

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The impact of the Applied Progressive Muscle Relaxation Training to the level of Depression, Anxiety, Stress and Quality of Life among Prostate Cancer Patients

#### Protocol summary

##### Summary

This is a quasi-experimental study to determine the impact of the applied progressive muscle relaxation training to the level of depression, anxiety, stress and quality of life among prostate cancer patients. The objective of this study are: i. To determine the impact of progressive deep muscle relaxation to the levels of depression, anxiety, stress and quality of life among cancer prostate patients. ii. to determine the pattern and characteristics in the study population iii. to determine the prevalence of the anxiety, stress and depression in the study population iv. to assess the quality of life among the study population v. to describe the differences of the quality of life between the depression, anxiety and stress status in the study population. vi. to determine the correlation between depression, anxiety and stress level among study population vii. to compare the quality of life of the metastases status among prostate cancer patients. The inclusion and exclusion criteria: Inclusion criteria i. Patients diagnosed with prostate cancer confirmed by the histology of prostate gland cell. ii. Patients with 50 years old and above. Exclusion criteria i. Patients who have been diagnosed any cancer other than prostate cancer ii. Patients who have been diagnosed with any psychiatric diagnosis iii. Patients who are currently use of psychiatric medication iv. Patients who are having prior training or current use of relaxation therapy v. Patients who have presence of physical limitations for learning Applied Progressive Muscle Relaxation Training (eg: bed-bound) vi. Patients who did not understand Bahasa Malaysia and English. The study population is prostate cancer patients. Sample size estimation : 154 (77 for the intervention group and 77 for the control group). Intervention under study : Applied progressive muscle relaxation training. The main outcome measure: the impact of the applied progressive muscle relaxation training to the level of depression,

anxiety, stress and quality of life among prostate cancer patients.

#### General information

##### Acronym

Applied Progressive Muscle Relaxation Training, Depression, Anxiety, Stress, Prostate Cancer

##### IRCT registration information

IRCT registration number: **IRCT201103176085N1**

Registration date: **2011-04-16, 1390/01/27**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2011-04-16, 1390/01/27

##### Registrant information

###### Name

Mohamad Rodi Isa

###### Name of organization / entity

University of Malaya

###### Country

Malaysia

###### Phone

0060379674756

###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Postgraduate Research Fund (PRF), Unit Pengurusan Geran Penyelidikan, Institut Pengurusan dan Pemantauan Penyelidikan, University of Malaya (Account number PS228/2010A).

##### Expected recruitment start date

2011-05-01, 1390/02/11  
**Expected recruitment end date**  
2012-04-30, 1391/02/11  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
The impact of the Applied Progressive Muscle Relaxation Training to the level of Depression, Anxiety, Stress and Quality of Life among Prostate Cancer Patients

**Public title**  
The impact of the Applied Progressive Muscle Relaxation Training to the level of Depression, Anxiety, Stress and Quality of Life among Prostate Cancer Patients

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
Inclusion criteria i. Patients diagnosed with prostate cancer confirmed by the histology of prostate gland cell. ii. Patients with 50 years old and above. Exclusion criteria i. Patients who have been diagnosed any cancer other than prostate cancer ii. Patients who have been diagnosed with any psychiatric diagnosis iii. Patients who are currently use of psychiatric medication iv. Patients who are having prior training or current use of relaxation therapy v. Patients who have presence of physical limitations for learning Progressive Muscle Relaxation Training (eg: bed-bound) vi. Patients who did not understand Bahasa Malaysia and English vii. Patients with no contact number

**Age**  
From **50 years** old to **90 years** old

**Gender**  
Male

**Phase**  
0

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **154**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Other

**Other design features**  
Quasi-Experimental Study

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

University Malaya Medical Centre (UMMC) Medical Research Ethic Committee

##### Street address

University Malaya Medical Centre

##### City

Kuala Lumpur

##### Postal code

50603

##### Approval date

2010-04-23, 1389/02/03

##### Ethics committee reference number

MEC:781.10

## Health conditions studied

### 1

#### Description of health condition studied

prostate cancer patients

#### ICD-10 code

C61

#### ICD-10 code description

C61 Malignant neoplasm of prostate

## Primary outcomes

### 1

#### Description

The impact of Applied progressive muscle relaxation training to the level of depression, anxiety and stress

#### Timepoint

after 6 months from the first intervention

#### Method of measurement

Using DASS scale score

### 2

#### Description

The impact of the Applied Progressive muscle relaxation training to the level of quality of life

#### Timepoint

after 6 months from the first intervention

#### Method of measurement

SF-36 Quality of life questionnaire

## Secondary outcomes

### 1

#### Description

to determine the pattern and characteristics in the study population

#### Timepoint

at the baseline data collected

## **Method of measurement**

the socio-demographic, past medical and surgical illness, urological sign and symptoms and the status of the prostate cancer

## **2**

### **Description**

to assess the quality of life among the study population

### **Timepoint**

After the baseline data collected

### **Method of measurement**

SF-36 quality of life questionnaire

## **3**

### **Description**

to determine prevalence of depression, anxiety and stress among prostate cancer patient

### **Timepoint**

at the baseline data collected

### **Method of measurement**

by using DASS scale score

## **4**

### **Description**

to describe the differences of the quality of life between the depression, anxiety and stress status in the study population

