RESEARCH PROPOSAL

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Project Title:

FUNCTIONAL ELECTRICAL STIMULATOR FOR REHABILITATION AND MOVEMENT RESTORATION IN THE LOWER LIMBS.

Executive Summary:

Functional Electrical Stimulation (FES) is a technique known for its ability to restore movements utilizing electrical signals of suitable form targeting the nerves responsible for carrying out the task when the nervous system is intact. It is an established fact that electrical signals originate from the brain down to the nerves in the nervous system. A device known as the electrical stimulator or functional electrical stimulator is used to produce these electrical signals for the movement restoration. It can also be used for movement function restoration and for rehabilitation. Identified challenges are the different categories of the device for lower limb movement and absence of feedback during the process as subject encounter pains which could be corrected by adjusting the parameters automatically as the healthcare personnel could attending to others or take time to respond. Remote monitoring feature would also be incorporated for further flexibility allowing for remote monitoring and adjustments of device when the need arises. Therefore, adding these features would make the device universal for lower limbs applications and cut cost as single device can accommodate all required movements associated with the lower limbs. It would also reduce burden on the personnel as well as saving costs; since the facility would reduce the involvement of the workers, meaning a single personnel can handle more subjects or would be less busy. It is expected that a stimulator would emerge which is universal for FES lower limb assisted movement (improved range of operation). And also the overall system with reduced personnel burden or ability to handle higher number of individuals. The system would be realized in stages: starting from the design and simulation of the FES device, implementing the device and creation of the overall system software and integration and finally conducting initial test after which the final test would be carried after fixing all observed lapse during the initial tests.

Introduction:

Functional electrical stimulation (FES) is a technique commonly used for temporal movement restoration function. Patients with nervous system disorders incapable of active or accomplishing proper movements (Maneski et al., 2020). It is accomplished by supplying appropriate electrical signals to the targeted muscles that usually produce the movement under normal condition when such originate from the brain through the nervous system which are electrical in nature. This therapy can make the disaffected nerve center efferent nerve excited again through safe and reliable electrical stimulation pulse when the patient cannot move normally during the exercise process, so that the muscle function can be restored (Yoo, Kim, Shin, & Lee, 2023). Functional electrical stimulation belongs to the category of physical factor therapy in rehabilitation therapy. A large number of studies have proved that it can also enhance the muscle strength of stroke patients, improve the muscle tone and the limb function in hemiplegia. The stimulation pulse in the design of electrical stimulator is an important research focus of this design. Human skin impedance is about 1 k Ω, unidirectional current stimulation can cause charge accumulation causes tingling, damage to the electrode, and other issues. There is a kind of stimulus pulse with bipolar output ability. This pulse requires the BOOST circuit to ensure the stimulation ability and the constant current output to ensure the stability of the stimulus level (Dolinar &

Bajd, 2019). The field of rehabilitation for individuals with spinal cord injury (SCI) has witnessed significant advancements, and Functional Electrical Stimulation (FES) stands out as a prominent technique employed in clinical and home settings (Yan et al., 2019). In the past two decades, efforts have been concentrated on the investigation and refinement of Activities of Daily Living (ADLs) based on FES with surface electrodes, particularly in the realm of upper extremity home rehabilitation (Popovic-Maneski et al., 2020). Various forms of surface electrodes, such as textile electrodes, knitted electrodes, electrode arrays, and self-adhesive gel electrodes, have been utilized in FES applications (Popovic-Maneski Maneski et al., 2020). However, standard FES, employing self-adhesive electrodes, faces challenges including time-consuming manual positioning, issues related to adhesion to the skin, the complexity of cable management, and product size concerns (Dolinar & Bajd, 2019). In parallel, a distinct focus on FES emerges in the context of foot droop treatment, aiming to restore muscle function through safe and reliable electrical stimulation pulses. The design of the electrical stimulator includes a crucial emphasis on the stimulation pulse, addressing challenges related to human skin impedance and the need for bipolar output capability (Zhang & Zhou, 2019). Expanding beyond the individual design initiatives, a broader landscape of FES applications, emphasizing its role in neurologically impaired individuals' rehabilitation strategies (Knutson & Harley, 2006). Biologically inspired control, hierarchical structures, and the incorporation of machine learning in FES gait systems represent ongoing advancements in the field (Thrasher et al., 2016). Regarding the pain management during stimulation, the Transcutaneous Electrical Nerve Stimulating Machine (TENS Machine), which employs electrical currents to reduce acute and chronic pain was introduce by (Popovic-Maneski et al., 2018). It explores the varying frequencies and intensities used in TENS, shedding light on their impact on pain modulation and central mechanisms. The exploration of FES extends to its application in addressing spinal cord injuries, muscular atrophy, and motor disabilities (Popovic-Maneski et al., 2020). There was an examination on the technological aspects of FES systems, particularly the output stage responsible for transferring energy safely to stimulated tissues (Yan et al., 2019). Internet of things was first integrated into Electrical Muscle Stimulation (EMS) devices as a modern approach to enhance usability and real-time monitoring by (Pop ovic-Maneski et al., 2019). This introduces an IoT-based EMS device designed to constantly analyze real-time data signals, enabling patients to use the device independently, with physicians having the capability to monitor and modify treatments remotely (Popovic-Maneski et al., 2019). There was a comprehensive review which extends to the broader spectrum of disabilities, emphasizing the diverse types and prevalence in different populations (Popovic-Maneski et al., 2020). It underscores the role of electronic equipment, such as electro stimulators, in facilitating therapeutic treatments for various disabilities (Popovic-Maneski et al., 2019). The significance role played by FES devices in muscles stimulation and the needs for a user friendly safe to use devices forms the basis for this research work.

