

Nurse one to one consultation manual

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IMPORTANT NOTES FOR THE CONSULTATION

PRIOR TO THE SESSION

- **1. Environment:** Make sure the tables and chairs are placed in an appropriate manner to allow for a one to one consultation to take place.
 - Lighting is very important for this population we suggest you start by utilising the natural light in the room. Then at the start of the session ask the participant if the lighting is ok.
 - Heating is also important, make sure the room is not too hot. Again at the start of the session ask the participant if the temperature is adequate.
 - Remember you will not always be able to please everyone but if you can show that you are mindful of these issues it can be helpful.
- **2. Paperwork:** Make sure you have the relevant paperwork for the session.
- **3.** Audio recordings: As part of our process evaluation for the overall trial we would like to audio record each of the consultations. Participants have provided consent to say they are happy for the audio recordings to take place. Please therefore ensure your audio equipment is appropriately charged and ready for use on the day.

AT THE START OF THE SESSION

- **1. Audio recordings:** Explain to the participants that the session will be recorded as part of the trial processes. Please then make sure the equipment is turned on. You should switch off the recordings after each participant and restart after for the next consultation.
- **2. Participant attendance:** If a participant cancels and lets the research team know we will contact you to let you know. If the participant does not attend of the day, please let the research team know.
- **3. Conduct consultation using this manual as a guide:** There are three main parts to the consultation, please make sure you have covered all of these. We have allocated up to two hours per participant but you may find this varies from person to person however we do not envisage the consultation to last any longer and it should provide sufficient time to complete the relevant paperwork.

END OF THE SESSIONS

1. Summarising: It can be really helpful to summarise at the end of the consultation.

2. After you have completed the consultation:

- Provide the participant with the relevant information sheet(s) based on their headache classification and the discussion you have had.
- Advise the participant that a copy of the relevant written information will also be sent to their GP.
- Agree with the participant when and how often telephone support should be provided (you are able to offer them up to eight weeks of telephone support from the day of the one to one consultation).
- Advise the participant that should they wish to contact you they can do so via the research team. Provide them with the details of the research team

- o Confirm the best number and time to call the participant
- Complete the nurse consultation form <u>taking particular care to include the TNO on all</u> documentation (Appendix 1).
- Send the completed form and the headache diary (please ensure the TNO is written on the diary) to the research team in the envelopes provided. Please send to:

CHESS trial team
Warwick Clinical Trials Unit
Warwick Medical School
University of Warwick
Coventry
CV4 7AL

- **3.** Secure storage of patient material: You will be provided with an A4 lockable facility to allow you to store all patient material.
- **4. Personal reflections**: We encourage personal reflection from facilitators whereby we ask you to send us a daily reflection email to chess@warwick.ac.uk recording your thoughts and feelings about the consultations, noting things that went well and where things could have gone better. Your email will help us support you if you are experiencing any difficulties with your group.

If at any time you need to speak to a member of the CHESS team, please call <u>XX</u> on 02476 151 634 who will be able to direct your query to the relevant person.

ADVERSE AND SERIOUS ADVERSE EVENTS

Our experience across multiple studies of group interventions is that adverse events that are directly attributable to the intervention are rare. This includes events during the session, e.g. severe psychological disturbance, or a fall during travel to and from the venue. We must manage any suspected adverse events during group or one-to-one sessions in line with Warwick CTU's standard operating procedures.

An Adverse Event/Serious Adverse Event is any event that takes place on the way to, during, or on the way home from the intervention course. This includes the two days of the group course and the one to one nurse appointment.

Adverse event (AE)

An AE is: "Any untoward medical occurrence in a patient or clinical investigation participant taking part in health care research, which does not necessarily have a causal relationship with the research". An adverse event can be any unfavourable and unintended sign, symptom, or disease that occurs during the time a participant is involved in the trial whether or not it is considered to be related to the intervention.

Serious Adverse Event (SAE)

An SAE is: Any untoward and unexpected medical occurrence that:

- 1. Results in death
- 2. Is immediately life-threatening
- 3. Requires hospitalisation or prolongation of existing inpatients' hospitalisation,
- 4. Results in long-term or significant disability or incapacity,
- 5. Is a congenital anomaly or birth defect
- 6. Requires medical intervention to prevent one of the above, or is otherwise considered medically significant by the investigator.

Those events that do not immediately fall into one of the above categories, but that jeopardise the participant, or require intervention to prevent one of the outcomes listed above, should also be considered serious.

Important note: "Serious" and "severe" are not the same

- "Serious" refers to a specific definition for the outcome of an event (see above)
- "Severe" refers to the intensity of a reaction (e.g. mild, moderate, severe)
- For example, it is possible to have a "severe" headache, but the headache itself is not a "serious" adverse event. The term 'life-threatening' in the definition of a serious adverse event refers to an event in which the participant was at risk of death at the time of the event. It does not refer to an event which, hypothetically, might have caused death if more severe.

Examples of Adverse event (AE)	Examples of Serious Adverse Event (SAE)
A participant becomes distressed or angry during the CHESS session. Participant was sufficiently consoled. Adverse Event> Reportable > call study team at the end of the consultation to provide details> relevant follow up by study team/facilitator.	A participant slips on the way home from the consultation and breaks their ankle, they attend A&E. Serious Adverse Event> Reportable> call study team for support immediately if required or at the end of the day to provide details> relevant follow up by study team/facilitator.
	A participant goes shopping on their way home

from the consultations, they slip and are injured,
and they attend A&E.
Not reportable.

If in doubt contact the CHESS Study team on 02476 151 634 a member of the team will be able to provide support and advise on the relevant reporting required.

Reporting an AE or SAE

Contact the study team following an adverse event or serious adverse event at your earliest opportunity. Serious Adverse Events should be reported to the study team within 24 hours of the facilitator being made aware of the event.

- In the first instance telephone the study team on 02476 151 634. A member of the team will confirm whether or not this is reportable. If the event is reportable the study team will take all the relevant information to be able to complete Part A of the Adverse Event CRF or the Initial SAE CRF.
- Depending on the nature of the event and when it took place either the study team or the
 facilitator will contact the participant to follow up on the event and confirm the outcome of
 the event. Following this contact Part B of the Adverse Event CRF or the follow up SAE CRF
 should be completed.

