Data Management Plan

Chronic Headache Education and Self-Management Study
Main RCT

Version:	2.3
Effective date:	13.07.2020
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Reviewer(s):	Emma Withers – Senior Project Manager Dr Dipesh Mistry - Statistician Dr Siew Wan Hee - Senior Statistician Dr Felix Achana - Health Economist Jill Wood – Quality Assurance Manager
Approved by*:	Name: Professor Martin Underwood Job Title: Chief Investigator CHESS Signature: *Q-Pulse Approval*
	By signing this document, you are confirming that it has been crossed checked with the current protocol, the statistical analysis plan, trial monitoring plan and the SOPs listed below.

** The data management plan should be approved by the Chief Investigator (CI) or Statistician only*

The DMP is next due for review on 13.07.2021

The CHESS DMP should be reviewed every 12 months unless any changes/updates are made as per below description.

The DMP should be reviewed in the occurrence of a serious breach, any CRF changes, substantial amendments, significant team changes, any changes to the study Risk Assessment of Monitoring Plan.

Revisions to CHESS DMP:

Revision Chronology:	Effective Date:	Reason for change:	Name of author	Name of person approving change:
V1.0		-		Please see Q-Pulse
V1.1				Please see Q-Pulse
V2.0		• Addition of processes for data deletion. • Addition of self-evident corrections.	Kimberley Stewart	Please see Q-Pulse
V2.1		• GP Data Collection processes added.	Kimberley Stewart	Please see Q-Pulse
V2.2		• Medication data cleaning process added	Chloe Norman	Please see Q-Pulse
V2.3		• COVID-19 adaptions added	Chloe Norman	Please see Q-Pulse

Contents:

Study Abbreviations:

Abbreviation	Explanation
AE	Adverse Event
CAPA	Corrective and preventative actions
CRF	Case Report Form
CTTH	Chronic Tension Type Headache
DC	Data Clerk
DCM	Definite Chronic Migraine
DMP	Data Management Plan
GP	General Practitioner
ICF	Information Consent Form
ISF	Investigator Site File
MOH	Medication Overuse Headache
NMC	National Migraine Centre
PCM	Probable Chronic Migraine
PIL	Participant Information Leaflet
QA	Questionnaire
RCT	Randomised Controlled Trial
RN	Research Nurse
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
TC	Trial Coordinator
TM	Trial Manager
TMF	Trial Master File

Relevant Reading:

The following documents should be read in conjunction with the CHESS DMP.

Document Title/Date	Version Number	Location
CHESS Protocol_07.Mar.2019	3.6	M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\2) Protocol\2.1 Current Version
CHESS Monitoring Plan_July 2017	1.0	M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\7) Monitoring\9.1 RA Monitoring Plan
CHESS Risk Assessment_14/02/2017	0.1	M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\7) Monitoring\9.1 RA Monitoring Plan
CHESS Working Instructions	N.A	See below (page 6) of CHESS DMP.

The following SOPs should be read in conjunction with the CHESS DMP, the SOPs can be found in the following location:
https://warwick.ac.uk/fac/sci/med/research/ctu/conducting/planning/sop

SOP Number	SOP Name
9	Randomisation / Blinding
12	Definitions of Responsibilities
15	Information Handling – Part 1 / Part 2 / Part 3
16	Case Report Forms
18	Risk Assessment and Monitoring
19	Quality Control
24	Training Records
25	Auditing of Clinical Trials
31	Deviations/violations, misconduct and serious breaches of GCP and/or study protocol

Study Working Instructions:

