



CHESS – INTERVENTION QUALITY ASSURANCE PROTOCOL

Version 1.0

April 2017

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Background

The CHES trial is a multi-centre randomised controlled trial comparing a group self-management and educational intervention with a relaxation control for participants living with chronic headache.

The CHES intervention is a complex intervention made up of many components that aim to precipitate behaviour changes that improve participants' coping strategies. The course is group based and runs over two days over a two week period. Each day runs from 10.00 – 15.00 and the sessions are facilitated by a nurse and allied health professional. Thereafter each participant will have a one to one appointment lasting up to two hours with the research nurse to help classify their headache type, discuss medication and look at lifestyle factors and goal setting. Participants are subsequently provided with up to eight weeks of telephone follow-up which is individually agreed with each participant during the one to one appointment.

The facilitators have attended appropriate training to enable them to successfully deliver the CHES interventions. The training was a total of three days, whereby all facilitators (nurses and allied health professionals) attended the first two days. The additional third day was for the nurses to provide them with the knowledge base and skills in order to conduct the one to one consultations. Table 1, below, shows a summary of the course content.

Table 1 Summary of the CHES course

Day	Modules	Content of sessions
1. Living, understanding and dealing with chronic headaches	1. Introduction to the course and each other	Session 1: Welcome and introductions Session 2: Course overview
	2. Understanding chronic headaches and acceptance	Session 3. Headache information and mechanisms Session 4. Acceptance of chronic headaches
	Taster activity – Relaxation and breathing	
	Lunch	
	3. Mind, body and pain link	Session 5. Impact of thoughts, mood and emotions on headaches Session 6. Headache cycle and breaking the cycle
	4. Dealing with unhelpful thought patterns	Session 7. Unhelpful thinking patterns: recognising and finding alternatives
5. Summary	Session 8: Summary and reminders from day 1	
2. Learning how to adapt and take control of your life with chronic headaches	1. Reflections	Session 9. Reflections from Day 1
	2. Back to basics	Session 10. Identifying barriers to change and exploring problem solving and goal setting Session 11. Lifestyle factors and impact on headaches
	3. Making headaches more manageable	Session 12. Managing stress and anxiety Session 13. Managing sleep better Session 14. Mindfulness and

		relaxation for headaches
	Lunch	
	Taster activity - Mindfulness practice	
	5. Treatment options	Session 15. Medication management
	6. Communication – explaining your headaches to others	Session 16. Relationships and communication with family, carers and friends Session 17. Communicating better with Health Professionals
	7. Future management	Session 18. Managing setbacks – what to do when things don't go to plan
	8. Summary	Session 19. Summary of course
3. One to one session with nurse	Session covers: <ul style="list-style-type: none"> • Classification assessment with headache diary • Discussion around medication • Lifestyle factors and personalised goal setting. 	

CHES is a two centre study held in the West Midlands and East London. The lead centre is at the Warwick Clinical Trials Unit. Operationally the protocols and materials are the same for both centres, with the exception of some location specific alterations to patient information for contact details.

We aim to recruit around 338 people to the intervention arm of the trial and 316 people to the control arm. These numbers are split equally between the two centres. Recruitment is via screening of general practices, posters in practice waiting areas and posters in local pharmacies serving these practices.

Requirement for quality assurance of the intervention

We identified the following areas for consideration for quality assurance purposes of the CHES intervention:

1. *Training and selection of facilitators*
2. *Course delivery*
3. *Control group*

In this document we have detailed each of these and our existing and proposed plans for monitoring these areas.

