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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	[_] Prospectively registered [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?
Prof Goedele Louwagie, goedele.louwagie@up.ac.za
Prof Olalekan Ayo-Yusuf, lekan.ayo-yusuf@smu.ac.za

Contact information

Type(s)
Scientific

Contact name
Prof Goedele Louwagie

ORCID ID
http://orcid.org/0000-0002-4384-2318

Contact details
Ganzendries, 106
Gent
Belgium
9000
+32 93115063
goedele.louwagie@up.ac.za

Type(s)
Scientific

Contact name
Prof Olalekan Ayo-Yusuf

Contact details
Sefako Makgatho Health Sciences University
P.O.Box 222
Medunsa, Tshwane
South Africa
0204
+ 27 12 521 4611
lekan.ayo-yusuf@smu.ac.za

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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; ghpdbbh@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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
See additional files

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

Secondary outcome measures
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

Overall study start date
01/05/2016

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

Age group
Adult

Sex
Both

Target number of participants
45

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

Sponsor details
PO Box 19070
Tygerberg
South Africa
7505
+27 21 938 0911
info@mrc.ac.za

Sponsor type
Research council

Website
https://www.samrc.ac.za

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

Publication and dissemination plan
Publication in a high impact journal, Tranlational Behavioural Medicine

Intention to publish date
31/12/2018

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?
Other files	Fieldworkers Training Manual		16/12/2021	No	No
Protocol file	version 9		16/12/2021	No	No
Results article		31/12/2020	12/04/2022	Yes	No