NIHR | National Institute for Health and Care Research

Health Technology Assessment

Check for updates

Extended Research Article

Effects and costs of a group-based educational intervention to reduce opioid use in people with chronic pain: I-WOTCH RCT

Harbinder K Sandhu,[1*] Katie Booth,[1] Sheeja Manchira Krishnan,[2] Charles Abraham,[3] Sharisse Alleyne,[1] Shyam Balasubramanian,[4] Lauren Betteley,[1] Tom Bromilow,[5] Dawn Carnes,[6] Andrea D Furlan,[7,8,9] Vijay S Gc,[10,11] Kirstie L Haywood,[12] Maddy Hill,[1] Cynthia P Iglesias-Urrutia,[2,13] Ranjit Lall,[1] Andrea Manca,[10] Dipesh Mistry,[1,14] Joe WE Moss,[5] Sian Newton,[6] Vivien P Nichols,[1] Jennifer Noyes,[15] Emma Padfield,[1,16] Anisur Rahman,[17] Kate Seers,[12] Jane Shaw,[15,18] Nicole KY Tang,[19] Stephanie JC Taylor,[6] Colin Tysall,[20,21†] Martin Underwood[1,22] and Sam Eldabe[15,23]

[1]Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, Coventry, UK
[2]Department of Health Sciences, University of York, York, UK
[3]School of Psychology, Deakin University, Geelong, Australia
[4]Department of Anaesthesia and Pain Medicine, University Hospital Coventry and Warwickshire NHS Trust, Coventry, UK
[5]York Health Economics Consortium, University of York, York, UK
[6]Wolfson Institute of Population Health, Barts and The London School of Medicine and Dentistry, Queen Mary University of London, London, UK
[7]Toronto Rehabilitation Institute, University Health Network, Toronto, Canada
[8]Department of Medicine, University of Toronto, Toronto, Canada
[9]Institute for Work & Health, Toronto, Canada
[10]Centre for Health Economics, University of York, York, UK
[11]School of Human and Health Sciences, University of Huddersfield, Huddersfield, UK
[12]Division of Health Sciences, Warwick Medical School, University of Warwick, Coventry, UK
[13]Danish Centre for Healthcare Improvements, Aalborg University, Aalborg, Denmark
[14]Statistics and Decision Sciences, Johnson & Johnson, Research & Development, High Wycombe, UK
[15]Department of Pain Medicine, James Cook University Hospital, Middlesbrough, UK
[16]IQVIA, Reading, Berkshire, UK
[17]Centre for Rheumatology Research, University College London, London, UK
[18]Boston Scientific, Hemel Hempstead, UK
[19]Department of Psychology, University of Warwick, Coventry, UK
[20]University/User Teaching and Research Action Partnership, University of Warwick, Coventry, UK
[21]Service User and Carer Engagement, Coventry University, Coventry, UK
[22]University Hospitals Coventry and Warwickshire NHS Trust, Coventry, UK
[23]Hôpital de Morges, Morges, Switzerland

[*]**Corresponding author** harbinder.k.sandhu@warwick.ac.uk

[†]In Memoriam

To Colin Bernard Tysall, thank you for your valuable contribution to this study which would not have been a success without you.

Disclaimer: This report contains transcripts of interviews conducted in the course of the research, or similar, and contains language which may offend some readers.

Published May 2026
DOI: 10.3310/GJHS2715

Scientific summary

Effects and costs of a group-based educational intervention to reduce opioid use in people with chronic pain: I-WOTCH RCT

Health Technology Assessment 2026; Vol. 30: No. 35
DOI: 10.3310/GJHS2715

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Chronic non-malignant pain is the leading cause of years lived with disability globally and is defined as pain that persists or recurs for longer than 3 months. Despite a lack of evidence that they improve pain, function or quality of life, opioids are widely used to treat chronic non-malignant pain. Adverse effects from opioids include sedation, nausea, respiratory depression/sleep apnoea, depression, abdominal pain, hormone imbalance, overdose and death. Up to 80% of opioid users report at least one adverse effect. In 2017, there were 110,000 deaths from opioid overuse disorder worldwide — a 77% increase from 2007 with further increase reported during the COVID-19 pandemic. Data published in 2020 from a retrospective cohort study using UK primary care electronic health records from the Clinical Practice Research Data Link found that between 2006 and 2017 a total of 1,968,742 new adult patients with chronic non-malignant pain were prescribed an opioid. Codeine was the most commonly prescribed opioid, with use increasing fivefold from 2006 to 2017, reaching 2456 prescriptions/10,000 people/year. Prescribing of other opioids such as morphine, buprenorphine, and oxycodone also continued to increase during this period. At the time we were developing this study, there were few data supporting interventions that assist people to reduce opioid doses. A 2017 Cochrane review found one randomised controlled trial of acupuncture (*N* = 35) and one of computerised therapeutic voice support (*N* = 51). The reviewers were unable to make recommendations for practice. This review also identified five observational studies (*N* = 1800) from one unit suggesting that an intensive 3-week pain management programme can substantially reduce opioid use.