1. Selection and training of facilitators

We require one nurse and one allied health professional (AHP) to run each group education and self-management course. We would consider running a course with two nurse facilitators if there were any difficulties getting an AHP facilitator. Selection of facilitators was done using the following process:

Advertising and short-listing according to eligibility criteria

To recruit interested facilitators two adverts were placed on NHS jobs in December 2016, one for the nurse facilitators the other for the AHPs. The following criteria was used to shortlist the applications:

Essential

- Qualified Nurse, currently registered with the Nursing and Midwifery Council **OR** Qualified Allied Health Professional with current registration to the appropriate governing body
- Interest in research
- Ability to take responsibility and work on own initiative
- Ability to work autonomously or within a team
- Ability to work strictly to study Standard Operating Procedures and Guidelines
- Excellent interpersonal and communication skills
- Good organisational skills
- Good IT skills (Word, Outlook, internet use)
- Willingness and ability to travel within the West Midlands region

Desirable

- Experience of facilitating or presenting to groups
- Knowledge and/or experience of working in chronic pain
- An interest in long-term pain self-management approaches
- Research experience
- Good Clinical Practice (GCP) training

Interviews with shortlisted candidates

Those shortlisted were invited to the University of Warwick for an interview to discuss the role and access their skills and experience in becoming a facilitator. A set of interview questions were decided based on the essential and desirable characteristics. Interviews were conducted by two members of the CHES team.

Train the trainers

For the main RCT we have run a training course on the 3rd and 4th of April covering the material for the two day group education and self-management programme. This was followed up by an additional day of training on the 10th of April for the Nurses alone to focus on the one to one consultation. This training course was for the facilitators based in the West Midlands and held at the University of Warwick (see Appendix 1 for facilitator training timetable). The training will be re-run for those that will eventually deliver the courses down in North-east London.

The training course was observed by the process evaluation team to ensure that all sessions had been adequately covered, facilitator skills had been taught and adverse events (AEs) procedures had been addressed and discussed.

Facilitator assessment of learning and feedback

After the training course each facilitator will complete a learning evaluation form which includes some questions to test their knowledge gained over the two days of learning (see Error! Reference source not found.). Only those facilitators that have demonstrated competency and learning according to the above assessments will be asked to facilitate. Where possible we will pair non-experienced with experienced facilitators.

Within this feedback form we will collect information on any improvements to the training and confidence in delivering a course.

Monitoring selection and training of facilitators

The research team will keep record of the following:

- Interested facilitators with all relevant HR paperwork including shortlisting criteria and CVs
- Number of trained facilitators at each site, including a split of nurses and AHPs.
- Register of those attending the facilitator training courses
- Copies of the facilitator assessment of learning and feedback
- Any feedback from the observer during the training course

2. Intervention delivery

Quality assurance of the intervention is important to ensure that the trial intervention is delivered consistently and in accordance with the trial protocol and manuals. As part of the intervention development we have produced two very detailed manuals, the first which covers the two days of group sessions and the second which details the process for the one to one consultations. All facilitators have been appropriately trained on the delivery of the intervention in accordance with the manual. They have been instructed to use the manual to guide them through delivery of the intervention.

As mentioned previously we require one nurse and one allied health professional (AHP) to run each group education and self-management course. Where possible we will try to pair more experienced facilitators with less experienced facilitators. We would consider running a course with two nurse facilitators if there were any difficulties getting an AHP facilitator.

We will assess the delivery of the intervention using observations, audio recordings, personal reflections and participant feedback. Below we have detailed how this will be undertaken.

Observations

To quality assure the course delivery we will aim to observe each facilitator. We will observe each facilitator early in their facilitation to allow any difficulties or challenges to be addressed. Subsequently they will be observed mid-way through. Observations will be by session and the number of sessions observed will depend on the ability of the observer to capture the required information.

The observations will be conducted by members of the CHES team who have knowledge of the intervention and its delivery. Observers will complete an observation form (Appendix 3) which will address facilitator skills and adherence to content delivery. These notes will be used to give the facilitators feedback on their performance to maximise the quality of delivery of the intervention and to make sure they are following the manual. Feedback will be provided on the day where possible. If this is not possible the observer will arrange to contact the facilitator by phone. The study team will discuss any difficulties with the facilitator to minimise impact on the rest of the course and to help with the delivery of future courses.

For any facilitators struggling the central research team will monitor their personal reflections for the remaining duration of the course and follow-up with phone calls if required.

