Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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 muscel relaxation training. The main outcome measure: the impact of the applied progressive muscel 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

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Malaysia

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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 Progrressive 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, anxietyand stress

Timepoint

after 6 months from the first intervention

Method of measurement

Using DASS scale score

2

Description

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

Timepoint

after 6 months fro mthe 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 questionnnaire

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 sccale 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 iss given at the rehabilitation clinic or at the patients' house if they unable to go 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 is 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 rational and general description of the purpose of the relaxation. Each intervention patients is provided a written training manual of PMRT and PMRT picture guide is 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 relaxes. The breathing technique took almost 10 minutes to get proper abdominal breathing properly (breathe in for 5 seconds and breathe out for 7 second). 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 provides participants with written material. A pamphlet included general information on depression, anxiety and stress as well as quality of life in prostate cancer. Patient will giving 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 iss 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

Kuala Lumpur

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Malaya

Full name of responsible person

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Street address

Unit Pengurusan Geran Penyelidikan, Institut Pengurusan dan Pemantauan Penyelidikan, A205 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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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