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Participant Information Sheet
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Study Title: Determining a standard test battery for the assessment of auditory-vestibular impairments in adults with a traumatic brain injury: Delphi study

IRAS Project ID: 334689

Name of Chief Investigator: Kathryn Fackrell, PhD, Senior Research Fellow
Co-investigator: Laura Edwards, PhD, Clinical Associate Professor
Lead Researcher(s): Kübra Bölükbaş, PhD student

We would like to invite you to take part in a research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take time to read this carefully and discuss it with others if you wish. Ask us if there is anything that is not clear.

For more information or take register to take part please contact:
Kübra Bölükbaş: kubra.bolukbas@nottingham.ac.uk

What is the purpose of the study?

Traumatic Brain Injury (TBI) is defined as brain damage resulting from an external force, leading to a wide range of effects, from mild concussions to severe impairments. TBI can be broadly categorized into two groups: non-blast and blast related TBI. Non-blast-related TBI includes incidents like accidents, falls, and sports injuries, while blast-related TBI results from events such as war injuries and military combat. Our study focuses on non-blast related TBI due to the distinct characteristics of these groups.

The complexity and variability of deficits seen in TBI patients, coupled with the co-occurrence of auditory and vestibular impairments, pose challenges for audiologists. Issues such as equipment

inadequacies, calibration problems, high patient volumes, time constraints, varying clinician expertise, patient cooperation difficulties, and physical limitations in clinical practice make it challenging for audiologists to determine the appropriate test battery for adults with TBI.

Our goal is to establish a national consensus on the standard test battery for audio-vestibular assessment in adults with non-blast-related TBI. By gathering and integrating perspectives from experienced audiologists in the field of TBI, we aim to generate insights and recommendations for the assessment of this unique patient group. Following this, we will conduct a follow up study to evaluate the acceptability of auditory (hearing) tests determined by audiologists by adults experiencing auditory impairments following a non-blast related TBI.

Why have I been invited?

You are being invited to take part because you have a clinical qualification in audiology.

You may be able to take part if you:

- Are based in the UK and currently employed by a public or private institution that provides auditory and/or vestibular assessments to patients.
- Have experience of assessing, diagnosing, or managing auditory and/or vestibular impairments in adults with non-blast related TBI.
- can fill out questionnaires on your own.
- are willing to provide informed consent.

We are inviting 20 participants like you to take part.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign an electronic consent form as part of the survey. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights. Participation is on a voluntary basis.

What will happen to me if I take part?

If you agree to take part, you will be asked to complete a series of questions on three separate occasions (which are referred to as Rounds) online via Joint Information Systems Committee (JISC) survey system. You will be given a personalised login to access the survey and so that we can track your responses across the rounds.

Round 1 involves answering open-ended questions about your role and professional experience (e.g., years of experience, type of institution), your views on current practices, the specific tests used in the assessment, the sequences of assessment, and routine tests recommended for non-blast related TBI patients. The first round is expected to take up to 40 minutes to complete. You can take breaks, if needed.

You will be sent a link to complete Round 2 by the research team once the analysis from Round 1 is complete. This could take between 4-10 weeks depending on when you completed Round 1. In Round 2, you will review a list of test/assessment statements based on the results from Round 1. For each statement, you will be asked to rate the importance of conducting these assessments with non-blast related TBI patients. To do this you will use a simple 1-9 scoring system. You will have the chance to provide any comments about the statements that you think are important for us to know.

You will be sent a link to complete Round 3 by the research team approximately 2-6 weeks after you complete Round 2. In Round 3, you will review the same list of test/assessment statements. We will remind you of the previous scores you gave and show you a summary of the scores from the other participants. Based on this information, you will have chance to change your scores or keep your score the same. No-one else will be able to see your individual scores or know who you are.

Round 2 and 3 are expected to take up to 20 minutes to complete. You will be able to take breaks if needed. All information you provide will be strictly confidential and used only for the purposes of this study. When you have clicked the submit button at the end of the questionnaire, it will be uploaded into a password-protected database with a code number.