What to do if a participant gets distressed during the session

- 1. The facilitator's role in this instance is to calm the person and listen to ascertain the problem. The facilitators must stay with the participant until they are satisfied that an appropriate course of action has been decided upon and implemented.
- 2. If the person has calmed/collected themselves, ask them if they wish to continue the session or if they would like to withdraw from the one to one on that day, or completely.
- 3. For distressed participants who *do not* express suicidal ideas, calling the Samaritans (116 123) or NHS Direct (111) may help to get appropriate advice.
- 4. If the facilitator has any concerns about a participant they fear may be at risk of suicide (or very severe depression) they should contact the participants GP (take details form the participant if they are able to provide these, alternatively please call the research team on 02476 151 634).
- 5. The facilitator can contact the participant's GP to inform of the situation if they have safety concerns or if there is chance of significant harm to the participant or to others.
- 6. If the participant cannot be left alone at all and the situation is deemed an emergency, the facilitator should call 999 and stay with the participant until an ambulance arrives.
- 7. Listen to the participant- if they would like to contact a family member to help them in this situation or take them home, the facilitator can make a call to the family member.
- 8. Contact the study team following an adverse event or serious adverse event and follow guidance as detailed above for reporting of these events.

LONE WORKING POLICY

During the one to one consultations you will be working on your own with each participant. Appointments for the one to one's will take place in community venues or GP practices. When working in a community venue there is a chance that the venue could be unstaffed. If a venue is likely to be unstaffed the study team will inform you and agree any additional arrangements.

At the end of the second group session you should have completed a form to make all your one to one bookings. A copy of that form should have been provided to the study team for record and safety.

Participants will be asked to contact the study team directly if they are unable to make their appointment (these details will be on the booking card you provide them with when you make their appointment). The study team will then contact you, this will be via telephone and email. If at any point you become aware of any changes to the planned appointments you should notify the study team at your earliest convenience.

You will be provided with a study mobile phone, this is primarily for completing the telephone follow up calls. This can be used during the one to one appointments to contact the study team and should be kept fully charged.

You are reminded to use the processes detailed above for any adverse event reporting or dealing with participants if they get distressed.

CHESS CONTACT NUMBERS

In an emergency please call in the first instance using the details below. Should she not be available we have provided the contact details of other members of the CHESS team at the Warwick and London sites.

Name	Contact for	Contact details	Location

AIM AND LEARNING OUTCOMES

Aim:

• To make a classification of headache type and discuss medication management based on the classification. To also review lifestyle factors and goal setting to enable the participant to engage in behaviour change.

Rational

Provision of pharmacological information and support as well as embedded learning.

Learning outcomes:

- To understand the type of headache they have and be aware of drug management options
- To appreciate the importance of headache management with lifestyle factors as well as medication
- Understand that medication overuse can be problematic and if this is the case they may want to consider coming off or reducing medication which can be difficult and may require careful planning
- To remember that it's important to set SMART goals to help with management of chronic headaches.

Delivery methods:

One to one session with discussion lasting up to two hours.

Content of one to one:

During the one to one session the nurse will:

- Conduct a classification assessment
- Discuss medication
- Discuss lifestyle factors and personalised goal setting.

STRUCTURE OF THE CONSULATION

We envisage each consultation will last no more than two hours and will be split into the following three parts:

Part 1 – Classification assessment with headache diary

Use the logic model together with the headache diary to help classify the patient's headache into:

- Definite chronic migraine (with or without medication overuse)
- Probable chronic migraine (with or without medication overuse)
- Chronic tension type headache (with or without medication overuse).

*if the participant has failed to bring their headache diary, proceed with the classification using the logic model only.

Part 2 – Discussion around headache medication

- > Find out what medication the participant has taken and is currently taking
- Based on this:
 - Have a general discussion around acute and preventative treatment options
 - Address medication overuse headache, if present

Part 3 – Discussion around lifestyle factors and personalised goal setting

- Lifestyle factors and challenges
 - Discuss how they are managing after the course. Are there any particular challenges they are faced with?
 - Depending on the discussion it may be possible to reiterate the core messages from the programme around lifestyle factors and the need to be realistic about their expectations.
- ➤ Discuss SMART goal setting with patient use the sheet if they have completed and bought to the session to start the discussion:
 - Find out how they are getting on
 - Any challenges/barriers
 - Go back to problem solving if there have been challenges to look at other options
- If they have not looked at the goal setting sheet encourage them in the session to start to think about setting some realistic goals by choosing something that they have the power to change.
 - Discuss SMART goals with them and see if you can work with them to go through a potential goal.
- Encourage them to work towards goal discuss what they will do if they have setbacks
 - Go back to problem solving and look at alternate options.





Part 2: Discussion around headache medication



Part 3: Discussion around lifestyle factors and personalise goal setting

Nurse notes:

- During the one to one we have a number of aims but in order to achieve these it would be helpful to start the session in a more generic manner, maybe focusing on how the participant felt the group sessions went. A more generic discussion about their headaches will also lead well into the classification of headache type.
- As part of the CHESS study we have developed a logic model to help classify chronic headache types. In this section we have provided a guide to help you through the classification process.
- The classification assessment will allow classification of the participant's headache type and allow targeted, individualised, treatment and advice.
- ❖ If the participant has completed and brought the headache diary to the consultation it should be used to help with the classification process. If they have not brought it with them, you should continue with the classification using the logic model.

PART 1 - CLASSIFICATION ASSESSMENT WITH HEADACHE DIARY

Part 1: Generic discussion

To start off the consultation, it might be helpful to use a generic approach to help build rapport. You could ask:

- how the participant found the group sessions
- was there anything that particularly resonated with them
- how are their headaches at present
- how are they managing them.

You may find some of the information that you need for the classification is described in the generic conversation therefore keep note and you can refer to this when you take the participant through the logic model.

Here might also be a good opportunity to ask if they have had a chance to keep the headache diary and have they bought it to the consultation. A sample copy of the headache diary is in Appendix 2. The dairy can be used as part of your discussion and will particularly be helpful when looking at the number of days per month on which migrainous symptoms present as well as the number of days per month acute medication has been used.

Part 2: Classification assessment structure (see Appendix 3 for classification guide)

Although the classification assessment is based around a logic model, it is not intended to be a rigid interview schedule, the logic model is to help inform clinical reasoning and decision-making. The

structure and sequence of the interview will be determined by individual consultation style, questioning, and by participants' responses.

