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Improving TB outcomes by modifying life-style behaviours through a behavioural intervention comprising motivational interviewing counselling strategy augmented with subsequent short text messaging

Submission date
23/02/2018

Recruitment status
No longer recruiting

Registration date
13/04/2018

Overall study status
Completed

Last Edited
09/07/2024

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tuberculosis (TB) is an infectious disease caused by a bacterium that spreads from person-to-person. However, compared to the general population, people who smoke tobacco and drink excess amounts of alcohol are more likely to catch TB and die from it. Furthermore, they are also less likely to take their TB and HIV (if co-infected) medicines, leading to treatment failure and death. Unfortunately, alcohol use and/or tobacco smoking are common among TB patients in South Africa. Therefore, addressing these major risk factors should be a key priority in TB treatment.
This study aims to develop and test a new approach, called the PROLIFE model, to change these behaviours and medication adherence in TB patients.

Who can participate?
Adults aged 18 years or older with drug-sensitive pulmonary TB (PTB) who are smokers or hazardous/harmful drinkers

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the PROLIFE package. This consists of three counselling sessions covering medication adherence, smoking and drinking alcohol, in addition to usual TB care. The individual counselling sessions are re-enforced with short text message reminders regarding information supporting tobacco cessation, alcohol use and treatment adherence. Text messages are delivered twice a week over 12 weeks.
Participants in the second group receive usual care. They are seen by a TB nurse and receive the same medical investigations and treatment as those in the first group. This includes HIV testing with pre- and post-test counselling by a nurse or lay counsellor. Participants in this group do not receive the additional counselling and text messages.

What are the possible benefits and risks of participating?
Whilst there are no guaranteed benefits, participants may benefit from reduced tobacco smoking, reduced alcohol consumption and improved medication use (if appropriate). These factors may resultantly improve their recovery from TB.
There are no direct risks to participating in the study, however those in the intervention group attend follow up sessions which take up some time.

Where is the study run from?
Primary care clinics in the following areas:
1. Sedibeng district, Guteng province (South Africa)
2. Lejweleputswa district, Free State province (South Africa)
3. Bojanala district, North West province (South Africa)

When is the study starting and how long is it expected to run for?
May 2015 to August 2020

Who is funding the study?
South African Medical Research Council (South Africa)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
SMUREC/D/234/2017:IR

Study information

Scientific Title
ImPROving TB outcomes by modifying LIFE-style behaviours through a brief motivational intervention followed by short text messages: a randomised controlled trial

Acronym
PROLIFE

Study objectives
The PROLIFE package comprising motivational interviewing (MI) counselling and short text messaging is more effective and cost-effective than usual care in improving TB outcomes and modifying tobacco smoking, hazardous or harmful drinking and medication adherence among TB patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Sefako Makgatho Health Sciences University, 07/09/2017, ref: SMUREC/D/234/2017:IR
2. University of Pretoria, 28/09/2017, ref: 434/2017
3. University of Free State, 27/09/2017, ref: HREC 71/2016
4. Health Sciences Research Governance Committee University of York, 15/01/2018, no ref number given
5. University of Witwatersrand, 08/11/2017, ref: M160455

Study design
Multi-centre open-label two-arm parallel individual randomised controlled superiority trial with concurrent economic evaluation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tuberculosis

Interventions
Participants are randomised (stratified by clinic) using a randomised sequence generator performed by the trial statistician to one of two groups.
Those in the first group receive the PROLIFE package - three motivational interviewing (MI) counselling sessions, each one month apart, from a trained lay counsellor at their TB clinic. Each MI counselling session is expected to last not more than 20 minutes.
In the initial MI session at the start of TB treatment the counsellor establishes the participant's tobacco smoking, problem drinking and other potential obstacles and facilitators for treatment adherence or initiation (both TB and ART treatment) are determined. This first session is concluded with agenda setting for the problem identified by the participant as the most salient. This could be a plan either to quit tobacco smoking, reduce or quit drinking or deal with other

