Clinical Trial Protocol
Iranian Registry of Clinical Trials
04 Jul 2019

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: 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
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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.
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
None

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

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
**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 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 rational 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 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 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 is given to the patients two weeks after the second therapy. The investigator made telephone calls to encourage the patient's skill mastery and to discuss their concerns. 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. 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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 encourage 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).

The 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).

Recruitment centers

1

Recruitment center
Name of recruitment center
University Malaya Medical Centre
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Sponsors / Funding sources

1

Sponsor
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Unit Pengurusan Geran Penyelidikan, Institut Pengurusan dan Pemantauan Penyelidikan, A205 Bangunan IPS, Universiti Malaya
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Grant name
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
empty
Type of organization providing the funding
empty

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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