**UNIVERSITY OF HERTFORDSHIRE**

**ETHICS COMMITTEE FOR STUDIES INVOLVING THE USE OF HUMAN PARTICIPANTS**

**(‘ETHICS COMMITTEE’)**

**FORM EC6: PARTICIPANT INFORMATION SHEET**

1 **Title of study**

 Hydrodistension injection in the treatment of frozen shoulder. An online survey of UK based Physiotherapists decision making processes and current practice.

2 **Introduction**

 Thank you for showing an interest in taking part in this research project. My name is Matthew Cowan-Dickie and I am the lead researcher undertaking this study in order to fulfil my Masters of Science (MSc) programme in advanced physiotherapy at the University of Hertfordshire. I work as a musculoskeletal physiotherapist with a special interest in ultrasonography, both diagnostic and interventional.

Before you decide whether to participate in this study, it is important that you have an understanding of the study that is being undertaken and what your involvement will include. Please take the time to read the following information carefully and discuss it with others if you wish. Do not hesitate to ask us anything that is not clear or for any further information you would like to help you make your decision. Please do take your time to decide whether you wish to take part. The University’s regulations governing the conduct of studies involving human participants can be accessed via this link:

<http://sitem.herts.ac.uk/secreg/upr/RE01.htm>

Thank you for reading this.

## 3 **What is the purpose of this study?**

Frozen shoulder, otherwise known as contracted shoulder or adhesive capsulitis, is commonly stated to affect 2-5% of the population (Lin et al., 2018; Whelton & Peach, 2018). It is a condition characterised by severe pain and restricted passive and active range of movement of the shoulder (Prodromidis & Charalambous, 2016), leading to a significant loss of function (Jones et al., 2013).

 A wide number of treatment options are considered appropriate for frozen shoulder including oral analgesia or anti-inflammatories, intra-articular corticosteroid injection, physiotherapy, manipulation under anaesthetic, arthroscopic capsular release, physiotherapy and hydrodistension injection (HDI) (Hanchard et al., 2012; Yip et al., 2018).

 Hydrodistension involves the injection of a volume of fluid into the glenohumeral joint capsule, with the aim of stretching or rupturing the contracted capsule. In theory this increase in capsule volume will allow an increase in range of motion (Wu et al., 2017).

 Recent systematic reviews suggest similar efficacy of HDI to that of intra-articular cortico-steroid injection alone with conflicting evidence leading to the inability to suggest a preferential treatment option (Wu et al., 2017). Recent systematic reviews have highlighted limitations in the current evidence base for HDI. Variation in HDI techniques, differing methods used for control groups, timing of intervention in terms of stage of frozen shoulder, numbers of injections given and differences in post treatment physiotherapy have all been given as reasons for this conflict within the literature (Catapano et al., 2018; Wu et al., 2017).

This study aims to investigate clinicians’ rationale in considering HDI as a treatment option for frozen shoulder and to compare results to the current evidence base. A better understanding of current practice and clinical reasoning processes underpinning the use of HDI may help guide future comparative research studies.

 The objectives of the study are outlined below:

1. Report participants professional characteristics including work setting, years of musculoskeletal physiotherapy experience, Agenda for Change banding if working in the NHS, whether participant has a special interest in frozen shoulder, number of patients seen with a diagnosis of frozen shoulder, number of frozen shoulder patients receiving HDI.
2. Identify current frozen shoulder treatment pathways or guidelines that incorporate HDI.
3. Investigate clinicians’ rationale for considering HDI for the treatment of frozen shoulder.
4. Investigate relationships between professional characteristics and variation in rationale for considering HDI.
5. Compare current practice to recent evidence in the use of HDI for frozen shoulder.

4 **Do I have to take part?**

It is completely up to you whether or not you decide to take part in this study. If you decide to participate, it is assumed you have read the participant information and you are providing implied consent. Agreeing to join the study does not mean that you have to complete it. You are free to withdraw at any stage without giving a reason, although once you have submitted the survey it will be impossible to withdraw your data as it will be anonymised.