Expenses and payments

Participants will receive a £20 Amazon gift voucher.

What are the possible disadvantages and risks of taking part?

There is no risk in your participation in the study. However, we are asking you to give up your valuable time to take part and this is appreciated.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help us determine the most appropriate assessment battery to be applied in audiology clinics for individuals with non-blast related TBI. If you would like to receive updates on this project and future studies, then please let us know that you are happy for us to keep your contact details on our participant database. You can ask us to remove your details at any time.

What happens when the research study stops?

This is a consensus study with healthcare professionals like yourself, to identify a standard set of tests. Following this study, we will evaluate the acceptability of the auditory tests identified with patients experiencing auditory impairments following a non-blast related TBI. The results of both studies will be used to inform clinical practice.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the Chief Investigator (Dr Kathryn Fackrell), who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet. The researcher should acknowledge your concern and give you an indication of how he/she intends to deal with it. If you remain unhappy and wish to complain formally, you can do this by contacting:

- Professor Dorothee Auer, Director of Mental Health and Clinical Neurosciences, School of Medicine, Room W/B 1441 Queen's Medical Centre, Queen's Medical Centre, Nottingham, NG7 2UH

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

How will we use information about you?

The University of Nottingham are the sponsor of this study. This means we are responsible for looking after your information and using it properly.

We will need to use information from you for this research project. This information will include your name/ contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. If you agree we will also keep your contact details to send you the findings of the study and/or to contact you about participating in future research studies. 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. 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.

Your research data will be stored in a password-protected folder on a restricted access server at the University under the terms of its data protection policy. To help ensure your privacy, you will be assigned a volunteer study identification number (for example P01 for participant number 1), and it will be used instead of your name. We will save all the research data using that volunteer study identification number so that none of the research data will have your real name or other individual identifiers associated with them. Your name and any information about you will not be disclosed outside the study centre. Your personal data, including your emails, will be confidential to the study team recipients only and will be stored separately on a password protected secure University network.

We may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data shared in this way will be anonymised.

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, but we will keep information about you that we already have.
- 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.

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

You can find out more about how we use your information

- reading our privacy statement https://www.nottingham.ac.uk/utilities/privacy/privacy-information-for-research-participants.aspx
- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to kubra.bolukbas@nottingham.ac.uk, or
- by ringing us on 01158232600 reception.

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

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you would like to withdraw, contact the research team and they can organise this for you. If you withdraw from the study any reason, we will no longer collect any information about you or from you, but we will keep the information about you that we

have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What will happen to the results of the research study?

The results will be written up as a thesis. On successful submission of the thesis, it will be deposited both in print and online in the University archives to facilitate its use in future research The overall anonymised data from this study may be shared for use in future research and teaching (with research ethics approval). The thesis will be published open access.

The research findings will also be published in scientific journals and presented at national and international conferences. All study data will be anonymised, and you will not be identified in any arising reports or publications. If you would like to receive updates on this project and future studies, then please let us know that you are happy for us to keep your contact details on our participant database. You can ask us to remove your details at any time.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the Ministry of National Education of the Republic of Türkiye and supported by the NIHR Nottingham Biomedical Research Centre.

Who has reviewed the study?

All research in healthcare is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by [*please add name of committee submitting* to] Research Ethics Committee.

Further information and contact details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Kübra Bölükbaş PhD student, Lead researcher

NIHR Nottingham Biomedical Research Centre, Ropewalk House, 113 The Ropewalk, Nottingham, NG1 5DU

Tel: 01158232600 (reception)

Email: **kubra.bolukbas@nottingham.ac.uk**

Research Team

The research team also includes Chief Investigator and co-investigators, clinical advisors, and patient advisors. The research team are happy to answer any questions you have before you agree to take part or when you are taking part.

Dr Kathryn Fackrell

Chief Investigator

Kathryn.Fackrell@nottingham.ac.uk

Dr Laura Edwards

Co-investigator

Laura.Edwards@nottingham.ac.uk