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PARTICIPANT INFORMATION SHEET

Understanding family relationships, roles and psychological well-being following brain injury

Predictors and psychological outcomes associated with perceived boundary ambiguity in families affected by acute, non-progressive neurological conditions

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

- This study focuses on families who have experienced a sudden onset neurological event, such as a stroke or traumatic brain injury. Following a sudden-onset neurological event some families can understandably find it challenging to adjust to the changes that can occur.

- It is common for spouses/partners to experience a sense of loss and to feel uncertain about the changing roles within the family and within the partnership. This uncertainty is known as “boundary ambiguity” and it is associated with psychological distress and tensions in the family relationships.

- The current study aims to gain a better understanding of partner/spousal boundary ambiguity in the context of sudden-onset neurological events. Firstly, we will look at what might make someone more vulnerable to experiencing boundary ambiguity. We will also explore how boundary ambiguity is linked to relationship satisfaction and how it is associated with psychological distress, including mood and anxiety symptoms.

- We hope that this research will help us better understand boundary ambiguity as experienced by partners/spouses and as an extension it will also help us highlight the needs of partners/spouses as they are adjusting to life after an acute, neurological event.

Why have I been invited?

- You have been invited to take part in this study because:

1. You are a partner or spouse of an individual who has been affected by an acute, non-progressive neurological event (such as a traumatic brain injury, stroke, a hypoxic brain injury, meningitis or encephalitis).
2. Your partner has no co-morbid neurodegenerative conditions (e.g. Parkinson's disease, dementia, multiple sclerosis, motor neuron disease etc.) in addition to the acute brain injury.
3. You live with your partner and he/she has been discharged home for at least 3 months.

- We are hoping to recruit as many partners/spouses as possible.

Do I have to take part?

- No, there is no obligation to participate in the research, if you don't want to, and this won't affect any current or future care that you or your spouse receive from any relevant service (e.g. from the NHS).
- If you decide to take part now and then change your mind, you can withdraw from the research at any time without having to give a reason. Withdrawing from the study will not affect your clinical care or your partner's clinical care.

What will happen to me if I decide to take part?

There are two parts to this research.

- Time point 1: If you are happy to take part in the research after reading this participant information sheet and discussing any questions you have with the research team, you will be asked for your preferred contact details. A member of the research team will contact you to consent your participation. Consenting can be done remotely (over the phone or over video call) or face to face in a community setting or on hospital site, subject to room availability. You will be given a copy of the signed consent form (in person or using your preferred contact method), with the responsible researcher's signature added to the form. Once you have given consent, you will be presented with the survey, either electronically or on paper, depending on your preference. If you choose the pen and paper format this can either be mailed to your home address or completed face to face in a community setting or on hospital site, subject to room availability. The electronic version of the survey will be accessed by a link, sent to you by the research team. First, you will be asked to complete a short set of questions about yourself (e.g. your age, gender). This section will also ask for your contact details which we will use to contact you for the second part of the research. Then you will be presented with a set of 6 questionnaires. The questionnaires will ask about your partner's level of functioning since their neurological event, your coping with uncertainty, your current mood, your anxiety levels, your satisfaction with your relationship with your partner and about boundary ambiguity. It will take around 20-25 minutes to complete all of the questionnaires.

- Time point 2: 3 months after you have completed the first set of questionnaires, you will be invited to the follow-up survey, using your preferred contact method. You will have the choice of completing the survey either online or in pen-and-paper format. If you choose the pen and paper format this can either be mailed to your home address or completed face to face in a community setting or on hospital site, subject to room

availability. The follow-up should take about 20 minutes to complete. If you do not complete the survey within a week of us contacting you, we will send you a reminder about the questionnaire.

What should I consider?

- If you're taking part in other research projects, you are still able to take part in this study, if you wish.
- Please note, we will not ask for any identifiable information about your partner/spouse (e.g. age, name, contact information) or the details of their injury at any point in the study.

Are there any possible disadvantages or risks from taking part?

- The study questions will ask you to think about your relationship with your partner, their level of functioning, and your psychological well-being, including your mood and anxiety. Therefore, it is possible that some of the questions may be upsetting or distressing to you.

- A debrief sheet will be provided for every participant, which will give you important information about who to speak to if you have been at all distressed by completing the questionnaires. If you do find any parts of this study distressing, please let the research team know.

- If you are worried about your health or well-being, please contact your GP about any concerns. They can refer you for further specialist support if required.

What are the possible benefits of taking part?

- By taking part you will be contributing to our understanding of the uncertainty surrounding family relationships and roles as experienced by spouses/partners following their partner's brain injury. In turn this could help us identify those partners/spouses early who are more vulnerable or at greater risk of experiencing relationship of psychological distress. By taking part you will also be highlighting any unmet needs which can then shape services and interventions offered to support partners/spouses of individuals after a sudden-onset neurological event in the future.

- Participation could also inform future research.

- Whilst taking part might not benefit you directly, participation can have an impact on future developments of the service and our understanding.

Will my General Practitioner (GP) be informed of my participation?

- Your GP will not be notified of your participation. However, if based on your questionnaire responses we find that you show clinically significant levels of anxiety and/or low mood, we will contact you to inform you of this finding and will advise you to contact your GP or to self-refer to your local NHS Talking Therapies Service so you can discuss further support and help.

Will my taking part in the study be kept confidential?

- All information collected about you during the course of the research will be kept confidential and conform to UK GDPR and the 2018 Data Protection Act with respect to data collection, storage, and destruction. This means all electronic information will be password protected and stored on secure University of Oxford servers. Access will be restricted to study personnel.

