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Counseling to improve adherence to the taking of medications for tuberculosis in Bali, Indonesia

Submission date
12/12/2020

Recruitment status
No longer recruiting

Registration date
21/12/2020

Overall study status
Completed

Last Edited
16/02/2022

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Tuberculosis (TB) is a bacterial infection spread through inhaling tiny droplets from the coughs or sneezes of an infected person. It mainly affects the lungs, but it can affect any part of the body, including the tummy (abdomen), glands, bones and nervous system. TB is a potentially serious condition, but it can be cured if it's treated with the right antibiotics.
Medication adherence refers to whether patients take their medications as prescribed (eg, twice daily), as well as whether they continue to take a prescribed medication.
Motivational interviewing is a counselling method that involves enhancing a patient's motivation to change.
This study aims to use motivational interviewing to improve medication adherence in patients with tuberculosis.

Who can participate?
Patients aged 18 - 65 years with tuberculosis.

What does the study involve?
Participants will receive drug treatment for TB as usual. They will also be randomly allocated to receive motivational interviewing or conventional counseling. Their sputum (coughed-up mucus) will be tested for TB bacteria to assess whether the drug treatment has worked and the number of pills taken will be counted to assess whether they have taken the treatment as prescribed. Participants will be interviewed after the end of treatment to gather their views on the counseling they received and why they took the treatment as prescribed or not.

What are the possible benefits and risks of participating?
Benefits of taking part are the possibility of improving treatment by taking medicines correctly. This research procedure poses a very low (negligible) risk of discomfort during the interview and time loss during the interview.

Where is the study run from?
Udayana University (Indonesia)

When is the study starting and how long is it expected to run for?
October 2020 to September 2021 (updated 15/06/2021, previously: August 2021 (updated 24/02/2021, previously: April 2021))

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Ni Made Parwati, parwati.md@gmail.com

Contact information

Type(s)
Public

Contact name
Mrs Ni Made Parwati

ORCID ID
http://orcid.org/0000-0002-5216-1434

Contact details
Gatot Subroto Street Vic/4
Denpasar
Indonesia
80231
+62 81246767538
parwati.md@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MI/HBM/2020

Study information

Scientific Title
Motivational Interviewing Based on the Health Belief Model: Improving Medication Adherence and Treatment Success of Patients with Pulmonary Tuberculosis

Acronym

MIBHBM

Study objectives
1. Increasing compliance with tuberculosis patients with motivational interviewing based on the Health Belief Model is better than conventional motivation
2. The improvement of treatment success for pulmonary tuberculosis patients with motivational interviewing based on Health Belief Models is better than conventional motivation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/10/2020, Ethics Research Commission, Faculty of Medicine, Udayana University /Public Hospital, Sanglah Center, Denpasar, 80114, Bali, Indonesia; +62 (0)361 227911-15; no email provided), ref: 2006/UN14.2.2.V11.1 4/LT/2020

Study design
Mixed methods interventional randomized controlled trial with qualitative case series

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Medication adherence and treatment success in patients with tuberculosis

Interventions
A total of 38 health centers was randomly selected and allocated to the intervention (n = 19) and the control group (n = 19) by generating random numbers using a computer program. The number of samples in each community health center is proportionally adjusted according to the target.

The research methodology was a mixed-methods design with the sequential explanatory design which consisted of two stages, namely quantitative (experimental design with randomized post-test only control group design) followed by qualitative (case study) where the two research approaches were carried out sequentially, starting with quantitative research and explained with qualitative research.

The study was conducted on tuberculosis patients who received anti-tuberculosis drug treatment according to WHO standards. The treatment in each group with tuberculosis treatment was category 1 anti-tuberculosis drugs based on the treatment program and was given in two stages:
1. In the intensive phase, the duration of treatment was 2 months with the following drugs taken daily: isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E)
2. In the advanced phase drug treatment lasted 4 months, with the following drugs taken three times weekly: isoniazid (H) and rifampicin (R)

The counselling intervention was a maximum of eight sessions over 2 months to increase medication adherence and successful treatment of pulmonary tuberculosis patients. There were two groups consisting of a treatment group that received a Motivational Interview intervention based on the Health Belief Model theory and a control group that was given conventional motivation treatment.

The follow-up in each group or arm was carried out in three stages, namely after the 2-month intervention was completed in each group. In the second month of treatment, treatment adherence was determined by pill count and success of treatment was determined using sputum examination. At the fifth month of treatment, success of treatment was determined using sputum examination. At 6 months, adherence was evaluated by counting pills and success of treatment was determined using sputum examination. The follow-up data on adherence and treatment success were collected by the enumerator through an online questionnaire so that the data were reported automatically.

