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<p><b>FACULTY OF PHYSICAL THERAPY APPLICATION FOR ETHICAL REVIEW</b></p>
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**NOTES:**

- Answers to questions must be entered in the space provided.
- An electronic version of the completed form should be submitted to the Research Ethics Officer, at the following email address: [...ethical@pt.cu.edu.eg](mailto:...ethical@pt.cu.edu.eg)..... Please **do not** submit paper copies.
- If you have any queries about the form, please address them to the [Research Ethics Team](#).

**FACULTY OF PHYSICAL THERAPY  
APPLICATION FOR ETHICAL REVIEW**

**OFFICE USE ONLY:**  
Application No:  
Date Received:

**1. TITLE OF PROPOSAL**

Effect of exercise in obese patients with chronic kidney diseases

**2. THIS PROPOSAL IS:**

**Physical Therapy Staff Research Proposal** ☒ ☒ ☐

Physical Therapy Postgraduate Research (PGR) Student Proposal ☐

Master ☐

Doctoral ☐

**Other** ☒ ☐

Other ☐ (Please specify):

**3. INVESTIGATORS**

**a) PLEASE GIVE DETAILS OF Student (FOR PGR STUDENT PROPOSAL) or first author for staff Research Proposal**

Name: Title / first name / family name	<b>Dr. Manal Kamel Youssef</b>
Highest qualification & position held:	Assistant professor of Physical Therapy
Department/ Faculty/ University	- Physical therapy, department of internal medicine, Cairo university hospitals - Cairo University
Telephone:	01007734694
Email address:	<a href="mailto:Manal.kamel@cu.edu.eg">Manal.kamel@cu.edu.eg</a>

**a) PLEASE GIVE DETAILS OF ANY CO-SUPERVISORS OR CO-INVESTIGATORS (FOR PGR STUDENT PROPOSAL) or co- first author for staff Research Proposal**

Name: Title / first name / family name	
Highest qualification & position held:	
Department/ Faculty/ University	
Telephone:	
Email address:	

**4. SUMMARY OF PROPOSAL**

**PURPOSE:** To compare between the effect of aerobic exercise and resistance exercises on patients with obese chronic kidney diseases.

**BACKGROUND:** excessive adiposity is well recognized as an amplifier for the risk of renal disease progression in patients with chronic kidney diseases of various aetiology. Renal alterations induced by obesity include hyperfiltration, pathological proteinuria/ albuminuria and reduced glomerular filtration rate

**HYPOTHESES:** There will not significantly effect of neither aerobic nor resistance on obesity, in patient with chronic kidney disease.

**RESEARCH QUESTION:** Aerobic exercise and resistance exercise which of them has significant effect on obesity in patient with chronic kidney disease?

## 5. CONDUCT OF PROJECT

### Please give a description of the research methodology that will be used

#### Therapeutic Procedures

Group(1): Each exercise training session included 3 to 5 minutes of warm-up, range-of-motion exercises, interval training(aerobic training), cool-down, and post-exercise range-of-motion exercises. Patients exercise at 40 to 60% of maximum heart rate.

Group(2): Resistance exercise training of the lower extremities was performed three times per week. Starting weights for knee extension and hip abduction and flexion were determined from a three-repetition maximum (3RM) using ankle weights that can be adjusted in 1 lb. increments. A 3RM is the maximum weight that can be lifted three times with proper technique. Training started at approximately 60% of 3RM for two sets of 10 repetitions and was increased to three sets as tolerated.

#### For evaluation the following instruments will be used:

1-Timed-Up-and-Go Test (TUG).

2-sit-to-stand tests (STS).

STS5 (the time taken to complete 5 sit-to-stand-to-sit cycles) is a surrogate measure of muscle power

3- STS60 (number of sit-to-stand-to-sit cycles in 60 s) is a surrogate measure of muscular endurance.

4- 6 minutes walking test.

5-Blood pressure (systolic/diastolic blood pressures).

6-Mean blood pressure.

7- heart rate (HR) were measured before and after test.

8- blood glucose was measured before exercise by on call plus made in USA.

9-BMI

10-Waist circumference

11-Waist to hip ratio

## 6. PARTICIPANTS AS THE SUBJECTS OF THE RESEARCH

Describe the number of participants and important characteristics (such as age, gender, intellectual ability etc.). Specify any inclusion/exclusion criteria to be used.

60 obese diabetic patients with chronic kidney diseases (36 males and 24 females) (BMI) >30 kg/m<sup>2</sup>, age between 26 and 60 years, divided randomly into two groups:

#### **Inclusion criteria:**

chronic kidney diseases Stages 2-4

BMI ≥30

Diabetes mellitus

#### **Exclusion Criteria**

uncontrolled hypertension or diabetes mellitus.

cardiac failure,

motor disorders,

dementia.

## 7. RECRUITMENT

Please state clearly how the participants will be identified, approached and recruited.

*Note: Attach a copy of any poster(s), advertisement(s) or letter(s) to be used for recruitment.*

participants will be recruited from referral to physical therapy, department of internal medicine, Cairo university hospitals, Giza, Egypt.

## 7. CONSENT

Describe the process that the investigator(s) will be using to obtain valid consent. If consent is not to be obtained explain why. If the participants are minors or for other reasons are not competent to consent, describe the proposed alternate source of consent, including any permission / information letter to be provided to the person(s) providing the consent.

I am freely and voluntarily consent to participate in a research program under the direction of Dr. Manal Kamel Youssef  
 A thorough description of the procedure has been explained and I understand that I may withdraw my consent and discontinue participation in this research at any time without prejudice to me.  
 Date Participant

*Note: Attach a copy of the Consent Form, Participant Information Sheet (if applicable).*

## PARTICIPANT WITHDRAWAL

a) Describe how the participants will be informed of their right to withdraw from the project.

the researcher will explain right of withdrawal from the study and this right is signed in consent form.

b) Explain any consequences for the participant of withdrawing from the study and indicate what will be done with the participant's data if they withdraw.

there will be no problem about participant's withdrawal from the study and his data will not be included in the statistical analysis.

## 8. CONFIDENTIALITY

- a) Will all participants be anonymous?  
 b) Will all data be treated as confidential?

Yes ☒ ☐  
 Yes ☒ ☐

No ☐  
 No ☐

Note: Participants' identity/data will be confidential if an assigned ID code or number is used, but it will not be anonymous. Anonymous data cannot be traced back to an individual participant.

## 9. RISKS

Outline any potential risks to **INDIVIDUALS**, including research staff, research participants, other individuals not involved in the research and the measures that will be taken to minimise any risks and the procedures to be adopted in the event of mishap

Overload of exercises may lead to muscle soreness and fatigue.  
 These avoided by adjustment of intensity of exercises

## 10. DECLARATION BY APPLICANTS

I submit this application on the basis that the information it contains is confidential and will be used by the Faculty of Physical Therapy for the purposes of ethical review and monitoring of the research project described herein, and to satisfy reporting requirements to regulatory bodies. The information will not be used for any other purpose without my prior consent.

I declare that:

- The information in this form together with any accompanying information is complete and correct to the best of my knowledge and belief and I take full responsibility for it.
- I will report any changes affecting the ethical aspects of the project to the Faculty of Physical Therapy Research Ethics Officer.
- I will report any adverse or unforeseen events which occur to the relevant Ethics Committee via the Faculty of Physical Therapy Research Ethics Officer.

**Name of Principal investigator/project supervisor:**

**Manal Kamel Youssef**

**Date:**

29-12-2019