

Study Protocol:

**Approach to Sexuality from
Occupational Therapy in People with
Acquired Brain Injury in Subacute
Stage**

Study Protocol Code: 2017/587

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1. Summary

- **Project title:** Approach to Sexuality from Occupational Therapy in People with Acquired Brain Injury (ABI) in Subacute Stage
- **Study protocol code:** 2017/578
- **Promoter:** Thais Pousada García
- **Principal investigator:** Thais Pousada García
- **Centers where the study is planned:** University Hospital Complex of A and Faculty of Health Science of University of A Coruña (UDC).
- **Qualification of the person responsible for monitoring:** Occupational Therapist of the Rehabilitation Service
- **Design:** Qualitative study with a phenomenological approach
- **Condition to study:** The relevance of the approach to sexuality from Occupational Therapy in people with Acquired Brain Injury in the subacute stage
- **Objectives:**
 - **General objective:** Explore the perceptions of people with ABI, who are in a subacute situation and their relatives and partners, about their assessment of the relevance of the sexuality approach during their occupational therapy intervention.
 - **Specific objectives:** Describe and analyze the perspectives of users, family members and partners about the importance of this occupation and its relevance in daily life; what includes the approach to sexuality; the differences that may arise between the perspectives of the participants according to gender; and the differences that may arise between the perspectives on the subject by age groups.
- **Study population and total number of participants:** The study population is made up of people with ABI in the subacute stage who go to Occupational Therapy to the Physical Rehabilitation Unit of the Maritime Hospital of Oza of the University Hospital Complex of A Coruña and their families and partners. The size of the sample is conditioned by the qualitative study's own design. The number of participants will be established when the theoretical saturation of the data is reached.
- **Timeline and expected date of finalization of the study:** The study will be carried out between September and June 2018. The field work will be carried out from February to May. The expected completion date is the first week of June 2018.

2. General information

- **Project title:** Approach to Sexuality from Occupational Therapy in People with Acquired Brain Injury (ABI) in Subacute Stage
- **Study protocol code:** 2017/578
- **Promoter:** Thais Pousada García
- **Principal investigator and sub-investigators:** Thais Pousada García (Principal investigator), Nuria Rico Alonso, Pablo A. Cantero Garlito and María Isabel Francisco de Miguel (sub-investigators).
- **Center in which the study is planned:** The bibliographic search and the analysis of the codified data will be carried out in the Faculty of Health Sciences in the Oza Campus of the University of A Coruña (UDC). Observation and field work will be done at the Maritime Hospital of Oza (University Hospital Complex of A Coruña). The data will be stored in the custody of the hospital's Occupational Therapist. The information used for the analysis of results, carried out in the facilities of the faculty will be fully codified by the therapist, and guarded under lock and key by the principal investigator in a location of the Faculty of Health Sciences.
- **Qualification of the person responsible for monitoring:** Occupational Therapist of the Rehabilitation Service

3. Background and justification of the project

Occupational Therapy is a discipline that proposes a client-centred practice and that conceives of this in a holistic way (1). Therefore, when an Occupational Therapist develops his professional practice he should take into account all the spheres of the person. The American Association of Occupational Therapists (AOTA), in its Occupational Therapy Practice Framework (2010) (2), collects sexual activity as an Activity of Daily Living. However, this activity is not completely addressed by the professionals of the discipline when it comes to working together with its clients. Sexuality constitutes another part of the person and, according to authors such as Malón, it must be considered, respected and cultivated by professionals (2009) (2). In addition, it is important to note that when a person suffers an acquired brain damage, for various reasons, the sexual activity of that person can be altered by physical, neuropsychological, emotional or behavioral conditions (3). If the Occupational Therapist really looks for the empowerment of the person and to promote that this one recovers the greater possible independence, it must be able to assume that the sexuality also forms part of his day to day. Therefore, its approach may be another objective to be taken into account in therapeutic intervention.

