Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Investigation of the effects of Occupational Therapy's Interventions on Occupational Performance in advanced cancer patients at home during covid-19 crisis

Protocol summary

Study aim
The Investigation of the effects of Occupational Therapy's Interventions on Occupational Performance in advanced cancer patients at home during covid-19 crisis

Design
This study is an experimental randomized clinical trial and is single blind because the assessor is not aware of the patients in the intervention or control group. The method of work in this study is that two groups of clients including the control and intervention groups are examined.

Settings and conduct
Patients will be referred by oncologists, and those who meet the inclusion criteria will be sampled. After selecting the patients, according to the group in which the patient is located, presentation of interventions will be done at home.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age range of 18 to 65 years old having an acceptable level of cognitive function as a score of 21 or higher based on the Mini Mental Status Examination (MMSE) In at least one case the Katz questionnaire needs help Exclusion criteria: Recurrence of the disease leading to hospitalization. The purpose is to create conditions or receive new drugs that can lead to a change in the evaluated cases before starting treatment and thus a change in the results of the initial evaluation.

Intervention groups
The control group receives traditional occupational therapy interventions in palliative medicine. The intervention group of palliative medicine receives occupational therapy interventions such as interventions based on improvement. ADL and IADL, management of pain symptoms, fatigue management and energy storage, correction and adaptation of the environment, providing assistive and adaptive equipment, improving functional mobility and home exercises such as strengthening and stretching exercises.

Main outcome variables
Occupational performance, Quality of life , Ability to perform activities of daily living.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180908040970N2**
Registration date: **2021-11-29, 1400/09/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-29, 1400/09/08**
Update count: **0**

Registration date
2021-11-29, 1400/09/08

Registrant information

Name
Mahnoosh Khanipour

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 7711 2441

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-21, 1400/08/30

Expected recruitment end date
2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Investigation of the effects of Occupational Therapy's Interventions on Occupational Performance in advanced cancer patients at home during covid-19 crisis

Public title

The investigation of the effects of occupational therapy's intervention on occupational performance in advanced cancer patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

patients with advanced cancer age range of 18 to 65 years old having an acceptable level of cognitive function as a score of 21 or higher based on the Mini Mental Status Examination (MMSE) In at least one case the Katz questionnaire needs help

Exclusion criteria:

Existence of other diseases such as neurological problems, orthopedics and mental disorders.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

0

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting and determining the number of samples, individuals are by using a table of random numbers are divided into two groups (intervention and control). This means that the evaluator and therapist do not interfere in the placement of samples in any of the groups and their placement in each group will be done only through a table of random numbers. Since we have two groups of intervention and control, the total number of samples should be divided into two groups, the number of both groups will be equal. Therefore before the entrance of patients in the study, the total number of samples is divided into two categories. For example, 80 patient samples are needed to study, divide 80 by two, and place 40 patients in each category. The first group of patients will be the control group and the second group of patients will be the intervention group. Then a number will be randomly selected from inside the table of random numbers in the vertical or horizontal direction. After that, the selection of numbers will continue until the first group ends. For example, in a table of random numbers we have a set of 4-digit numbers that are placed in columns and rows. In one of the rows, select a number and select the numbers in pairs. For example, from 4576, two numbers 45 and 76 will be selected. We will proceed in the same way until the first 40 samples are selected. Then, a number in the vertical or horizontal direction will be selected randomly and in the same order as before (in rows or columns) the selection of numbers will continue until the number of second group samples is determined. After the patients enter, the code will be assigned to the patients in the order of their entrance. After matching that code with the desired number in each of the categories, it will be determined in which group the patient will be placed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessor does not know the placement of patients in any of the groups during the evaluation

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Iran University of Medical Science

Street address

Neuromusculoskeletal Research Center, Firoozgar hospital, Beh-afarin ave, Karimhanzan ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۵۹۳۷۴۷۸۱۱

Approval date

2021-09-28, 1400/07/06

Ethics committee reference number

IR.IUMS.REC.1400.597

Health conditions studied

1

Description of health condition studied

Advanced Cancer

ICD-10 code

Z51.5

ICD-10 code description

Encounter for palliative care

Primary outcomes

1

Description
Occupational Performance rate in the Canadian Occupational Performance Measure
Timepoint
Time intervals for evaluation at the beginning of the study(before the interventions), and by passing 6nd, and 14th weeks from the intervention(Follow-up)
Method of measurement
Canadian Occupational Performance Measure(COPM)

