



COPERS STUDY

COping with persistent Pain, Effectiveness Research into Self-management

GENERAL PRACTICE INFORMATION SHEET

What is the purpose of the study?

To conduct a randomised controlled trial to explore the effectiveness and cost effectiveness of a newly developed self-management course for those with chronic musculoskeletal pain.

What will happen if my practice takes part in the study?

If you take part, you will help to identify patients living with chronic pain and recruit them for the COPERS study. We will ask you to search your electronic records, use your existing knowledge of patients and put up adverts in the public areas of your surgery to help generate patient interest. The identified patients will be screened by the clinician for suitability. Those eligible for inclusion will be sent an invitation letter from the clinic, with an attached reply slip to complete if they are interested and a patient information leaflet. The study team (who are trained and CRB checked) will then follow up patients who have indicated they might be interested in taking part. Interested patients can contact the study team directly via email, phone or reply slip, we will send them a baseline questionnaire and a trial consent form and enrol them in the study once consent is confirmed and they are randomised.

The study team will provide the envelopes, information leaflets, consent forms, postage stamps and pre-paid envelopes. The General Practice will be required to print out the invitation and reminder letters on clinic headed paper and provide the study team with an anonymised list of patients they have contacted (i.e. gender, age and ethnicity).

We will also need to review patient records at 12 months; patient consent will have been sought for this.

The general practices participating in the study will receive payment for their part in recruiting participants to the study.

What does the study involve for patients?

Patients will be asked to participate in a two arm randomised controlled trial. One arm of the trial will be the intervention, the self-management group based course, and the other the control or relaxation arm of the trial. Those on the course will be booked onto a three day course (10.00 till 3.00 every other day over a week) with a two hour follow up two weeks later. The course will teach them techniques to manage their pain. This will include: pain education, acceptance, cognitive behavioural therapy, attention control and distraction, relaxation, imagery, visualisation, posture and movement. Those in the control arm will be given a relaxation pack with instructions about relaxation technique and an audio CD.

Participants will be required to complete a baseline questionnaire, a self-efficacy questionnaire 12 weeks after randomisation and two further questionnaires at 6 and 12 months.

What happens next and who can I ask if I have any questions?

Please return the reply slip indicating whether you would like to take part in the study.

Please contact Dr Dawn Carnes on **020 7882 2546** if you have queries. Alternatively you can email at **d.carnes@qmul.ac.uk**. The correspondence address is Dr Dawn Carnes, COPERS Study Manager,

Centre for Primary Care and Public Health, Barts and The London School of Medicine and Dentistry, 2 Newark Street, London, E1 2AT.

Has the study got approval and who is it funded by?

The study has been approved by Cambridgeshire 4 Research Ethics Committee (**11/EE/0046**) and by (Research Governance office at PCT or new consortia). Indemnity insurance and sponsorship is provided by Barts and The London Joint Research Office, 5 Walden St, London E1 2EF. The study is funded by the National Institute for Health Research. **ISRCTN: 24426731**

Who is responsible for this study?

Professor Stephanie Taylor, Centre for Primary Care and Public Health, Barts and The London School of Medicine and Dentistry, 2 Newark Street, E1 2AT and Professor Martin Underwood at Warwick Medical School, Clinical Trials Unit, Gibbet Hill Road, Coventry CV4 7AL.

WE LOOK FORWARD TO YOUR SUPPORT IN THE STUDY

We would like to take part in the study.

Practice

Name

Key

Contact

Address

.....

.....

Email

Telephone number(s)

Convenient times to contact

us

Signed

Date

Please sign and return this form in the **FREEPOST** envelope provided.

.....

Office Use Only

Date received



COPERS STUDY

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Effectiveness **R**esearch into
Self-management

Participant Information

London **020 7882 2546**

Warwick **024 7657 2905**



Warwick
Medical School

The COPERS study team thank you for taking an interest in our research.

