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UNIVERSITY of STIRLING

Shock wave therapy and frozen shoulder

DELPHI STUDY INFORMATION SHEET

We would like to invite you to take part in a Delphi consensus study. Before you decide whether you would like to take part, it is important for you to consider why the research is being done and what it will involve. Please read this information sheet carefully.

What is a Delphi Study:

The Delphi technique seeks to obtain consensus on the opinions of experts, termed panel members, through a series of structured questionnaires. As part of the process, the responses from each round are fed back in summarised form to the participants who are then given an opportunity to respond again to the emerging data. The Delphi is therefore an iterative multi-stage process designed to combine opinion into group consensus.

What is the purpose of the study?

Frozen shoulder is known to be a debilitating condition. Patients who do not respond to initial management are referred to a specialist which may result in longer wait times. Some treatments may be limited due to prior health conditions. The researcher wants to explore alternative non-invasive treatments for frozen shoulder. Shock wave therapy is commonly used to treat chronic tendon conditions. It has been used internationally and reported in peer-reviewed journals as a treatment for frozen shoulder with positive effects, respectively. Shock wave therapy is not currently used as a treatment for frozen shoulder in the UK.
The study aims to evaluate the feasibility of a clinical pilot trial of shock wave therapy as a treatment for frozen shoulder using the Swiss DolorClast© radial extracorporeal shock wave therapy device, and manufacturer's guidelines of three treatments, applied 7 to 10 days apart (EMS – Dolorclast 2021). The purpose of this Delphi study is to identify anatomical treatment location sites in relation to the structures affected by frozen shoulder that should be considered for inclusion in the expert clinical decision rule. The responses will then be collated by the study team to derive the final expert clinical decision rule.

Why have I been invited to take part?

As an established expert in this field, we are keen to gain your views about which anatomical treatment locations sites may be important to treat with shock wave therapy.

What will I be asked to do if I take part?

We are inviting you to participate as a Delphi panel member. This would involve completing a brief questionnaire, providing your opinion on shock wave therapy and potential treatment location sites around the shoulder. It is envisaged that this should take no more than 15 minutes to complete.

You would subsequently receive a reminder of your ratings, a summary of the whole panel's responses and a further online questionnaire to re-rate the original list of treatment locations. This process would continue until a group consensus is achieved or three Delphi rounds have been completed. To allow timely conclusion of the study we would respectfully request a response time of 1 week for completion of each round.

Who is organising and funding this research?

The Delphi study will be conducted by a University of Stirling Clinical Doctorate Student, Crystal Reno, and supervised by Dr Catherine Best, Associate Professor, and Dr Simone Tomaz, Lecturer in Exercise Physiology, at the Faculty of Health Sciences and Sport, University of Stirling.

Confidentiality

No personal information will be collected other than professional contact details, and survey responses will be pseudonymised using an identifying number known only to the participant and lead investigator. All responses received in the study will be strictly confidential, and your identity will not be divulged. Direct quotes to free-text answers may be used as part of the study report or later Delphi iterations, and any identifying information (e.g., geographical location) will be redacted and not be traceable back to you.

What happens to the data I provide?

Survey responses will be collated online using Microsoft Forms Office 365.

All data collected will remain strictly confidential and will only be shared with the researcher and researcher's University of Stirling academic supervisors. This will be processed in accordance with the General Data Protection Regulation (GDPR). Under GDPR the legal basis for processing your personal data will be public interest / the official authority of the University. The research data will be kept anonymous by providing you with an identification number, which will be used during your involvement in the study that links your data with your files. The researcher and supervisors will have access to your research data, but will have signed a University of Stirling confidentiality agreement.

All data will be securely stored on a password-protected computer using the University of Stirling's instance of Microsoft Office 365 using SharePoint. Files are stored in SharePoint and backed by SharePoint encryption. This is in accordance with the data protection and confidentiality NHS Scotland Code of Practice and the Data Protection Act (2018). Your research data will be kept for 10 years on University of Stirling's OneDrive, and then will be securely destroyed, with the final research reporting and results stored in University of Stirling dataSTORRE.

Future uses of the data:

Due to the nature of this research, it is likely that other researchers may find the data to be useful in answering other research questions. We will ask for your explicit consent for your data to be shared in this way and, if you agree, we will ensure that the data collected is untraceable back to you before letting others use it.

What will happen to the results?

The researcher will analyse and present the findings to the University of Stirling. The results will be written about in articles for journals and may be presented at conferences or meetings. When writing or talking about the study, your exact words may be used to give examples of things that you, and others say, but you will never be named or identifiable.

Who has reviewed this research project?

The ethical approaches of this project have been approved via the University of Stirling NHS, Invasive or Clinical Research Committee (NICR), favourable ethical opinion by the NHS Research Ethics Committee South East Scotland REC 02, and NHS Grampian Research and Development Department to protect your safety, rights, wellbeing, and dignity.

What do I do now?

Thank you for reading this information sheet and for considering taking part in this research. Please let us know whether you would like to take part by replying to this email. If you wish to participate, we would be very grateful if you could also complete the attached consent form.

Contact for further information:

If you have any questions or would like further information about the study, please contact the researcher Crystal Reno, by phoning 07746 048 035, or by sending an

email to c.a.reno@stir.ac.uk, or research supervisor, Dr Catherine Best at catherine.best2@stir.ac.uk.

Complaints related to the research study can be addressed to the Clinical Doctoral Programme Director, Dr Kathleen Stoddart, at the Faculty of Health Sciences and Sport, by phoning 01786 466395 or by email at k.m.stoddart@stir.ac.uk.

You have the right to lodge a complaint against the University regarding data protection issues with the Information Commissioner's Office (https://ico.org.uk/concerns/).

The University's Data Protection Officer is Joanna Morrow, Deputy Secretary. If you have any questions relating to data protection these can be addressed to data.protection@stir.ac.uk in the first instance.

Thank you *for taking the time to read this information sheet and your consideration to participate in this study.*