1. Distinguishing between chronic migraine, probable chronic migraine and chronic TTH

Differentiating between migraine attacks and tension type headache attacks should be relatively simple as the two types of headache have quite distinct features. The distinction between chronic migraine and chronic TTH however is more challenging; participants can experience more than one headache type, and the characteristics of the headache may change from day to day, or even within the same day. The logic model has been designed to help guide the classification of the participant's headache type into one of three categories: definite chronic migraine, probable chronic migraine and chronic TTH.

Migrainous symptoms

If the participant has completed and brought along their headache diary, use it as part of your discussion. It may help to identify the number of days with migrainous symptoms.

Aura

Around 10- 30% of people with migraine experience aura. Aura is a unilateral, fully reversible, visual, sensory or other central nervous system symptoms that usually develop gradually and are usually followed by headache and associated migraine symptoms. The attacks tend to develop over 5-20 minutes and last 20-60 minutes. Visual aura is the most common form (90 %), followed by sensory aura, in the form of pins and needles or numbness affecting one side of the body, face and/or tongue. Less frequent are speech aura symptoms. When the aura includes motor weakness, the disorder is called hemiplegic migraine.

Many patients who have migraine attacks with aura also have attacks without aura.

Example questions:

- Do you experience aura with your headaches?
- Do you experience any of the following symptoms immediately before or during your headaches?
 - o Blind spots or black spots in your vision
 - Zig zags, wavy lines or shimmering patterns
 - Pins and needles or tingling of your lips, tongue, fingers or legs
 - Weakness or numbness on one side of your body

Migraine characteristics

The headache has at least two of the following four characteristics:

- unilateral location
- throbbing/pulsating quality
- moderate or severe pain intensity
- aggravated by or causing avoidance of routine physical activity (e.g. walking or climbing stairs)

Associated features

Plus during the headache at least one of the following two associated features:

- nausea and/or vomiting
- photophobia and/or phonophobia

Example questions:

Headache characteristics:

- Is the pain usually on one side of the head?
 - o Prompt: on either the right or left side?
- What words would you use to describe the pain (throbbing, pulsating, pressing, tightening, or squeezing)
- On your worst days would you describe your pain as mild, moderate or sever?
- Do you prefer to sit still when you have a headache?
 - o Prompt: Does exercise like walking or climbing stairs tend to make it worst?

Associated features:

- When the pain is there, does light bother you?
 - o Prompt: do you prefer to be in the dark?
- When pain is there, does sound bother you?
 - o Prompt: do you prefer to be in the quiet?
- When the pain is there do you vomit, or feel like you may be sick?

Definite Chronic Migraine

Headache occurring on 15 or more days per month for more than three months, which has features of migraine on at least eight days per month.

Probable Chronic Migraine

Headache occurring on 15 or more days per month for more than 3 months, which has
features of migraine on less than 8 days per month and at least 2 of 4 headache
characteristics and at least 1 of 2 associated features.

Chronic Tension Type Headache

Headache occurring on 15 or more days per month for more than 3 months, lasting hours to days, or unremitting, and with at least two of the following four characteristics:

- bilateral location
- pressing or tightening (non-pulsating) quality
- mild or moderate intensity
- not aggravated by routine physical activity such as walking or climbing stairs.

Plus the following:

- no more than one of photophobia, phonophobia or mild nausea
- neither moderate or severe nausea nor vomiting

Following the logic model, participants who report headache with less than two of four headache characteristics and no associated features other than mild nausea have chronic tension type headache.

2. Identifying medication overuse headache

If the participant has completed and brought along their headache diary, use it as part of your discussion. It may help to identify the number of days acute medication has been used.

Medication overuse headache

This is a headache occurring on 15 or more days per month developing as a consequence of regular overuse of acute or symptomatic headache medication on 10 or more, or 15 or more days per month, depending on the medication, for more than 3 months. If a participant does not take acute or symptomatic headache medication (not preventative medication) on at least 10 or more days per month they do not have medication overuse headache.

Example questions:

- How many days a month do you take medication to relieve your headache attacks?
- What type of medication do you take?

NSAIDs/paracetamol only (≥ 15 days/month for 3 months

Participants taking simple analgesics (paracetamol and acetylsalicylic acid) and/or non-steroidal antiinflammatory drugs (NSAIDs) on 15 or more days per month, for the acute or symptomatic treatment of headache for more than three months have medication overuse headache. Common examples include:

- Paracetamol
- Aspirin
- Ibuprofen
- Naproxen
- Tolfenamic acid
- Diclofenac

Other 'combination' drugs (≥ 10 days/month for 3 months)

Participants taking ergots, triptans, or a combination of analgesics (any combination of ergots, triptans, simple analgesics, NSAIDs, and/or opioids) on 10 or more days per month, for the acute or symptomatic treatment of headache for more than three months have medication overuse headache.

These will include opiates (tramadol, codeine etc), mixed analgesics (co-codamol, co-dydramol etc) and over the counter headache preparation such as migraleve which are often a mixture of things like paracetamol/codeine/caffeine. If participants mention a medication that you don't recognise, write it down, and 'google it' later to check what's in it. There are so many OTC medications, and even preparations bought on the internet, the list is endless! The most commonly prescribed triptans are:

- Sumatriptan
- Rizatriptan
- Zolmitriptan
- Almotriptan
- Eletriptan
- Frovatriptan
- Naratriptan

Medication overuse headache usually, but not always, resolves after the overuse is stopped. Approximately half of people with chronic headaches have medication overuse headache.	

PART 2 – DISCUSSION AROUND HEADACHE MEDICATION

Nurse notes:

- Your role here is not to recommend specific treatment options but to discuss what the participant has previously used and discuss more broadly the treatment options for their headache type.
- In this section we have provided guidance based on recommendations, this is to help you with your discussions.
- At the end of the one to one consultation based on your assessment of this participant we will write to their GP to inform them of the classification and at the same time provide the GP with broad information, based on the guidance, on the management of these patients.
- Any actual changes to medication the participant wishes to make would need to be discussed with their GP.

PART 1. CURRENT MEDICATION

During the session - find out what medication the patient has taken and is currently taking for their headaches and complete the nurse facilitator consultation form with the relevant details of the drugs.

