Participant Information Sheet

Study title

Improving the **W**ellbeing of people with **O**pioid **T**reated **CH**ronic Pain (**I-WOTCH**)

Introduction

We would like to invite you to take part in a study that is developing a support programme to improve the wellbeing of people living with chronic (long-term) pain and reduce their opioid (strong morphine like painkillers) use.

Before you decide if you want to take part, please take the time to carefully read this information and talk to others if you wish. This sheet will inform you of what will be involved.

What is the purpose of the study?

The I-WOTCH study is a randomised controlled trial which is comparing two different treatments for people with long-term pain. The two treatments are:
1) Your usual GP care plus a self-learning manual
2) A support programme in addition to the above.

The purpose is to find out which treatment is best at helping people to live better with their pain and reduce their use of opioids. This trial will help us identify which treatment works best. It will measure the everyday functioning and opioid use of all the people in the trial at different time points. We hope that the results of this study will be used to help patients with long-term pain in the future.

What is a randomised controlled trial?

This is a study where people are chosen at random (by chance alone) to be in one of two groups. The two groups of people are compared to find out any differences. For the I-WOTCH study the two groups are:

- The self-learning manual group and
- The support programme group

What is usual GP care plus a self learning manual?

If you are in the self-learning manual group, we will send you a manual with advice about chronic pain management and the potential implications and adverse effects of using opioids. We will also send you a relaxation CD and provide instructions on how to use it. You will be asked to practice and use the relaxation techniques. You will continue to receive your usual GP care whilst taking part in the I-WOTCH study.

What is the support programme?

If you are allocated to the support programme, we will invite you to attend a short course led by two tutors. The course runs over three days. During the course you will be encouraged to talk with others who use opioids to manage long-term pain and think about your own lifestyle, experiences and behaviours. There will be an average of 12 people in a group (with a maximum of 16 in a group). The course will include sessions about:

- Understanding your pain
- Coping techniques
- Posture and movement advice
- Relaxation techniques
- Prescribing opioids for long-term pain
- Short and long term effects of opioids
- Advantages and disadvantages of a slow supervised reduction of painkillers, and how to manage the associated symptoms
- Pain control after opioids
- Management of reducing opioids

The courses will be run by a healthcare professional and a person who has long-term pain and has stopped their use of opioids. They have been specially trained by members of the study team to run the course.

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As part of the support programme you will also have two one-to-one meetings and two telephone calls with the healthcare professional. In the first one-to-one meeting, the healthcare professional will work with you to create a plan to help you reduce your use of opioids slowly over time. Over the following weeks the healthcare professional will make two phone calls and arrange another one to one meeting to discuss how you are getting on with your reduction plan. The one to one meetings will last approximately one hour each. The telephone calls will last approximately half an hour each.

All support programmes will be audio recorded and some may be observed by a member of the research team for quality control purposes. This will also help us understand the issues discussed throughout the support programme.

If you are allocated to the support programme you will also receive the self-learning manual and relaxation CD plus your usual GP care.

Why have I been chosen?

Your practice or clinic has agreed to help us with this study. They have identified you as someone who may have been prescribed opioids for long-term pain in the past year.

Do I have to take part in the study?

No. It is up to you to decide whether you want to take part. You are free to change your mind and withdraw from the study at any time and you do not have to give a reason why. Your decision will not affect the care you receive from the NHS in any way. We would however, with your consent, continue to use data already collected from you.

What will happen to me if I take part?

First make sure you have read all the information. If you have any questions, would like any further information or want to discuss participating further, please call us on 02476 150 285.

Expression of interest to take part

If you are interested in taking part, please complete the expression of interest form and post it back to us using the pre-paid envelope provided (no stamp is required). The expression of interest form gives the research team consent to contact you.

Confirming eligibility and consent

When we receive your expression of interest form, a member of the study team will then call you to find out if you are eligible to take part. If you are eligible and happy to take part, we will send you a study consent form and questionnaire pack to complete and return to the study team. When we receive these documents, we make sure your details are stored with an anonymous study identification number.
Upon receiving your consent form and baseline questionnaire, we will call you to check you understand the consent process. We will then also sign your consent form and send a copy of this back to you for your own records.

Randomisation

You will then be randomly allocated to either the usual GP care and self-learning manual group or the support programme group. We will write to you to confirm which group you are in. If you are in the self-learning manual group we will post out your manual, a relaxation CD and instructions. If you are in the support programme we will include details of where the course will be held and on what dates and times.

Follow up questionnaires

We will ask all study participants in both groups to complete a weekly diary for the first four months. The diary contains two short questions which will provide us with very important data for the study. We will post these diaries out to you when we write to confirm which group you are in. A pre-paid envelope will be provided for their return.

We also ask all study participants in both groups to complete three questionnaires four, eight and 12 months after they join the study. A pre-paid envelope will be provided for their return.