### **Timepoint**

At the baseline data collected

### **Method of measurement**

DASS scale score and SF-36 Quality of life questionnaire

## **5**

### **Description**

to determine the correlation between depression, anxiety and stress level among study population

### **Timepoint**

At the baseline data collected

### **Method of measurement**

DASS scale score and SF-36 Quality of life Questionnaires

## **6**

### **Description**

to compare the quality of life of the metastases status among prostate cancer patients

### **Timepoint**

At the baseline data collected

### **Method of measurement**

SF-36 quality of life questionnaire

## **Intervention groups**

## **1**

### **Description**

Intervention group : The applied progressive muscle relaxation training (APMRT) therapy that is provided to

the intervention group included three 50-minute group education sessions over 6 weeks. The therapy is given at the rehabilitation clinic or at the patients' house if they are unable to go to the hospital during home visit. During the training, the patient is seated in a quiet room and asked to imitate the different exercises demonstrated by the investigator's presentations. Each patient is covered with a comfortable blanket and the room lights are then dimmed. Participants in the experimental group are advised to practice the applied relaxation regularly, and they kept daily home relaxation practice records during the study. The patients are refrained from smoking, strenuous physical exercise, eating and consuming caffeine for at least one hour prior to testing.

1 The first session: The first session of the training is an introductory group discussion of psychology issues and quality of life in prostate cancer, as well as a rationale and general description of the purpose of the relaxation. Each intervention patient is provided a written training manual of PMRT and PMRT picture guide in order to provide visual illustrations supplementing the therapist's demonstration for them to make it easier to understand the therapy.

2 The second session: The second session is related to teach the patients to do breathing technique in order to enhance more relaxation. The breathing technique took almost 10 minutes to get proper abdominal breathing properly (breathe in for 5 seconds and breathe out for 7 seconds). It is also to get more oxygen to muscle and tissues.

3 The third session: The third session related to relax with the help of a shortened version of progressive relaxation (tense for 5 seconds and relax for 10 seconds) in the 16 large muscle groups of the hands, arms, face, shoulders, back, chest, stomach, breathing, hips, legs, and feet. It also included "release-only" relaxation; this exercise deletes the tensing of the muscle groups to reduce the time it takes the client to become relaxed. It will take around 20 to 30 minutes to complete. The patients in turn demonstrated the relaxation technique using the audiocassette instruction with the instructor's voice (the audiocassette was provided by the Department of Psychological Medicine, Faculty of Medicine, University of Malaya).

4 The fourth session: The fourth session is related to end of the relaxation therapy. It took around 5 minutes to complete.

5 The final session: The final session is to start the applied PMRT from the breathing technique, the PMRT and the end of the relaxation therapy. All the session took around 40 to 50 minutes. At the end of the teaching session, the therapist discussed relaxation training with the patients to confirm that they had mastered the technique. To supplement the presentations and to provide a more effective program, the researchers used posters and provided participants with written material. A pamphlet included general information on depression, anxiety and stress as well as quality of life in prostate cancer. Patients will be given the audiocassette with the instruction home with them to practice APMRT twice daily throughout the study period. They are asked to record the relaxation practice on a practical log. The second therapy is held next two weeks later to reassess the patient's skill mastery and to discuss their concerns about the APMRT practice. The investigator initiates

biweekly telephone calls to encourage the patient's compliance and clarify related problem. The third therapy is given to the patients two weeks after the second therapy. The investigator made telephone calls biweekly to ensure the compliance of the patients to the therapy. After 4 months from the first therapy, the intervention group is asked to complete a questionnaire as the posttest (T1). After the posttest (T1), the intervention group is asked to do the relaxation therapy by their own by using the audiocassette and the script that have been given to them. The after 6 months from the first therapy, once again, the intervention group is asked to complete a questionnaire as the posttest (T2)

**Category**

Other

**2****Description**

Control group: The control in a quasi-experimental trial should not give any intervention. However, it was unethical to withhold information which could benefit the subjects. Therefore the control group is given information of about depression, anxiety and stress and minimal health promotion with the principle of better quality of life without having any psychological problem. Telephone calls made biweekly thereafter throughout the 6 months study period in order to avoid missing of follow up. After 4 months from the first interview, the control group is asked to complete a questionnaire as the posttest (T1). The after 6 months, once again, the control group is asked to complete a questionnaire as the posttest (T2).

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

University Malaya Medical Centre

**Full name of responsible person**

Mohamad Rodi bin Isa

**Street address**

Department of Social & Preventive Medicine, Faculty of Medicine

**City**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

University of Malaya

**Full name of responsible person**

Mohamad Rodi bin Isa

**Street address**

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Bangunan IPS, Universiti Malaya

**City**

Kuala Lumpur

**Grant name****Grant code / Reference number**

PS228/2010A

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

Yes

**Title of funding source**

University of Malaya

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Mohamad Rodi bin Isa

**Position**

Postgraduate student/ Doctorate degree

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## Person responsible for updating data

### Contact

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**Position**  
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**Other areas of specialty/work**  
**Street address**  
Department of Social & Preventive Medicine, Faculty  
of Medicine, University of Malaya  
**City**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

*empty*

### Study Protocol

*empty*

### Statistical Analysis Plan

*empty*

### Informed Consent Form

*empty*

### Clinical Study Report

*empty*

### Analytic Code

*empty*

### Data Dictionary

*empty*