There have been three subsequent systematic reviews. Two reviews focused on opioid reduction interventions. They identified 10 randomised controlled trials of patient focused opioid de-prescribing interventions (*n* = 835). These trials did not show evidence of reduced opioid consumption or increased opioid cessation. The third review, looking at the wider pain management literature, included two trials of pain self-management (*N* = 238) in a meta-analysis that found positive effects on opioid cessation [odds ratio (OR) 2.15, 95% confidence interval (CI) 1.02 to 4.53] and five (*N* = 428) that found a reduced daily morphine equivalent dose of 14.3 (95% CI 7.1 to 21.6)]. These data suggest that a pain management programme might have some potential to reduce opioid use by people living with chronic non-malignant pain.

An effective pain management programme that specifically targeted opioid use could be expected to help people live better with their pain both directly through its effect on pain self-efficacy and indirectly through an improved quality of life from reduced opioid use. However, an alternative outcome could be that successful opioid tapering leads to increased pain, and worse quality of life due to loss of their analgesic effect. This means that any trial of an opioid reduction intervention needs to consider both any changes in opioid uses and how pain affects people.

Tapering opioids too quickly without a lack of alternatives to manage pain can cause substantial harm. Individuals motivated to reduce their opioid use need appropriate advice on how to do this safely. In the Improving the Wellbeing of People with Opioid Treated Chronic Pain (I-WOTCH) study, we tested the combination of a pain management approach and an individualised and supported opioid tapering plan on pain interference and opioid use.

Aims

The aim of the I-WOTCH study was to test the clinical and cost-effectiveness of a patient-centred multicomponent self-management intervention (targeting withdrawal of opioids and assessing impact of their withdrawal on pain interference with daily living) for people living with chronic non-malignant pain, compared with a best usual care (i.e. the control group intervention) in a two-arm pragmatic randomised controlled trial. An embedded process evaluation was used to inform the interpretation of the findings and, if indicated, implications for the implementation of the intervention.

Study objectives were:

1. To develop and refine a patient-centred, group-based, multicomponent, self-management intervention for people living with chronic non-malignant pain.
2. To assess the acceptability of the intervention and to optimise participant recruitment during the internal pilot phase.
3. To conduct a pilot accompanied with a process evaluation to establish efficient recruitment.
4. To run a multicentre trial to examine the clinical effectiveness and resource use implications of the I-WOTCH intervention versus usual care over a 12-month follow-up period.
5. To develop an initial decision-analytic cost-effectiveness model and value of information analysis based on existing evidence.
6. To update the decision-analytic cost-effectiveness model and value of information analysis with the data from the definitive trial and model the long-term cost-effectiveness of the I-WOTCH intervention versus usual care.
7. To conduct process evaluation of the trial which will aid interpretation of the trial findings and, if indicated, to inform the implementation of the intervention across the NHS.
8. To disseminate the findings from the trial and, where necessary, results providing materials to support wider implementation of the intervention.

Methods

We conducted a pragmatic, multicentre, 1 : 1 randomised controlled trial design to test the superiority of a multicomponent, psychologically informed, group self-management support programme, including a one-to-one discussion with a trained nurse and the development of an opioid tapering programme, against enhanced usual care for reducing opioid consumption in people with chronic non-malignant pain. The trial was approved by the Yorkshire and The Humber – South Yorkshire Research Ethics Committee on 13 September 2016 (16/YH/0325) and sponsored by the University of Warwick, UK. It was conducted according to good clinical practice guidance and overseen by an independent Trial Steering Committee, with an independent Data Monitoring and Ethics Committee.

Participants were adults (aged ≥ 18) using strong opioids as defined in the *British National Formulary* (BNF) published at the time of the study design, for at least 3 months for chronic non-malignant pain, and on most days in the preceding month. Since the study was developed, the BNF has changed its approach and no longer makes a distinction between weak and strong opioids.

To identify potential participants, general practices searched their records for people aged 18 years and over, who had more than one prescription for a strong opioid (buprenorphine, dipipanone, morphine, diamorphine, fentanyl, hydromorphone, methadone, oxycodone, papaveretum, pentazocine, pethidine, tapentadol and tramadol) in the previous 3–6 months and in the previous 0–3 months as indicated by their health record.

General practices invited potentially eligible people to express an interest in the study. They excluded people known to be using opioids for malignant pain, care home residents, the housebound, and those using methadone not prescribed for chronic pain. People could also self-refer. Posters were placed in general practitioner surgeries, pharmacies, pain clinics and musculoskeletal physiotherapy clinics and the study website had details of the trial. We confirmed eligibility in a subsequent telephone call. Eligible participants then completed baseline questionnaires and returned signed consent forms. In a further telephone call, medication use, as reported in the baseline questionnaire, and consent to join the study were checked and confirmed.