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If you have indicated on the consent form that you are happy to receive text messages from the study, we may send a text message to remind you when these diaries and questionnaires should be completed. We will not send you text messages if you have not given consent for this.

Interviews

At a later date, some people will be asked to take part in an interview about the experience of being in either the self-learning manual group or the support programme group. The interview will cover topics such as your responses, how easy or hard you found different aspects of the course, any challenges you may have experienced.

If you are selected for this interview study we will send you a separate letter with an information sheet so that you can make an informed decision on whether or not you would like to take part.

What are the possible benefits of taking part?

We hope that you will learn how to manage your pain and reduce your use of opioids. Whilst there may not be any direct benefits to you, we hope that the information we gather will inform our development of a self-support and education programme for patients living with long-term pain treated with opioids.

Are there any risks in taking part?

We do not believe there are any major risks when taking part in this study. However, there may be a small risk of flu-like illness, muscle aches and pains and diarrhoea. These are side effects linked with reducing the use of opioids and usually disappear in time.

Will my details be kept confidential?

All information that is collected during the study will be kept confidential at all times and held in compliance with the Data Protection Act 1998. All electronic data will be stored in a secure format. We will always ensure that any material that may identify who you are, has the identifiable data removed before there is any analysis of the data.

Trial documentation and data will be archived for at least ten years after completion of the trial.

Any disclosures of information regarding use of non-prescription or illegal medications to a member of the study team will not be disclosed further.

If you agree to take part, we will let your GP know you are participating in the study and provide them with a copy of the Participant Information Leaflet. The only reason we would break confidentiality would be in an emergency. If your own health, or somebody else's health, was in danger, we would contact your GP.

If you are put in the support programme group, although we will encourage confidentiality during the group sessions, we cannot guarantee confidentiality of what is discussed within the group.

Any audio recording of the support programme or interviews will be transcribed by a third party transcription service or a member of the research team contracted to work on the research project. On all occasions we will ensure that any material that may identify who you are is removed before there is analysis of the transcripts. We may use written quotations from the transcripts in academic presentations or publications based on this research. In the future we may use the anonymous transcripts for other research. We might agree to share these with other, carefully selected, researchers; any such sharing will be closely monitored by the university.

We may use your data to link with Health Episode Statistics (HES) data in order to observe your resource use over time and gather data from the Office of National Statistics (ONS) on mortality. HES data is a record of admissions, outpatient appointments and A&E attendances at NHS hospitals in England and is held and maintained by The Health and Social Care Information Centre (HSCIC). We will ask for your consent to access this data if you agree to participate in the study. All information will be held in compliance with HSCIC data confidentiality and security arrangements and the Data Protection Act 1998.

How long does the study last?

You will be asked to remain in the study for 12 months. After you have either used the self-learning manual and relaxation CD or attended a support programme course, we will contact you with a questionnaire at four months (this will take about 30 minutes to complete). We will then contact you again at eight and 12

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months to complete the same questionnaires (these will take around 30 minutes each to complete). If you agree to take part in an interview, this will be carried out after your 12 months in the study.

What will you do with the results of the study?

We will present the findings in a study report and in health and medical journals. You will not be identified in any of the publications. The study team will make sure that you know about the results by sending you a brief summary of the study findings.

Who can I contact if I need more information?

If you have any questions about the study, or your involvement in it, either now or in the future, do please contact the study team using the details below.

Sharisse Alleyne, Trial Coordinator
Warwick Clinical Trials Unit, Warwick Medical School
University of Warwick,
Coventry, CV4 7AL
IWOTCH@warwick.ac.uk
Tel: 02476 150 285

What happens if there is a problem?

This study is covered by the University of Warwick's insurance and indemnity cover. If you have any concerns about this study, please contact the Chief Investigators of the study:

Dr Harbinder Sandhu
Associate Professor, Warwick Clinical Trials Unit
Warwick Medical School
The University of Warwick
Coventry, CV4 7AL
harbinder.k.sandhu@warwick.ac.uk
Tel: 02476 574664

Professor Sam Eldabe
Consultant in Pain Management
Cheirton House
The James Cook University Hospital
Marton Road, Middlesbrough, TS4 3BW
sam.eldabe@stees.nhs.uk
Tel: 01642 282417

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance
Research & Impact Services, University House
University of Warwick, Coventry, CV4 8UW
Tel: 024 76 522746
Email: researchgovernance@warwick.ac.uk

Who is organising and paying for the study?

The study is being co-ordinated by the University of Warwick and is being led by Dr Harbinder Sandhu and Professor Sam Eldabe (The James Cook University). The study is funded by the National Institute for Health Research, Health Technology Assessment (project number 14/224/04.

Who has reviewed the study?

Any research that involves the NHS and patients is subject to review by an independent group of people called a Research Ethics Committee. This committee is there to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire and The Humber – South Yorkshire Research Ethics Committee, Reference 16/YH/0325.

Thank you for taking time to read this information leaflet and for considering the study.

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