Based on this discussion and your conclusion of the participant's headache classification you should go on to explore acute and preventative treatment options as well as medication overuse headaches (if present). This is detailed in the following sections.

Remember for any changes in medication the participant would need to speak to their GP – we are not recommending any specific drugs or prescribing as part of the CHESS study.

PART 2. EXPLORING ACUTE TREATMENTS OPTIONS

This section provides a summary of the guidelines on acute treatments for headaches (drugs taken when a headache attack occurs). This information is for your knowledge to enable you to have a broad discussion with the participant.

The following points might help aid the discussion:

- If they have not tried any acute medication for their headaches is this something they might want to consider?
- If they are taking acute medication and it is not helping could they consider changing it?
- If the acute medication they are taking is helping in some way, could they stay on it?
- If you have classified them as having medication overuse headaches, what do they think about stopping or reducing this medication?

Remember - All acute medications should be limited to a maximum of 10 days a month as they can cause medication overuse headache and worsen the headaches. If the acute medication being take is paracetamol or NSAIDs a maximum of 15 days a month is allowed.

Guidance on migraine and acute medication:

- Combination therapy of oral triptan and an NSAID <u>or</u> oral triptan and paracetamol usually offered, taking into account the person's preference, comorbidities and risk of adverse events.
- 2. For people who prefer to take only one drug, consider monotherapy with an oral triptan, NSAID, aspirin or paracetamol, taking into account the person's preference, comorbidities and risk of adverse events.
- 3. For those who have found acute treatment of migraine ineffective or they cannot tolerate them: NICE recommend a non-oral preparation of metoclopramide or prochlorperazine **and** considering the addition of a non-oral NSAID or triptan if these have not been tried. (Only such preparation easily available in the community is buccal prochloperazine)
- 4. Ergots or opioids should not be used for the acute treatment of migraine.

This table is included for your reference and information only – you are not expected to go through each of the drugs under the categories with dosage during the consultation

Type of drugs	Drugs used with dose	
Non-specific treatments for headache	Paracetamol 1 g	
Non-steroidal anti- inflammatory drugs (NSAIDs)	Aspirin 900 mgIbuprofen 400-800 mgNaproxen 500mg	
Specific treatments for migraine – Triptans	 Sumatriptan 50-100 mg orally; 20 mg nasal spray or 6 mg subcutaneous injection Rizatriptan 10 mg tablet or wafer Zolmitriptan 2.5-5 mg tablet or melt Almotriptan 12.5 mg Eletriptan 40-80mgs Frovatriptan 2.5 mg Naratriptan 2.5 mg 	
Opioids	Codeine Tramadol	
Prokinetics (anti sickness drugs)	The above treatments are improved when also taking one of the following anti sickness drugs: Domperidone 10mgs Metoclopramide 10mgs	

^{*}Table adapted from Miller and Matharu (2014)

Guidance on tension type headache and acute medication:

- 1. Aspirin, paracetamol or an NSAID are usually used for acute treatment of tension type headache, taking into account the person's preference, comorbidities and risk of adverse events.
- 2. Opioids should not be used for the acute treatment of tension type headache.

PART 3. EXPLORING PREVENTIVE TREATMENT OPTIONS (PROPHYLACTIC TREATMENT)

This section provides a summary of the guidelines on preventative treatments for headaches (drugs used when people are having very frequent attacks). This information is for your knowledge to enable you to have broad discussion with the participant.

The following points might help aid the discussion:

- If they have not tried a preventative is this something they might want to consider?
- If they are taking a preventative and it is not helping could they consider changing it?
- If a preventative is being taken and is helping in some way, could they stay on it?

Guidance on migraine and preventative medication:

- Topiramate, propranolol, or amitriptyline usually offered as a prophylactic treatment of
 migraine according to the person's preference, comorbidities and risk of adverse events.
 (Advised women of childbearing potential that topiramate is associated with a risk of fetal
 malformations and can reduced the effectiveness of hormonal contraceptives).
- 2. If both topiramate and propranolol are unsuitable or ineffective, a course of up to 10 sessions of acupuncture over 5–8 weeks according to the person's preference, comorbidities and risk of adverse events.
- 3. Those already having successful treatment with another form of prophylaxis should continue as required.
- 4. Prophylaxis medication should be reviewed after 6 months.
- 5. Riboflavin (400 mg once a day) may be effective in reducing migraine frequency and intensity for some people.

This table is included for your reference and information only – you are not expected to go through each of the drugs under the categories with dosage during the consultation

Type of drugs	Drugs used with dose	Selected side effects
beta -blockers	 Propranolol 40-120mg twice daily* Metoprolol 100-200mg daily 	Reduced energy Tiredness Postural symptoms Erectile dysfunction Contraindicated in asthma
Anti-epileptic agents	Topiramate 25-200mg daily*	Pins and needles Thinking problems Weight loss Angle-closure Glaucoma Kidney stones Foetal malformations Can impair the effectiveness of hormonal contraceptives.
	Valproate 600-1000mg twice daily	Drowsiness Weight gain Tremor Hair loss Foetal abnormalities Blood I and liver abnormalities

Antidepressants	Amitriptyline 10-75mg nocte*Nortriptyline 10-75mg nocte	Drowsiness Dry mouth	
	, and the same of	Some patients are very sensitive and may only need a total dose of 10mg, although generally 1-1.5mg/kg body weight is required for a response	
Serotonergic modulators	Pizotifen 0.5 to 3mg daily	Drowsiness Weight gain	
Angiotensin-based	Lisinopril 10-20mg daily	Persistent dry cough	
modulators	 Candesartan 8-32mg daily 		
	Telmisartan 20-80mg daily		
Nutraceuticals	Riboflavin 400mg daily*	Diarrhoea – only with magnesium	
	Co-enzyme Q10 30-600mg daily	These products are not available from the NHS	
	 Magnesium 600mg daily 		
Acupuncture*		Some people find that treatment by an	
		acupuncturist can help chronic	
		migraine. This is not usually available	
		as an NHS treatment	

^{*}Table adapted from Miller and Matharu (2014)

Botulinum Toxin (Botox)

Botox has been recommended by NICE as a preventative treatment option for patients with chronic migraine and usually provided by specialist centres. It can be offered to patients who:

- have already tried at least three different preventative treatments for chronic headaches which have not worked
- do not have medication overuse headaches.