Therefore, what we want to investigate in this study is whether, really, for people who suffered an acquired brain injury, as well as their families and partners, if possible, it is relevant to intervention from Occupational Therapy in sexuality. They want to know their perspectives on this occupation in order to know whether they consider it a priority in the sub-acute stage of the recovery process or believe that, on the contrary, it should not be intervened or should be done later, in a chronic phase.

4. Objectives

The **general objective** of this study will be to analyze whether people with acquired brain damage, who are sub-acute and their relatives and partners, consider relevant or not the approach to sexuality during their Occupational Therapy intervention.

In addition, the **specific objectives** will be the following:

- Describe and analyze the perspectives of users, family members and couples about the importance of this activity and its weight in a person's daily life.
- Describe and analyze the perspectives of users, family members and couples that covers the approach to sexual activity.
- Describe and analyze the differences that may arise between the perspectives of male and female users, family members or couples on the subject of the study.
- Describe and analyze the differences that may arise between perspectives on the subject by age groups in users, family or couples.

5. Type of study

The study that will be carried out will have a qualitative methodology. This will have a phenomenological focus since it seeks to know the subjective experience of the people with whom we work. We seek to know the experiences and perspectives of these Persians in order to analyze them and draw conclusions related to the central theme of the work. To obtain this information the main data collection tool will be the interview. The semi-structured interview will also be used Canadian Occupational Performance Measurement Instrument of Occupational Therapy.

6. Materials and methods

- **Scope of study:** This is a study from the Occupational Therapy discipline in a hospital space, specifically in the Maritime Hospital of Oza, with clients with acquired brain injured and their relatives and partners.
- **Selection of participants:** For the selection of participants, it is important to indicate that there will be three groups of informants. The main group will be the clients of the service that present acquired brain damage and the other two groups will be composed of their partners and relatives who agree to participate in the present study. The use of these three groups aims to know if there are differences between their perspectives regarding the main topic of study in order to know the possible differences, coincidences or contradictions that could have existed. Therefore, there will be criteria for inclusion and exclusion of users and others for partners and relatives.

- **Selection criteria of people with acquired Brain Injury:**

- Inclusion Criteria:

- Being over 18 years.
 - Have a diagnosis framed within the concept of Acquired Brain Injury.
 - To be in the sub-acute stage after the Acquired Brain Injury.
 - Take Occupational Therapy to the Neurology Service of the Rehabilitation Unit of the Maritime Hospital of Oza (CHUAC) for a minimum of two months.

- Exclusion Criteria:

- Do not accept to participate in the study.
 - Present a decrease in the level of consciousness.
 - Present alterations at the cognitive level that suppose a score of less than 20 on the Mini-mental State Examination (MMSE).
 - Present disinhibition after acquired brain damage.
 - Present sensory aphasia.

- **Selection criteria of relatives and partners of people with Acquired Brain Injury:**

- Inclusion Criteria:

- Being over 18 years.
 - Being partner or relative of a person who has a diagnosis framed within the concept of Acquired Brain Injury.
 - Being partner or relative of a person who is in the sub-acute stage after the Acquired Brain Injury.
 - Being partner or relative of a person who takes Occupational Therapy to the Neurology Service of the Rehabilitation Unit of the Maritime Hospital of Oza (CHUAC) for a minimum of two months.

- Exclusion Criteria:

- Do not accept to participate in the study.
 - Present a decrease in the level of consciousness.

→ Present alterations at the cognitive level that suppose a score of less than 20 on the Mini-mental State Examination (MMSE).

