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**PARTICIPANT INFORMATION SHEET**

**CLINICAL TRIAL**

**FUNCTIONAL SCREENING TESTS IN CERVICAL DYSTONIA**

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**Title:** An observational study of functional screening tests in cervical dystonia.

**Short title:** Functional screening tests in cervical dystonia.

**Protocol Number:** HREC:

**Coordinating Principal Investigator:** Dr Neil Mahant

**Associate investigators:** Melani Boyce

Prof Arianne Verhagen

Dr Lynley Bradnam

Dr Alana McCambridge

 A/Prof Victor Fung

 Dr Florence Chang

 Professor Colleen Canning

**1. Introduction**

You are invited to take part in this research project “An observational study of functional screening tests in cervical dystonia”. This is because you have adult onset cervical dystonia, which is a movement disorder whereby you have uncontrollable spasms in your neck or shoulder muscles, and you can walk unassisted. The research project is aiming to assess the balance, walking and function of people with cervical dystonia.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.



Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to the tests and research that are described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2. What is the purpose of this research?**

The purpose is to investigate the whether the balance and function of people with cervical dystonia is different from people without cervical dystonia. Balance and function has not been investigated in people with cervical dystonia in the past and the information gained in this study will show us if cervical dystonia does affect the whole body and in what ways.

Depending on the information gained from this study, physiotherapy treatments designed to improve balance and function may be used in future research to improve the lives of people with cervical dystonia.

The results of this research will be used by the study physiotherapist Melani Boyceto obtain a PhD degree. This research has been initiated by the study physiotherapist Melani Boyce, and has been funded by the My Westmead Early Career Research Scholarship awarded to Melani Boyce.

**3. What does participation in this study involve?**

If you agree to participate in this study, you will be asked to sign the Participant

Consent Form. This study will be conducted on the same day as your routine Botox injection, and will be performed in the physiotherapy department of Westmead Hospital. You will be assessed by a Neurologist at Westmead Hospital to ensure you meet the criteria to join the study. During this assessment, you will be asked to give a brief history of your cervical dystonia including any medications that you may be taking and any falls you may have had in the preceding 6 months. You will then be assessed by the study physiotherapist and there may be a second physiotherapist



from Westmead Hospital present during your assessment. You will be asked to complete a test assessing the severity of your dystonia, have your dystonia measured by a device that sits on your head and complete a series of commonly used questionnaires and balance and walking assessment scales.

None of the assessments will induce pain, however if you need to rest between assessments, you will be allowed to. Two of the scales will require a video to be taken of you performing common movements like walking, standing up, sitting down, turning your body 180 degrees and turning your head to each side. You may view the video immediately following the assessment. Your name will not appear on the video, and it will be only viewed by the researchers for the purposes of the study.

The assessment will take approximately 2 ½ hours to complete. After the assessment, you will be asked to keep a diary of any falls you may have in the upcoming 6 months. This information will be collected by the researchers at the end of 6 months.

You may be asked if you would be willing to undergo the same testing after your next Botox injection at Westmead Hospital. If you agree, the same procedure will be followed. This second testing would enable us to determine how reliable the measurement scales are when assessing people with cervical dystonia over time.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid. Tea and coffee will be provided to participants during the assessment if desired.

**4. What do I have to do?**

If you decide to join the study, you will be assessed by the physiotherapist following your routine Botox injection. If you do not have Botox injections, then you may be assessed at any time convenient to you. You do not need to prepare for the assessment and you do not need to change your lifestyle or behaviours in any way to join the study. However you will need to commit to the 2 ½ hour session of testing by the physiotherapist. If you choose to repeat the testing after you next Botox injection, you will again need to commit the time for the testing session.



**5. Other relevant information about the research project**

There will be 30 participants joining the study at Westmead Hospital. The study will only be conducted at Westmead Hospital. The Principal Investigator of this study, Dr Neil Mahant and the associate investigators Melani Boyce, A/Prof. Victor Fung and Dr Florence Chang are all employed at Westmead Hospital. The other investigators are physiotherapists employed by the University of Technology Sydney (Dr Lynley Bradnam and Dr Jooeun Song) and the University of Sydney (Prof. Colleen Canning). These physiotherapists are expert research physiotherapists and will assist with the research analysis. This is novel research that has not been conducted before anywhere in the world.