Guidance on tension type headache and preventative medication:

1. A course of up to 10 sessions of acupuncture over 5–8 weeks may be useful as a prophylactic treatment of chronic tension-type headache.

PART 4. ADDRESS MEDICATION OVERUSE HEADACHE (IF PRESENT)

This section only needs to be discussed for those participants you have classified as having MOH.

<u>Just a reminder that</u> - MOH is a headache occurring on 15 days or more per month developing as a consequence of regular overuse of acute or symptomatic headache medication on 10 or more, or 15 or more days per month, depending on the medication, for more than 3 months. If acute or symptomatic headache medication (not preventative medication) is taken on 10 or less days per month then it is not classed as MOH.

^{*} Recommended by NICE. Only topiramate and pizotifen have a product licence for use in prevention of migraine. The other drugs are widely used for other disorders but are not licensed for use for the prevention of migraine.

Remember - All acute medications should be limited to a maximum of 10 days a month as they can cause medication overuse headache and worsen the headaches. If the acute medication being take is paracetamol or NSAIDs a maximum of 15 days a month is allowed.

Discussion reflecting back on group session

It might be useful to ask the participant if they can recall what was said about medication overuse headache during Day 2 of the course. Depending on the discussion you may wish to reiterate some of the core messages presented during that session (Day 2, session 15) summarised below:

- Doctors are not all aware of this concept and they are only just getting to grips with the idea of MOH
- > Remember it's not your fault if you have MOH and it is not considered an addiction
- MOH is the notion that people can develop headaches as a consequence of regular overuse of acute or symptomatic headache medication which prevents headaches improving
- The concept of MOH can be difficult and for some it may be upsetting
- The aim is to look forward to a life without so much medication

Where MOH has been classified, discuss the following with participant

- The suggestion for people with MOH would be to abruptly rather than gradually stop acute medication but if this is not possible then a reduction in medication to 10 days or less a month would be a good starting point.
- ➤ If they wish to consider stopping the medication then the overused medication should be stopped for 1-2 months to determine impact. It can them be restarted but limited to 10 days or less a month
 - Planning is important as headache symptoms are likely to get worse in the short term before they improve. They may also experience withdrawal symptoms.
 - A prophylactic treatment could be considered for the underlying headache during withdrawal.

For any withdrawal or reduction, the participant should be advised to seek GP support if they:

- Are taking strong opioids such as
 - Tramadol
 - Oxycodone
 - Morphine
 - Buprenorphine
 - Dipipanone
 - Diamorphine (heroin)
 - Methadone
 - Pentazocine
 - Pethidine
 - Tapentadol
 - Any participants using transdermal preparations, fentanyl or buprenorphine should be refereed to their GP.
- ➤ Have other relevant comorbidities that have substantial impact on health e.g. severe COPD, severe ischaemic heart disease, poorly controlled diabetes etc.
- ➤ Have made previous attempts at withdrawal which have been unsuccessful.

<u>Where MOH has been classified but the participant is taking the medication for other pain</u> disorders

It is likely that participants may have other conditions for with they are taking medication. If MOH is present and participant is taking medication for other pain disorders, use the following guide to help aid the discussion.

- Ask the participant what is more problematic, the headache or the other pain disorder?
 - If it is the headaches then still consider withdrawing/reducing medication as per usual trying to limit them to 10 days per month. If they find their other pain condition worsens and the participant cannot cope then it would be reasonable to abandon withdrawal/reduction.
 - If the participant feels it is the other pain condition that is worse than headaches, then be wary about advising withdrawal/reduction unless the participant wants to try it in the hope that he/she can cope with the other pain. If this is the case it may be worth mentioning that some of the self-management strategies learnt on the CHESS two day programme can be beneficial for other pain disorders too.

<u>PART 3 – DISCUSSION AROUND LIFESTYLE FACTORS AND PERSONALISED</u> <u>GOAL SETTING</u>

PART 1. LIFESTYLE FACTORS AND CHALLENGES

- It might be useful to ask the participant if they can recall what was said about lifestyle factors during Day 2 of the course.
- ➤ Initiate a discussion about general lifestyle factors and the importance of these in ongoing management of chronic headaches.

Example questions:

- Are there any areas they struggle with?
- Are there any areas they want to make changes to?
- > Depending on the decision it might be helpful to reiterate the core back to basics messages from Day 2 session 11 of the programme using the table below:

Get Regular Sleep	 Go to bed and wake up at regular times each day, even at weekends Do not sleep excessively on the weekends and too little on the weekdays Most adults need approximately 6-8 hours of sleep per night Try to avoid shift work or stick to the same shift all the time
Eat Regular Meals	 Low blood sugar can trigger a headache Eat regular meals three times each day Ensure you have a balanced diet including protein, fruits, vegetables and carbohydrates.
Get Moderate Amounts of Routine Physical Activity	 Moderate physical activity (enough to raise your heart rate) three to five times each week will help reduce stress and keep you physically fit Too much physical activity or inconsistent patterns of activity may trigger headache
Drink Plenty of Water	 A normal adult should drink plenty of water throughout the day (at least 2-3 litres per day) Dehydration may cause headaches
Limit Caffeine, Alcohol and other Drugs	 Caffeine is a stimulant and caffeine withdrawal may cause headaches when blood levels of caffeine fall Excessive caffeine can lead to a worsening of headache and even cause chronic daily headaches Alcohol may be a trigger for headaches Regular painkillers (especially codeine containing drugs) will lead to a gradual worsening of headache and stop anti-migraine drugs from working (medication overuse headache)
Reduce Stress	 Stress may lead to an increase in headache Relaxation and stress management may help reduce headaches.

A few points to discuss as a reminder:

- Remind them that they have to be realistic about what they expect from such lifestyle changes, aiming to reduce how often you get headaches is a sensible expectation but wanting to be headache free for life is not.
- Lifestyle changes can be difficult as it is often difficult to break routines and for some of the major changes you may need can take a lot of time, energy and support. However, if you strive to make changes they can lead to an improvement in your quality of life.
- These basic lifestyle management may help with headache management. These are lifestyle factors that can have a positive impact on your general health and wellbeing.
- > It is important to strike a balance between lifestyle factors and drug treatment.

PART 2. PERSONALISED GOAL SETTING

Ask the participant if they have had a chance to look at the goal setting sheet given to them during the group session (copy provided in Appendix 4).