2

Description
Level of Quality Of Life
Timepoint
Time intervals for evaluation at the beginning of the study(before the interventions), and by passing 6nd, and 14th weeks from the intervention(Follow-up)
Method of measurement
European Organization for Research and Treatment of Cancer-of-life Questionnaire Core30 (EORTC QLQ-30)

3

Description
Ability to perform Activities of Daily Living
Timepoint
Time intervals for evaluation at the beginning of the study(before the interventions), and by passing 6nd, and 14th weeks from the intervention(Follow-up)
Method of measurement
Katz Index

Secondary outcomes

1

Description
Ability to perform Instrumental Activities of Daily Living
Timepoint
Time intervals for evaluation at the beginning of the study(before the interventions), and by passing 6nd, and 14th weeks from the intervention(Follow-up)
Method of measurement
The Lawton Instrumental Activity of Daily Living

2

Description
The amount of pain
Timepoint
Time intervals for evaluation at the beginning of the study(before the interventions), and by passing 6nd, and 14th weeks from the intervention(Follow-up)
Method of measurement
Brief Pain Inventory

3

Description
The amount of fatigue
Timepoint
Time intervals for evaluation at the beginning of the study(before the interventions), and by passing 6nd, and 14th weeks from the intervention(Follow-up)
Method of measurement
Cancer Fatigue Scale

Intervention groups

1

Description
Control group: Receive home-care services and traditional palliative care. Since occupational therapy services are not currently available to cancer patients, if the patient is referred and placed in the control group, the patient will not receive any new intervention and an educational pamphlet Includes introduction of assistive devices and training in their use, adaptive equipment required, compensation techniques, correct bed rest positions and how to transfer the patient are presented. In fact, by providing an educational pamphlet, all the needs of patients and caregivers are considered and the necessary training is given to them, but they will not receive any new occupational therapy intervention. By recording the evaluations in three periods, the results of this group will be compared with the results of the intervention group, which receives palliative medicine interventions in accordance with international standards.
Category
Rehabilitation

2

Description
Intervention group: Receiving Home-care services are found to meet international standards and as set out in articles and books. These interventions include occupational therapy treatment strategies such as ADL and IADL-based interventions, observation and management of pain symptoms, fatigue management and energy storage, correction and adaptation of the environment, provision of assistive and adaptive equipment, improvement of functional mobility, home exercises such as stretching, strength training, and range of motion and provide essential health education programs in times of coronary crisis. In other words, after evaluating patients and determining their current condition in all aspects of physical, pain, fatigue and ability to perform daily activities of life, occupational therapy interventions will begin. Occupational therapy interventions focus on all these dimensions and include providing the necessary movement exercises for the foundational skills as movement bases, training in correct positioning to prevent bed sores, joint contractures and muscle injuries, training on how to perform activities. Daily life (personal hygiene, dressing, eating, etc.) in accordance with the patient's abilities and with the aim of increasing the patient's independence in

performing them and thus improving the quality of life, providing the necessary aids and if necessary It will be environmental adaptations.It should be noted that all of the above are general interventions that can be provided to these patients and due to the difference in physical condition and type of cancer and the rate of disease progression, the details of each of these interventions will be different in each patient and depends on Evaluation before starting treatment.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Firoozgar Hospital

Full name of responsible person
Mahnoosh Khanipour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

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

Title of funding source
Iran University of Medical Sciences

Proportion provided by this source
50

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Gholamreza Raissi

Position
Head of Neuromuscular, Skeletal Research Center of Firoozgar Hospital

Latest degree
Specialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Yes - There is 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

All of the data and information on the main and secondary outcomes of the post-print study are shared.

When the data will become available and for how long

The access period begins 6 months after the results are published.

To whom data/document is available

Learn to pronounce data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

1. Use data only to evaluate effective therapies. 2. Applicants must be legal entities registered in educational or scientific centers. 3. The applicant shall undertake not to use the data for personal gain or unrelated scientific studies and in other fields. 4. The requesting person shall undertake not to misuse data in unrelated contexts.

From where data/document is obtainable

The data can be accessed by contacting the following person and sending the requested information up to one week after receiving the request and confirming the conditions: Mahnoosh Khanipour by Email Address: mah.pouroushan@gmail.com

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

Access to the data can be done first via e-mail with the lead researcher studying the correspondence. Subsequently, the necessary information is sent by providing substantiated evidence of the eligibility requirements for the data and confirming the stated evidence and reasons. Also, if the main researcher does not respond, the necessary correspondence can be made with the corresponding author , and the information will be sent again through the conditions and steps mentioned above.

Comments