Effect of cycle ergometer training on balance and cognition in moderate to severely demented elderly, a Randomized Clinical Trial

21/11/2024 21:38:05

Main Information

Primary registry identifying number

LBCTR2020012391

Protocol number

LBCTR2020012391

MOH registration number

NA

Study registered at the country of origin

Yes

Study registered at the country of origin: Specify

Type of registration

Retrospective

Type of registration: Justify

We thought that IRB approval (2018) was enough to start recruiting, especially that the intervention is not invasive. Additionally, the subjects are either treated by random exercises or not treated by exercise

Date of registration in national regulatory agency

Primary sponsor

Centre National de Recherche Scientifique (CNRS) Lebanon

Primary sponsor: Country of origin

Lebanon

Date of registration in primary registry

29/01/2020

Date of registration in national regulatory agency

Public title

Effect of cycle ergometer training on balance and cognition in moderate to severely demented elderly, a Randomized Clinical Trial

Acronym

NA

Scientific title

Effect of cycle ergometer training on balance and cognition in moderate to severely demented elderly, a Randomized Clinical Trial

Acronym

NA

Brief summary of the study: English

Studies on demented populations worldwide have dramatically increased in the last decades. Demented people present with a set of
symptoms that may include memory loss and difficulties with thinking, problem solving or language, as well as change in mood and behavior.
Physical activity was proved to be the most successful key factors in preserving mental and physical health among elderly persons. Nowadays, physical therapists and health professionals are seeking passive exercise tool that can provide the demented elderly the needed
amount of daily physical activity despite the cognitive impairment they are suffering from. One of those passive exercise tool is the motorized
cycle ergometer (MCE), which is a motorized bicycle that can be run on passive mode. Therefore, we will investigate the effectiveness of
cycle ergometer as a method of exercise for elderly persons with moderate to severe dementia.

Brief summary of the study: Arabic

ان الدراسات على كبار السن وخاصة اولئك الذين يعانون من الخرف قاد زادت بشكل ملحوظ. قد لقد تم اثبات ان النشاط البدني هو من اهم الاستراتيجيات العلاجية والتي برهنت فعالية بالحفاظ على الصحة
الجسدية والعقلية لدى المسنين. ان من اهم المشاكل المصاحبة لكبار السن، خاصة المصابين بالخرف، هي صعوبات التفكير، الذاكرة، بالإضافة الى الى التغيرات السلوكية والمزاجية. حالياً يقوم المعالجين
الفيزيائيين والعاملين بالقطاع الصحي بمحاولات للتغلب على هذه الصعوبات عبر ادراج هذه المجموعة من المرضى ضمن برامج رياضية تدريبية لا تتطلب مستوى مشاركة فكرية من قبل المريض.
احدى هذه الطرق قد تكون الدراجة الثابتة المزودة بمحرك احدى هذه الطرق العلاجية. ان هذه الدراسة تهدف الى معرفة تأثير التريب بالدراجة الثابتة المزودة بمحرك على التوازن والقدرات المعرفية عند
المسنين المصابين بالخرف المتوسط او الشديد.

Health conditions/problem studied: Specify

Geriatric
Moderate to severe dementia

Interventions: Specify

exercise program
motorized cycle ergometer

Key inclusion and exclusion criteria: Inclusion criteria

•Inclusion criteria:
□Subjects should be above the age of 65
□They should be diagnosed with moderate to severe dementia
□They should not have any other severe orthopedic or neurological conditions like stroke, Parkinson, or hip fracture
□They should be ambulating independently with or without the need for a gait assistance device (walker or crutches...)

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

65

Key inclusion and exclusion criteria: Age maximum

99

Key inclusion and exclusion criteria: Exclusion criteria

Exclusion criteria:
□Patients previously suffering or still suffering from severe neurological condition
□Any orthopedic surgery on the lower limbs in the last 12 months prior the recruitment in this study
□Subjects that were diagnosed with mild dementia or mild cognitive impairment
□Subjects that are below the age of 65.

Type of study

Interventional

Type of intervention

Rehabilitation strategies

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Open (masking not used)

Study design: Control

Active

Study phase

N/A

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

NA

Therapeutic indication

NA

Therapeutic benefit

NA

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

None retained

Biospecimen description

NA

Target sample size

60

Actual enrollment target size

60

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

03/01/2019

Date of study closure: Type

Anticipated

Date of study closure: Date

31/01/2020

Recruitment status

Complete

Recruitment status: Specify

Date of completion
31/03/2020

IPD sharing statement plan
No

IPD sharing statement description
NA

Additional data URL

Admin comments

Trial status
Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Beirut Arab University	2018H-0043-HS-R-0270

Sources of Monetary or Material Support

Name
Beirut Arab University
Centre National de Recherche Scientifique (CNRS) Lebanon

Secondary Sponsors

Name
Dar Al Ajaza Al Islamiah Hospital

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	rami Abbas	Beirut	Lebanon	009613942067	r.abbas@bau.edu.lb	BAU
Scientific	Ibtissam Saab	Beirut	Lebanon	009613959040	ibtissam.saab@bau.edu.lb	BAU
Scientific	Ayman El Khatib	Beirut	Lebanon	0096171587317	a.elkhatib@bau.edu.lb	BAU
Scientific	Hassan El Charif	Beirut	Lebanon	009613819772	hassanne@gmail.com	Dar Al Ajaza Isalamiah Hospital
Scientific	Nabil Naja	Beirut	Lebanon	009613725449	nabilbnaja@gmail.com	Dar Al Ajaza Isalamiah Hospital

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Dar Al Ajaza Al Islamiah Hospital	Rami Abbas	Physical Therapy	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Beirut Arab University	22/03/2018	Dr. Issam Othman	irb@bau.edu.lb	00961376695224

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
dementia	Dementia in other diseases classified elsewhere (F02)	Dementia

Interventions

Intervention	Description	Keyword
exercise	regular exercise program	Ex
motorized cycle ergometer	motorized cycle ergometer	Mo

Primary Outcomes

Name	Time Points	Measure
Cognition	Before and after 12 weeks of intervention	Mini Mental State Exam
Balance	Before and after 12 weeks of intervention	Berg Balance Scale
Gait	Before and after 12 weeks of intervention	Timed up and Go test

Key Secondary Outcomes

Name	Time Points	Measure
Gait	before and after 12 weeks	Timed up and go test

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files