ISRCTN49470934 https://doi.org/10.1186/ISRCTN49470934

Improving the wellbeing of people living with opioid treated chronic pain

Submission date
21/11/2016

Recruitment status
No longer recruiting

Registration date
06/02/2017

Overall study status
Completed

Last Edited
07/12/2023

Condition category
Signs and Symptoms

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Nearly eight million people (15%) in England suffer from moderate to severe long-term (chronic) pain. Chronic pain can severely impact on overall health and functioning, and can greatly reduce quality of life. Treatment with opioids (strong pain relief medication) is often recommended, however the side effects of taking these medications can often outweigh the benefits of long term use. Previous work has found that self-management and cognitive behavioural therapy (a type of talking therapy that changes the way people think and behave) can support pain management. In this study, these techniques have been adapted and developed a self-management course to help people cut down on opioid use. The aim of this study is to test the effectiveness and cost effectiveness of this new self-management program in helping people to reduce their opioid consumption and improve quality of life.

Who can participate?
Adults who are taking opioid medication for long-term pain (not cancer related).

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group continue to receive usual care from their GP and are sent a manual containing advice about how to manage long-term pain and information about the side effects of taking opioids to use as a learning tool. They also receive a relaxation CD so that they can practice relaxation techniques. Participants receive the same as those in the first group but are also invited to take part in a short three-day course. During the course, participants take in groups with others who use opioids to manage chronic pain and think about their own lifestyle, experiences and behaviours. The course also involves education about a range of topics, including understanding pain, coping techniques, relaxation techniques, prescribing opioids for chronic pain, short and long term effects of opioids, pain control after opioids and managing reduction of opioids. All participants are asked to complete a weekly diary for the first four months of the study. They then complete follow up questionnaires at four, eight and twelve months about their pain levels, opioid use and activities of daily living (what they can do).

What are the possible benefits and risks of participating?
Participants may benefit from learning to better manage their pain and to reduce their use of

opioids. There are no major risks involved with taking part however some participants may experience withdrawal symptoms from lowering their opioid dose.

Where is the study run from?
1. Warwick Hospital (UK)
2. University Hospital Coventry and Warwickshire (UK)

When is the study starting and how long is it expected to run for?
September 2016 to November 2021

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
I-WOTCH Trial Management Team, IWOTCH@warwick.ac.uk

Study website
https://warwick.ac.uk/fac/sci/med/research/ctu/trials/iwotch

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CPMS 32567

Study information

Scientific Title
Improving the Wellbeing of people with Opioid Treated Chronic pain: I-WOTCH

Acronym
I-WOTCH

Study objectives
The aim of this study is to test the effectiveness and cost effectiveness of a multicomponent self-management intervention targeting withdrawal of strong opioids on activities of daily living for people living with chronic non-malignant pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire and The Humber – South Yorkshire Research Ethics Committee, 13/09/2016, ref: 16/YH/0325

Study design
Randomized; Both; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Musculoskeletal disorders; UKCRC code/ Disease: Other/ General symptoms and signs

Interventions
Participants are randomised to one of two groups.

Self-learning manual group: Participants will be sent a manual with advice about chronic pain management and the potential implications and adverse effects of using opioids. It is a learning tool. These participants will also receive a relaxation CD and instructions on how to use it.

Participants will be asked to practice and use the relaxation techniques in their own time. Participants will continue to receive their usual GP care whilst taking part in the I-WOTCH study.

Support programme group: Participants will be invited to a short course in addition to the above. The course is led by two facilitators and runs over 3 days. During the course participants will be encouraged to talk in a group with others who use opioids to manage chronic pain and think about their own lifestyle, experiences and behaviours. There will be an average of 12 people in a group. The course will include sessions about understanding pain, coping techniques, relaxation techniques, prescribing opioids for chronic pain, short and long term effects of opioids, pain control after opioids, managing reduction of opioids and more.
Participants will attend the first and second group days and then meet on a separate day with the I-WOTCH nurse for a one to one consultation. At this consultation the nurse and participant will create an opioid tapering plan. The third group day will follow the consultation. These activities happen over approximately 4 weeks.
From weeks 5-10 the participant has two telephone consultations with the nurse and then a further face to face consultation with the nurse to see how they are getting on with their tapering plan.

