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HEADED PAPER



UNiTY

A randomised controlled trial evaluating the clinical and cost effectiveness of IVF versus IUI for **UN**explained infertili**TY**

QUALITATIVE SUBSTUDY
PARTICIPANT INFORMATION SHEET
PATIENTS

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Why have I been invited to take part?

You have been invited to take part in a discussion with a researcher (known as an interview) because you were approached about taking part in the UNiTY trial. We are hoping to talk to a number of couples who were eligible for UNiTY including those who did or didn't agree to take part in the trial.

We would like to talk to couples; however, you can choose to speak to the researcher on your own, or alongside your partner, whichever you prefer.

Taking part in a discussion is entirely up to you. Before you decide, we would like you to understand why the research is being done and what it will involve for you. A member of our research team will go through this information sheet with you, to help you to decide whether you would like to take part and to answer any questions you may have. Please feel free to talk to others about the study if you wish.

This Participant Information Sheet (PIS) tells you the purpose of the study, what will happen to you if you take part and detailed information about the conduct of the study. Please take the opportunity to ask any questions you have and to ask for more information if anything is unclear.

What is the purpose of the study?

The main purpose of the discussion is to understand your experiences of being approached about taking part (or not) in the UNiTY trial.

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. We would like to talk to you at a time that is convenient for you/both of you if you are taking part together. The discussion will take place remotely via telephone or video call (e.g. Skype; Zoom; WhatsApp) depending on what is easiest for you. 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 last about an hour, but can be shorter or longer depending on how much there is to talk about. Throughout the discussion, the researcher will check regularly that you are comfortable and happy to continue.

What are the possible benefits of taking part?

We do not know whether you will benefit personally from taking part in this study, but the knowledge gained, thanks to your help, will inform future treatments and research. We hope that this will lead to improved treatment options for couples seeking fertility support. Some individuals and couples also appreciate an opportunity to talk about their experiences with somebody who is there to listen.

What are the possible disadvantages and risks of taking part?

Taking part does not involve any treatments or tests, so there is no physical risk involved. We will however ask you to complete a short questionnaire during the interview to tell us a little bit about yourself and talk to us about your experiences and treatment whilst receiving

fertility support.

As this may be a difficult time, you may find this difficult to talk about. The questionnaire does contain some personal questions (such as about your age, ethnicity and employment status). If you become upset during the discussion the researcher will stop to check that you are okay to continue, and if you wish they can move the discussion away from the topic that upset you. If you feel the interview is causing undue distress or emotional discomfort, you can end the interview at any time. If you feel that you need further support, the research team will have the contact details of relevant people and agencies that can help you. If you are taking part as a couple if one of you wants to stop the interview but the other partner wishes to continue, then the researcher may continue after a discussion about what is best for both of you.

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

Participation in a discussion is entirely voluntary. If you decide to take part, you will be given this information sheet to keep and be asked to give your formal consent. We can support you to consent online, on paper or verbally which will be recorded. If you do not wish to take part, you will not have to give a reason and your decision will not affect the care you will receive. 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 the front of 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. If you are taking part as a couple and one of you wishes to withdraw your contribution within the two weeks, then we will remove their data but retain the other partner's data for analysis.

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. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. The UNiTY trial 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 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 qualitative study interview will be handled strictly in accordance with your consent, 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.

Your interview will be kept strictly confidential. The only time this may change is if something is shared which suggests either yourself and/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.

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](https://www.birmingham.ac.uk/research/bctu/data-protection.aspx)).

The University of Birmingham is the data controller for the personal data that we process in relation to you.

How will we use information about you?

We will need to use information from you or your clinician for this research project. This may include:

- Your name and
- Your contact details
- Background demographic information

The UNiTY Study 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 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 who 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 or 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 my personal data be kept secure?

The University takes great care to ensure that personal data is handled, stored and disposed of confidentially and securely. Our staff receive regular data protection training, and the University has put in place organisational and technical measures so that personal data is processed in accordance with the data protection principles set out in data protection law.

How will the data be anonymised?

The transcript will be checked carefully for anything that might identify you (e.g. your name, the fertility centre where you received care) and these details will be removed. Each participant will be given a unique qualitative study number and we will only use this to identify quotes in study reports and publications.

Will I get paid for taking part?

No. Couples will be offered a £25 (per individual participant) electronic voucher (e.g.,

Amazon) for taking part in the interview. This covers £20 as a thank you for your time and £5 for consumables such as electricity/internet access given that the interview may be held remotely or via phone.

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 final 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 take part in the UNiTY interview, then you will retain the same legal rights as any other patient. If you are not satisfied with any aspect of the way in which you have been approached or treated during the course of our study, then please first contact our researchers at unityqualstudy@trials.bham.ac.uk or 0121 414 3024.

If you are still unhappy and wish to complain formally, patients being treated with NHS funding, or privately-funded patients being treated at NHS centres, can do this through the National Health Service complaints procedure. **Details can be obtained from the hospital's PALS (Patient Advice and Liaison Service) Office [ADD LOCAL PALS CONTACT DETAILS].** The PALS Office offer confidential advice and will advise you how to contact someone for **independent advice.**

Self-funded patients receiving treatments at private healthcare centres who remain unhappy and wish to complain formally can do this directly through the healthcare provider **[ADD CONTACT DETAILS OF LOCAL COMPLAINTS OFFICE].**

If you remain unhappy and wish to complain formally, you can contact the research Sponsor. Please email Dr Birgit Whitman at researchgovernance@contacts.bham.ac.uk

If you would like further support, you can contact the local fertility counselling service based at your healthcare provider on **[INSERT LOCAL FERTILITY COUNSELLING SERVICE DETAILS].**

CONTACT INFORMATION

If you would like to speak to someone about the study please contact the UNiTY trials team

unityqualstudy@trials.bham.ac.uk

Support can also be found through the NHS Patient Advisory and Liaison Service (PALS) or equivalent
(Patient Advice and Support Service in Scotland)



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 the back of this leaflet.

For more information you can also visit our website at www.birmingham.ac.uk/UNiTY

Also, the UK Clinical Trials Gateway (www.ukctg.nihr.ac.uk) is a useful resource, providing information about the process of and reasons for taking part in medical research, which may be of interest to you.