Birmingham Clinical Trials Unit FUNDED BY NIHR | National Institute for Health and Care Research

UNiTY: A randomised controlled trial evaluating the clinical and cost effectiveness of IVF versus IUI for UNexplained infertiliTY

QUALITATIVE SUBSTUDY
PARTICIPANT INFORMATION SHEET
HEALTHCARE PROFESSIONALS

Chief Investigator: Professor Jackson C Kirkman-Brown

Qualitative Study Lead: Dr Laura Jones

unityqualstudy@trials.bham.ac.uk

Thank you for being involved in the UNiTY trial. We would like to invite you to take part in the UNiTY qualitative sub-study. Before you decide whether to take part, it is important for you to understand why this qualitative sub-study is being undertaken and what it will involve. Please take the time to read the following information carefully. Talk to others about

the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

What is the purpose of this qualitative sub-study?

The purpose of the UNiTY qualitative sub-study is to understand how healthcare professionals (HCPs), like you, feel about being part of the UNiTY trial including for example approaching couples with unexplained infertility to participate, how you decide who should and should not be approached, your views on randomisation and on different fertility treatment options etc.

What have I been asked to take part?

You have been asked to take part because you are an HCP who has experience of caring for couples requiring fertility support and have been involved in approaching couples about participating in the UNiTY trial.

Do I have to take part?

No, it is up to you to decide whether to participate in an interview or not.

What would taking part involve?

You will be invited to take part in a one-off discussion (informal interview with a researcher from the University of Birmingham) to explore your experiences of being involved in the delivery of the UNiTY trial. We would like to talk to you at a time that is convenient for you. This will take place remotely via phone or video call (e.g. Skype; Zoom; WhatsApp) whichever is your preference. The discussion will be audio recorded to allow the researcher to pay full attention to what you are saying. Recording the interview will also allow the research team to do further analysis later. Typically, interviews can last about an hour, but can be shorter or longer depending on how much there is to talk about.

What are the possible advantages and benefits of taking part?

There are no direct benefits to you for taking part in this study, other than an opportunity to express your views and opinions and shape the full trial. However, by taking part in this research you will help provide information that will inform future care of couples who require fertility support.

Participants will receive a £25 electronic voucher (e.g., Amazon) for taking part in the interview if they take part outside of their working time. This covers £20 as a thank you for your time and £5 for consumables such as electricity/internet access given that the interview will be held remotely.

What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks in taking part; however, it will take up some of your time.

What if I do not want to take part, or decide later to withdraw?

Participation in an interview is entirely voluntary. If you do decide to take part, you will be given this information sheet to keep and be asked to complete a consent form online, on paper or recorded verbally. Your decision not to take part or withdrawing from the study will not affect your employment, or your legal rights. Similarly, if you do decide to take part, you will be able to withdraw from the study within two weeks of the interview without giving a reason (although we will appreciate it if you tell us why you changed your mind). Please contact us using the contact details on this information sheet if you would like to withdraw. If you ask to withdraw from the study more than two weeks after the interview, then we will keep the information about you that we have already collected.

Who has reviewed and organised the study?

This study has been funded by the National Institute for Health Research (NIHR). It is organised, managed, and coordinated by the Birmingham Clinical Trials Unit (BCTU) at the University of Birmingham, and data will be collected and securely stored by this institution. The study is sponsored by the University of Birmingham. The UNiTY study has been reviewed and has received a favourable opinion by Derby Research Ethics Committee**.** Additionally, the study will be supervised on a regular basis by a Data Monitoring and Ethics Committee (DMEC) and a Trial Steering Committee (TSC). The primary role of the DMEC is to ensure the absolute safety of all participants in the study.

Will my taking part in this study be kept confidential?

All the information collected as part of the UNiTY study interview will be handled strictly in accordance with your consent and the UK General Data Protection Regulation (GDPR) 2018. The audio recording of your interview will be stored securely until we publish the main findings of the study. It will then be securely deleted.

More information on how the University processes personal data can be found on the University's website on the page called 'Data Protection - How the University Uses Your Data' (https:// www.birmingham.ac.uk/research/bctu/data-protection.aspx).

Your interview will be kept strictly confidential. The only time this may change is if something is shared which suggests either yourself or others are at risk of harm. If this is the case, we would talk to you about appropriate steps we would take in communication with others to prevent

harm from occurring.

How will information about me be collected?

We will need to use information from you including your:

- Name
- Contact details
- Background demographic information (e.g., your age, ethnicity)

The UNiTY qualitative research team will use this information to do the research and other regulatory organisations may check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a unique code number instead.

We will keep all information about you safe and secure.

For example, the audio-recording of the interview will be used to produce a typed record of the discussion, known as a transcript. This transcription will be done by a UK based specialist transcription company who has signed an agreement to keep your data confidential and stored securely. They will only have access to your audio recording and no further information about you. We will analyse the anonymised transcripts as part of our research. If you needed an interpreter to support you to take part, then they will be from a specialist Interpretation company and they will have signed an agreement to keep your data confidential and stored securely.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason.
- If you choose to take part, you will be able to withdraw your data from the study within two weeks of the discussion.
- If you ask to withdraw from the study more than two weeks after the interview, then we will still use your anonymised data as it will have been included in our ongoing analysis by that point.
- Please contact us using the contact details on this information sheet if you would like to withdraw.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

- If you agree to take part in this study, you will have the option to take part in future research in two ways. A) using anonymised data saved from this study to answer future research questions, and or B) for us to recontact you about future research studies.

Where can you find out more about how your information is used?

You can find out more about how we use your information at

- www.hra.nhs.uk/information-about-patients/
- The NHS Health Research Authority leaflet available from http://www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to unityqualstudy@trials.bham.ac.uk
- by ringing us on 0121 414 3024
- Or you can contact the University of Birmingham Data Protection Officer via e-mail to dataprotection@contacts.bham.ac.uk

How will the data be anonymised?

The transcript will be checked carefully for anything that might identify you (e.g. your name, your employer) and these details will be removed. Each participant will be given a unique study number and we will only use this to identify quotes in study reports and publications. Publications from this study may contain direct quotes from interviews and brief details of individuals' professional experience of caring for couples requiring fertility support. No information which can be used to identify you will be published in the study reports.

What will happen to the results of the research study?

When the results of the study are known, we will inform you of the findings by email and/or via our website. The results of the study will be reported to the funders of the research, and they will be published in appropriate academic and professional journals and presented at conferences.

What if something goes wrong?

If you are worried about any part of this study or have a minor complaint, you should ask to speak to the qualitative researcher team who will do their best to answer your questions. Unresolved matters will be escalated to the Chief Investigator.

Alternatively you can contact Dr Birgit Whitman, Sponsor Representative at researchgovernance@contacts.bham.ac.uk

Do you have any further questions?

Thank you for taking the time to read this information. If you have any questions, then please feel free to get in touch with us using the contact details on this leaflet. For more information you can also visit our website at www.birmingham.ac.uk/UNiTY.

CONTACT INFORMATION

If you would like to speak to someone about the study, please contact the UNITY trials team:

unityqualstudy@trials.bham.ac.uk