All participants will be asked to complete a weekly diary up until 4 months from their randomisation into the study. At 4, 8 and 12 months all participants will be asked to complete a follow up questionnaire.

Intervention Type
Other

Primary outcome measure
Activities of daily living are measured using the Patient-Reported Outcomes Measurement Information System (PROMIS) Pain Interference Short Form (8A)(PROMIS-PI-SF-8A) at baseline, 4, 8 and 12 months.

Secondary outcome measures
1. Self-reported data on opioid use will be collected using a postal questionnaire at baseline, 4, 8 and 12 months
2. Pain severity is measured using the PROMIS Scale V1.0 – Pain Intensity Short Form 3a at baseline, 4, 8 and 12 months
3. Symptoms are measured using the Severity of Opioid Withdrawal (Symptoms): Short Opiate Withdrawal Scale (ShOWS) at baseline, 4, 8, 12 months and weekly from randomisation to 4 months
4. Health related quality of life is measured using the SF12 V2.0 and EQ5D-5L at baseline, 4, 8 and 12 months
5. Sleep quality is measured using the Pittsburgh Sleep Quality Index at baseline, 4, 8 and 12 months
6. Emotional wellbeing is measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 4, 8 and 12 months
7. Self-efficacy is measured using the Pain Self Efficacy Questionnaire (PSEQ) at baseline, 4, 8 and 12 months
8. Resource use is measured using a combination of routinely collected NHS data, GP data, HES data and patient self-reported data at 4, 8 and 12 months

Overall study start date
01/09/2016

Completion date
11/11/2021

Eligibility

Key inclusion criteria
1. Provision of written informed consent
2. Aged 18 years old or above
3. Using opioids for chronic non-malignant pain
4. Report using strong opioids for at least three months and on most days in the preceding month
5. Fluent in written and spoken English
6. Willingness for General Practitioner to be informed of participation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 468; UK Sample Size: 468

Total final enrolment
608

Key exclusion criteria
1. Regular use of injected opioid drugs
2. Report chronic headache as the dominant painful disorder
3. Serious mental health problems that preclude participation in a group intervention
4. Using opioids for malignant pain
5. Unable to attend group sessions
6. Previous entry or randomisation in the present trial.
7. Participation in a clinical trial of an investigational medicinal product in the last 90 days.

Date of first enrolment
01/03/2017

Date of final enrolment
31/01/2019

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Warwick Hospital
South Warwickshire NHS Foundation Trust
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
University Hospital Coventry and Warwickshire
University Hospitals Coventry & Warwickshire NHS Trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University of Warwick

Sponsor details
Research & Impact Services
University House
Coventry
England
United Kingdom
CV4 8UW

Sponsor type
University/education

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type

Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 23/05/2023:
1. Planned presentation of findings to the professional community at scientific meetings such as the British Pain Society and relevant International Conferences (e.g. World Pain Congress)
2. Planned presentation of findings at meetings of professional bodies such as The Royal College of General Practitioners, British Psychological Society and The Royal College of Nursing
3. Planned publication of the results in high-quality peer-reviewed journals and have requested funding for open-access publishing
4. All results and updates about the trial will also be shared on the I-WOTCH website (https://warwick.ac.uk/fac/sci/med/research/ctu/trials/iwotch)

Previous publication and dissemination plan:
1. Planned presentation of findings to the professional community at scientific meetings such as the British Pain Society and relevant International Conferences (e.g. World Pain Congress)
2. Planned presentation of findings at meetings of professional bodies such as The Royal College of General Practitioners, British Psychological Society and The Royal College of Nursing
3. Planned publication of the results in high-quality peer-reviewed journals and have requested funding for open-access publishing

Intention to publish date
01/06/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from IWOTCH@warwick.ac.uk or WCTUDataaccess@Warwick.ac.uk

Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from IWOTCH@warwick.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/08/2019	03/09/2020	Yes	No
Protocol article	process evaluation protocol	10/10/2019	22/10/2020	Yes	No
Protocol article	health economics analysis protocol	01/11/2020	27/11/2020	Yes	No
Other publications	intervention development and testing	16/03/2022	18/03/2022	Yes	No
Results article		23/05/2023	06/06/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Process evaluation	06/12/2023	07/12/2023	Yes	No