Pill percentage was calculated from the ratio between the number of drugs consumed and the number of drugs that should be consumed x100%. If there was overuse (calculation result >100%), then the patient adherence percentage was calculated from the ratio between the difference between the amount of drug consumed minus the amount of excess drug consumed and the amount of drug that should be consumed x100%. From the calculation results, there will be two categories, namely if the calculation result is <80%, it is categorized as non-adherence and if the calculation result is 80-100% is in the adherent category.

For the qualitative research, participants were selected using purposive sampling taken from a sample of the treatment group as well as health center officers as counselors. The selection of informants was based on the principles of appropriateness and adequacy, meaning that informants are selected based on conformity with the research topic and the number of informants is considered sufficient if the data obtained is declared to have reached saturation point.

Qualitative data were collected by semi-structured interviews by telephone or video call performed 3-4 weeks after treatment completion. This included an interview with counselors to obtain information about the obstacles faced during the counseling process and the effectiveness of counseling. Interviews were also conducted with patients who were not adherent in taking medication and did not succeed in treatment in the treatment group after being given counseling to explain the reasons for non-adherence and treatment failure.

The process of data analysis using thematic data analysis is the identification of several patterned themes, with the first stage of collecting data and making transcripts of data from interviews. The researcher listened to the results of the in-depth interviews repeatedly and transferred them to verbatim which was then combined with field notes. The transcript is read repeatedly and compared back with the recording results to ensure its accuracy. Informant statements are coded and grouped according to the themes that have been determined

according to the interview guide guidelines and an explanation of the theme description is made and analyzed based on the theme. The researchers can then interpret the information, making a detailed analysisof contents of the theme.

Intervention Type
Behavioural

Primary outcome measure
1. Medication adherence measured using pill counts in the second, fifth and sixth months of treatment
2. Treatment success based on sputum examination data in the second, fifth and sixth months of treatment

Secondary outcome measures
1. Barriers to counseling efficacy identified using interviews with participants at 3-4 weeks after completion of the 6-month treatment
2. Reasons for non-adherence or treatment failure identified using interviews with participants at 3-4 weeks after completion of the 6-month treatment

Overall study start date
15/10/2020

Completion date
30/09/2021

Eligibility

Key inclusion criteria
For the interventional trial:
1. New patients who are diagnosed with early pulmonary TB based on records registered with TB in the health center and have never received OAT
2. Patients diagnosed with pulmonary tuberculosis, the treatment has not yet passed the two-month treatment period (intensive phase), seen from the records in the public health center TB register
3. Based on the register, the patient was diagnosed with pulmonary TB through a bacteriological examination (positive smear) using the Molecular Rapid Test (TCM)
4. Adult patients aged 18 - 65 years

For qualitative data collection:
1. Patients who have received HBM-based MI intervention
1.1. Non-compliance with taking medication
1.2. Failure in treatment
1.3. Able to communicate well and willing to be informants.
1.4. Own and be able to use a smartphone
1.5. Willing to be interviewed using online media via telephone/video call for approximately 30 minutes
2. Officer/counsellor
2.1. Easy contact to communicate
2.2. Own and be able to use a smartphone

2.3. Able to communicate well and willing to be informants
2.4. Willing to be interviewed using online media via telephone/video call for approximately 30 minutes

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The total target was 214 pulmonary tuberculosis patients

Total final enrolment
214

Key exclusion criteria
For interventional trial:
1. MDR TB patients who are registered in the TB register
2. Have other comorbidities such as diabetes mellitus, cirrhosis of the liver, hepatitis; cardiovascular disease based on the doctor's examination on the TB register
3. Patients are not willing to follow Tuberculosis treatment until the advanced phase
4. Families of sufferers do not have/are unable to use a smartphone

Date of first enrolment
01/11/2020

Date of final enrolment
30/07/2021

Locations

Countries of recruitment
Indonesia

Study participating centre
Udayana University
Panglima Besar Sudirman Street
Denpasar
Bali
Indonesia
80234

Sponsor information

Organisation
Udayana University

Sponsor details
Panglima Besar
Sudirman street
Denpasar
Bali
Indonesia
80234
+62 (0)361 223797
info@unud.ac.id

Sponsor type
University/education

Website
http://www.unud.ac.id/eng/

ROR
https://ror.org/035qsg823

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/08/2021

Individual participant data (IPD) sharing plan
Data sharing plans for the study are currently unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/12/2021	16/02/2022	Yes	No