- If they have look through and discuss what they have written:
 - o If the goals are SMART
 - What progress have they made
 - Have they faced any challenges and if so how did they /could they problem solve.
- If the participant has not bought the goal setting sheet with them or has struggled to complete the sheet, have a general discussion with them about the importance of goal setting and explore with them if there are any goals they would like to consider (this maybe based on your earlier discussion on lifestyle factors).
- They may wish to look at goals related to medication overuse if that applies to them, if this is the case work with the participant to make sure the goal is SMART.

ONGOING TELEPHONE FOLLOW-UP

As part of the intervention participants should be offered up to eight weeks of telephone support (eight weeks start from the one to one consultation). The amount of contact should be agreed with each participant during the consultation. This support is probably going to be most important for those with medication overuse headaches planning to withdraw.

The frequency of calls will vary from participant to participant and should be individually negotiated. This frequency can also be varied after the first telephone follow-up depending on the participant's progress and needs.

During the consultation:

- Agree how often you should call them
- When is the best time to call?
- What is the best number to call on?

Inform participants that they can get in touch with the research team on 024 76151634 or via email chess@warwick.ac.uk should they wish to get in touch with you. The research team will pass the message onto you.

Contacting the participant:

The following provides a guide to contacting participants:

- If there is no response to your first planned phone call, call again either later on the same day or the day after.
- On the second attempt if there is still no answer, leave the participant a voice message and advise them that you have called twice and should they wish to contact you they may do so via the central CHESS team. Please provide them with the following number:

CHESS team 024 7615 1634

In order to help the central CHESS team if you could send an email to chess@warwick.ac.uk
to inform us of any participants you have not been able to contact, the team will then be able to monitor this.

After each telephone follow-up call:

Once you have had a telephone conversation with the participant please complete the nurse followup form in **Appendix 5**. <u>Please ensure the participants TNO is on all paperwork</u>. These should be returned to the research team in the prepaid envelopes provided.

APPENDIX

Appendix 1: Nurse consultation form
Appendix 2: Headache diary
Appendix 3: Classification guide
Appendix 4: Goal setting sheet
Appendix 5: Nurse follow up form

Appendix 1: Nurse consultation form	
Appendix 1. Warse consultation form	
	28

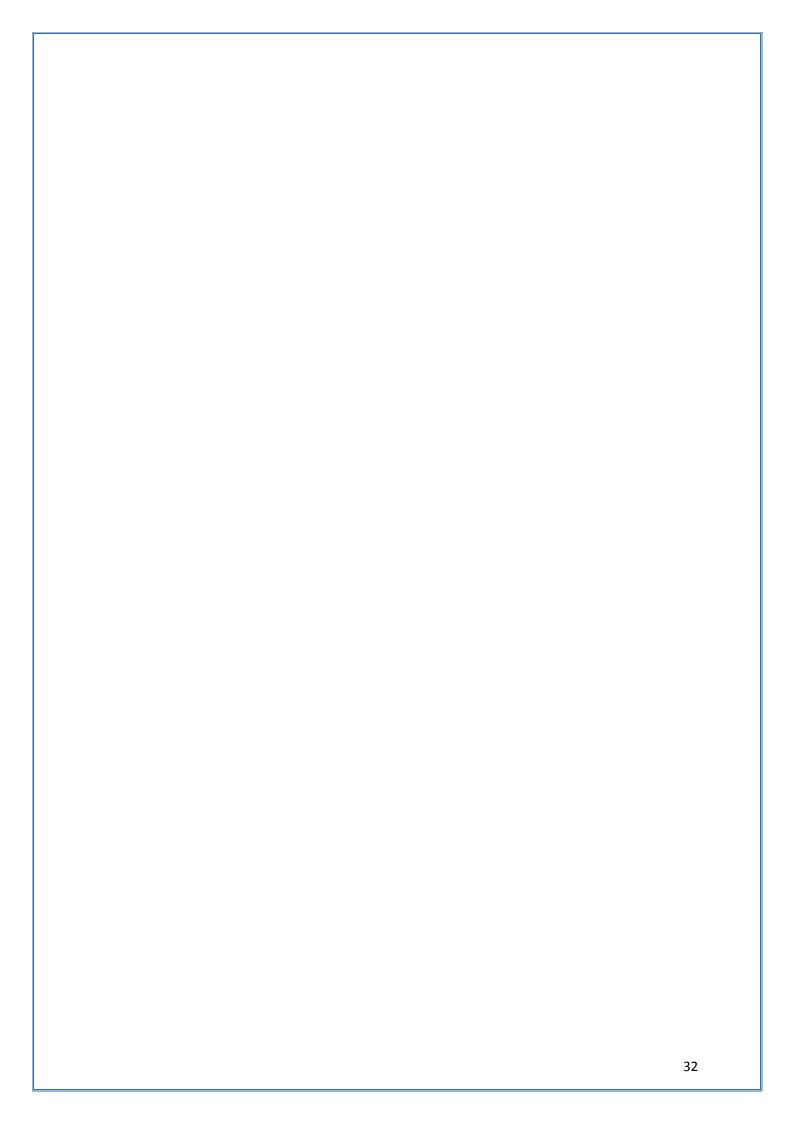
Form number: 6 **Nurse Facilitator Consultation Form** Participant Identification Number: Participant Initials: Date of Appt Attend? Duration Diary? No Yes Nο Yes DD/MON/YYYY MINS If no, please tick ONE option.. If no, please tick ONE option... Spoke to participant, alternative Participant forgot to bring to appointment made appointment Participant forgot to complete Spoke to participant, declined appointment Other (please specify)... 3 Other (please specify)... If yes please provide 1. Is the participant currently taking a migraine specific prophylactic? A list of migraine specific prophylactic drugs are detailed below details... Dose Drug name Frequency Propranolol Metoprolol Topiramate Valproate Amitriptyline Nortriptyline Pizotifen Lisinopril Telmisartan Riboflavin Co-enzyme Q10 Riboflavin Magnesium Other...