- Each participant will be assigned a randomly-generated unique identification number, which will be stored separately from the research database in a password protected excel spreadsheet on a secure shared drive hosted on Oxford University servers. The spreadsheet will only be accessible by the research team. The unique identification numbers allow a member of the research team to link questionnaire data to personal information under specific circumstances (e.g. if we identify clinically significant levels of anxiety or low mood). Any physical documents containing personal data that may be collected will be stored appropriately (I.e. in a locked cupboard on the Oxford University Foundation Trust NHS site in which the primary research team are based). Access to documents containing personal information will be restricted to the direct research team.

- Responsible members of the University of Oxford (and the relevant NHS Trust if recruited via a participating NHS site) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

- There is no reimbursement offered for participating.

What will happen to my data?

- Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study, based in the United Kingdom, is the data controller and is responsible for looking after your information and using it properly.

- We will be using information from you in order to undertake this study and will use the minimum personally-identifiable information possible (name, contact details). Once the study has finished, de-identified questionnaire data will be kept for 5 years. This is to ensure that we will be able to conduct any additional analyses which may be needed when results are being prepared for publishing in scientific journals.

- We will keep identifiable information about you (name, contact details) only as long as contact is necessary, or for longer but only with your agreement in place to be approached in future research. For those participants that opt in to receive a newsletter about the study the results, their contact details will be kept up to 12 months following study completion. For participants who do not wish to receive a newsletter, their identifiable information will be deleted once the follow-up survey at 3 months is completed.

- This excludes any research documents with personal information, such as consent forms, which will be held securely, either in locked cabinets or in a password protected file on a secure shared drive, hosted on University of Oxford servers for 5 years after the end of the study. The only exception to this time limit is if you agree to your details being held to be contacted regarding future research. If you agree to your details being held to be contacted regarding future research, we will hold a copy of your consent form until such time as your details are removed from our database.

- If you were recruited via a participating NHS site, the relevant Trust will use identifiable information about you (name, contact details) to oversee the quality of the study. They will retain this information about you from this study for up to 1 year after the study has finished.

- If you complete the survey online your data will be stored via an online survey platform called Qualtrics. The online survey data will be stored on a secure and encrypted third-party storage centre which is GDPR-compliant. Survey data will be stored separately from personally identifiable information (i.e. name or contact details) and only linked by a unique participant code. Once data collection is complete, this data will be downloaded and stored in a password protected file on a secure shared drive, hosted on University of Oxford servers.

- Questionnaire data will be extracted to a password-protected electronic database by Mariann Kovacs to enable data analysis. Further information about the storage of data using this survey software is available here: https://www.qualtrics.com/security-statement

- UK data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

- You can find out more about how we use your information by contacting mariann.kovacs@hmc.ox.ac.uk

What will happen if I don't want to carry on with the study?

- Participation is completely voluntary. If you decide you no longer wish to participate, you are free to withdraw from the study at any time without giving a reason. You will need to inform a member of the research team of your intent to withdraw.
- Withdrawal will not affect the current or future care that you or your spouse receive from any relevant service (e.g. for patients, from the NHS).
- If you withdraw from the study all data (personal and questionnaire data) we have obtained from you will be destroyed.
- Please note, that if you withdraw at the time when the study is already in the write up stage, we will no longer be able to delete your questionnaire data as this would have already been used to run analyses and draw study conclusions. However, your personal data can be removed any time.

What will happen to the results of this study?

- On completion of the study, a summary of the findings will be made available to participants who wish to receive them. You can opt in to receive the summary on the consent form. The results should be available shortly after the end of the study. If you would like a copy of the results, your name and contact details will be retained on a password-protected shared drive hosted on secure University of Oxford servers until the summary of findings is ready to be sent to you. Personal contact information will be deleted once the report has been sent to you.

- The study findings will be reported in academic and health related journals and presented to relevant health professionals and academics at meetings and conferences. Findings will also contribute to the researcher's doctoral thesis in Clinical Psychology. You will not be identified in any reports or publications arising from the study.

What if we find something unexpected?

- If based on your questionnaire responses we find that you show clinically significant levels of anxiety and/or low mood, we will contact you to inform you of this finding and will advise you to visit your GP so you can discuss further support and help.

What if there is a problem?

- The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.
- If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Mariann Kovacs (mariann.kovacs@hmc.ox.ac.uk) or you may contact the University of Oxford Research Governance, Ethics and Assurance (RGEA) office on 01865 616480, or the head of RGEA, email RGEA.Complaints@admin.ox.ac.uk

How have patients and the public been involved in this study?

- We have taken into account the opinions of people with lived experience about the study topic and design. In addition, potential participants were involved in reviewing study documentation.

Who is organising and funding the study?

- The study is being sponsored by the University of Oxford, and the study is part of a doctoral dissertation which is funded by Oxford Institute of Clinical Psychology Training and Research.

Who has reviewed the study?

- All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been

reviewed and given favourable opinion by the South East Scotland Research Ethics Committee (reference 23/SS/0010).

What if I would like to be informed about future research?

- If you opt into being informed about future research projects, your contact details will be held separately from this study in a password protected file on secure University of Oxford servers.
- All contact will come from the relevant research team running the study in the first instance to inform you about future studies. Please note that opting in to hear about future research projects does not oblige you to participate. You can ask to be removed from this register at any time you wish.

Further information and contact details:

Please contact Mariann Kovacs by email (mariann.kovacs@hmc.ox.ac.uk)

Contact details

If you are interested in participating, please provide your preferred contact details below so we can contact you to collect consent and give you access to the survey.

Phone number:

Email address:

Postal address:

Thank you for considering taking part.