Audio recordings

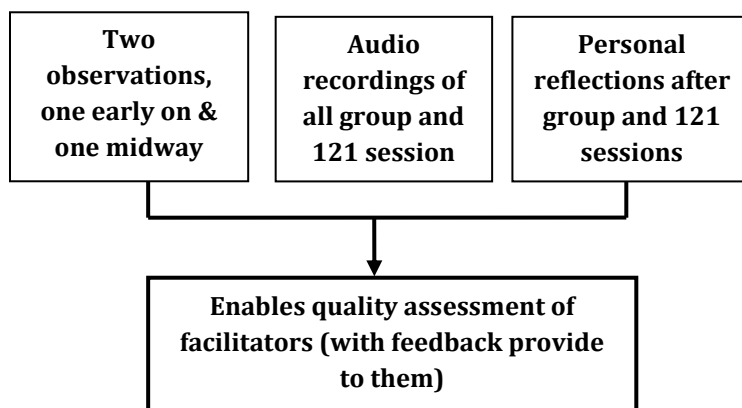
Fidelity of delivery of the intervention (i.e. do the facilitators deliver what they are supposed to deliver) will be formally assessed via the audio recording of the sessions). Facilitators have been made aware that we would like all courses and one to one sessions to be audio recorded. Details of this have been provided in the facilitator manuals. This forms part of the detailed process evaluation for which we have a separate protocol. The recording may also be useful if problems have been highlighted with particular sessions for quality assurance purposes. This will enable appropriate feedback to facilitators if required.

Sessions will be audio recorded using encrypted, PIN protected audio recorders. Facilitators will be asked to return these to the study team at Warwick CTU on completion of the course. The Trial coordinator will download the files onto the Warwick CTU M: Drive and file in a PGP encrypted folder. To access the recordings the Trial Coordinator must decrypt the audio files which will only be completed on request from delegated members of the CHES team. Once the recordings have been used for analysis they will be destroyed at all sites. The recordings will not be transcribed.

Personal reflections

We will encourage personal reflection from facilitators whereby we ask facilitators to send us a daily reflection email to chess@warwick.ac.uk recording their thoughts and feelings about the sessions, noting things that went well and where things could have gone better. These emails will help us support facilitators that may be experiencing difficulties.

We have included details of these personal reflections in both the group intervention manual and the one to one manual.



Participant feedback

At the end of day 2 we will ask participants to fill out a simple form to capture their feedback and experience from the course (Appendix 4).

Group intervention booking process

Eligibility phase:

- As part of the eligibility call participants will be given the dates of the course and asked to confirm they can make both of the days. They will only be eligible if they can make both dates and agree to attend the sessions. If they are unable to make either of the days they will, where possible, be offered further course dates.

Post randomisation but pre course:

- Those that call to say they cannot attend day 1 of the course will be offered up to two further chance to attend another course. After this they will be advised to contact the research team should they wish to attend. The research team will then offer a course if it is within a suitable timeframe and one is available locally.
- If the participant informs the research team that they do not wish to attend because they have changed their mind then they will remain in the study as intention to treat and still receive questionnaires. The research team will send the participant the relaxation CD, mindfulness CD and the Living with Chronic Headaches DVD with a covering letter and instructions of use. They will be provided with a link to the CHES website where they can download the relaxation and mindfulness CDs.

Day 1 of course:

- Those that have been booked in and do not attend will be classed as a DNA. The research team will attempt to call these participants to find out why they were unable to attend. Where possible the team will attempt to call those due to attend and then DNA in the first hour of the course starting, just in case they may have forgotten and can make the rest of the course.

- Those that call and cancel on the day will be offered up to two further opportunities to attend.

