

The UNiTY Trial Introductory Pamphlet

(For couples who may be interested in participating in the UNiTY Trial)



A randomised controlled trial evaluating the clinical and cost effectiveness of IVF versus IUI for Unexplained Infertility

Thank you for taking time to read this pamphlet which will explain briefly about the UNiTY Trial.

You are being invited to take part in this study because as a couple you have been diagnosed with unexplained infertility (UEI) and this means you are eligible for fertility treatment to help you conceive.

What is the UNiTY Trial investigating?

UNiTY aims to find out the best way to help couples with unexplained infertility to have a child.

We want to find out if 3 cycles of IUI (Intrauterine Insemination) treatment is as successful and more cost effective than 1 cycle of IVF (In-Vitro Fertilisation) treatment.

Why is UNiTY important?

One in three couples with fertility issues have unexplained infertility.

To find out which treatment is best for these couples we are carrying out a study where they will be randomly allocated to have either three cycles of IUI or one IVF cycle.

IVF involves hormone injections, egg collection, fertilisation in a lab. If fertilisation is successful an embryo is placed into the womb.

IUI is simpler, using lower doses of hormones and placing prepared sperm directly into the womb.

European and NICE guidance recommend IUI, but it is not routinely used in the UK.

What will happen if I take part?

Which treatment you will get is decided by a computer at the UNiTY Trial Office which will allocate the treatment randomly.

You have an equal chance of receiving *either* 3 cycles of IUI *or* 1 cycle of IVF.

All couples who are allocated into the IUI treatment group will also be offered IVF after their IUI, if their 3 IUI cycles are all unsuccessful.

Do I have to take part?

No. Participation in UNiTY is entirely voluntary.

If you decide to take part, we will check you are eligible and ask you to sign a consent form.

If you do not wish to take part, you do not have to give a reason, and your decision will not affect the care you will receive.

What if I change my mind?

You are free to change your mind at any time, and this will not affect the care you receive.

What will we need to do?

There are some questionnaires to complete which you can do online from home. The study does not usually require you to attend any additional appointments than those needed for your treatment plan.

If you become pregnant without treatment, we would like to follow how your pregnancy goes, but there will be no extra hospital visits.

What happens to our sperm samples?

We will take videos of the sperm sample that is used in your treatment and fix a sperm sample to a microscope slide. These samples may help us better diagnose and treat patients in the future.

This will not affect the sperm that is used for your treatment.

Is it safe?

Yes, both IVF and IUI have been extensively tested and have been used routinely within the UK and worldwide. Your treatment and follow up will remain the same as in standard practice guidelines.

What are the risks?

Taking part in UNiTY will not increase the risks involved of having IVF or IUI treatments.

Your fertility team will explain the risks which come with any type of treatment.

What are the benefits?

For many couples, being in the UNiTY trial offers the opportunity for additional chances to conceive. It should not reduce your chance of having a child.

If you are allocated to the IUI treatment group, you may have access to extra free treatment that is not routinely funded.

By taking part in UNiTY, you will help to improve our understanding of how we routinely treat couples like yourselves with unexplained infertility.

We are self-funding our treatment, can we still take part?

Yes, as a self-funding couple you will be asked to pay up-front for your IVF cycle before you are entered into the trial.

If you are allocated to the IUI treatment group, and have a live birth, the payment you made will be refunded.

If you are allocated IVF, or have IVF after IUI, your payment will be used to cover this cost.

Who are we?

Our research team is very experienced.

UNiTY's **Chief Investigator is Jackson Kirkman-Brown MBE**, who is a Professor of Human Reproductive Science, HFEA Person Responsible, and Science Lead at **Birmingham Women's Fertility Centre**.

Website: <https://www.spermeggembryo.com/>

UNiTY is managed by the **Birmingham Clinical Trials Unit (BCTU)**.

Email: UNITY@trials.bham.ac.uk

UNiTY is funded by **National Institute of Health and Care Research (NIHR)** and sponsored by **University of Birmingham**.

Where can I get support?

If you would like further support, you can contact the local fertility counselling service based at your healthcare provider on 0121 335 8270.

How do I learn more about the study?

For more information, contact the Fertility Research Team on the details below or access the full **UNiTY Patient Information Sheet** by scanning the QR code.



The Fertility Research Team are happy to provide you with any additional information. Please get in touch.

07469 375162 / bwc.gynaereseach@nhs.net