The type of research study we are doing is called a randomised controlled trial. Please read the following information carefully. If you have any queries please call us.

What is the purpose of the study?

The COPERS study is comparing a chronic pain management course with a relaxation programme plus usual GP care. The trial will help us identify which approach is more effective and for whom. The study measures how all the people in the trial cope with their pain at different time points. We hope that the results will help to improve the outlook for people with chronic 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 treatment or intervention groups. The two groups of people are compared to find out any differences between interventions.

What is the difference between the two interventions in the trial?

If you are allocated to the course we will invite you to attend a short course led by two tutors. The course runs over 3 days from 10 am to 2.45 pm each day, with a 2 hour follow up session two weeks later. During the course you will be encouraged to talk with others who have chronic pain and think about your own lifestyle, experiences and behaviours. There will be up to

12 people in a group. The course will include sessions about:

- Understanding your pain
- Pain and mood
- Dealing with unhelpful thinking
- Communication skills
- Attention control techniques
- Activity
- Posture and stretching

The courses will be run by a healthcare professional and a person who has chronic pain and has been trained to run the course.

If you are in the relaxation group we will send you a booklet with advice about chronic pain management and a relaxation CD. We will give you instructions about relaxation and how to use a relaxation CD. You will be asked to practise and use the relaxation techniques for 3 weeks. You can continue to receive your usual healthcare whilst taking part in the COPERS study.

Some courses may be audio recorded for quality control purposes only.

How long does the study last?

You will be asked to remain in the study for 12 months. After you have either done a course or completed the relaxation programme we will contact you with a short questionnaire at 12 weeks (this will take about 5 minutes to complete and return to us). We will then contact you again at 6 months, and one year, to fill in follow-up questionnaires (these will take around 10-20 minutes to complete).

Do I have to take part?

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 and are satisfied that we have answered all your questions. Then fill out the trial consent form and the baseline questionnaire and post them back to us using the FREEPOST envelope provided (no stamp is required).

When we receive your trial consent form and baseline questionnaire we make sure your details are stored with an anonymous study identification number. We will then telephone you to check you are happy to be in the study and understand the process. We will then randomly allocate you to the course or relaxation group.

If you are allocated to the course we will agree a course date suitable for you and if you are allocated to the relaxation group we will post out your booklet and CD and instructions.

Are there any risks in taking part?

We do not foresee any risks to your health in taking part in the study.

Who will know that I am taking part?

The only people who will know that you are taking part are the study team and your GP.

What will you do with the results of the study?

We will present the findings in a study report and in medical journals. You will not be identified in any of the publications. The study team will make sure that you know about the results through a newsletter and you can look at our website: www.icms.qmul.ac.uk/chs/pctu/current_projects/operations/25507.html

Will my details be kept confidential?

Yes. Your personal details will be kept strictly confidential from outside sources. Any information about you which leaves your GP practice will have your name and address removed so that you cannot be recognised from it. 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.

Who is responsible for this study?

Professor Stephanie Taylor (London), Professor Martin Underwood (Warwick). The National Institute for Health Research has funded the study (This is a government funded research body). The Cambridgeshire 4 Research Ethics Committee approved the study and Queen Mary University of London provide the indemnity insurance cover.

What happens if there is a problem?

Queen Mary University of London has agreed that if in the unlikely event that you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention you received during the course of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action.

If you have a complaint:

Please contact Patient Advisory Liaison Service if you have any concerns regarding the care you have received, or as an initial point of contact if you have a complaint.

Please telephone **020 7377 6335** or email pals@bartsandthelondon.nhs.uk

Who should I contact if I need more information?

Dr Dawn Carnes, Study Manager, who will be happy to answer any queries. Telephone: **020 7882 2546** or email: d.carnes@qmul.ac.uk

THANK YOU FOR YOUR TIME

**If you would like a large print version of this information sheet please call
020 7882 2546**

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