Day 2 of course:

- Those that have been booked in and do not attend will be classed as a DNA for that day. They will be contacted by the research team to see if they would like to be booked in for a one to one consultation with the nurse. If they are happy to be booked in they will be provided with the missed material from day 2 at that consultation and have the opportunity to ask any questions.
- If we are unable to contact the participants they will be classed as DNA.
- If a participant does not attend day 1 but turns up to day 2 they will be advised that they need to complete the first day of the course in order for the material on the second day to make sense. They will be encouraged to contact the research team to see if there are any forthcoming courses. If they are insistent on staying we will allow them to do so and the missed material will be covered during the one to one consultation.

Group size

Where possible we will try and book groups to fill 12 confirmed participants. We anticipate a couple will cancel or will not turn up on the day giving us our anticipated group of 10. Should there be any difficulty with recruitment in a particular area we would still run the group if we had a minimum of 6 confirmed participants.

Participant attendance and compliance

The facilitators will ensure an attendance register is completed for each day of the course. A copy has been provided in Appendix 5. We will record the number of sessions each individual attended including attendance at a one to one consultation and number of subsequent follow up calls and their duration.

Monitoring course delivery

The research team will keep record of the following:

- Who delivery each course (was it a nurse and an AHP?)
- Did each course had at least one experienced facilitator?
- Which courses were audio recoded, were there any gaps in the recordings
- Attendance and attrition rates
- Feedback to facilitators following observations and any action taken
- Content fidelity as per process evaluation protocol to ensure delivery is in accordance with the manual.

3. Control intervention

The control participants will be provided with a relaxation CD to use. The CD comprises of a progressive muscle relaxation track. It will be available in both CD format as well as an MP3 download from the CHES website: www.warwick.ac.uk/chess. Additionally those in the control arm of the study, and their GPs, will be provided with the final outcome of the classification interview/s. Participants will also receive a brief advice sheet on treatment options that is consistent with NICE guidance.

Monitoring course delivery

The research team will keep record of the following:

- When packs have been sent to participants
- Any contact with control participants
- Attrition rates
- When letters have been sent to the GP
- Date of classification interview

Appendix 1: Facilitator training timetable

Monday 3rd April 2017 – All facilitators

Time	Topics	Trainer
9:00 - 9:30	ARRIVAL, TEA AND COFFEE	
9:30 – 10:00	Welcome and introductions (session 1) & aims of training	Dr Shilpa Patel
10:00 - 10:30	Background to the CHESSTrial	Dr Shilpa Patel
10:30 – 10:45	Aims and structure of the self-management programme (session 2)	Dr Shilpa Patel
10:45 - 11:00	BREAK	
11:00 - 12:00	Facilitation skills training	Dr Harbinder Sandhu
12:00 – 13:00	Session 3. Headache information and mechanisms	Prof Martin Underwood
13:00 – 13:30	LUNCH BREAK	
13:30 -14:15	Session 4. Acceptance	Dr Shilpa Patel
14:15 – 15:15	Session 5. Mood and headaches Session 6. Pain cycle and breaking the cycle	Dr Harbinder Sandhu
15:15 – 15:30	BREAK	
15:30 – 16:30	Session 7. Unhelpful thinking patterns – barriers to change Session 8. Reframing negative thoughts to positives	Dr Shilpa Patel
16:30 – 17:00	Questions / summary so far	Dr Shilpa Patel & Dr Harbinder Sandhu

Tuesday 4th April 2017 - All facilitators

Time	Topics	Trainer
9:00 - 9:15	ARRIVAL, TEA AND COFFEE	
9.15 – 9:30	Session 9. Reflections from Day 1	Dr Harbinder Sandhu
9:30 – 10:30	Session 10. Problem solving, action planning & goal setting Session 11. Lifestyle advice	Dr Shilpa Patel
10:30-10:45	BREAK	
10.45 – 11:45	Session 12. Stress and anxiety management Session 13. Sleep and sleep management	Dr Harbinder Sandhu
11:45 – 12:15	Session 14. Mindfulness for headaches	Dr Shilpa Patel
12:15 – 13:00	Session 15. Medication management	Prof Martin Underwood
13:00 – 13:30	LUNCH BREAK	
13:30 – 14:30	Session 16. Communication with family and carers Session 17. Communication with Health Professionals	Dr Harbinder Sandhu
14:30 – 15:00	Session 18. Managing setbacks	Dr Shilpa Patel
15:00-15:15	BREAK	
15:15 – 15:30	Session 19. Summary of course	Dr Shilpa Patel & Dr Harbinder Sandhu
15:30 – 16:00	SAEs and paperwork	Kim White
16:00 – 16:30	Overall summary and questions	Dr Shilpa Patel & Dr Harbinder Sandhu

