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	Recruitment status No longer recruiting	Prospectively registered		
14/12/2021		[X] Protocol		
Registration date 03/01/2022	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 12/04/2022	Condition category Other	[] 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?

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Contact information

Type(s)

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

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 Witswatersrand (Research Office, Faculty of Health Sciences, University of the Witswatersrand, 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; qhpdbbh@ufs.ac.za), ref: HSREC-71/2016
- 4. Approved 29/06/2016, The South African Medical Research Council (Francie Van Zijl Drive, Parowvallei, 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, 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 9		16/12/2021	No	No