The proposed study on the design and development of a Functional Electrical Stimulation (FES) system, particularly in the form of a wearable device, holds immense significance in the field of rehabilitative technology and healthcare. the significance of this study lies in its potential to revolutionize the landscape of FES technology, making rehabilitation more accessible, personalized, and effective for individuals with spinal cord injuries. The outcomes of this research could lead to practical solutions that address the current challenges faced by users of traditional FES systems, ultimately improving the quality of life for those undergoing rehabilitation. The following points underscore the importance of this study:

a. Selection of a suitable microcontroller with enough processing power, I/O capabilities, and timers for real-time stimulation control.
b. Development of embedded firmware for the microcontroller to generate and control the stimulation pulses.
c. Ensure a reliable communication between the microcontroller and other device components.
d. Remote monitoring and reconfiguration.

Problem Statement/Justification:

Functional Electrical Stimulation (FES) has emerged as a crucial rehabilitative technique, particularly for individuals with spinal cord injuries (SCI). Despite its proven effectiveness in inducing muscle contraction and facilitating motor learning, the existing FES systems, notably those utilizing self-adhesive electrodes, face significant limitations. Challenges include time-consuming manual positioning, issues with adhesion leading to skin burns, the presence of a large number of cables, and cumbersome product sizes (Smith, J. 2021). Another point of great concern is the high cost of purchase which has significantly hinder its wide spread among hospitals and health care facilities (Maneski et al., 2020).

In view of the above, there is need to look into the existing limitations and come up with an innovative FES device that can be use with ease and comfort by developing a system with inter-pulse duration capability as well as cost-effectiveness without compromising standard. The proposed system will also employ the use of GUI for remote monitoring.

Objective (s) of the study:

The main aim of this research work is to develop a functional electrical stimulation (FES) device for temporary movement restoration and rehabilitation with GUI for both supervisory and feedback functions and the objectives are:

1. To design and simulate an effective FES device with the specified movement parameters.
2. To achieve targeted muscle stimulation for desired therapeutic or assistive purposes.
3. To implement user-selectable stimulation parameters (e.g., pulse width, frequency, amplitude).
4. To evaluate the performance of the developed device through experimentations.

Literature Review:

The literature reviewed in the context of the development of a functional electrical stimulation system for movement encompasses a diverse range of topics and perspectives. Summary of areas that needs attention and further research, this will give a brief overview and form the basis of this research gap. Optimization of stimulation protocols: While FES has been shown to be effective in improving movement in individuals with neurological disorders, there is a need for more research on optimizing stimulation protocols to achieve optimal outcomes (Kessler et al., 2017). Development of personalized stimulation algorithms: To improve the efficacy of FES, there is a need for the development of personalized stimulation algorithms that take into account individual patient characteristics and variability in muscle response to stimulation (Harris et al., 2018). Integration of sensory feedback: FES devices often lack sensory feedback, which can lead to reduced motor control and decreased movement accuracy. There is a need for research on integrating sensory feedback into FES devices to improve movement outcomes (Hofmann et al., 2019). Addressing discomfort and pain: FES devices can cause discomfort and pain, which can be a significant barrier to long-term use. There is a need for research on reducing discomfort and pain associated with FES devices (Liu et al., 2019). Development of user-friendly interfaces: To improve user adoption and adherence, there is a need for the development of user-friendly interfaces that simplify the use of FES devices (Wu et al., 2019). Clinical trials and evidence-based practice: While FES has shown promise in improving movement outcomes, there is a need for more rigorous clinical trials to establish the efficacy of FES devices and to develop evidence-based practice guidelines (Kuiken et al., 2019). Neural adaptation and long-term effects: There is a need for research on the long-term effects of FES therapy on neural function and motor control, as well as the potential for neural adaptation to stimulation protocols (Tang et al., 2019). Hence, research would focus on improving the range of the FES device so as to accommodate all restored movements in the lower limbs, creating user friendly interfaces for both the subject feedback and remote monitoring, and fast and automated response due to pain or discomfort at real time allowing for remote reconfigurations or adjustments by personnel in situations whereby there is escalation of the problem beyond automated ability.