Form number: 6

	Nu	ırse Faci	litatoı	Cons	sultatio	n Form
	CHESS	Participant Identif	ication Numb	er:	Participant Init	ials:
1	Chronic Headache Education and Self-management Study		$\overline{}$			
•						
<u>2.</u>	Total number days in 4	weeks participant	t using migrai	ne specific tr	eatments:	
	Please specify the num	ber of days each t	reatment is ta	ken for:		
	Drug name	List Drug Name			ays taken in past	4
	Triptan			weeks		
	NSAID					
	Codeine / DHC					
	Paracetamol					
	Other Opioid					
	Other, please specify	,				
		No Yes				
<u>3.</u>	Is participant pregnant?		N	o Yes		
	If yes, has participant b					
<u>4. 1</u>	reatment Programme:	_				
	Preventative Treatment: N.A Consider Change No Change Stop					
	Consider Proph	ylaxis:				
	Acute Treatment:		Consider	Change	No Change	Stop
	Consider Acute	N.A	Consider	Citalige	No Change	
	Medication Overuse:	N.A	Advised	Via Self	Via Support	
Advised Stopping:						
5. Information given to participant: No Yes						
- Chronic Tension Type Headache Leaflet						
	- Migraine Leafl	et				
	- Medication O	veruse Leaflet				

			Form number:					
Nurse Facilitator Consultation Form								
Choric Headache Educator cod Self-management Study	ipant Identificatio	n Number:	Participant Initials:					
Have the following been di	scussed with the p	earticipant?						
Headache Classification	No Yes	If no, reason						
Medication	No Yes	If no, reason						
S.M.A.R.T Goals & Lifestyle factors	No Yes	If no, reason						
If yes, please detail S.M.A. Ideas brought by participar			Goal set					
lephone Follow Up : elephone appointment ma	No Yes	Date of telephone a	ppointment:					
If no, please give reason:		Time:						

CHESS Nurse Facilitator Consultation Form. Version 0.1, DRAFT



Form number: 6

8. GP Documentation:								
Please select from the following options: (on returning the CRF to the study office the selected information will be sent to the GP):								
Please tick ONE option								
Chronic Tension Type Headache - Medication Overuse Chronic Tension Type Headache + Medication Overuse + Self Chronic Tension Type Headache + Medication Overuse + Support Definite Chronic Migraine - Medication Overuse Definite Chronic Migraine + Medication Overuse + Self Definite Chronic Migraine + Medication Overuse + Support Probable Chronic Migraine - Medication Overuse Probable Chronic Migraine + Medication Overuse + Self Probable Chronic Migraine + Medication Overuse + Support								
Comments:								
***Please attach the participant headache diary to this *** CRF when returning to the study office								
If you have any queries regarding the completion of this CRF please contact the CHESS Study on Tel: 02476 151 634 or via email:								
chess@warwick.ac.uk								
Form completed by (print name):								
Signature: Date signed: ddd - mon - yyyyy								

Appendix 2: Headache diary

Daily headache diary

While you are waiting to attend the CHESS headache self-management programme please fill in this diary every day. The information you record will be very important for helping the nurse to identify your headache type, assess how much it is affecting you and make a plan for optimising drug treatment.

PLEASE REMEMBER TO BRING YOUR DIARY TO YOUR APPOINTMENT





Reproduced with permission from Dr Cristina Tassorelli: Jensen R, Tassorelli C, Rossi P, Allena M, Osipova V, Steiner TJ, Sandrini G, Olesen J, Nappi G, and the Basic Diagnostic Headache Diary Study Group. A basic diagnostic headache diary (BDHD) is well accepted and useful in the diagnosis of headache. A multicenter European and Latin American study. Cephalalgia 2011,31(15) 1549–1560

CHESS_HeadacheDiary_V1.0_22.Nov.16 IRAS ID: 215304

INSTRUCTIONS FOR FILLING IN THE DIARY

Begin by entering your name (last, then first), your date of birth and the date on which you started to keep the diary. Then, in answer to question one, enter today's date (day of the month only) in the first column. If you wish, you can enter the dates now all the way along this row to remind you to keep the diary daily.

Please complete the diary at the end of each day, as you go to bed. Please tick the boxes in today's vertical column. Your entries should be a summary of any headache(s) that you have had during today. If you have had no headache today, please answer questions 2 and 15 only.

After you have filled up one diary, please continue in another (we enclose several copies).

The following is guidance for particular questions.

- 1: Enter only the day of the month (eg, 12), not the month or year.
- 2: Tick "yes" or "no", then continue with the rest of the questions or jump to question 15 if you had no headache.
- 3: Enter the time (to the nearest hour, remembering to put AM or PM) when you first noticed you a headache was starting. If you woke up with it already there, enter the time of waking. (If it is yesterday's headache still present, please put a cross [X] in this space).
- 4: Enter the time (hours and minutes, remembering to put AM or PM) when the headache was completely gone. If the headache is still there when you go to sleep for the night, leave this question until tomorrow. If it has gone next morning, enter the time you fell asleep. If the headache is still there next morning, put a cross [X] in the space and another in the space for question 3 in the next day's column. Then continue your recording for the next day in the usual way.
- 5: Some people have trouble with their eyesight in the hour or so before a headache starts. This usually takes the form of flashing lights or zigzag lines, which you may see even with your eyes closed. It may also take the form of holes, blank areas or blind spots in your vision. Tick "yes" if you had any of these or "no" if you did not. If you were bothered by light but nothing else, you should tick "no".
- 6: Tick the box to indicate whether the pain was mostly on one side or mostly on both sides of the head.
- 7: There are many words for describing headache, but most headaches are either "throbbing" (in time with the heart beat) or "pressing" (feeling like a tight band around the head). Tick whichever is closer to describing your headache.
- 8: Some headaches are made worse even by light physical activity (such as walking upstairs), or cause you to avoid doing such things. Tick "yes" if your headache was like this, "no" if not.
- 9: The intensity of headache is important in making the diagnosis. As a guide, headache that is "not bad" will not prevent you doing work or other things you would normally do. Headache that is "quite bad" will make it difficult to do work and other activities, but not wholly prevent them. "Very bad" headache is likely to stop you doing anything. Try to take an overall view, throughout the day. For instance, if your headache was not bad for half of the day and then became very bad for the other half, tick the "quite bad" box. Conversely, if you had very bad headache for most of the day, tick the "very bad" box.
- 10: Tick "no" if you did not feel nauseated (sick) at all during the day. If you did feel nausea but were not bothered by it, and it did not cause any retching, tick the "a little" box. Otherwise, tick the "more than a little" box.
- 11: Tick "yes" or "no" as appropriate. Retching alone should not be counted as vomiting.
- 12: This question is about ordinary daylight or room lighting, not about particularly bright lights. Tick "yes" if the light bothered you, or if you tried to avoid it by darkening the room or wearing dark glasses. Otherwise tick "no".
- 13: This question is about ordinary noise, not about particularly loud noises. Tick "yes" if noise bothered you, or if you tried to avoid it by going to a quiet room. Otherwise tick "no".
- 14: Write down anything that you believe may have caused your headache. This could be something you ate or drank, something you did (like missing lunch or having your period) or something that happened (such as a change in the weather).
- 15: Write down the name(s) and number(s) of tablets, suppositories, injections or nasal sprays of any medication(s) you took because of your headache or for any other pain. Then add the time (to the nearest hour, remembering to put AM or PM) you took each medication. Do not enter medications taken for other reasons than headache or pain.