Participants were randomised 1 : 1 to either usual care or the I-WOTCH intervention. Both groups received enhanced usual care, including a booklet ‘My Opioid Manager’ based on the 2010 Canadian Opioid Guideline, a self-help guide containing information about pain, opioids and tapering, and a relaxation compact disc. The intervention group was offered the I-WOTCH intervention package.

Two primary outcomes were Patient-Reported Outcomes Measurement Information System Pain Interference Short Form (8A) (PROMIS-PI-SF-8A) (T-score range 40.7–77, 77 indicates worst pain interference) and the proportion of participants who discontinued opioids at 12 months, measured by self-report. Secondary outcomes were Patient-Reported Outcomes Measurement Information System Pain Intensity Short Form 3a (PROMIS-PI-SF-3A), severity of opioid withdrawal symptoms [Short Opiate Withdrawal Scale (ShOWS)], health-related quality of life [SF-12v2 health survey and EuroQol-5 Dimensions, five-level version (EQ-5D-5L)], sleep quality (Pittsburgh Sleep Quality Index), emotional well-being [Hospital Anxiety and Depression Scale (HADS)], self-efficacy (Pain Self-Efficacy Questionnaire), and proportion of patients who reduced opioids by 50% from baseline. All outcomes were collected at baseline, 4, 8 and 12 months.

Sample size

As originally designed, we sought to demonstrate a 3.5-point difference in PROMIS-PI-SF-8A at 1 year at a significance level of 5% with 90% power as a single primary outcome. To show this with a simple sample size calculation requires data on 346 participants. Allowing for the possibility of clustering effects in the intervention group, we inflated this to 374. Allowing for 20% loss to follow-up, we aimed to recruit 468 people. We anticipated recruiting from around 100 practices in the West Midlands, The North East of England and London: 33 from each area. We were unable to run the study in London because we could not secure excess treatment costs from London Clinical Commissioning Groups and therefore the study ran in the wider midlands area and the North East.

Due to the nature of the recruitment process, and the need to have sufficient participants to populate an intervention group in a particular locality, we substantially exceeded our original recruitment target. Since we considered that if the intervention were to have no impact on pain interference but did reduce opioid usage this could be an important benefit, we sought approval to add difference in opioid use as a second primary outcome. This was agreed by the Trial Steering Committee and Data Monitoring Committee while data collection was still in progress. The actual group sizes were less than expected reducing the sample size inflation needed to account for clustering effects. Recalculating the sample size, accounting for this, and a significance level of 2.5% required to assess the two primary outcomes, opioid reduction and pain interference, was 542 participants (271 per group).

Health economics

We conducted a prospective within-trial cost–consequences analysis and a model-based long-term cost-effectiveness analysis (CEA) to assess the value for money of the I WOTCH intervention compared with the best usual care to support withdrawal of strong opioids, among those living with chronic non-malignant pain.

Process evaluation

An embedded process evaluation was also conducted to better understand people's experiences of the intervention and assess fidelity of the intervention. We interviewed 18 intervention facilitators, 20 intervention and 20 control group participants. Fidelity of group sessions and 1 : 1 consultations were evaluated, assessing adherence and competence. Participant feedback forms were also utilised. Interviews were analysed using framework analysis and feedback forms analysed using thematic analysis.

Results: clinical

Between 17 May 2017 and 30 January 2019, we randomised 608 people after screening in 191 general practices, 3 hospitals, and allowing self-referrals. We randomised 303 to control and 305 to intervention; we ran a total of 35 intervention groups in 25 locations.

At 12 months, 29% (65/225) in the intervention group and 7% (15/208) in the usual-care group had fully tapered off opioids [OR 5.55 (95% CI 2.80 to 10.99); $p < 0.001$]. At 12 months, the PROMIS-PI-SF-8A scores did not show a statistically significant between-group difference [adjusted mean difference −0.89 (95% CI −2.12 to 0.33); $p = 0.15$]. Over the 12-month study period, PROMIS-PI-SF-8A scores did improve in both groups: −4.1 (95% CI −4.98 to −3.22) in the intervention group and −3.17 (95% CI −4.10 to −2.24) in the usual care group.

