

Title:

**EFFECT OF TRANSCRANIAL DIRECT CURRENT  
STIMULATION ON SENSORY INTEGRATION  
AND RISK OF FALLING IN DIABETIC  
POLYNEUROPATHY**

NCT: not yet assigned

Document Date : 15/07/2018

<p style="text-align: center;"><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](#).

<b>FACULTY OF PHYSICAL THERAPY APPLICATION FOR ETHICAL REVIEW</b>	<b>OFFICE USE ONLY:</b> Application No: Date Received:
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**1. TITLE OF PROPOSAL**

**EFFECT OF TRANSCRANIAL DIRECT CURRENT STIMULATION ON SENSORY INTEGRATION AND RISK OF FALLING IN DIABETIC POLYNEUROPATHY**

**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	Sara Salah El-Din Abdel Megeed
Highest qualification & position held:	MSc. Of Neurologic Physical Therapy, Assistant Lecturer at MTI University
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**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. Moshera Hassan Darwish
Highest qualification & position held:	Professor
Department/ Faculty/ University	Neurology/Physical Therapy/ Cairo University
Telephone:	
Email address:	

Name: Title / first name / family name	Prof. Hatem Samir
Highest qualification & position held:	Professor
Department/ Faculty/ University	Neurology/ Medicine/ Cairo University
Telephone:	
Email address:	

Name: Title / first name / family name	Dr. Heba Metwally
Highest qualification & position held:	Lecturer
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#### 4. SUMMARY OF PROPOSAL

To determine the effect of Transcranial direct current stimulation on sensory integration and risk of falling in diabetic polyneuropathy.

##### **PURPOSE:**

To determine the effect of Transcranial direct current stimulation on sensory integration and risk of falling in diabetic polyneuropathy.

##### **BACKGROUND:**

Diabetic polyneuropathy is the most prevalent chronic complication affecting 30% - 50% of diabetic patients. Diabetic polyneuropathy usually affect the peripheral, autonomic, and central nervous systems with several clinical symptoms .About 80% of the cases of DN manifest as distal symmetrical sensorimotor polyneuropathy which is responsible for cases of chronic pain; impaired sleep quality; increase of the falling risk associated with weakness and increase of the risk of extremities amputation. Transcranial direct current stimulation is neurophysiologic intervention that alters cortical excitability to enhance lower extremity somato-sensation and thus improve functional outcomes.

##### **HYPOTHESES:**

There will be no effect of Transcranial direct current stimulation on sensory integration and risk of falling in diabetic polyneuropathy

##### **RESEARCH QUESTION:**

Is there an effect of Transcranial direct current stimulation on sensory integration and risk of falling in diabetic polyneuropathy?

## 5. CONDUCT OF PROJECT

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

1. Biodex balance system will be used to assess sensory integration test and risk of falling test.
2. Transcranial direct current stimulation will be used to stimulate somatosensory cortex.

## 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.

Thirty female patients will be recruited.  
Ages range from 50-65 years old.  
They will be diagnosed with diabetic polyneuropathy and all patients have type II diabetes, they complained from glove stock hyposthesia, numbness, burning sensation and mild distal motor weakness.

## 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.*

1. Patients will have diabetic polyneuropathy.
2. They will have type II diabetes.
3. They will have glove stock hyposthesia, numbness, burning sensation and mild distal motor weakness.

Patients will be selected, evaluated and treated at the outpatient clinic of the Faculty of Physical Therapy, Modern University for Information and Technology.

## 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.



## 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

Delay in the treatment of diabetic polyneuropathy complications may result in substantial and chronic impairments It affects sensory and motor systems and consequence on balance and lead to increased risk of falling .Diabetic neuropathy severely decreases patients' quality of life. This study will determine if transcranial direct current stimulation can improve the conservative treatment of balance and decrease the cost of treatment and disability of the patient.

## 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:**

Sara Salah El-Din Abdel Megeed

Prof. Moshera Hassan Darwish

**Date:**

15<sup>th</sup> of July, 2018