Monday 10th April 2017 - Nurses only

Time	Topics	Trainer
9:00 - 9:15	ARRIVAL, TEA AND COFFEE	
9:15 - 9:30	Welcome, aims and structure	Dr Shilpa Patel
9:30 - 11:00	Classification assessment with headache diary	Dr Manjit Matharu and Dr Rachel Potter
11:00 - 11:15	BREAK	
11:15 - 13:00	Classification assessment with headache diary cont.	Dr Manjit Matharu and Dr Rachel Potter
13:00 - 13:30	LUNCH BREAK	
13:30 - 15:30	Management plan - Medication	Dr Manjit Matharu
15:30 - 15:45	BREAK	
15:45 - 16:15	Lifestyle factors and personalised goal setting	Dr Shilpa Patel
16:15 - 16:30	Ongoing telephone support	Dr Shilpa Patel
16:30 - 17:00	Paperwork	Kim White

Appendix 2: Facilitator feedback and assessment of learning



Facilitator feedback and assessment of learning
April 3rd and 4th 2017, University of Warwick

Thank you for attending the two day CHESS facilitator training. Please complete the feedback and short questionnaire below. This information will be used to inform our training in the future as well as help us provide feedback and further guidance to you on specific topics should it be required. Please answer all the questions.

Name: _____

SECTION 1. FEEDBACK AND COURSE SATISFACTION

1. Were the aims of the course made clear?

Yes [] No [] Don't know []

2. Were the aims of the course met?

Yes [] No [] Don't know []

3. What were the three most useful things you learnt on this course?

1) _____

2) _____

3) _____

4. What three things would you recommend to make this course better for future trainees?

1) _____

2) _____

3) _____

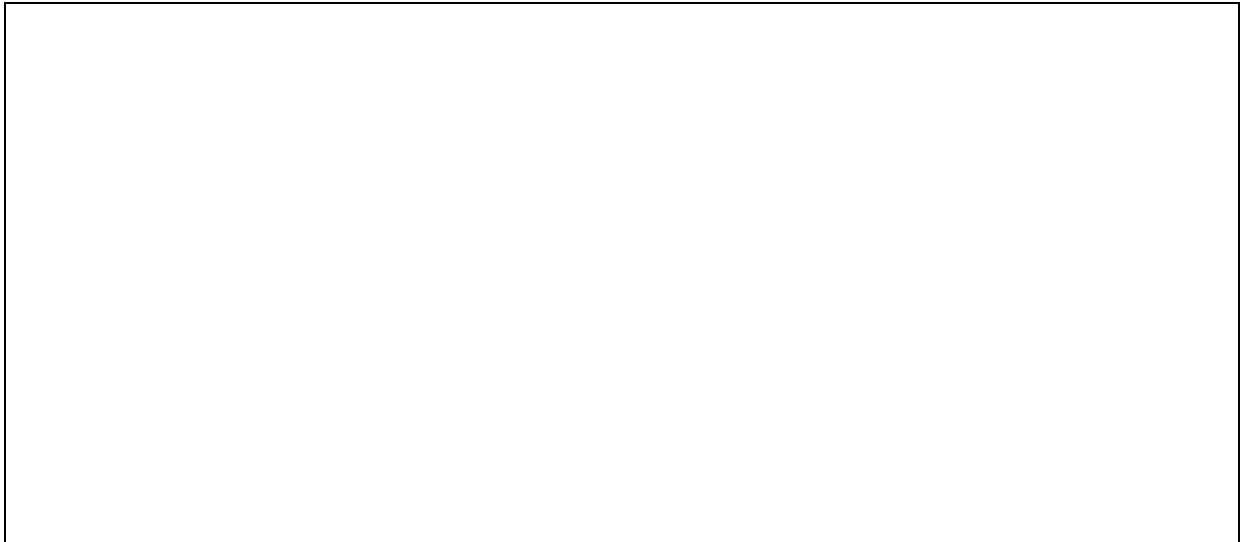
4. Name 3 characteristics of a tension type headache?

