Official Title of Study:-

Effect of Preoperative Graduated Abdominal Exercises and Russian Stimulation on The Abdominal Muscles Strength After Abdominoplasty

Document Date: - 01/09/2021.

Human Subjects protection review board approval

date: - 07/15/2020

FACULTY OF PHYSICAL THERAPY APPLICATION FOR ETHICAL REVIEW

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: <u>...ethical@pt.cu.edu.eg.....</u>. Please **do not** submit

paper copies.

> If you have any queries about the form, please address them to the <u>Research Ethics Team</u>.

FACULTY OF PHYSICAL THERAPY APPLICATION FOR ETHICAL REVIEW

OFFICE USE ONLY: Application No: Date Received:

1. TITLE OF PROPOSAL

Effect of Preoperative Graduated Abdominal Exercises and Russian Stimulation on The Abdominal Muscles Strength After Abdominoplasty

1. THIS PROPOSAL IS:

Physical Therapy Staff Research **Proposal** Physical Therapy Postgraduate Research (PGR) Student Proposal Master Doctoral

Other

Other (Please specify): post doctoral research

2. INVESTIGATORS

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

Name: Title / first name / family name	Ayman M. Elmakaky
Highest qualification & position held:	Lecture of physical therapy/ faculty of physical therapy
Department/Faculty/ University	South valley university
Telephone:	
Email address:	

a) PLEASE GIVE DETAILS OF ANYCO-SUPERVISORS ORCO-INVESTIGATORS (FOR PGR STUDENT PROPOSAL) or co- first author for staff Research Proposal

b)

Name: Title / first name / family name	Mohammed E. Ali
Highest qualification & position held:	Lecture of physical therapy/ faculty of physical therapy,
Department/Faculty/ University	South Valley university
Telephone:	01011212425
Email address:	m.essam@svu.esu.eg

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

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

3. SUMMARY OF PROPOSAL

PURPOSE:...

This study aimed To investigate the effect of preoperative graduated abdominal exercises and Russian stimulation on the abdominal muscles' strength after abdominoplasty.

Sixty patients will undergo abdominoplasty, their age ranged from 20 to 45 years, they were randomly distributed into four equal groups. The ultrasonography was used to evaluate abdominal muscle thickness as indicator for muscle strength at 4 occasions, initial assessment, pre-operative assessment, 2 months post-operative assessment, and finally 4 months post-operative assessment). For study group (A); received graduated abdominal exercises, group (B); received Russian stimulation on abdominal muscles, group (c); received combination between graduated abdominal exercises and Russian stimulation on abdominal muscles, the study groups received the treatment protocol for 30 min., 3 times per week for 6 weeks preoperatively for control group (D); were instructed to presume in normal activities of daily living preoperatively.

4. CONDUCT OF PROJECT

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

5. 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.

Subjects:

Sixty patients will undergo abdominoplasty, their age ranged from 20 to 45 years, they were randomly distributed into four equal groups. The ultrasonography was used to evaluate abdominal muscle thickness as indicator for muscle strength at 4 occasions

Inclusion Criteria:

Age range between 20-45 years. All patients desire an elective surgical repair. All patients were diagnosed with ventral hernia based on surgeon assessment. All patients will participate in the study. All patients enrolled to the study will have their informed consent. All patients are able to act in abdominal training program. All patients are able to follow orders during testing and training times.

Exclusion Criteria:

A strangulated hernia. History of surgical interference (abdominal surgery) less than one year. Liver cirrhosis with or without ascites. Hip or spine deformities or contractures. Bowel obstruction, peritonitis, or perforation. Local or systemic infection. Patient is pregnant or intended to become pregnant during this period. Patient has indication for urgent surgery determinate by surgeon

6. 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.

The patients will be recruited from pediatric surgery Outpatient Clinic of Qena faculty of medicine , South valley University

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.

lam	freely and voluntarily consent to participate in a research program under the
direction of M.Sc.	
	of the procedure has been explained and I understand that I may withdraw tinue participation in this research at any time without prejudice to me.
Date	Participant
Note: Attach a conv.o	f the Consent Form Participant Information Sheet (if applicable)

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.

All patients will sign a written consent form after receiving information about the study purpose, whole procedures, possible benefits, privacy and use of data to ensure full cooperation. patients well understand that they may withdraw their consent and discontinue participation in the research at any time without prejudice to them.

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.

All data of withdrawn participant will be excluded form analysis.

8. CONFIDENTIALITY

a)	Will all participants be anonymous?	Yes	No
b)	Will all data be treated as confidential?	Yes	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. SIGNIFICANCE/BENEFITS

Outline the potential significance and/or benefits of the research

10. 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

No risk			

11. 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 TherapyResearch Ethics Officer.

Name of Principal investigator/project supervisor:

Dr nehad ahmed youness abo-zeid

Date: 24 /3 /2019

Dr nezar Abd Elrouf Abo Halawa