

# Evaluation of the Origo prototype for enhancing women\*s labor & delivery experience. A pilot study.

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The objective of this study is to gain insights into the value of the proposition \*Origo\* for women and their loved ones, medical staff and care institution.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Pregnancy, labour, delivery and postpartum conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON37102

### Source

ToetsingOnline

### Brief title

Origo

### Condition

- Pregnancy, labour, delivery and postpartum conditions

### Synonym

child birth experience

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Philips Design

**Source(s) of monetary or material Support:** Benodigde apparatuur (o.a. iPod) wordt door Philips verstrekt en Philips voorziet in een compensatie voor dit onderzoek uitgevoerd in MMC. Zie G3a.

## Intervention

**Keyword:** ambient experience, childbirth, expectations, experiences

## Outcome measures

### Primary outcome

To gain an estimate of the effect size (in means of improvement/change in maternal quality of life), as well as an estimate of the variability in our measures. (feasibility study)

### Secondary outcome

Secondary Objectives: Secondary objective of this study is to gain insights into the value of the proposition \*Origo\* for women and their partners and/or relatives, medical staff and care institution. This entails the following sub objectives:

- Gain a deep understanding of how this concept influences the woman\*s experiences before, during and after giving birth: most important secondary objective is maternal quality of life
- Understand how this concept is used in practice by the different stakeholders
- Investigate how it affects the clinical workflow in and around the delivery rooms
- Gather feedback on proposition for future development and improvement

## Study description

### Background summary

Patient consumers are becoming increasingly assertive and knowledgeable which makes it more than ever important for a hospital to improve the quality of care

they provide in order to differentiate. As a result of this current competitive care market, the focus of perceived user value will have to include patients' experiences and comfort next to functionality (Ford and Myron, 2000).

In obstetrics, this trend has focused on women's experiences of childbirth. A delivery is one of the major events in life: a radical experience that evokes strong emotions. A good delivery experience is crucial for the woman's wellbeing, health and relationship with her infant (Goodman et al., 2004; Buitendijk, 2010 )

M. Rijnders concluded in her study that a one of six Dutch women looked back negatively on their birth experience 3 years postpartum. Especially women who gave birth in a hospital context are less satisfied with this (Rijnders et al., 2008)

The \*Origo\* prototype consists of an iPod app and a specially adapted delivery room. The app can be used during pregnancy as well as during labor, both at home and in the hospital. Furthermore, the delivery room is equipped with an AE system, which is connected to the app with which the woman and her partner are already familiar with. It contains an interactive wall projection that is representative of the physiological data.

### **Study objective**

The objective of this study is to gain insights into the value of the proposition \*Origo\* for women and their loved ones, medical staff and care institution.

### **Study design**

open label randomized trial

### **Intervention**

Origo concept, existing of an app for the Ipod

### **Study burden and risks**

No risks

All participants will be asked to fill questionnaires. Some of the participants will be asked for an interview or to participate in a focus group.

## **Contacts**

### **Public**

Philips Design

High Tech Campus 33  
Eindhoven 5656 AE  
NL

**Scientific**

Philips Design

High Tech Campus 33  
Eindhoven 5656 AE  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Maternal age \* 18 years
- Nulliparae
- Singleton pregnancy
- Planned vaginal delivery
- Gestational age beyond 20 weeks
- Dutch speaking
- Informed consent

### Exclusion criteria

- High patients (tertiary care)-risk
- Known fetal anomaly

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	05-02-2013
Enrollment:	120
Type:	Actual

## Ethics review

Approved WMO	
Date:	13-12-2012
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
ClinicalTrials.gov	NCT3490
CCMO	NL41219.015.12