Republic of Iraq

Ministry of Health & Environment

Approval form of a Research Protocol/ Ministry of Health & Environment (Form number 02/2021)

استمارة الموافقة على مشروع بحث في وزارة الصحة والبيئة (استمارة رقم 2021/02)

- This form should be filled in electronically (Manually filled in form will not be accepted) by the researcher and submitted manually to the research unit at the relevant Health Directorate to be displayed at its Research committee. No research is allowed to be conducted at the institutions of Ministry of Health without having in advance the committee's approval.
- This form can be downloaded from the official website of Ministry of Health & Environment/ Iraq.

1. PERSONAL INFORMATION

1.1 Principal Investigator

Name	Specialty	Place of work	Phone number	E mail
Munib Abdullah Fathe	Injuries Rehabilitation	University of Mosul College of Physical Education and Sport Science	07701680770	m.a.fathi@uomosul.edu.iq muneeb.fathe@yahoo.com

1.2 Other investigators

Name	Specialty	Place of work	Phone number	E mail
Wassim Moalla	Biology sport sciences	High Institute of sport and Physical Education Sfax University, Tunis	0097466224243 WhatsApp	Wassim.moalla@gmail.com
Saad Kazim Karim	Consultant Neurologist	Azadi Teaching Hospital, general directorate of Health, Duhok, Iraq	07504260287	Saad.71.karin@gmail.com
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2. RESEARCH INFORMATION

2.1 Is the research title from the Ministry of Health's list of priorities:

☐ Yes ☒ No

2.1: The list is issued every year and found on MoH website.

2.2 The purpose of doing the research: **Postgraduate Study**

If the answer is others, please, specify:

Click or tap here to enter text.

3. RESEARCH TOPIC

" Traumatic Spinal Cord Injury Community Survey Comprehensive Study in North, West and Kurdistan Region of Iraq"

Click or tap here to enter text.

3.2 The Research Question:

3.2: Write down the smart research question.

How many numbers of individuals who infected with traumatic SCI according to assess (levels, causes, and type of therapy), and what are the side effects of injury from a psychological and social point of view?

3.3 Research Background (with references in Vancouver style):

3.3: Write concisely the scientific bases of your research question. Use updated and new references.

Traumatic spinal cord injury (TSCI) is a devastating and life-changing event that affects both the local site of injury and the entire body, an SCI has far-reaching consequences for a person's functioning and health. This will loss of sphincter control that will be led to reactive depression. furthermore, which can hinder the rehabilitation process and reduce the quality of life, as compared with that of the general population (1). The initiative of international spinal cord injury data sets was proposed by the international spinal cord society (ISCoS) in collaboration with the American Spinal Injury Association (ASIA)(3). This injury has an increased internationally which it spreads as a result of violence, falling, sport, or car accidents. Most of countries in world had statistical data per year, but in Iraq this injury is less than another injury which is cared about it, so clearly there is no statistical numeric for this injury. Therefore, the study suggests that health promotion for those with disabilities, including those with SCI, has historically been directed at primary prevention of injury disability rather than prevention of secondary conditions (4). To answer on research question, the research will be developing International Spinal Cord Injury Data Sets is to gather consistent data elements to enable worldwide SCI data and outcomes to describe the health care, design, and initial findings of an Iraqi survey portraying the life situation of people with SCI living in the community. Specifically, the survey aimed to (a) identify the number of infected, reasons the proportion of people with SCI requiring services of community living, the levels of their injury, the type of therapy, and the extent of met and unmet needs, (b) determine the barriers or facilitators to service utilization, and (c) describe the outcome in the lives of people with SCI (occurrence of SHCs, degree of participation in major life areas including productive activities, quality of life) and their interrelationships with service needs (met and unmet).

3.4 Justification of Choosing this topic (Rationale):

3.4: Show the rationale of choosing this research question and what are the expected gab that this research is going to fill.

The researcher decided to choose this topic because the lack of research statistics on SCI during the war against ISIS, in addition the number of injured, the type, causes, and the levels of this injurie, as well as follow-up of the injured from a therapeutic, psychological and social point of view to detect the side effects of this injury and the level of rehabilitation for those individuals.

3.5 The Objective/s of the Research:

3.4: Write down primary and secondary objectives

The aim of this study is developing International Spinal Cord Injury Data Sets is to gather consistent data elements to enable describe the health care, design, and initial findings of an Iraqi survey portraying the life situation of people with SCI living in aimed to (a) identify the number of infected, reasons the proportion of people with SCI requiring services of community living, the levels of their injury, the type of therapy, and the extent of met and unmet needs, (b) determine the barriers or facilitators to service utilization, and (c) describe the outcome in the lives of people with SCI (occurrence of SHCs, degree of participation in major life areas including productive activities, quality of life) and their interrelationships with service needs (met and unmet).

