**Research Information Sheet for Practices**

|  |  |
| --- | --- |
| **Study Title** | **CHESS - Chronic Headache Education and Self-management Study** |
| **Sponsor** | University of Warwick |
| **Funders** | National Institute for Health Research Programme Grants for Applied Research |
| **Chief Investigator** | **Professor Martin Underwood, Clinical Trials Unit, University of Warwick** |
| **Study design** | Feasibility Study |
| **Primary Study Aim & Objectives** | The overall aim of the CHESS research programme is to develop and test a self-management support programme for people living with chronic headaches.The objectives of this feasibility study are:1. To test the feasibility of recruiting people living with chronic headache from primary care.
2. To evaluate a brief diagnostic classification interview to support classification of the three common chronic headache disorders: migraine, tension type and medication overuse.
3. To pilot and evaluate a new group self-management support intervention for the management of common chronic headache disorders
4. To evaluate our proposed package of outcome measures
5. To demonstrate the feasibility of doing a future randomised controlled trial of the clinical and cost-effective of the intervention
 |
| **Practice target & study duration** | Approximately 15-25 patients per practice dependent on list size.6 months duration  |
| **Recruitment period** | October 2015 to July 2016 (inclusive) |
| **Summary of Eligibility Criteria (refer to Protocol for full criteria)** | Inclusion criteria1. Aged ≥18 years with chronic headache; defined as headache for 15 or more days per month for at least three months.
2. Fluent in written and spoken English.

Exclusion criteria1. Has an underlying serious psychiatric or psychological disorder that precludes participation in a group intervention.
2. Known secondary cause of headache other than medication overuse headache; e.g. primary or secondary brain tumour.
3. Is currently participating in another headache trial.
4. No access to a telephone.
 |
| **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
* Mail merge the identified list with the practice-headed patient invitation letter and mail to identified patients (postage costs will be covered by the study)
* Provide access to patient records for 3 month data collection of consultations, health service activity, and medication use related to headaches
* 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, 2 weeks and 3 months
* Complete an electronic diary of headache frequency, duration and severity

(smartphone app or paper version available) weekly for three months* Complete a telephone interview with a research nurse to classify headache type
* A subsample of patients will be asked to take part in qualitative interviews
* A subsample of participants will be asked to pilot the intervention and attend a short self-management support group for one week
 |
| **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 support and assistance from local CRN team
 |
| **Reimbursement** | * NHS support costs will be available for the study
 |

#  Study Flow Diagram

****