Title:

Effect of shock wave for primary dysmenorrhea

NCT: not yet assigned

Document Date : 1 /6 /2019

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: ...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

The effect of shock wave for primary dysmenorrhea

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	Shaimaa Mohamed hamed
Highest qualification & position held:	MSc. Of women health Physical Therapy, Assistant Lecturer at MTI University
Department/ Faculty/ University	Women health /Physical Therapy/MTI university
Telephone:	+2 01008585299
Email address:	2sho@windowslive.com

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

Name: Title / first name / family name	Prof.Dr.Sohair Mahmoud ELKoseiry
Highest qualification & position held:	Professor and Chairman of physical therapy Department for Women's Health
Department/ Faculty/ University	Faculty of Physical Therapy Cairo University
Telephone:	01100691280
Email address:	

Name: Title / first name / family name	Prof.Dr. Hoassam El-din Hussien kamel

Highest qualification & position held:	Professor of gynecology and obstetrics faculty of medicine
Department/ Faculty/ University	Azhar University
Telephone:	01223141816
Email address:	

4. SUMMARY OF PROPOSAL

PURPOSE:

- to investigate the effect of shock wave for primary dysmenorrhea

BACKGROUND:

Dysmenorrhea is the medical term for pain with menstruation. There are two types of dysmenorrhea: "primary" and "secondary". Dysmenorrhea, also known as painful periods, or menstrual cramps and pain during menstruation. Its usual onset occurs around the time that menstruation begins. Symptoms typically last less than three days. The pain is usually in the pelvis or lower abdomen. Other symptoms may include back pain, diarrhea, or nausea

HYPOTHESES:

- We hypothized that the shockwaves has no effect on the primary dysmenorrhea.

5. CONDUCT OF PROJECT

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

Assessment tools:

1-Numeric rating scale

Numeric rating scale is 10 cm calibrated line with 0 (zero) representing no pain and 5 representing worst pain, will be used to assess the severity of pain before and after treatment for all patients in both groups (A&B). Every patient of both groups (A&B) will be asked to mark on the line that represents her level of pain before and after treatment .

2-Prostaglandins level:

It will be used to measure level of pain. A sample of blood will be taken to measure level of prostaglandins for them which will refer to level of pain. It will be used to assess the severity of pain before and after treatment for all patients in both groups (A&B).

Treatment tools :.

1- Shock Wave instrument (Pagani Elettronica, Milano, Italy

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.

Fifty volunteer, virgin females diagnosed to have primary dysmenorrhea will be selected randomly from students in Modern Academy University in Cairo

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

Inclusive criteria:

1- Their ages will range from 18 to 25 years old.
2- There body mass index (BMI) will not exceed 30kg/m^2.
3- All patients should be diagnosed by the physician as primary dysmenorrheal.
4- All patients are virgin female with regular menstrual cycle.

Exclusion criteria:

1- Secondary dysmenorrhea .
2- Mental health problem such as depression and anxiety.
3- Women with BMI exceed 30kg/m^2.
4- Patients who have migraines and chronic fatigue syndrome.
5- Skin disease interferes with foot reflexology application.

8. 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 Misses / freely and voluntarily consent to participate in research study under the direction of researcher / Shaimaa Mohammed Hamed Elmarakby, a through 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.

Participant: Date :

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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.

They can withdraw at anytime without prejudice to them as mention in signed consent.

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.

No consequences will take place. They have the utmost freedom.

9. 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.

10. SIGNIFICANCE/BENEFITS

Outline the potential significance and/or benefits of the research

Primary dysmenorrhea is common menstrual cramps that are recurrent (come back) and are not due to other diseases. Pain usually begins 1 or 2 days before, or when menstrual bleeding starts, and is felt in the lower abdomen, back, or thighs. Pain can ranged from mild to severe, can typically last 12 to 72 hours, and can be accompanied by nausea-and-vomiting, fatigue, and even diarrhea. Common menstrual cramps usually become less painful as a woman ages and may stop entirely if the woman has a baby.

Dysmenorrhea is defined as cramping pain in the lower abdomen occurring just before or during menstruation, in the absence of other diseases such as endometriosis. Prevalence rates are as high as 90 percent. Initial presentation of primary dysmenorrhea typically occurs in adolescence. It is a common cause of absenteeism and reduced quality of life in women. There is no studies done the effect of shock wave treatment of primary dysmenorrhea so this study was to investigate the effect of shock wave on primary dysmenorrhea

11. 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

Risk of Infection: minimizing the risk through adequate sterilization of the treated areas during evaluation and treatment.

12. 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:	Shaimaa Mohamed hamd Prof. sohier ELKoseiry
Date:	12 of june, 2019