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WeBirthStudy: Questionnaire for assessing waterbirth experience design and validation

Submission date
21/06/2020

Recruitment status
Recruiting

Registration date
01/07/2020

Overall study status
Ongoing

Last Edited
15/01/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Water birth is the process of giving birth in water using a deep bath or birthing pool. Being in water during labour can help with pain as well as being more relaxing and soothing than being out of water. The water can help to support the weight, making it easier to move around and feel more in control during labour. Waterbirth has become an increasingly popular childbirth option. However, there is no specific questionnaire for evaluating waterbirth experience. The aim of this study was to design and develop a self-reporting questionnaire to evaluate the waterbirth experience.

Who can participate?
Adult women who have experience of waterbirth, and can speak Spanish.

What does the study involve?
The study sample will be recruited in Hospital Germans trias i Pujol, located in the Barcelona region and belong to the Catalan Health Service. Participants will be informed of the nature of the study and recruited in the delivery room or hospitalization ward. Recruitment will be continuous throughout different time periods on all days of the week during the period October 2022 to December 2024. Spanish Questionnaire for Assessing Waterbirth Experience (QAWE) version will be sent to the participants online between 1 and 3 months postpartum together a questionnaire on sociodemographic and clinical variables.
The study involves the waterbirth experience questionnaire creation and the description of the obstetrical and neonatal results obtained and also the description of the facility agents and barriers of waterbirth.

What are the possible benefits and risks of participating?
There are no risks of participating since postpartum women have to answer an online questionnaire after one month of birth. However, they will be contributing to the creation of a valid and reliable instrument, which allows health professionals to evaluate waterbirth experience and can be used to assess the quality of health care, incorporating the point of view of women, and contribute to the evaluation and monitoring of the changes introduced with the new delivery care model.

Where is the study run from?
Hospital Germans Trias i Pujol (Badalona) Spain.

When is the study starting and how long is it expected to run for?
June 2020 to December 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Design and validation of a questionnaire for assessing waterbirth experience

Acronym
WeBirthStudy

Study objectives
Waterbirth has become an increasingly popular childbirth option. However, there is no specific questionnaire for evaluating waterbirth experience. The aim of this study was to design and develop a self-reporting questionnaire to evaluate the waterbirth experience

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/12/2021, COMITÉ DE ÉTICA DE LA INVESTIGACIÓN - HOSPITAL UNIVERSITARIO GERMANS TRIAS I PUJOL (Ctra. de Canyet s/n, Badalona, Barcelona, 08916, Spain; +34 934 65 12 00; avaluacionsceic.germanstrias@gencat.cat), ref: PI-21-326

Study design
Multicentre observational transverse trial

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Screening tool for evaluating waterbirth experience

Interventions
Participants will be informed and recruited in the delivery room or hospitalization ward. They will receive an e-mail from one to two months after waterbirth, inviting them to answer the online questionnaire that includes the created waterbirth questionnaire and a questionnaire on sociodemographic variables. If they do not answer, they will be recalled by the researcher's team. Once they answer the e-mail, their participation will be finished.

Intervention Type
Other

Primary outcome measure
Waterbirth Experience will be evaluated using the created specific questionnaire one month after birth as a minimum.

Secondary outcome measures
1. Obstetrical results from participants will be obtained and of measured using hospital records
2. Neonatal results of participants' children will be obtained and measured using hospital records
3. Waterbirth facilitators and barriers will be obtained and measured from two focus group composed of 5 postpartum women who gave birth in water. Information will be recorded, transcribed and triangulated to obtain those barriers and facilitators identified by women participating in this phase of the study. Phase I: questionnaire creation

Overall study start date
15/06/2020

Completion date
01/12/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/10/2023:

1. Older than 18 years
2. Able to understand Spanish
3. Have computer knowledge in order to answer an online questionnaire
4. Have used water immersion during birth

_____

Previous inclusion criteria:

1. Older than 18 years
2. Able to understand Spanish
3. Have computer knowledge in order to answer an online questionnaire
4. Have given birth using waterbirth

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Between 15 and 20 per item

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
11/10/2022

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Germans Trias i Pujol
Ctra. de Canyet s/n
Badalona
Spain
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Sponsor information

Organisation
Hospital de Mollet

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Sponsor type
Hospital/treatment centre

Website
https://www.fsm.cat/web/

Organisation
Fundació Hospital Sant Joan de Déu de Martorell

Sponsor details
Av. Mancomunitats Comarcals, 1, 3
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uac@hmartorell.es

Sponsor type
Hospital/treatment centre

Website
https://fhsjdm.cat/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/11/2026

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			03/07/2020	No	Yes