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# The Oxford Conception Study - a randomized controlled trial to determine whether daily information about potential fertility from a fertility-monitoring device will increase the conception rate in women wishing to achieve a pregnancy

**Submission date**
28/10/2005

**Recruitment status**
No longer recruiting

**Registration date**
02/03/2006

**Overall study status**
Completed

**Last Edited**
29/08/2018

**Condition category**
Pregnancy and Childbirth

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
N/A

# Study information

## Scientific Title
The Oxford Conception Study - a randomized controlled trial to determine whether daily information about potential fertility from a fertility-monitoring device will increase the conception rate in women wishing to achieve a pregnancy

## Acronym
OCS

## Study objectives
The Oxford Conception Study is a three-arm randomized controlled trial investigating whether daily information about potential fertility from a digital fertility-monitoring device will increase the conception rate in women wishing to achieve a pregnancy. A third of women are randomized to receive information about the early fertile time, a third of women are randomized to receive information about the late fertile time and third are a control group who do not receive any information. The women are followed up for six months or until they are pregnant.
The primary outcome is to compare the cumulative three-cycle pregnancy rate between women using a modified fertility monitor when the monitor displays high fertility from the first appearance of Luteinizing hormone (LH) and for the next two days, (i.e. the days that identify the late fertile time) and women using a modified fertility monitor which gives no fertile status.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics approval for the Oxford Conception Study was received in September 2002, reference number CO1.282

## Study design
The Oxford Conception Study is a prospective three-arm randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Time to pregnancy

## Interventions
Three modified versions of a fertility monitor (supplied by Unipath Ltd. and currently not available in the UK, have been developed for the study so that the daily result for potential fertility will be displayed (or not) according to the experimental design. The monitor allows the womans fertility status to be assessed independently. For the purpose of this trial, the fertility monitor is set to request all the women to test their urine on 20 days of the cycle from day 6 to day 25 inclusive. The fertility monitor identifies a womans fertile period by measuring via

immunochromatography the levels of estrone-3 glucuronide (E3G), a metabolite of estrogen, and LH in urine. A recent independent study has demonstrated that the LH surge accurately predicts the day of ovulation.

The trial has two intervention arms and a control arm. Volunteers are randomized to one of the three arms using computer generated random numbers. The randomization method uses opaque sealed envelopes. The volunteers are randomized into one of three groups; each group receives different information from the fertility monitor:

1. The late fertile time group: monitor shows high fertility from the first appearance of LH and for the next two days. It then shows low fertility until the end of the menstrual cycle
2. The early fertile time group: monitor shows high fertility from the first appearance of E3G and low fertility from the appearance of LH until the end of the menstrual cycle
3. The control group: monitor reveals no information about the fertility status although they still perform urine tests on 20 days of the cycle as requested

### Intervention Type
Device

### Phase
Not Specified

### Primary outcome(s)
The primary outcome measure is whether the pregnancy rate (assessed in terms of 3-month and 6-month cumulative pregnancy rates) in couples given information about the womans potential fertility is higher than those who do not receive the information. The women in the late fertile group (LH day + 2 days) will be compared with women in the control group. The days of intercourse and the monthly conception rates will be compared between those in the late fertile group who receive daily information from the monitors and those who do not.

### Key secondary outcome(s))
Secondary outcome questions include:

1. Whether the pregnancy rate (assessed in terms of 3-month & 6-month cumulative pregnancy rates) in the women in the early fertile group (E3G until LH rise) is higher than that of the pregnancy rate of the women in the control group
2. Whether the pregnancy rate (assessed in terms of 3-month & 6-month cumulative pregnancy rates) in the late fertile group (LH day + 2 days) is higher than that of the women in the early fertile group (E3G until LH rise)
3. Whether information from a fertility-monitoring device helps couples to target sexual intercourse more effectively than no information
4. Whether there is an association between the following variables on conception rates and pregnancy outcome: age of woman, age of partner, Hospital Anxiety And Depression (HAD) score, stress scores, salivary cortisol, salivary amylase, Body Mass Index (BMI) of women, smoking, alcohol, caffeine intake, vitamin supplementation, medication consumption, age of the gametes, intercourse frequency, cycle length variability

### Completion date
01/12/2006

## Eligibility

### Key inclusion criteria
1. Women aged 18 to 40 years who are having sexual intercourse with a regular partner
2. Trying to conceive for less than three months
3. Menstrual cycle length of 21 to 35 days for the past three months
4. Willing to record all medication use and sexual intercourse during the study
5. Willing to travel to Oxford for one recruitment session or agree to phone recruitment
6. Willing to be randomized into one of three groups
7. Willing to have a baseline pregnancy test to ensure that they are not pregnant at entry

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
Female

### Key exclusion criteria
1. Either partner has a history of infertility or is currently undergoing infertility treatment
2. Either partner is using any form of contraception
3. Woman is breastfeeding
4. Woman has used hormonal contraception during the past three menstrual cycles
5. Woman has used emergency contraception in the past two menstrual cycles
6. Woman has used injectable contraceptive in the past year

### Date of first enrolment
01/11/2003

### Date of final enrolment
01/12/2006

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Department of Public Health**
Oxford

United Kingdom
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# Sponsor information

**Organisation**
Department of Public Health (UK)

# Funder(s)

**Funder type**
Government

**Funder Name**
National Health Service Executive (NHSE) National Career Scientist award

**Funder Name**
National Institute for Childhood Health & Disease US

**Funder Name**
The DLM Charitable Trust

**Funder Name**
Unipath non-commercial funding

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| | protocol | | | | |

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| Protocol article | 01/11/2006 | Yes | No |