

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Gamified-Reality-Video-Observed-Therapy (GRVOTS) Mobile Apps Impact On Tuberculosis Treatment Adherence Among Working Age Population

Protocol summary

Study aim

This study's general objective is to develop GRVOTS mobile apps and assess its impact on TB treatment adherence among working-age populations.

Design

Single Arm Intervention Study

Settings and conduct

Health care facilities (Clinics and Hospital)

Participants/Inclusion and exclusion criteria

Inclusion 1-Ability to speak and read English or BM 2- Working-aged TB patients (18-64 years old) 3-Newly diagnosed with PTB (first-line treatment) 4-Has completed the in-person DOT at least two weeks (ensuring medications tolerance) (Garfein et.al., 2015) 5- Willing and able to provide informed consent 6- Knowledge in smartphone and apps usage Exclusion 1- Patients with drug-resistant TB 2-Patients with health conditions that disallow them to use smartphone (severe arthritis, vision impairment)3-Patients with no knowledge of smartphone usage

Intervention groups

Patient will be given GRVOTS mobile apps that enable them to virtually record their medication intake via Video Direct Observed Therapy (VDOTS) as a method to monitor their medication adherence daily instead of coming to the healthcare facilities to enable their drug intake being observed physically . Supervisor or the healthcare staff will received the VDOTS daily via the GRVOTS mobile apps and approved them. After 2 months of usage, we calculate the numbers of video sent and ask them to fill up the questionnaire to see their level of motivation and medication adherence

Main outcome variables

Numbers of video (VDOTS) received

General information

Reason for update

Acronym

GRVOTS

IRCT registration information

IRCT registration number: **IRCT20230308057657N1**
Registration date: **2023-03-15, 1401/12/24**
Registration timing: **retrospective**

Last update: **2023-03-15, 1401/12/24**

Update count: **0**

Registration date

2023-03-15, 1401/12/24

Registrant information

Name

Siti Aishah Abas

Name of organization / entity

Universiti Teknologi MARA

Country

Malaysia

Phone

+60 11-1931 4599

Email address

aishah.abas@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-31, 1401/11/11

Expected recruitment end date

2023-03-28, 1402/01/08

Actual recruitment start date

2023-01-31, 1401/11/11

Actual recruitment end date

2023-02-10, 1401/11/21

Trial completion date

2023-04-10, 1402/01/21

Scientific title

Gamified-Reality-Video-Observed-Therapy (GRVOTS)
Mobile Apps Impact On Tuberculosis Treatment

Public title

GRVOTS for Tuberculosis patient

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Ability to speak and read English or BM Working-aged TB patients (19-64 years old) Newly diagnosed with PTB (first-line treatment) Has completed the in-person DOT at least two weeks (ensuring medications tolerance) Willing and able to provide informed consent Knowledge in smartphone and apps usage

Exclusion criteria:

Patients with drug-resistant TB Patients with health conditions that disallow them to use a smartphone (severe arthritis, vision impairment) Patients with no knowledge of smartphone usage

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Actual sample size reached: **71**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Research Ethics Committee Universiti Teknologi Mara

Street address

47000 Sungai Buloh, Selangor, Malaysia

City

Sungai Buloh

Postal code

47000

Approval date

2021-07-23, 1400/05/01

Ethics committee reference number

REC/07/2021(MR/595)

Health conditions studied

1

Description of health condition studied

Tuberculosis patient treatment adherence

ICD-10 code

A16.0

ICD-10 code description

Tuberculosis of lung, bacteriologically and histologically negative Tuberculous: bronchiectasis, fibrosis of lung, pneumonia, pneumothorax, bacteriologically and histologically negative

Primary outcomes

1

Description

Number of video received via the mobile apps (VDOTS)

Timepoint

Baseline (before intervention) and 4 and 8 weeks after intervention

Method of measurement

Number of video (VDOTS) received

2

Description

Medication Adherence Score

Timepoint

Baseline (before intervention) and 4 and 8 weeks after intervention

Method of measurement

My MAAT (Malaysian Medication Adherence Assessment Tools)

3

Description

Motivation Score

Timepoint

Baseline (before intervention) and 4 and 8 weeks after intervention

Method of measurement

Intrinsic Motivation Inventory (IMI Tools)

Secondary outcomes

empty

Intervention groups

1

Description

Patient will be given GRVOTS mobile apps that enable them to virtually record their medication intake via Video Direct Observed Therapy (VDOTS) as a method to

monitor their medication adherence daily instead of coming to the healthcare facilities to enable their drug intake being observed physically . Supervisor or the healthcare staff will received the VDOTS daily via the GRVOTS mobile apps and approved them. After 2 months of usage, we calculate the numbers of video sent and ask them to fill up the questionnaire to see their level of motivation and medication adherence

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Malaysia Ministry of Health health facilities

Full name of responsible person

Siti Aishah Binti Abas

Street address

Jalan Nusari 4/4

City

Seremban

Postal code

70300

Phone

+60 11-1931 4599

Email

aishah.abas@gmail.com

Web page address

<https://www.uitm.edu.my/index.php/en/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

World Health Organization

Full name of responsible person

Nurhuda Ismail

Street address

47000 Sungai Buloh, Selangor, Malaysia

City

Sungai Buloh

Postal code

47000

Phone

+60 3-6126 7174

Fax

+60 3-6126 7234

Email

yuda@uitm.edu.my

Web page address

<https://www.uitm.edu.my/index.php/en/>

Grant name

Joint TDR/World Health Organization Western Pacific Region Small Grant Scheme for Implementation Research.

Grant code / Reference number

TR590324

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

World Health Organization

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Foreign

Category of foreign source of funding

UN agencies and international organizations

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Universiti Teknologi MARA

Full name of responsible person

Nurhuda Ismail

Position

Dr

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

Street address

47000 Sungai Buloh, Selangor, Malaysia

City

Sungai Buloh

Province

Selangor

Postal code

47000

Phone

36126500

Fax

+60 3-6126 7234

Email

yuda@uitm.edu.my

Web page address

<https://www.uitm.edu.my/index.php/en/>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Universiti Teknologi MARA

Full name of responsible person

Siti Aishah Abas

Position

Dr

Latest degree

Master

Other areas of specialty/work

Public Health/Community Medicine

Street address

Jalan Nusari 4/4, Nusari Aman2, Bdr Sri Sendayan

City

Seremban

Province

Negeri Sembilan

Postal code

70300

Phone

+60 11-1931 4599

Fax

Email

aishah.abas@gmail.com

Web page address

<https://www.uitm.edu.my/index.php/en/>

Person responsible for updating data

Contact

Name of organization / entity

Universiti Teknologi MARA

Full name of responsible person

Siti Aishah Abas

Position

Dr

Latest degree

Master

Other areas of specialty/work

Public Health/Community Medicine

Street address

Jalan Nusari 4/4, Nusari Aman2, Bdr Sri Sendayan

City

Seremban

Province

Negeri Sembilan

Postal code

70300

Phone

+60 11-1931 4599

Email

aishah.abas@gmail.com

Web page address

<https://www.uitm.edu.my/index.php/en/>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Published research report that contains all the findings of the study.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

people working in the academic area

Under which criteria data/document could be used

for scientific use

From where data/document is obtainable

scientific journal

What processes are involved for a request to access data/document

none

Comments

none