**Research Information Sheet for Practices**

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| **Study Title** | **I-WOTCH - Improving the Wellbeing of People Living With Opioid Treated Chronic Pain** |
| **Sponsor** | University of Warwick |
| **Funders** | National Institute for Health Research, Health Technology Assessment (project number 14/224/04) |
| **Chief Investigator** | **Dr Harbinder Sandhu, Clinical Trials Unit, University of Warwick** |
| **Study design** |  |
| **Primary Study Aim & Objectives** | The overall aim of the I-WOTCH study is to conduct a randomised controlled trial to test the effectiveness and cost effectiveness of a multicomponent self- management intervention targeting the withdrawal of strong opioids on activities of daily living in comparison to best usual care for people living with chronic non-malignant pain. |
| **Practice target & study duration** | Approximately 4-5 patients per practice dependent on list size.  15 months duration |
| **Recruitment period** | March 2017 to May 2018 (inclusive) |
| **Summary of Eligibility Criteria (refer to Protocol for full criteria)** | 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   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. |
| **Core Practice Activities** | * Run a database search, predetermined Read codes will be provided by the study team * GP to check list of identified patients and remove any inappropriate patients * Upload the list of identified patients to Docmail- a secure service responsible for mail merge and mail outs (See page 3) * Provide access to patient records for collection of prescription data and provide an anonymous data set containing gender, age and ethnicity for calculation of response rates. * Report any serious adverse events (hospitals admissions / deaths) |
| **Patient Involvement** | * Receive telephone call to confirm eligibility and explain study * Provide written consent and complete postal questionnaires at baseline, 4, 8 and 12 months * For those randomised to intervention: Participants will attend the self-management intervention- a 3 day support programme. The programme also includes 2 face to face consultations and 2 telephone consultations. * For those randomised to usual care: Participants will receive standard usual care plus receive a manual with advice about chronic pain management and the potential implications and adverse effects of using opioids. Participants will also receive a relaxation CD and instructions on how to use it * A subsample of patients will be asked to take part in qualitative interviews that will explore participant responses to the intervention or control e.g. how they felt they were able to use it, specific barriers or enablers etc |
| **Resources provided by the study team** | * Study team will provide each participating practice with all resources for the mail out, a study Site File and will update practices with any study amendments for the study duration * Trial specific research nurse and assistance from local CRN team to support search and mail out |
| **Reimbursement** | An estimated NHS service support payment of £XXX has been calculated for this study. This figure is based upon the information provided by the study team regarding the likely activities to be performed by your practice; it is an approximation only and may be adjusted in line with the level of practice activity and the amount of CRN support received. |

# Study Flow Diagram

Search GP electronic records (100 practices)

GP screen search list

Invitations sent from practice

Expression of interest returned to study team

Interviews: The experience of the control arm (N= ~20)

Phone interested patients to confirm eligibility

Consent and baseline questionnaires

Phone interested patients to confirm consent and medication use

Randomise patient into study

(N=425)

Self Management Intervention: 3 day Support Programme (N=213)

Follow up questionnaires at 4, 8 and 12 months (N=425)

Control Arm Usual care plus self- learning manual and relaxation CD (N=213)

Interviews: The experience of the support programme (N= ~20)

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| **Further details on DocMail**  Docmail is provided by CFH Docmail Ltd a secure print and mailing company who provide print and mailing services for Local Government, GP’s, Dentists, Opticians, Medical Practices, Schools, Exam Boards and Banks etc. throughout the UK. The system can be found online at [www.docmail.co.uk](https://web.nhs.net/OWA/redir.aspx?SURL=D8G-lwcPoUHPjHTqnVAx4_gUscnjDBPMLHZw1hidKyl2bTgzljTTCGgAdAB0AHAAOgAvAC8AdwB3AHcALgBkAG8AYwBtAGEAaQBsAC4AYwBvAC4AdQBrAA..&URL=http%3a%2f%2fwww.docmail.co.uk) and requires a user name and password for businesses to send secure mailings via the website, print driver ([www.docmail.co.uk/printdriver](https://web.nhs.net/OWA/redir.aspx?SURL=xqmIexKDcI27-n7jt_Y4AZQBUVQPnOutZXeVGuymPQ12bTgzljTTCGgAdAB0AHAAOgAvAC8AdwB3AHcALgBkAG8AYwBtAGEAaQBsAC4AYwBvAC4AdQBrAC8AcAByAGkAbgB0AGQAcgBpAHYAZQByAA..&URL=http%3a%2f%2fwww.docmail.co.uk%2fprintdriver)) or API ([www.docmail.co.uk/api](https://web.nhs.net/OWA/redir.aspx?SURL=6YFGzh7o8Ftk1MCGjS8oskqGvzPqI9io_uiCfmR-Tfp2bTgzljTTCGgAdAB0AHAAOgAvAC8AdwB3AHcALgBkAG8AYwBtAGEAaQBsAC4AYwBvAC4AdQBrAC8AYQBwAGkA&URL=http%3a%2f%2fwww.docmail.co.uk%2fapi))    Docmail currently has over 50 health research studies and 3000 medical practices registered and using Docmail to send out their mailings.  Docmail, this is approved by the following:     * GP System of Choice – Lot 2 supporting services * Crown Commercial Service for Hybrid Mail, which allows all government organisations to use Docmail. * Health Trust Europe and London Procurement Programme for Outgoing Mail Solutions * Caldicott Guardians across a number areas have approved the use of Docmail * Ethics Committees have approved the use of Docmail by surgeries for use in medical studies. * EMIS Partner Programme * Connecting For Health - achieved a 100% rating when completing the Dept. of Health's Information Governance Toolkit Assessment for 2014-2015 and meets the terms and conditions of the DH Information Governance Assurance Statement. The assessments are available at:   [https://www.igt.connectingforhealth.nhs.uk/reportsnew.aspx?tk=401634495202720&cb=10%3a49%3a25&lnv=6&clnav=YES](https://web.nhs.net/OWA/redir.aspx?SURL=JECOCjl_lsWm7cDQje-00Kr-a4ek4DUqdBjrnEeJ-C_2q_PC5zLTCGgAdAB0AHAAcwA6AC8ALwB3AHcAdwAuAGkAZwB0AC4AYwBvAG4AbgBlAGMAdABpAG4AZwBmAG8AcgBoAGUAYQBsAHQAaAAuAG4AaABzAC4AdQBrAC8AcgBlAHAAbwByAHQAcwBuAGUAdwAuAGEAcwBwAHgAPwB0AGsAPQA0ADAAMQA2ADMANAA0ADkANQAyADAAMgA3ADIAMAAmAGMAYgA9ADEAMAAlADMAYQA0ADkAJQAzAGEAMgA1ACYAbABuAHYAPQA2ACYAYwBsAG4AYQB2AD0AWQBFAFMA&URL=https%3a%2f%2fwww.igt.connectingforhealth.nhs.uk%2freportsnew.aspx%3ftk%3d401634495202720%26cb%3d10%253a49%253a25%26lnv%3d6%26clnav%3dYES)  For further information on the Docmail system please visit FAQs page at <http://www.cfhdocmail.com/faqs.html>. |