# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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

Adherence Among Working Age Population

**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 negativeTuberculous: 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 heath facilities
**Full name of responsible person**
Siti Aishah Binti Abas
**Street address**
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## 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
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**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
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Public Health/Community Medicine
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## Person responsible for updating data

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Public Health/Community Medicine

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## 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