perceived obstacles relating to ART or TB treatment. As all TB patients are eligible for ART, for participants who are HIV-infected and not yet on ART, beliefs and attitudes regarding HIV-testing or ART are explored to facilitate ART initiation and adherence. The second session builds on the previous one and deal with challenges relating to the previous agenda setting, but then moves on to the next behavioural problem (T, A or TA) where applicable. The third session deals with the last identified problem.
The individual counselling sessions are re-enforced with short text message reminders regarding information supporting tobacco cessation, alcohol use and treatment adherence. Text messages are delivered twice a week over 12 weeks and pre-tested as outlined above. All participants first receive 10 TB-related messages. These messages are followed by seven alcohol or smoking-related messages depending on whether the participant smokes or drinks. Co-joint users receive all sets of messages (i.e. 24 in total).

Participants in the second group are the control and receive usual treatment, counselling and support offered to TB patients. Participants are seen by a TB nurse and receive the same biochemical investigations and medical treatments as the intervention arm. They do not receive the MI and short text message package of care as described above. The usual care consists of HIV testing with pre-and post-test counselling by a lay counsellor or a nurse (varies by district). Health education is given on:
• TB: nature of TB, treatment adherence (including DOTs), treatment side-effects / complications, drug interactions (especially ARVs), tobacco use, alcohol use and other substance abuse. This is mostly done by the TB nurses as part of usual care and is not intense – more of education than counselling.
• Healthy diet by a Dietician where possible
• Social problems and family support for treatment by a Social worker as needed and depending on the availability of social workers.
• Point of care blood glucose, Hb and pregnancy test are done. If co-infected with HIV, full blood count, liver function test and Creatinine are also done.

Changes made in response to the Covid-19 pandemic (added 17/06/2020):
We changed 6 month CRF from in-person questionnaires to shorter telephonic interviews as a result of the Covid-19 pandemic. All outstanding 6-month follow-up participant interviews were done telephonically in lieu of in person. For this purpose, the questionnaires were shortened to the questions essential for the determination of the study outcomes, namely the secondary outcomes on tobacco cessation, reduced alcohol use AUDIT scores and increased treatment adherence.
These telephonic interviews have now been completed and data collection was closed on 30 April 2020. The primary outcome, TB treatment outcomes, however, had to be obtained from TB records. This was no longer possible as the data collectors were no longer allowed to visit clinics. Because we had already obtained 83% of TB outcomes by the time of the lockdown, the decision was taken to consider the TB outcome data collection complete and this data collection was also closed on 30 April 2020.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 15/10/2021:
TB treatment success rate measured according to treatment outcomes defined by the WHO and adopted in South Africa, at 6 to 9 months

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Previous primary outcome measure:
TB treatment success rate measured according to treatment outcomes defined by the WHO and adopted in South Africa, at 6 months

Key secondary outcome(s))

Current secondary outcome measures as of 15/10/2021:
1. Cure rates (determined by TB nurse by negative culture or smears at the end of treatment) in the group of participants who had bacteriology confirmed PTB at baseline
2. Sustained smoking abstinence measured using a self-report of not smoking more than 5 cigarettes from the start of the abstinence period, supported by a negative biochemical test (exhaled Carbon Monoxide <7) at 3 and 6 months
3. Reduction in harmful or hazardous drinking measured using the AUDIT questionnaire administered at baseline, 3 and 6 months
4. TB medication and ART adherence are measured using a modified version of the AIDS Clinical Trials Group (ACTG) Adherence Questionnaire (to include TB medication adherence) administered by field workers at baseline, at 3 and 6 months
5. Proportion of HIV-positive participants on ART recorded as per the TB Treatment Record at 3 and 6 months. HIV positive participants will be asked about ART status at baseline, 3 months and 6 months using standardized questions on the CRF.

