**Participant Information Sheet**

**Acute Whiplash Injury Study: a cluster randomised pilot and feasibility trial of an active behavioural physiotherapy treatment for acute Whiplash Associated Disorder (WAD) II management in an insurance private setting**

Whiplash Associated Disorder is a neck injury usually from a road traffic accident. More people are affected by whiplash each year and it can lead to pain and disability. Therefore, it is important for a physiotherapist to prevent chronicity by using effective management in the acute stage. The evidence so far suggests that a combination of active and behavioural treatment programme when the patient is still acute, may be a useful strategy to manage Whiplash Associated Disorder.

We have developed an active behavioural physiotherapy treatment programme using international experts that we plan to use in a large clinical trial to see if it works.

**What is the purpose of this trial?**

To evaluate procedures, feasibility and acceptability of the active behavioural physiotherapy treatment for acute Whiplash Associated Disorder.

**Do I have to take part?**

It is entirely up to you. We believe that you can make a great difference by taking part in this trial. You do not have to participate if you do not want to. We are asking you to take part in this trial because you meet our inclusion criteria:

1. Your age is between 18-70 years old.

2. Your neck problems were caused by a road traffic accident within the last four weeks.

3. Your neck problems are classified as whiplash associated disorder.

We really believe that your participation will greatly help us to see how the active behavioural physiotherapy treatment works. This will help a lot of patients with acute Whiplash Associated Disorder to preventing chronicity.

**What will I do if I take part?**

We would like you to read this information sheet, sign the consent form and bring it to your first visit. If you have any questions when you read through the consent form please ask the physiotherapist.

After signing the consent form, you will be assessed by another physiotherapist for key clinical outcome measures. The process of assessment will take about 30 minutes. Then, you will receive your physiotherapy treatment programme. We will make another appointment with you to *8 April 2016 version 2 by Wiangkham et al.* Page 6

assess clinical outcome measures at 3 months after the first assessment. This follow-up assessment will also take about 30 minutes.

**What are the possible disadvantages and risk of taking part?**

You will be treated using either the developed active behavioural physiotherapy treatment or standard physiotherapy treatment. Both are a form of conservative treatment without any serious problem. Sometimes, you may feel muscle soreness from a physiotherapy treatment, but it will recover within 48 hours. You will be required to visit an assessing physiotherapist 2 times, when the project starts and 3 months later. Each visit will take about 30 minutes. You will be supported for journey costs.

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

You will receive physiotherapy treatment as part of this study. Some patients will receive current standard care and others will receive an active behavioural physiotherapy treatment. We are interested in whether one treatment is better than the other to improve management of patients with Whiplash Associated Disorder and to prevent chronic problems. If we can prevent chronic problems, patients can return to their quality of life, direct and indirect medical costs will be reduced.

**Will my taking part in the study be kept confidential?**

All information regarding each participant will be kept safely from any third party to keep the participants’ privacy. All collected documents will be stored in a secure place. The electronic information will be stored in a password protected computer during study. After completion of this trial, all information will be confidentially kept for 10 years at the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, before being securely destroyed. Data can only be seen by the primary researcher and his supervisors. To make sure that no participant can be identified, information emanating from this trial will only be published in a completely unattributable format or at an aggregate level.

**Can I withdraw from the study after it has started?**

You can withdraw your participation in the trial at any time up to 3 months after you signed the consent form agreeing to take part, by emailing the primary researcher with your reason(s), without any consequence. Providing a reason is voluntary but not required. In this event, we will send you an email confirming that you have been withdrawn. After that you will not be contacted anymore about this trial. Any data collected prior to your withdrawal will also be deleted. *8 April 2016 version 2 by Wiangkham et al.* Page 7

**What will happen to the results of the research study?**

The results of this trial will enable us to evaluate the findings to inform a future large trial involving a large number of patients. The findings from this trial will be submitted for publication to a medical journal and will be presented at conferences and local seminars.

**Who is organising the research?**

This project is being undertaken as part of a PhD in the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, United Kingdom.

|  |  |
| --- | --- |
| Please do not hesitate to contact us if further information is required. Taweewat Wiangkham Doctoral Researcher School of Sport, Exercise and Rehabilitation Sciences University of Birmingham B15 2TT Mobile: 07474410449 E-mail: txw214@bham.ac.uk  | Dr Alison Rushton Lead Supervisor Academic Lead Physiotherapy School of Sport, Exercise and Rehabilitation Sciences University of Birmingham B15 2TT Tel: 0121 415 8597 Email: a.b.rushton@bham.ac.uk  |