- **Withdrawal criteria:** Voluntary withdrawal from the study and / or discharge from hospital.
- **Recruitment of participants:** The recruitment of participants in this study will be done by the occupational therapist of the hospital in order to facilitate entry into the field of study for being a person known to people with ABI, relatives and partners. She will be the only person with full access to medical records. This professional will be in charge of recruiting the participants and will be the one who will offer to participate in the study those users who meet the inclusion criteria and who are the most representative in order to obtain the best possible information, as it is characteristic of the qualitative research the use of an intentional and convenience sample. In addition, the occupational therapist will be the person who presents the information sheet and the informed consent form, requesting authorization for the college student, with her supervision, to conduct the interviews that are presented in this document. In addition, once the user participants accept, the Occupational Therapist will offer their partners and family members their participation in it. Once the information is delivered, the people who freely accept participating in this study should contact the principal investigator and the student through a telephone or a contact email giving their consent. These means of contact appear in the Adult Participant Information Sheet.
- **Study period:** The study will be carried out between September and June 2018. The fieldwork will be carried out from February to the end of April, during the student's stay in their period of university clinical practices.
- **End of the study:** The estimated date of completion of the study will be the second week of May approximately.
- **Justification of the sample size:** The size of the sample is conditioned by the qualitative study's own design. The number of participants will be established when the theoretical saturation of the data is reached.
- **Measurements and intervention:** In order to collect the data, a semi-structured interview will be carried out by the student to the participants, with the support of the principal investigator and the supervision of the Occupational Therapist of the Maritime Hospital of Oza, once Participants agree to participate in the study and authorize the student to interview them. This interview will be different depending on whether we are doing it to the person who suffered the ABI (Annex I), to his partner (Annex II) or to his relative (Annex III). In addition, in order to know the occupational priorities of these, the semi-structured interview called the *Canadian Occupational Performance Measurement*

(Annex IV) of Occupational Therapy will be used. The use of this will be limited to knowing these occupational priorities and, therefore, the instrument will not be passed in its entirety. That is, since this instrument is used to assess the occupational priorities of a person over a period of time, only the section in which these priorities are known will be used, since there is no sense in carrying out the others.

These interviews will be conducted in one of the rooms that the Occupational Therapy area of the Rehabilitation Service of the Maritime Hospital of Oza presents. This classroom will be occupied only by the study participant, the person in charge of conducting the interview, and the occupational therapist of the hospital. No one can enter this room during the performance of the same in order to ensure maximum privacy and confidentiality of information.

The interviews carried out with the participants will be recorded in audio format guaranteeing maximum confidentiality of the person at all times. After the completion of each of the interviews, these will be transcribed in a coded manner and will be kept under lock and key by the occupational therapist of the hospital. The recordings will be destroyed immediately after the transcription of the same. At no time will access to the clinical history of the participant in the development of field work be necessary.

- **Schedule and expected completion date:** The study will be conducted between September and June of 2018. The field work will be carried out from February to April, during the student's stay in the period of university clinical practices in the unit. The expected completion date is the first week of June 2018.

SCHEDULE OF THE STUDY	
September 2017	Bibliographic search and reading of it.
October 2017	Preparation of the research Project.
November 2017	
December 2017	Submission of the proposal to the ethics committee
January 2018	
February 2018	Collection of information through the realization of fieldwork with the use of interviews with participants.
March 2018	Transcripts of the interviews.
April 2018	Analyze and interpret the results.
May 2018	Preparation of the discussion and final conclusions.
June 2018	Presentation of the work before the court.

- **Analysis plan:** The analysis of the data that will be collected from the interviews with the people participating in the project will be studied, triangulated and interpreted by the researchers of the project, once they are codified and can leave the Maritime Hospital of Oza to the Faculty of Health Sciences under the custody of the principal investigator, as already indicated above. The interviews will be transcribed (codified) and their content will be analyzed, including their categorization, in order to answer the study question. For this, an inductive approach will be used, which facilitates the themes to emerge from the data previously obtained. Thus, several categories will be identified that will make it possible to offer, in a reliable manner, the experiences and perceptions of the participants themselves, directly. In addition, in order to obtain an external verification of the qualitative results, apply a process of "researcher triangulation" or Intersubjective Verification. This will allow the contrast of information, analysis of data and discussion of them, acquiring greater credibility and objectivity.

