# Blended learning vs traditional learning in obstetrics education: a prospective randomised controlled trial

Submission date 16/04/2019	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>
		☐ Protocol
Registration date	Overall study status	Statistical analysis plan
19/04/2019	Completed	Results
Last Edited	Condition category	<ul><li>Individual participant data</li></ul>
18/04/2019	Other	Record updated in last year

## Plain English summary of protocol

Background and study aim

The European Higher Education Area (EHEA) was created with the aim of guaranteeing more comparable, compatible, and coherent higher education systems among the European countries. Their standards and guidelines for quality assurance promote the design of teaching programs that should stimulate motivation, self-reflection, and commitment of students in their own learning process. A student-centred learning and teaching process.

Blended learning (BL); which combines online and in-class teaching, and flipped learning (FL); a paradigm of the first, seem to be more appropriate models for learning by competencies than those based on traditional didactic lectures. It is assumed that BL, which encompasses different learning styles by breaking the barrier of time and place, creates a positive and collaborative atmosphere that supposes an increase in its effectiveness. FL turns the in-class lecture into a dynamic and interactive space, where the educator guides the students as they apply the concepts and become creatively involved in the subject. This requires individual work prior to the in-class sessions. Evidence on the effects of these new educational models on the acquisition of competencies (knowledge, skills. and attitudes) is scarce. Although a number of studies have been published since 2012, the heterogeneity in the designs and the scarcity of controlled studies prevent researchers from reaching consistent conclusions with regard to the effects of FL.

The purpose of the study is to assess the effectiveness of blended learning (BL) compared with traditional learning (TL) in the acquisition of obstetrics competencies in undergraduate students.

## Who can participate?

Fourth-year medical students from the Hospital of the Santa Creu i Sant Pau teaching unit of the Autonomous University of Barcelona (UAB), enrolled in first-semester obstetrics during the 2015-2016 and 2016-2017 academic years.

#### What does the study involve?

Participants were asked to join this study on the first day of the academic year. They were randomly allocated to one of two groups. Those in the first group were assigned to receive obstetrics subject teaching via traditional learning (TL), through classroom-based lectures. Those

in the second group were assigned to receive obstetrics subject teaching via blended learning (BL), which combines online and in-class teaching and used a flipped classroom approach that moves direct instruction outside the classroom so that class time can be used for interactive applied learning with the purpose of enabling teachers to engage students through a wide variety of active learning strategies. The study lasts two years in total. Competency in the obstetric subject was assessed using a 6-item test during the course, 50-item test at the end of the course, and six months later. To compare interventions, we analysed the results of these tests. Participants also completed a satisfaction questionnaire at the end of the study.

What are the possible benefits and risks of participating?

There is no immediate direct benefit to those taking part. But there should be benefits in the future because the results of the study are likely to influence the way classes are taught at the university. There was no risk of participating in this study.

Where is the study run from?

The study was being run by the Autonomous University of Barcelona (UAB) and took place in Hospital of the Santa Creu i Sant Pau teaching unit of the UAB in Barcelona (Spain)

When is the study starting and how long is it expected to run for? September 2015 to June 2017.

Who is funding the study?
This study was not funded by anyone

Who is the main contact?

- 1. Dr. Carmen Medina Mallén (scientific contact), mmedinam@santpau.cat
- 2. Juan José Espinós Gómez (scientific contact), jespinos@santpau.cat

# **Contact information**

# Type(s)

Scientific

#### Contact name

Dr Maria del Carmen Medina Mallén

#### ORCID ID

http://orcid.org/0000-0002-1219-5947

#### Contact details

Sant Quintí 89 Barcelona Spain 08041 +34 93 553 70 41 mmedinam@santpau.cat

# Type(s)

Scientific

#### Contact name

#### Dr Juan José Espinós Gómez

#### Contact details

Sant Quintí 89 Barcelona Spain 08041 +34 93 553 70 41 jespinos@santpau.cat

# Additional identifiers

#### **EudraCT/CTIS** number

Nil known

#### **IRAS** number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

2958

# Study information

#### Scientific Title

A randomised trial to determine whether blended learning is more effective than traditional learning when teaching medical students about obstetrics