Methodology (Description of Study area/site/subjects, data collection and data analysis)

Development of the FES device for movement restoration equipped with feedback and monitoring facilities would be accomplished in stages:

1. The design of the device and simulation of the device would be conducted with the specifications covering all movements that have to do with lower limb movement restoration in accordance with literature and existing devices specification. It would enhance the parameter ranges making the devices suitable/adaptable for if possible all movements accomplished by lower limbs. An up to date Personal Computer would be required and appropriate software.
2. Implementation of the device and overall system alongside the synthesis of algorithm for the monitoring as well as feedback system.
3. Configuration of the user-selectable stimulation parameters (e.g., pulse width, frequency, amplitude) with extensive testing.
4. Extensive evaluation of the device as well the overall system using appropriate test equipment such as oscilloscopes, frequency meter, voltmeter and ammeters. Modifications would be made where required until the desired response is obtained. Final test would be run for the entire system and documented.

Results (Expected outputs/Results):

The research is expected to produce an improved FES device for lower limb movement restoration with feedback and remote monitoring facility with outcomes as follows:

(i) Design and development of a robust FES device capable of taking care most if not all lower limb movement restoration.

(ii) Implementation of a FES device with feedback and remote facility having improved user friendly features. It would make the device/system with improved corrective ability through the feedback supplied by the patient during the rehabilitation process using an android phone. Further corrective measures can be made through the remote monitoring station. All these features would make supervision less for the supervising medical personnel easier and less burden.

(iii) Realization and testing of the concept via transmission of the FES device status, patient status and training status.

(iv) Extensive and careful testing of the device would be conducted all possible abilities.

(v) Additionally, it is expected that the research would make the technical knowledge of the device popular most especially locally such that further research capturing parameters which are peculiar can be captured.

Work Plan/Time Frame (Activity by activity in the form of a GANTT Chart):

S/ No.	Activities	Duration (Months)	Year	Quarter			
				1st	2nd	3rd	4th
1	Preparing guidelines for the study	1	2026	■			
2	Review of previous related works	1	2026	■			
3	Design and Simulation of the device and first conference/workshop attendance	2	2026	■	■		
4	Development of algorithms for the proposed monitoring and feedback system	1	2026		■		
5	Construction of the device	1	2026		■		
6	Testing the device developed	1	2026			■	
7	Making modifications if required	2	2026			■	
8	Conducting comprehensive test on the device and second conference/workshop attendance	1	2026				■
9	Preparing final report	2	2026				■

Budget (Break down by activity/line item):

Item	Quantity	Cost Per Unit (NGN)	Total (NGN)	Remarks
Personal Cost Principal Investigator Co-Researchers	1 2	15,000/month 10,000/month	180,000 240,000	Monthly Honorarium for the PI and Co-Researchers at 15,000 monthly for PI and 10,000 monthly for Co-r-Researchers. Total duration is 12 months.
Raspberry Pi Controller	2	155,000/unit	310,000	Microcontroller as the control unit of the proposed system
National Instruments USB-8451 Data Acquisition Card, NI DAQ DIO NI USB-8451 USB8451 And Shipment	2	NGN343,434.14 + NGN50000	786,868.28	Analog to Digital Converter (DAC) and Digital to Analog Converter (ADC)
Electronics Work Station and Digital Multi Meters	1	368,000	368,000	As the work station for the project
Work Station Monitoring/Server Station Desktop (Pentium 5 HP Desktop	1	355,000	355,000	Computer Dedicated at Monitoring Room as Server
Local Conference and workshop	2	240,000	480,000	For attending 1 local conference and 1 Local Workshop
AnyConnect IOT Visual Platform Subscription	1	492,000	492,000	IOT platform for real time monitoring
Electronics Components, Sensors and Actuator pack	1	120,000	120,000	Sensors and Actuators for the proposed system
Medical Manufacturing Snap Self Adhesive Disposable Electrode Patch Pads Ecg Electrodes	20 Packs	8,500	170,000	Electrodes for the Stimulation
2 KVA Inverter	1	360,000	360,000	Converting Back-up DC Power to AC
200AH Battery	2	310,000	620,000	Back-up Batteries
60A Charge Controller	1	50,000	50,000	Controlling the Charging current
300Watt Panel	6	95,000	570,000	For charging the Battery
Total	**NGN 4,811,868.20**			

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