The purpose of this analysis is to know first-hand the meanings and the definition of the situation itself, as well as the experiences on the part of the participants themselves.

7. Ethical and legal aspects

- **Compliance with Standards of Good Clinical Practice and Declaration of Helsinki:** In order to carry out the present work, compliance with the Good Clinical Practice Standards will be taken into account. It will not be necessary to take into account the Declaration of Helsinki, since one will not experiment with being human, but rather the research will be based on the information that is gathered from the interviews carried out with the participants without actually working with them directly after the collection of information.
- **Confidentiality of the information:** The confidentiality of the participants in this work will be given priority at all times. For that, the personal data will be encoded by a letter and a number. Therefore, all this information that is collected will be protected by complying with Organic Law 15/1999, of December 13, on the Protection of Personal Data of the Spanish law. The information sheets and transcripts of the interviews will be stored under lock and key in the facilities of the Faculty of Health Sciences (UDC), where the main researcher carries out her activity. In addition, it is essential to indicate that, following Order SSI / 81/2017, of January 19, which publishes the Agreement of the Human Resources Commission of the National Health System (Spanish legislation), in order to ensure and protect the right to privacy of the patient, the student will not be able to access the personal data of the patients nor will she be recruited for the present

investigation. The occupational therapist of the hospital will be in charge of these procedures and who will ask for the authorization of the patients so that the student can carry out the interviews that are presented in this project. Therefore, she will also be the custodian of said personal data until they are duly codified.

- **Informed consent:** It is essential that participants are informed of the project, therefore, the occupational therapist of the hospital must previously provide the information sheet to the adult participant, and subsequently, if they wish, they must sign the informed consent to be able to participate in the study. The Occupational Therapist must indicate that the student will be the one who will carry out the task of conducting the interviews under her supervision. Once this is done, participants who are interested in participating freely will contact the main researcher of the project and the student in order to confirm their participation.
- **Other ethical and legal aspects:** In addition, it has the approval of the Chief of Physical Rehabilitation Service of the Oza Hospital, and the support of the Occupational Therapist of the service and tutor of practices of the student.

8. Economic memory

8.1. Breakdown of expenditure

Resource	Description	Justificaton	Cost
Infrastructure	Occupational Therapy Area of the Rehabilitation Service of the Maritime Hospital of Oza (CHUAC) Faculty of Health Sciences of the University of A Coruña	These will be the places where the field work will be carried out with the study participants and where the study data will be kept under lock and key under the responsibility of the occupational therapist of the hospital. It will be where the bibliographic search will take place and where the already coded data of the present study will be analyzed and stored under lock and key.	€00.00
Human resources	Research team composed of four Occupational Therapists	They will be in charge of conducting the interviews, administering and analyzing the resulting data and writing the study.	€00.00*
Consumable material	1 pack of 500 sheet (€ 2.99 per unit) 3 pens (€ 0.15 per unit) 1 printer ink cartridge (€17.00 each unit)	These materials will be necessary to print the interviews and information sheets and informed consent, make notes and cover the different documents.	€20.44
Inventoriable material	Computer (own) Printer (own) Digital recorder (€22.99)	These materials will be necessary to write the study and the other documents, they will also be necessary to print the interviews and the information sheets and informed consent. The digital recorder will allow recording all the information that is collected during the interviews with the participants and will allow a more complete analysis of the information.	€22.99
TOTAL COST: €43.43			

* The hiring of any occupational therapist is not foreseen, since all those involved will participate as researchers in the project.

8.2. Funding sources

All the economic costs involved in the study will be borne by the research team. In addition, no assistance of a public or private nature will be requested at any time during the study, so there will be no external sources of funding.

9. Bibliography

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- (3) Malón Marco A. El sexo como valor humano. In: Malón Marco A. La sexualidad. Huesca, Spain: Cadis Huesca; 2009. p. 9-18.
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