**6. Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Westmead Hospital.

**7. What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. If you choose not to participate in this study, then your routine treatment at Westmead Hospital will continue.

**8. What are the possible benefits of taking part?**

This study aims to further medical knowledge and may improve future physiotherapy treatment of cervical dystonia however there will be no clear benefit to you from your participation in this research.

**9. What are the possible risks and disadvantages of taking part?**

While this research does not involve any interventional treatment, the assessments conducted may cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these

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side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects. These assessments involve commonly used physiotherapy techniques that are generally safe and would be the same techniques that would be applied if you were just attending for physiotherapy treatment. The possible risks of this study are:

* Fatigue – it is unlikely but possible that you may feel tired after completing the assessment. You will be allowed to rest during the assessment if you need to. If you are still fatigued after the assessment, you may need to rest at home.
* Inconvenience – it is possible that you may feel inconvenienced from the time spent at the hospital completing the assessment

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms.

Many side effects go away shortly after treatment ends. However, if any side effects are serious or long lasting, your doctor should discuss the best way of managing these side effects with you.

**10.** **What if new information arises during this research project?**

As this is an observational study of balance and function, there will no new treatments arising directly from this study during the course of your participation.

**11. Can I have other treatments during this research project?**

If you are receiving treatment from another physiotherapist outside of the study, this will not affect your participation in the study. You are advised to continue any of your usual medical treatments (including medication) throughout the study.

**12. What if I withdraw from this research project?**

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

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**13. Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include members of the research team leaving Westmead Hospital, or an inability to recruit further participants.

**14. What happens when the research project ends?**

You will resume your usual treatment at Westmead Hospital. A summary of the results from the study will be available from the researchers at the end of the study period. Please indicate if you would like to be informed of the results at the completion of the study and these will be sent to you.

**15. What will happen to information about me?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your identity will be coded on completion of the assessment and your information will be securely stored in a locked filing cabinet in the Physiotherapy department. Five years following the completion of the study, assessments will be permanently destroyed. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

In accordance with relevant Australian and/or NSW privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

**16. Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can

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receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**17.** **Who is organising and funding the research?**

This research project is being conducted by Melani Boyce. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**18. Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the Western Sydney local Health District (WSLHD).

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**19. Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact Melani Boyce the study investigator on 0407 978 386 or any of the following people:

**Clinical Contact Person:**

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| Name | Melani Boyce |
| Position | Physiotherapist and Associate investigator |
| Telephone | 0407 978 386 |
| Email | Melani.boyce@health.nsw.gov.au |

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For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

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| --- | --- |
| Position | Westmead Hospital Patient Advice and Liaison Service |
| Telephone | 02 8890 7014 |
| Email | Wslhd-pals-mail@health.nsw.gov.au |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research** **and HREC Executive Officer details**

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| --- | --- |
| Reviewing HREC name | WSLHD Human Research Ethics Committee |
| HREC Executive Officer | Kellie Hansen |
| Telephone | (02) 8890 8183 |
| Email | Wslhd-researchoffice@health.nsw.gov.au |

**Local HREC Office contact (Single Site -Research Governance Officer)**

|  |  |
| --- | --- |
| Name | Margaret Piper |
| Position | Research Governance Manager |
| Telephone | (02) 8890 9007 |
| Email | Wslhd-rgo@health.nsw.gov.au |



**CONSENT FORM -** *Adult providing own consent*

**Title:** An observational study of functional screening tests in cervical dystonia.

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 Dr Florence Chang

 Professor Colleen Canning

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I acknowledge that any regulatory authorities may have access to my medical records specifically related to this project to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

I understand that I will be given a signed copy of this document to keep.



Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of witness\* to Participant’s signature (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*Witness is not to be the investigator, a member of their study tem or delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witnesses must be over 18 years of age.

**Declaration by Study Doctor/Senior Researcher**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/Senior Researcher \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: All parties signing the consent section must date their own signature.