First name:	Family name:	Date of Birth (dd/mm/yy):
Diary start date (dd/mm/yy):		Diary end date (dd/mm/yy):

Please read carefully the instructions. Complete one column every evening by ticking the applicable boxes.

1. Day and date of the month		Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
1. Day and date of the month															
2. Did you have a headache today?															
(if no, go directly to question 15)	Yes														
3. If yes, when did you first notice it?	(hr:min)														
4. When did it finally go? (please see instructions poin	t 4) (hr:min)														
5. In the hour before it started, did you notice	No														
eyesight interference such as flashing lights, zigzag lines or blind spots?	Yes														
6. Was the headache on one side of the head or both?	On one side On both sides														
7. What was the headache like?	Throbbing														
7. What was the headache like:	Pressing														
8. Did physical activity (such as walking upstairs)	No														
make the headache worse?	Yes														
9. How bad was your headache overall?	Not bad														
(please see instructions point 9)	Quite bad														
q	Very bad														
10. Were you nauseated ?	No A little														
(did you feel you were going to be sick)?	More than a little														
	No		-												-
11. Did you throw up?	Yes														
12. Were you bothered by the light?	No														
12. Were you bothered by the light:	Yes														
13. Were you bothered by noise?	No														
	Yes														
14. Did you do anything, or did anything happen, that may have caused the attack?	If yes, please specify:														
15. Did you take any medication(s) today for headac pain?															
For each medication, please enter: a) the name b) the number you took c) the time(s) you took it (hr:min)															

Form number: 7 **Nurse Facilitator Clinical Record** Participant Identification Number: Participant Initials: 1. Date of Consultation: Aura ≥8 days a month for ≥ 3 months 1-7 days/month Yes 2 of 4 headache characteristics 2 of 4 headache characteristics Unilateral Differentiating between Chronic Headache Types Unilateral Pulsating Pulsating Moderate/severe pain intensity Moderate/severe pain intensity Aggravated by physical activity Aggravated by physical activity 1 of 2 associated features: 1 of 2 associated features: Nausea and/or vomiting Nausea and/or vomiting Photophonia and/or phonophobia Photophonia and/or phonophobia Yes to one Yes to both Yes to one or Yes to both ≥8 days a month ≥ 8 days a month for 3 months No No robable chro hronic tension Definite chroni migraine migraine Headache medication taken 10 days/ Not medication overuse month for 3 months NSAID/Paracetamol only ≥ 15 days/ Other combination of drugs ≥ medication month for 3 months 10days/month for 3 months medication overuse Medication overuse Yes overuse TTH can have Mild Nausea Definite Chronic Migraine - Headache occurring on 15 or more days per month for more than 3 months, which has features of migraine on at least Participant is classified as: 8 days per month. **Definite Chronic Migraine** Probable Chronic Migraine - Headache occurring on 15 or more days per month for more than 3 months, which has features of migraine on less than 8 days per month and at least 2 of 4 headache characteristics and at Probable Chronic Migraine least 1 of 2 associated features. Chronic Tension Type Headache Chronic Tension Type Headache - Headache occurring on 15 or more days per month for more than 3 months, and less than two of four headache No Yes **Medication Overuse** characteristics and no associated features other than mild nausea.

Form number: 7

O CHECC	Nurse Facilitator Clinical Record								
Chronic Headache Education and Self-management Study	Participant Identification Number:	Participant Initials:							
ona ser-management study									
2. Notes:									

Appendix 4: Goal setting sheet





Handout 7 – Personal goal setting sheet

	MY GOAL
SPECIFIC	
 clearly define your goal 	
(think of the who, what,	
where, why and how)	
MEASURABLE	
 make your goal 	
measureable to help you	
monitor your progress	
ACHIEVABLE	
 make sure the goal is 	
realistic, sensible and	
something you can	
accomplish	
RELEVANT	
 make sure the goal is 	
something that you want to	
engage in and of interest to	
you	
TIMEBOUND	
 Set a timescale for 	
achieving your goals	



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CHESS Participant Handout 7, V1.0, 22/11/16

								Fc	rm number	<u>: 8</u>
			Tel	epho	ne	Fol	llow	/ Up	Form	
(1)	CH	E		ant Identifica				Participan		
	Chronic Hec and Self-mo	adache E anageme	ducation of Study							
	Call M	ado?	Date	of Call	Time	of Call	Conta	ct Made?	Duration of Call	
,	Yes	No	Date	or Call	Hille	or Can	Yes	No	Duration of Can	
			DD/M0	ON/YYYY	HH:	MM			MINS	
			[
If	no, plea	se ti	t ck ONE option							
		1	Participant d	id not answe	r call					
		2	_	usy/not able					<u> </u>	
		4		as migraine/loes not wish			r follow u	n calls	井	
		5	Other (please		to nave	arry rui trie	i ioliow u	p cans	=	
										,
	Medica	tion		N.A No	Yes	If no, reas	son			
	S.M.A.F	2 T G	nals			If no, reas	on			
	3.W.A.F		Jais	N.A No	Yes	ii iio, reas	5011			
	Lifestyle	o fact	tors	N.A No	Yes	If no, reas	on			
	Lifestyli	elaci	tors			ii iio, reas	5011			
										1
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							Ple	ase continu	ue onto next page	

Form number: 8 Comments: No Yes Date of call: DD/MON/YYY Follow up call arranged? Time of call: HH:MM If No, please specify reason... Form completed by (print name): _____ ____ Date signed: Signature: _

