

Information letter

Date: 12 July 2023

You are being invited to participate in a research study titled “Alternative cast for distal radius fractures”. This study is being done by Anne-Marijn van der Plas as a master thesis project from the TU Delft Karin Thomassen and Gerwin Smit are supervising this project.

The purpose of this research study is to investigate the comfort, fitting and ease of application of a wrist immobilisation device and will take you approximately 30 minutes to complete. The data will be used to evaluate the design made for the master thesis. This thesis will later be published in the TU Delft repository. The researcher will install the device on your arm and you will undergo some measurements. We will be asking you to wear the device for some time and to answer some questions related to comfort of the device.

As with any online activity the risk of a breach is always possible. To the best of our ability your answers in this study will remain confidential. We will minimize any risks by minimizing the amount of personal data that is collected and by anonymizing the data by using numbers to refer to participants data. The data will be stored and is only accessible to the researcher and the supervisors. The results that are published in the master thesis are unidentifiable.

During the research the device will be fitted around your arm. There is a risk that the pressure on the arm is more than comfortable, we ask you to always communicate any discomfort to the researcher so it can be taken away.

Your participation in this study is entirely voluntary and you can withdraw at any time. You are free to omit any questions. You will know your participation number and you can request your data to be removed from the research within 2 weeks.

Kind regards,

Anne-Marijn van der Plas (corresponding researcher)

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Karin Thomassen

PhD candidate

Gerwin Smit

Assistant professor

PLEASE TICK THE APPROPRIATE BOXES	Yes	No
A: GENERAL AGREEMENT – RESEARCH GOALS, PARTICIPANT TASKS AND VOLUNTARY PARTICIPATION		
1. I have read and understood the study information dated 12/07/2023, or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	<input type="checkbox"/>	<input type="checkbox"/>
2. I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.	<input type="checkbox"/>	<input type="checkbox"/>
3. I understand that taking part in the study involves: Measurements of the forearm and hand, fitting of the wrist immobilisation device, an online questionnaire about the comfort and other aspects of the device. Some pictures can be taken but the face will not be in the picture or will be made unrecognizable.	<input type="checkbox"/>	<input type="checkbox"/>
4. I understand that I will not be compensated for my participation	<input type="checkbox"/>	<input type="checkbox"/>
5. I understand that the study will have a duration of 30-60 minutes	<input type="checkbox"/>	<input type="checkbox"/>
B: POTENTIAL RISKS OF PARTICIPATING (INCLUDING DATA PROTECTION)		
6. I understand that taking part in the study involves the following risks: uncomfortable pressure or skin irritation. I understand that these will be mitigated by communication with the researcher	<input type="checkbox"/>	<input type="checkbox"/>
7. I understand that taking part in the study also involves collecting specific personally identifiable information (PII) and associated personally identifiable research data (PIRD), including: age, gender and name and measurements of the upper extremity, with the potential risk of my identity being revealed.	<input type="checkbox"/>	<input type="checkbox"/>
8. I understand that the following steps will be taken to minimise the threat of a data breach, and protect my identity in the event of such a breach. I understand that all information making it possible to trace the data back to me will be stored separate from the collected data after the research has been undertaken.	<input type="checkbox"/>	<input type="checkbox"/>
9. I understand that personal information collected about me that can identify me, such as name, age and gender, will not be shared beyond the study team.	<input type="checkbox"/>	<input type="checkbox"/>
10. I understand that the (identifiable) personal data I provide will be destroyed after December 2023	<input type="checkbox"/>	<input type="checkbox"/>
C: RESEARCH PUBLICATION, DISSEMINATION AND APPLICATION		
11. I understand that after the research study the de-identified information I provide will be used for the master thesis of Anne-Marijn van der Plas. Possibly the results can be published in a scientific paper or used as an input for other research.	<input type="checkbox"/>	<input type="checkbox"/>
12. I agree that my responses, views or other input can be quoted anonymously in research outputs	<input type="checkbox"/>	<input type="checkbox"/>
D: (LONGTERM) DATA STORAGE, ACCESS AND REUSE		
13. I give permission for the de-identified measurements and answers from the questionnaire that I provide to be archived in a project Drive repository so it can be used for future research and learning.	<input type="checkbox"/>	<input type="checkbox"/>
17. I understand that access to this repository is restricted to the above mentioned researcher and supervisors.	<input type="checkbox"/>	<input type="checkbox"/>

Signatures

Name of participant [printed]

Signature

Date

I, as researcher, have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

Anne-Marijn van der Plas

Researcher name [printed]

Signature

Date

Study contact details for further information: Anne-Marijn van der Plas,

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