

Experiences and perceptions of lay counsellors and people with tuberculosis of a programme aimed at reducing alcohol drinking and tobacco smoking in South Africa

Submission date 14/12/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 03/01/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/04/2022	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Tobacco smoking and excessive alcohol use are harmful to one's health, even more so for patients who have tuberculosis (further abbreviated as TB). If patients with TB continue to smoke during their treatment, drink too much alcohol or forget to take their treatment, they may not recover from TB. The ProLife study aims to test how best to get TB patients to stop smoking, reduce harmful or hazardous drinking and be adherent to their treatment (TB and/or HIV-treatment as applicable).

Who can participate?

Adult patients with lung tuberculosis who smoke tobacco or drink alcohol to a harmful or hazardous extent, will be enrolled at 9 clinics in 3 districts in South Africa over the course of 3.5 months.

What does the study involve?

The intervention will comprise three brief motivational interviewing (MI) sessions augmented with a Short-Message Service (SMS) programme, targeting as appropriate: tobacco smoking, harmful or hazardous drinking and medication adherence. Patients will receive SMS-messages twice a week. We will measure how many participants we can recruit in that time period and how many participants remain in the study. We will also study how well the lay counsellors apply the required counselling techniques. At the end of the programme, we will ask the lay counsellors and patients what they liked or disliked about the programme.

What are the possible benefits and risks of participating?

The counselling sessions and SMS messages may help you to quit smoking or reduce alcohol consumption and help you to take your medication better. This will help you to heal from your TB.

You may feel a bit uncomfortable disclosing personal issues relating to tobacco smoking or alcohol use or problems with taking your medication. However, we are here to help you to

address any problem you may have with regards to those issues and we stress that all information will be kept confidential.

Where is the study run from?
Medical Research Council of South Africa

When is the study starting and how long is it expected to run for?
May 2016 to July 2017

Who is funding the study?
Newton Fund (UK)
Medical Research Council (UK)

Who is the main contact?
Prof Goedele Louwagie, goedele.louwagie@up.ac.za
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Addressing tobacco smoking and drinking to improve TB treatment outcomes, in South Africa: a feasibility study of the 'ProLife' programme

Acronym

ProLife

Study objectives

We tested the feasibility of the ProLife intervention - consisting of a combination of 3 Motivational Interviewing (MI) Sessions combined with Short Message Service (SMS) messages aimed at reducing tobacco smoking or alcohol drinking and improving adherence in a group of tuberculosis (TB) patients who smoked tobacco or drank alcohol in harmful or hazardous amounts, in South Africa. The study aimed to provide answers to the following questions:

1. What are the enrolment and follow-up rates of TB patients in this study?
2. What is the fidelity to MI sessions and the proficiency of Lay Health Workers (LHWs) in facilitating the MI sessions?
3. What are the experiences of TB patients and LHWs with the interventions?

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 21/04/2016, The University of Pretoria (31 Bophelo Road, HW Snyman South Building, Level 2, Room 2.33, Gezina, Pretoria, South Africa; +27 123541677; deepeka.behari@up.ac.za), ref: 119/2016
2. Approved 06/05/2021, The University of the Witwatersrand (Research Office, Faculty of Health Sciences, University of the Witwatersrand, Phillip Tobias Building, Offices 301-304, 3rd Floor, Cnr York Road and 29 Princess of Wales Terrace, Parktown, 2193, South Africa; +27 11 717 1252; Rhulani.Mkansi@wits.ac.za), ref: MI60455
3. Approved 02/06/2016, The University of the Free State (PO Box 227, Bloemfotein, South Africa; +27 51 405 2812; ghpdhbh@ufs.ac.za), ref: HSREC-71/2016
4. Approved 29/06/2016, The South African Medical Research Council (Francie Van Zijl Drive, Parowallei, 7505, Cape Town, Po Box 19070, Tygerberg, 7505, South Africa; +27 (0)21 938 0687; adri.labuschagne@mrc.ac.za), ref: EC010-4/2016

Study design

Interventional mixed methods feasibility study

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Reduction of alcohol and tobacco smoking and improving adherence in patients with tuberculosis

Interventions

3 Motivational Interviewing sessions and 10 adherence, 7 tobacco smoking and/or 7 alcohol related SMS-messages

Participants will receive three counselling sessions of about 20 minutes' duration - each one month apart- from a trained counsellor at the TB clinic. Participants will also receive Short Messages (SMS) via cell phone with helpful information. These messages will be sent to participants twice a week for 3 months.

After the final counselling session, participants will also be asked a few short questions about what they liked and disliked about the counselling sessions and the SMS messages

Intervention Type

Behavioural

Primary outcome(s)

Recruitment and retention rates measured at the end of the 3rd MI session (approximately at 2 months follow-up) using patient records

Key secondary outcome(s)

1. LHWs' experiences and perceptions using semi-structured interviews at the end of the 3rd MI session
2. TB patients experiences and perceptions using semi-structured questionnaires at the end of the 3rd MI session
3. MI fidelity using recorded MI sessions measured at the end of study by expert review

Completion date

30/07/2017

Eligibility

Key inclusion criteria

1. Adults who were due to start TB treatment, or who had been on treatment for less than one month for the current TB episode for bacteriologically or clinically confirmed drug sensitive pulmonary TB (PTB)
2. Current smokers, defined as having smoked any tobacco in the past month or hazardous or harmful drinkers (Alcohol Use Disorders Identification Test [AUDIT] score ≥ 8 for men or ≥ 7 for women and < 16 for hazardous drinking and between 16 and 19 for harmful drinking).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

45

Key exclusion criteria

1. Did not possess a functioning cell phone
2. Too ill to be interviewed
3. Did not speak any of the languages used in the exit questionnaires (English, Isizulu, Sesotho, and Setswana)

Date of first enrolment

15/11/2016

Date of final enrolment

30/03/2017

Locations**Countries of recruitment**

South Africa

Study participating centre**Hani Park Clinic**

Stand 31367

Matjhabeng Local Municipality

Free State

Welkom

South Africa

9459

Study participating centre**OR Tambo clinic**

12605 Leratsong Virginia,

Lejweleputswa District Municipality

Free State

Virginia

South Africa

9431

Study participating centre
K Maile clinic
65-64 Mpumalanga Section
Bothaville
South Africa
9660

Study participating centre
Mpumelelo clinic
1836 Rabotapi
Evaton
South Africa
1984

Study participating centre
Zone 3 clinic
Sebokeng Unit 3
Sebokeng
South Africa
1984

Study participating centre
Zone 14 clinic
Sebokeng Unit 14
Sebokeng
South Africa
1983

Study participating centre
Sunrise clinic
Boitekong, 25°38'00.6"S 27°16'42.2"E
Rustenburg
South Africa
0300

Study participating centre
Boitekong CHC
234 Monareng Street
Boitekong

Rustenburg
South Africa
0300

Study participating centre

Thekwane clinic

Thekwane 1723 Mablane Street
Tlhabane
Rustenburg
South Africa
0335

Sponsor information

Organisation

Medical Research Council of South Africa

Funder(s)

Funder type

Government

Funder Name

Newton Fund

Alternative Name(s)

The Newton Fund, NF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. goedele@louwagie.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/12/2020	12/04/2022	Yes	No
Other files	Fieldworkers Training Manual		16/12/2021	No	No
Protocol file	version 9		16/12/2021	No	No