1) _____

2) _____

3) _____

5. Please draw the pain cycle in the space below.



6. Name three unhelpful thinking styles (negative automatic thoughts)?

1) _____

2) _____

3) _____

7. What four elements are thought to be linked in cognitive behavioural therapy?

1) _____

2) _____

3) _____

4) _____

8. What does the acronym SMART stand for?

9. Name three lifestyle factors that might be important for someone with chronic headache to consider?

1) _____

2) _____

3) _____

10. Name the four types of symptoms caused by stress and give an example of each.

1) _____

2) _____

3) _____

4) _____

11. Name the two main categories of drugs used for the management of headaches and explain when they might be considered?

1) _____

2) _____

12. Define medication overuse headaches?

13. Name three core communication skills that can be used in one to one discussions?

1) _____

2) _____

3) _____

14. List three non-drug strategies for managing setbacks?

1) _____

2) _____

3) _____

15. What would you do if a person gets unduly upset during a group discussion?

16. Do you have any comments to add about the CHESS course and or the facilitator training course?

Thank you.

**Please could you return the completed form in the pre-paid envelope provided by [INSERT DATE].
It is important that you return this feedback as we will not be able to offer you a course to
facilitate without this this document.**

Appendix 3: Facilitator Quality Assessment Observation Form



Sample - Facilitator Quality Assessment Observation Form

Name of facilitator observed	
Date of observation	
Location	
Session observed	
Name of observer	

Environment (room set-up, lighting, temperature, equipment, noise, tea/coffee)
Comments:

Session content				
	Covered adequately	Not covered adequately	Missed	Comments
Core elements				

Facilitation skills	
Facilitator behaviours	Comments
Approachable and open body language with good eye contact	
Asked open questions	
Confident in delivery	
Articulate – clear explanation which are easy to understand	
Uses examples and narratives to illustrate points	
Enables group generated content	
Dealt with disruption/difficult situations effectively	
Recognises beliefs and behaviours that need challenging	

Challenged participants beliefs in a non-threatening manner	
Effectively listened	
Demonstrated humour	
Demonstrated empathy	
Effective collaboration between facilitators	
Appropriate facilitator/participant talk time	
Encouraged participations of all group members	
Summarised session	
Linked session content to other sessions	
Encouraged personal reflection	
Acknowledged member participation positively	
Uses silence appropriately	
Reflects back to the group appropriately	

Appendix 3: Participant feedback form



Participant feedback form

Thank you for attending the two day CHESS programme. We really welcome your feedback therefore please could you complete the form and return it in the envelope provided.

Please use the following scale to indicate your levels of satisfaction for the following questions where 0 indicates least satisfaction, and 5 indicates most satisfaction.

How satisfied were you with (please circle your answer):

1) The course over all?	0	1	2	3	4	5
2) The facilitators?	0	1	2	3	4	5
3) The group discussions process?	0	1	2	3	4	5
4) The amount of time spent on each topic?	0	1	2	3	4	5
5) The taster sessions?	0	1	2	3	4	5
6) The handouts?	0	1	2	3	4	5
7) The course venue?	0	1	2	3	4	5

8) What parts of this course, if any, did you enjoy or value the most? Please tell us why.

9) What parts of this course today, if any, did you least enjoy? Please tell us why.

Thank you.

Appendix 4: Course register

Chronic Headache Education and Self-management Study (CHESS)

<Insert Date> <Insert Location>

REGISTER

TNO	Name	Signature	AM	PM	NOTES (Please note any sessions missed and reason)