At 12 months, 57% (129/225) in the intervention group and 27% (57/208) in the usual-care group had reduced their daily opioid usage by ≥ 50% from baseline [adjusted OR 3.76 (95% CI 2.47 to 5.71); $p < 0.001$]. Similar results were also seen at 4 and 8 months follow-up. No other secondary outcomes showed meaningful differences between the intervention group and usual-care group at 12 months. At 4 months, statistically significant differences were found between groups for the SF-12 mental component [adjusted 2.29 (95% CI 0.30 to 4.27); $p = 0.02$], HADS depression score [adjusted −0.94 (95% CI −1.63 to −0.25); $p = 0.01$], pain self-efficacy [adjusted 4.19 (95% CI 1.97 to 6.41); $p < 0.001$], EQ-5D-5L utility score [adjusted 0.57 (95% CI 0.01 to 0.10); $p = 0.02$] and EQ-5D-5L visual analogue scale score [adjusted 4.43 (95% CI 0.70 to 8.16); $p = 0.02$], with all differences favouring the intervention.

There were 36 adverse events (AEs; 25 intervention, 11 usual care) reported by 30 participants (22 intervention, 8 usual care). Fifty-two serious AEs (32 intervention, 20 usual care) were reported by 41 participants (25 intervention, 16 usual care). The serious adverse events (SAEs) included five deaths (four intervention, one usual care), all five of which were unrelated to the trial intervention. The causes of death were metastatic prostate cancer, aortic dissection, subdural empyema secondary to otitis media, lymphoma complication and one unknown. In the intervention group, there was one probably related and expected SAE (hot flushes and shooting pains in limbs after tapering) of moderate severity and three possibly related SAEs, two unexpected (small intestinal bleed, and pain surges and hot sensations after tapering) and one expected (hospitalisation due to joint/back pain). There was one possibly related SAE in the usual-care group (hospitalised for arthritis flare-up).

Results: health economics

The complete case analysis results indicate that in the short term, I-WOTCH is a cost-incurring but a similarly effective (i.e. maintaining measures of health benefit at a similar level to that experienced while on strong opioids) management strategy for tapering opioids in patients with non-malignant chronic pain compared to best usual care. Individuals who are able to self-regulate their use of strong opioids, however, could also achieve a reduction in their exposure to the excess mortality rate associated with long-term consumption of strong opioids. Modelling these results as part of the base-case CEA indicates that in the long term the I-WOTCH intervention may be cost-effective compared to best usual care [deterministic incremental cost-effectiveness ratio (ICER): £29,594; probabilistic ICER: £34,614]. The model results reflect the large uncertainty in the model parameters. Scenario analyses confirm these conclusions. Overall, the findings suggest that there is value in conducting further research to reduce the uncertainty associated with the results of the health economics analysis.

Results: process evaluation

Four themes emerged from the data: (1) the right time to taper, (2) the backdrop of a complex life with chronic pain, (3) needing support and (4) the group effect. Being in a group was an important aspect of the process.

This process evaluation revealed the I-WOTCH intervention was well delivered and well received. Being ‘the right time’ to taper and having support throughout emerged as important aspects within the context of living with chronic pain.

Conclusions: implications for healthcare

The I-WOTCH intervention (incorporating group sessions and one to one support) achieved a substantial and sustained cessation in opioid use with no increase in pain, or pain-related disability with no drug or device substitution. Our recommendations for future research are

1. Replication of I-WOTCH in different populations and different settings.
2. Adaptation and evaluation of the I-WOTCH intervention for use in people who do not speak English.
3. Comparing I-WOTCH to alternative tapering interventions.

Trial registration

This trial is registered as Current Controlled Trials ISRCTN49470934.

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (NIHR award ref: 14/224/04) and is published in full in *Health Technology Assessment*; Vol. 30, No. 35. See the NIHR Funding and Awards website for further award information.

Health Technology Assessment

ISSN 2046-4924 (Online)

Impact factor: 4

A list of Journals Library editors can be found on the NIHR Journals Library website

Launched in 1997, *Health Technology Assessment* (HTA) has an impact factor of 4 and is ranked 30th (out of 174 titles) in the 'Health Care Sciences & Services' category of the Clarivate 2022 Journal Citation Reports (Science Edition). It is also indexed by MEDLINE, CINAHL (EBSCO Information Services, Ipswich, MA, USA), EMBASE (Elsevier, Amsterdam, the Netherlands), NCBI Bookshelf, DOAJ, Europe PMC, the Cochrane Library (John Wiley & Sons, Inc., Hoboken, NJ, USA), INAHTA, the British Nursing Index (ProQuest LLC, Ann Arbor, MI, USA), Ulrichsweb™ (ProQuest LLC, Ann Arbor, MI, USA) and the Science Citation Index Expanded™ (Clarivate™, Philadelphia, PA, USA).

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta.

Criteria for inclusion in the *Health Technology Assessment* journal
Manuscripts are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

This article

The research reported in this issue of the journal was commissioned and funded by the HTA programme as award number 14/224/04. The protocol was agreed in September 2016. The draft manuscript began editorial review in July 2023 and was accepted for publication in July 2025. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' manuscript and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

This article presents independent research funded by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care.

This article was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Newgen Digitalworks Pvt Ltd, Chennai, India (www.newgen.co).