis medication to notified TB patients on a directly observed therapy (DOT) basis.The CHW proved in the pilot study to be an important communication link between the farm workers, the employers and the health services.

The project intervention team

Project co-ordinator

A professional nurse will be seconded from the Winelands District Health Council for 18 months to act as the co-ordinator of the project. The function of the co-ordinator is to lead the project through all phases of the implementation and to provide a link between the role-players such as the employers, the CHWs, the trainer, the farming community and the research team.

Project trainer

A health advisor from the Winelands District Health Council will be seconded for 18 months to train, support and supervise the CHWs.

The training programme

Participation in the project requires the employer to provide the farm worker selected to receive training to attend an on-going training programme. The educational needs of the CHWs are assessed by the trainer. The training programme covers technical areas such as the management of TB, HIV/AIDS infection in the community, the principles of growth monitoring, oral rehydration, breast feeding, immunisation, female education, family spacing and food supplementation. Psycho-social aspects such as the role of the woman in the family and the development of positive self esteem are important parts of the training programme. A handbook reinforcing the educational material is given to each CHW. The training programme is continuously evaluated for relevance and trainee comprehension after each training session. The CHWs are given support and supervision while developing skills in the field.

Design of the intervention study

This study will be a unblinded two-group cluster randomised controlled trial with before and after data on TB case detection and patient outcomes in 103 farm units.

Unblinded 2-group cluster randomised controlled trial

Baseline study
To determine the size and type of farms (240) in area

Request permission to conduct study on farms
Exclude farms which refuse permission
Collect baseline data from health services

Farms randomised into different arms of the trial

Intervention	Control
120 farms	120 farms

Data collection from

- TB Register
- Laboratory register
- Patient folders
- CHW record cards
- Qualitative in-depth interviews with stakeholders

Analysis
Outcome variables

Outcomes
Case-finding
Adherence to treatment
Cure rates
Process outcomes

Final analysis

Recruitment and stratisfication of farms
In order to decide on the final randomisation of the farm units, the following baseline data will be considered:
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