4. Research Setting

4.1 When will the sample be collected?

Start 1 December 2019 **End** 31 January 2022

4.2 Where will the study be implemented?

	Name of Institution	Name of authorized person	Signature	Date and stamp
1	At Patient's home	Mohamed Sayfe , Mohamed Abdulazeez, Baravan Naje-Aldeen, and Ava Kurdw		4.6.2021
2	At Government's Hospitals or Centers of Physiotherapy	Al-Salaam General Hospital		
		A. Ebin-Sienna Teaching Hospital		
3	Private Hospital and Centers of Rehabilitation and some Healthy-Club	B. Al-Mosul General Hospital		
4	Click or tap here to enter text.			
5	Click or tap here to enter text.	C. Ninawa Center Rehabilitation of Disability People		

4.3 The resources needed from the institution selected to implement the research?

The resource needed	tick	Amount and types
Laboratory sample (Blood, urine, ...)	☐	Click or tap here to enter text.
Devices, instrument, tools	☐	Click or tap here to enter text.
Patients' or firm's records	☒	Private and Government clinic and hospital and centers of physiotherapy and rehabilitation
Persons (patients, employers)	☒	Approximately about 100-150 patients and about 10-25 employers
Others specified	☒	The experiment will be carried out with physical and functional tests, mostly in the patient's home

4.4 Who will fund the research? Govermental

If the answer is others, please, specify:

And personal support

5. RESEARCH METHODOLOGY

5.1 Study Design: choose one from below

Case Control

If the answer is others, please, specify: Click or tap here to enter text.

5.2

Case Definition: individuals who have Traumatic Spinal Cord Injury (TSCI) at any level this cases study, and the others who healthy people without SCI as control study.

5.3 Exclusion Criteria:

Any case who has non traumatic SCI like pathology reasons and who don't commit in a protocol treatment or rehabilitation program, this will limit by Neuro physician according to history date for patients and some fustigations and according to ASIA scale for limit the level of injury and type complete or incomplete.

5.4 Sampling Methods:

The researcher will survey the centers of physiotherapy in general Hospital, private clinic, and Neuro disease to select the case which type of injury traumatic SCI and the expectation of number of sample study about (40-50) injuries . The researcher will be depended on form which will prepare, this form contains a personal information and some morphological measurements for example (Mass, Length, BMI...) and injury information as example (date of injury, date of rehabilitation, the stage of rehabilitation, type of medical intervention, level of injury, type of injury....) the research will in depend on medical fustigation for each patient and it will use the (ASIA) International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) to access for date . And also another information which will be get it from researcher that is relate with the psychological and community integration by using a specific questionnaires for example (CES-D) Center for

5.1: write the design of the study that is going to answer your research question

5.2: It is the operational definition used to enroll participants in the study

5.3: the participants that fulfil case definition, but excluded from the study due to a specific cause

5.4: the method used to select the participants of the sample from the targeted sample.

5.5: Write details about how to allocate participants in study arms or blinding them if the study design is relevant

Epidemiologic Studies Depression Scale(3), (CIQ) Community Integration Questionnaire, (SWLS) Satisfaction with Life Scale, (DASS-21) Depression, Anxiety and Stress Scale, and (SAS) Scale of after Strock. This study will accredit the questions within the questionnaire (Appendix) were developed on the basis of the 20 data elements in the ISCICDS. Of these, four neurological data elements are to be collected at acute admission and at final inpatient discharge, respectively: that is, date of neurological examination, sensory level (SL), motor level (ML) and ASIA Impairment Scale (AIS). Other data elements include date of birth, injury, acute admission and inpatient discharge, total days hospitalized, gender, injury etiology, vertebral injury, associated injury, spinal surgery, ventilatory assistance and place of discharge.

What is mentioned above will be made with case study, and about the control sample who will be as a same number of case study and they will answer on psychological and social questionnaire and this outcome will be depended as a standard for statistical comparing.

5.5 Randomization and Blinding Methods (If relevant):

This study will accredit the questions within the questionnaire (Appendix) were developed on the basis of the 20 data elements in the ISCICDS. Of these, four neurological data elements are to be collected at acute admission and at final inpatient discharge, respectively: that is, date of neurological examination, sensory level (SL), motor level (ML) and ASIA Impairment Scale (AIS). Other data elements include date of birth, injury, acute admission and inpatient discharge, total days hospitalized, gender, injury etiology, vertebral injury, associated injury, spinal surgery, ventilatory assistance and place of discharge.

