

## Appendices

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**CONSENT FORM**

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Title of Project:

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

Name of Researcher:

**Taweewat Wiangkham**

Please tick all boxes

1. I confirm that I have read and understand the information sheet dated \_\_\_\_\_ for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw from the study by sending e-mail with a reason(s) to the researcher. I understand that I would then receive an e-mail confirming my withdrawal
3. I understand that I will be assessed by an assessor for clinical outcome measurements at the initial physiotherapy appointment (baseline) and at a 3-month follow-up assessment.
4. I understand that I will not be identified in any reports, publications or presentations related to this work.
5. I would like to take part in the above study.
6. When you withdraw in this study, would you like us to remove your data. 

<b>Yes</b>	<b>No</b>
<input type="checkbox"/>	<input type="checkbox"/>

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

E-mail:

Telephone:

\_\_\_\_\_  
Name of Researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

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**CONSENT FORM**

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Title of Project:

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

**[For the participants of focus group]**

Name of Researcher:

**Taweewat Wiangkham**

Please tick all boxes

1. I confirm that I have read and understand the information sheet dated \_\_\_\_\_ for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary. However, I cannot withdraw from the study during the interview because of the limitation of a group discussion setting.
3. I understand that I will be interviewed using focus group technique. The anonymity within a focus group setting cannot be made because of the nature of a group discussion.
4. I understand that I will not be identified in any reports, publications or presentations related to this work.
5. I would like to take part in the above study.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

E-mail:

Telephone:

\_\_\_\_\_  
Name of Researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

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## CONSENT FORM

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Title of Project:

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

**[Semi-structured interview for the physiotherapists in the experimental arm]**

Name of Researcher:

**Taweewat Wiangkham**

Please tick all boxes

1. I confirm that I have read and understand the information sheet dated \_\_\_\_\_ for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw anytime.
3. I understand that I will be individually interviewed by a researcher using a semi-structured interview.
4. I understand that I will not be identified in any reports, publications or presentations related to this work.
5. I would like to take part in the above study.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

E-mail:

Telephone:

\_\_\_\_\_  
Name of Researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

## **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

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.

### **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.

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## **Participant Information Sheet**

### **Focus Group**

#### **Acute Whiplash Injury Study: a cluster randomised pilot and feasibility trial of an active behavioural physiotherapy intervention 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 study?**

To evaluate acceptability of the active behavioural physiotherapy intervention for acute WADII management within the insurance/private sector

#### **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 project. You do not have to participate if you do not want to. We are asking you to take part in this project because you are a participation in the experimental group. We really believe that your participation will greatly help us to see how the active behavioural physiotherapy is. This will help a lot of patients with acute WADII in 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 the interviewed day. If you have any questions when you read through the consent form please ask us. The group interview will take your time around an hour. Please do not worry if you forget to bring the consent form to the interviewed day. We will provide it for you.

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

The group interview will take your time around an hour. Your opinions and any conversation in this interview cannot be anonymous because of the nature of a group discussion. However, your

information and the conversation in the group discussion will be kept safely from any third party and will therefore be confidential.

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

Your journey costs will be supported. Although there are no personal benefits for your taking part in this interview, your participation can contribute to acute WADII management and future studies. In this interview, the acceptability of the active behavioural physiotherapy intervention will be evaluated to see how it worked. Your experiences and opinions are a valuable factor to evaluate the acceptability of the active behavioural physiotherapy intervention which is developed by whiplash experts across the world. Your experiences and opinions will help us to explore the strengths and weaknesses of the developed intervention in order to consider for the future definitive trial.

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

According to the nature of a group discussion, anonymity within this setting cannot be assured. However, confidentiality of the information about you and your conversation in the group discussion will be kept safely from any third party to keep your information confidential. The group interview will commence by agreeing ‘ground rules’ for the group that will include not discussing the content of the group interview outside of the session. Your name will not be linked to any information in the reporting of findings from the group discussion, and findings will be reported for the whole group rather than for individual participants. 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 interview, 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 cannot withdraw your participation during the interview.

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

The results of this interview will enable us to evaluate the acceptability of the active behavioural physiotherapy intervention which is an important factor for considering the main trial. The findings from this trial will be submitted for publication to a peer reviewed 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.

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## **Participant Information Sheet**

### **Semi-structure Interview**

#### **Acute Whiplash Injury Study: a cluster randomised pilot and feasibility trial of an active behavioural physiotherapy intervention 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 study?**

To evaluate acceptability of the active behavioural physiotherapy intervention for acute WADII management within the insurance/private sector

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

Your participation is voluntary. We believe that you are able to make an important contribution to this project. You do not have to respond to our request if you do not want to participate. We are asking you to take part in this project because you are a physiotherapist who used the developed intervention in managing patients with acute WADII. We really believe that your participations will substantially assist us to see how the active behavioural physiotherapy worked. This would lead to help the vast number of patients with acute WADII in preventing chronicity.

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

We would like you to read this information sheet, sign the consent form and give it back to a researcher in the interviewed day. If you have any questions when you read through the consent form please ask the interviewer. The interview will take your time around 10-20 minutes.

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

The interview will take your time around 10-20 minutes. Your opinions and any conservation in this interview will be anonymous. So, you cannot be identified.

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

Although there are no personal benefits for your taking part in this interview, your participation can contribute to acute WADII management and future studies. As you are a physiotherapist who used the developed intervention, your experiences and opinions are a valuable factor to evaluate the acceptability of the active behavioural physiotherapy intervention which is developed by whiplash experts across the world. Your experiences and opinions will help us to explore the strengths and weaknesses of the developed intervention in order to consider for the future definitive trial.

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

Your personal information will be kept safely from any third party stored to maintain the participants' privacy. All collected documents will be stored in a secure place. The electronic information will be confidentially stored in a password protected computer during study. After completion of the interview, 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 accessed by the primary researcher and his supervisors. In order to ensure that no participant can be identified, information emanating from the interview will only be published in a completely unattributable format or at an aggregate level.

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

Your participation is voluntary and that you are free to withdraw anytime.

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

The results of this interview will enable us to evaluate the acceptability of the active behavioural physiotherapy intervention which is an important factor for considering the future definitive trial. The findings from this trial will be submitted for publication to a peer reviewed 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.

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