Titre	**I-WOTCH** (**I**mproving the **W**ellbeing of people with **O**pioid **T**reated **CH**ronic pain) – Gérer la médication d'opioïdes lors de douleurs chroniques.
Acronyme	I-WOTCH
Statut (dates début-fin)	En cours
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Source de financement (partenaire financier)	• NIHR (National Institute for Health Research, UK, http://www.nihr.ac.uk/about/)
Résumé	Cet essai clinique randomisé évalue l'efficacité d'un programme de gestion de la réduction d'opioïdes lors de douleurs chroniques. **Abstract** Background Living with chronic pain can have a major impact on wellbeing, quality of life and productivity and affects nearly eight million people (15%) in England. Strong opioids are increasingly being prescribed despite limited data supporting the effectiveness of long-term use for chronic non-malignant pain. Adverse effects often outweigh the benefits of long-term opioid treatment on pain including sedation, decreased concentration and memory, drowsiness, changes in mood, constipation, dry mouth, abdominal pain, nausea and hormonal changes with consequences such as sexual dysfunction. People on long-term opioid treatment report inadequate analgesia; due to development of tolerance. Prescription data from the UK show substantial increases in the use of opioids for non-cancer pain with a 466% increase in the number of strong opioid users between 2000 and 2010 with large regional differences in prescribing also reported. There are no formal UK guidelines for opioid reduction in this population and limited support available to help people reduce. Aims The overall aim of I-WOTCH is to test the effectiveness and cost effectiveness of a patient-centred multicomponent self-management intervention targeting withdrawal of strong opioids, on activities of daily living and opioid related adverse events for people living with chronic non-malignant pain. Method A definitive randomised controlled trial; I-WOTCH will recruit 468 participants from primary care, pain clinics and pharmacies. Eligible participants will include those with chronic non-malignant pain, aged ≥18, using strong opioids (as defined by the British National Formulary for at least three months and on most days in the preceding month) and fluent in written and spoken English. Participants will be randomised into receiving either the I-WOTCH Intervention; consisting of a three day cognitive behavioural approach based group facilitated course (led by a trained nurse and a lay person with chronic pain and experience of opioid withdrawal/tapering) and one-to one sessions (face to face and telephone with the trained nurse) or the control intervention a self-help manual for people using opioid drugs for chronic pain (My Opioid Manager) and a relaxation CD. A process evaluation will track how: the intervention is delivered, staff experiences of delivery, possible mediating processes and patients' perceptions and experiences of participation in the intervention. Results

	The primary outcome measure is 'activities of daily living' measured by the Patient-Reported Outcomes Measurement Information System, Pain Interference Short Form (8A)(PROMIS-PI-SF-8A). The main secondary outcome is Opioid use defined as mean difference in morphine equivalent dose in the four weeks prior to one-year follow-up expressed as mg of morphine per day. We will also compare proportions achieving a complete and partial withdrawal (defined as ≥50% reduction in morphine equivalent doses taken, between intervention and control groups). Other secondary outcomes include: Adverse events using the Short Opiate Withdrawal Scale, Health Related Quality of Life using the SF-12, and EQ-5D-5L, Sleep quality using the Pittsburgh Sleep Quality Index, emotional wellbeing using the Hospital Anxiety and Depression Scale, Self-Efficacy using the Pain Self Efficacy Questionnaire and Resource use. Data will be collected at base line, four, eight and twelve months. Conclusion The findings from this trial will inform clinical practice on the identification and management of patients with non-malignant chronic pain to reduce and withdraw from their opioid use.
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