Within the Spinal Cord Injury Core Data Documentation Questionnaire, the numbers of the first 12 questions correspond to the first 12 data elements within the ISCICDS. The remaining four questions are related to neurological data. To facilitate answering the questionnaire

Lastly, the results will disseminate on all governmental hospitals and rehabilitation centers.

5.6 Selection of Participants in control group (If Relevant):

5.6: Criteria of enrolling participants in the control group

The sample which will be as a control group will be from healthy people who don't have SCI to be a normal stander for comparison.

5.7 Definition of Outcomes and how to measure it:

5.7: Variables used to answer the research question. Write them in details; how do you measure them, when and by whom.

The data will collect by depending on an official health documents for government h physiotherapy and rehabilitation which care by TSCI information. Author will visit all specialism hospit TSCI and collect the number of injured, age, gender, level of injury according to ASIA Impairment Scale(8), causes of injury, type of intensive care, and type of treatment. The author will depend on a questionnaire adapted from the data elements within the ISCICDS which consist of multiple items and questions for data collecting and achieving the goals of study. According to the data collection form, the data within the ISCICDS can be collected in clinical settings. If the method of data collection used in clinical practice is in accordance with the information in the ISCICDS, then such data may be retrieved retrospectively from the charts, whereas other data will have to be collected using the guidelines contained in the ISCICDS to ensure consistency across centers. In this study, the practice of collecting information described in the ISCICDS in individuals with SCI performed by physicians in Iraq was investigated. A questionnaire adapted from the data elements within the ISCICDS was used to allow comparison between current practice and that described in the ISCICDS. The results of this study will provide a preliminary overview of SCI core data collection among Iraqi SCI physicians and hospitals. On the basis of these results, recommendations regarding data collection across Iraqi SCI centers will be elaborated to ensure that uniform data, comparable to other SCI centers worldwide, will be gathered.

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5.8 The Procedure (steps) of the Study:

The researcher will do survey study by touring on all Hospitals and centers which care with Neuro-disease and amount the number of cases and type, cause, level of injury as also the type of treatment. The researcher will interview will patients and collect some information by questionnaire to determine and assess the psychological and social case. All of three researches will have a control group sample for stander of all tests.

5.8: Steps of performing the study.

5.9 Statistical Analysis and sample size:

The researchers will do statistical analyze by using SPSS bag to out put the results. They will use T-test for similar sample pre-post test. And also, will use correlation person, spearman, LSD, Stander division, average, and some statistical tools which will determine next.

5.9: define types of variables. What are the statistical tools used to measure p value? How are you going to show your results? ... etc

6. ETHICAL CONSIDERATION

I pledge to obligate with protocol of research ethics and provide a copy of it and I abide the ter researches.

6: Write down the type of consent and provide a copy of it. Show how you abide by the terms of Code of ethics in research.

7. ATTACHED DOCUMENTS (Tick the appropriate box)

☒ **Participants' Consent Form**	☒ **Questionnaire & Data Retrieving form**	☒ **University letter (Student)**
☐ **Professional ID**	☐ **Others:** Click or tap here to enter text.	

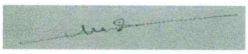
8. SIGNING A PLEDGE

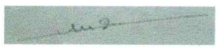
We, the undersigned researcher/ researchers, pledge to:

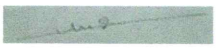
1. Implement the research project as described in this version, and that we do not perform any changes or modifications, after it was approved by the research committee, only with the written agreement of the Research Committee in the Health Directorate that approved the mentioned project.
2. That the preliminary approval was obtained from (Click or tap here to enter text.) to undertake research in the aforementioned hospital and to take advantage from the facilities it provides to the researcher based

on what is mentioned in this project, and we herein certify the validity of the signature and stamp set out paragraph (2-4).

3. That we will abide by all orders, instructions and regulatory directives issued by the management of the health institution in which the research will be implemented.
4. That we will maintain all the property of the health institution, including premises, devices, machines, tools, material and documents, and not to misuse it physically or morally, not to impede or disrupt the daily work of the institution as well while we are inside it to accomplish the research.
5. To obtain only what we are entitled to by the approval decision in order to conduct research based on the preliminary approval of the health institution in which the research will be conducted.
6. That we have read the **Code of Ethics in Research** approved by the Ministry of Health and that we will adhere to its entire provisions in all stages of implementing the research and that it is seen as complementary to the decision of the Research Committee.
7. That we will brief the health institution on the research results for the purpose of taking advantage of 8them.

Principal researcher's name, signature, date: Munib Adullah Fathe / 5/6/2021 

Researcher's name, signature, date: Wassim Muala / 5/6/2021 

Researcher's name, signature, date: Saad Kazim Karim / 5/6/2021 

Researcher's name, signature, date: Click or tap here to enter text.