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Previous secondary outcome measures:
1. Sputum conversion measured by negative culture or smears in the group of participants who had bacteriology confirmed PTB at baseline at the end of treatment
2. Sustained smoking abstinence measured using a self-report of not smoking more than 5 cigarettes from the start of the abstinence period, supported by a negative biochemical test (exhaled Carbon Monoxide <7) at 3 and 6 months
3. Reduction in harmful or hazardous drinking measured using the AUDIT questionnaire administered at baseline, 3 and 6 months
4. TB medication and ART adherence are measured using a modified version of the AIDS Clinical Trials Group (ACTG) Adherence Questionnaire (to include TB medication adherence) administered by field workers at baseline, 3 and 6 months
5. Proportion of HIV-positive participants on ART recorded as per the TB Treatment Record at baseline, 3 and 6 months. HIV positive participants will be asked about ART status at baseline, 3 months and 6 months using standardized questions on the CRF

Completion date

31/08/2020

Eligibility

Key inclusion criteria

1. Adult patients (18 years or older) with drug-sensitive pulmonary TB (PTB)
2. Current smokers OR hazardous/harmful drinkers who are not alcohol dependent (AUDIT score ≥ 8 for men or ≥ 7 for women but <20)
3. Initiating TB treatment or on current TB treatment for less than 1 month (these include both “new” and “retreatment patients”)
4. Access to a functional cellphone
5. Understands one of the 4 languages used for the trial (Sesotho, Setswana, Zulu or English)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
574

Key exclusion criteria
1. On TB treatment for more than one month
2. Alcohol dependent participants (AUDIT score more than or equal to 20) provided they are non-smokers
3. Extrapulmonary tuberculosis provided they don't also have pulmonary tuberculosis
4. Drug resistance to one or more TB drugs at baseline.

Date of first enrolment
12/11/2018

Date of final enrolment
31/08/2019

Locations

Countries of recruitment
South Africa

Study participating centre
Primary care clinics in Sedibeng district, Gauteng province
South Africa
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Study participating centre
Primary care clinics in Lejweleputswa district in the Free State province
South Africa
0001

Study participating centre
Primary care clinics in Bojanala district in the North West province
South Africa
0001

Sponsor information

Organisation
South African Medical Research Council

ROR
https://ror.org/05q60vz69

Funder(s)

Funder type
Research council

Funder Name
South African Medical Research Council

Alternative Name(s)
The South African Medical Research Council, The SAMRC, SAMRC

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
South Africa

Results and Publications

Individual participant data (IPD) sharing plan
Current Individual participant data (IPD) sharing statement as of 23/11/2021:

The study protocol was previously published (ImPROving TB outcomes by modifying LIFE-style behaviours through a brief motivational intervention followed by short text messages (ProLife):

study protocol for a randomised controlled trial). The de-identified participant and SMS data sets are stored in labelled Stata files and are accompanied by a statistical analysis plan and metadata explaining each variable. Although data can be viewed immediately, data will be embargoed for data analysis until 30 June 2023. Thereafter, permission must be obtained from the principal investigators (OA and KS) for any data analysis not yet performed by the primary research group. Data are stored in the institutional data repository at Sefako Makgatho Health Sciences University called Discover research (https://smu-za.figshare.com/) with a CC-BY 4.0 (Attribution) license (Creative Commons — Attribution 4.0 International — CC BY 4.0). The study protocol and statistical analysis plan are available as supplementary material.

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Previous Individual participant data (IPD) sharing statement:

The study protocol was previously published (see trial outputs). The de-identified questionnaire and SMS data sets are stored in labelled Stata files and are accompanied by a statistical analysis plan and metadata explaining each variable. Data access will be embargoed until 30/06/2023. Data are stored in the institutional data repository at Sefako Makgatho Health Sciences University called Discover research (https://smu-za.figshare.com/) with a CC-BY 4.0 (Attribution) license (Creative Commons — Attribution 4.0 International — CC BY 4.0). The data will have an embargo for additional analysis.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/02/2022	21/06/2022	Yes	No
Protocol article	protocol	26/07/2019	30/07/2019	Yes	No
Statistical Analysis Plan	version 1.2	25/10/2020	09/07/2024	No	No