# Study objectives

Blended learning (BL) compared with traditional learning (TL) is better in the acquisition of obstetrics competencies in undergraduate students.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Approved 28/06/2015, Ethics Committee on Animal and Human Experimentation [CEEAH] of the Autonomous University of Barcelona [UAB] (Campus de la UAB, Plaça Cívica, 08193 Bellaterra, Barcelona, Spain; +34 93 581 3578; ceeah@uab.cat), ref: 2958

# Study design

Prospective randomised controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

#### Study setting(s)

Other

## Study type(s)

Other

#### Participant information sheet

not available in web format

#### Health condition(s) or problem(s) studied

Pedagogical methodology for the acquisition of obstetrics competencies

#### **Interventions**

The study involved 171 fourth-year medical students from the Hospital of the Santa Creu i Sant Pau teaching unit of the UAB in Barcelona enrolled in first-semester obstetrics during the 2015-2016 and 2016-2017 academic years.

A teacher checked the students for eligibility and these were then randomly allocated to the study or control group using a list generated by a syntax program (IBMP SPP) in such a way that it was unpredictable but reproducible. It was a blocked randomization procedure to ensure close balance of the numbers in each group. In this way, 64 students followed the BL model for the course, which in turn was divided into smaller groups (3 groups per year composed of 10 and 14 students each) and 67 students followed the traditional model (TL). The team of teachers was blinded to the group assignment.

#### Intervention Type

Behavioural

#### Primary outcome measure

Short, medium and long-term effectiveness of a pedagogical methodology based on the combination of blended learning (BL) and flipped learning (FL), and traditional learning (TL) expressed from the academic results of tests. The three tests were made for the study. The 6-item test was taken immediately the participants finished the class attendance. A 50-item test was taken 1 month after the end of the instruction, and another 50-item test was taken 6 months after the intervention.

#### Secondary outcome measures

Assessed two years after recruitment:

- 1. Students satisfaction with the pedagogical methodology BL and TL measured using the Dundee Ready Education Environment Measure (DREEM).
- 2. Student satisfaction with Blended Model's education tools measured using an analogous numeral scale (0-10) to evaluate each education tool.

# Overall study start date

26/05/2015

#### Completion date

20/06/2017

# **Eligibility**

#### Key inclusion criteria

Medical students from the Hospital of the Santa Creu i Sant Pau teaching unit of the Autonomous University of Barcelona, enrolled in first semester obstetrics during the 2015-2016 and 2016-2017 academic years.

#### Participant type(s)

Healthy volunteer

#### Age group

Adult

#### Sex

Both

#### Target number of participants

A minimum of 63 students per group was determined to detect a difference

#### Key exclusion criteria

- 1. Students repeating the course
- 2. Students who were in an Erasmus study abroad program during 2015-2016 and 2016-2017 academic years

#### Date of first enrolment

16/09/2015

#### Date of final enrolment

16/09/2015

# Locations

## Countries of recruitment

Spain

# Study participating centre Hospital De La Santa Creu I Sant Pau

Sant Quintí 89 Barcelona Spain 08041

Study participating centre Universidad Autónoma de Barcelona

Campus UAB Plaça Cívica

# Sponsor information

# Organisation

Universidad Autònoma de Barcelona

#### Sponsor details

Plaça Cívica Bellaterra Spain 08193 34 93 581 11 11 informacio@uab.cat

#### Sponsor type

University/education

#### **ROR**

https://ror.org/052g8jq94

# 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

01/06/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the informed consent signed by the participants did not contemplate the option of sharing the information with other researchers.

# IPD sharing plan summary

Not expected to be made available