5 **Are there any age or other restrictions that may prevent me from participating?**

The study is designed for UK based physiotherapists (including physiotherapists on a career break or maternity leave), who have had a role in the use of HDI for the treatment of frozen shoulder within the past 12 months. This role might include discussion of this treatment option with the patient, senior physiotherapist or doctor. It may be that you are an advance practice physiotherapist administering the HDI, or you could be the treating physiotherapist following a HDI.

6 **How long will my part in the study take?**

If you decide to take part in this study, completion of the survey should take between 15-20 minutes.

7 **What will happen to me if I take part?**

If you take part in the study, you will be directed to an online survey consisting of a number of short questions. Most questions will be closed with specific responses to choose from, but there will be some open questions allowing you to provide comments. Personal identifiable details are not collected. You will be asked to provide details regarding your “professional characteristics” including the sector you work in (e.g. NHS, private, primary or secondary care), banding on the Agenda for Change pay scale if working primarily in the NHS and your level of musculoskeletal experience.

8 **What are the possible disadvantages, risks or side effects of taking part?**

No physical or psychological harm is expected from completing this survey. It simply requires 15-20 minutes of your time. Some potential participants may feel that the time to complete the questionnaire is an inconvenience.

The survey is designed to gain insight into current use of HDI as a treatment option for frozen shoulder patients. It does not set out to test your knowledge and therefore there are no right or wrong answers.

Participants who have concerns regarding confidentiality of data provided and issues of anonymity should be reassured that no personal identifiable information will be collected.

9 **What are the possible benefits of taking part?**

Your response will identify current practice in the use of HDI as a treatment option for frozen shoulder. You will be adding to the evidence base around clinical reasoning and rationale for considering HDI. Your participation may help to guide future interventional research.

10 **How will my taking part in this study be kept confidential?**

All survey responses are anonymous and confidential. At no stage will you be asked to provide any personal or identifiable details.

11 **What will happen to the data collected within this study?**

 Participant responses will be submitted via “Online Surveys”. This tool is approved by the University of Hertfordshire to conduct online questionnaires. This anonymous data will be analysed alongside other respondents’ information, and will be stored electronically in encrypted, password protected files accessible to the research team only.

The results will be written up as part of the lead researcher’s MSc dissertation project.

 The data collected will be kept for a mandatory period of three years, after which it will be destroyed in accordance with the University of Hertfordshire Data Protection Policy 2016 and the Data Protection Act 1998.

1. **Will the data be required for use in further studies?**

 The data will not be used in any further studies.

13 **Who has reviewed this study?**

This study has been reviewed by Andrew McCarter, University Research Supervisor and Senior Lecturer, School of Health and Social Work, University of Hertfordshire.

 AND

 The University of Hertfordshire Health Science, Engineering & Technology Ethics Committee with Delegated Authority.

The UH protocol number is ***HSK/PGT/UH/03743***

14 **Factors that might put others at risk**

Please note that if, during the study, any medical conditions or non-medical circumstances such as unlawful activity become apparent that might or had put others at risk, the University may refer the matter to the appropriate authorities.

15 **Who can I contact if I have any questions?**

If you would like further information or to discuss any details personally, please get in touch with me by email:

Matthew Cowan-Dickie mcowan-dickie@nhs.net

 OR

 Andrew McCarter, University Research Supervisor, University of Hertfordshire. a.mccarter@herts.ac.uk

**Although we hope it is not the case, if you have any complaints or concerns about any aspect of the way you have been approached or treated during the course of this study, please write to the University’s Secretary and Registrar at the following address:**

Secretary and Registrar

University of Hertfordshire

College Lane

Hatfield

Herts

AL10 9AB

**Thank you very much for reading this information and giving consideration to taking part in this study.**

**The survey can be completed via this link:**

[**https://herts.onlinesurveys.ac.uk/hydrodistension-injection-in-the-treatment-of-frozen-shoulder**](https://herts.onlinesurveys.ac.uk/hydrodistension-injection-in-the-treatment-of-frozen-shoulder)