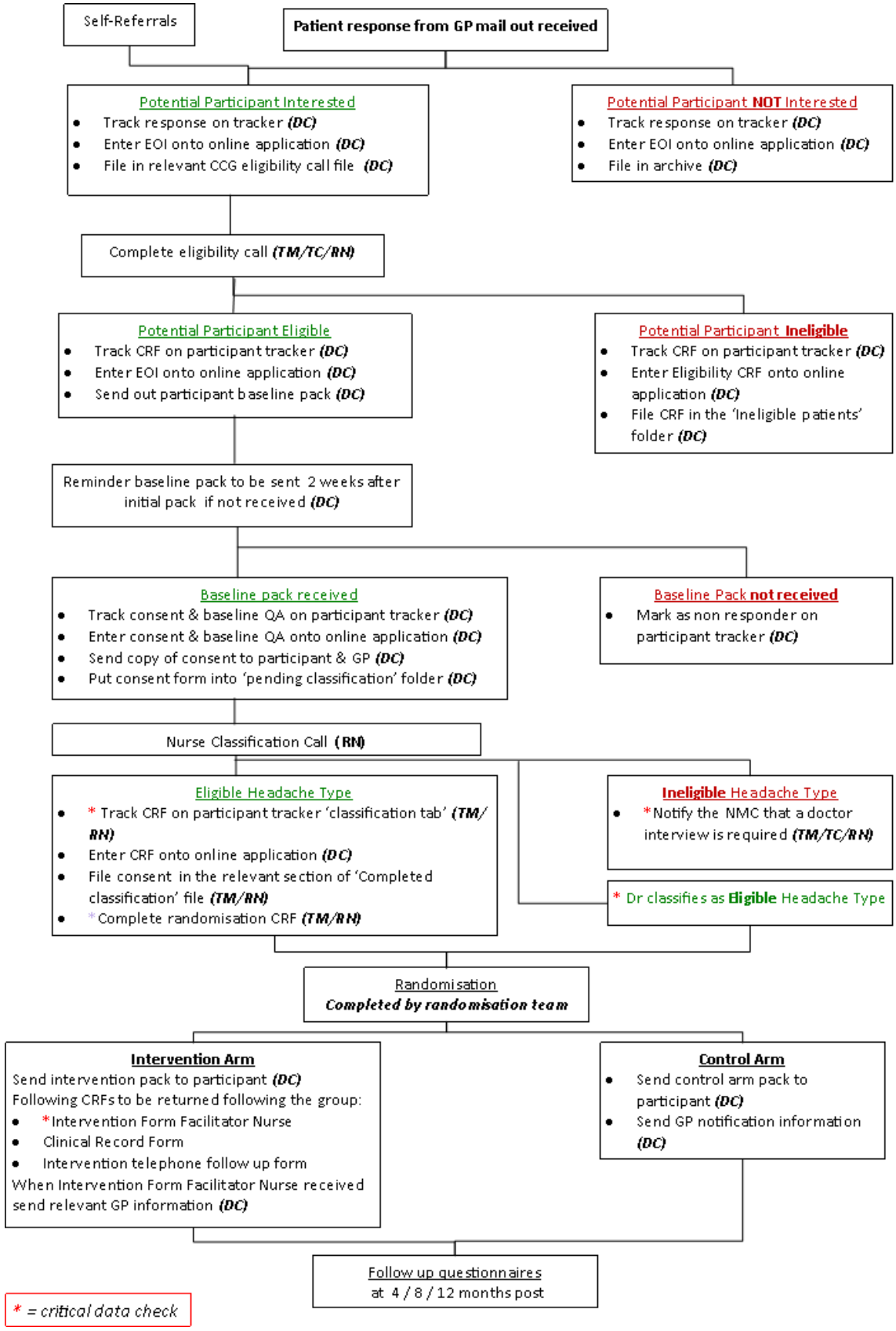
There are a number of working instructions that correspond to the processes outlined in the study data flow diagram. These are detailed in individual documents which can be found in the following location on the CHESS M: Drive (Location: **M:\WMS\CTU\Rehabilitation\ CHESS\2) MAIN RCT\14) Trial Specific Working Instructions\16.1) Copies of Trial instruction Docs/Data Management Plan**). Always refer to the current approved version.

Current Working Instructions:

Title of working instruction	Current Version
Recruiting GP Practices	V1.0
Document Tracking	V1.0
Tracking EOI (Expression of Interest) Forms	V1.0
Baseline Packs	V1.0
Tracking Consent Forms	V1.0
Tracking and Entering Nurse Classification CRFs	V1.0
Referring Pt to the NMC for Doctor Interview	V1.0
Randomisation Process	V1.0
Sending out Randomisation Allocation Packs	V1.0
Intention to Treat Packs	V1.0
Sending out 4_8_12 Month QAs with vouchers	V1.0
Smartphone App Tracking	V1.0
Non-compliance Flow Diagram	V1.0
Non-compliance Process	V1.0
Monthly Data Check	V1.0
Interview Study Crib Sheet – Identifying and sending info	V1.0
Requesting Invoices – Payment for GP Practice Involvement	V1.0
Sending the second QA reminder	V1.0

Smartphone App Summaries	V1.0
CHESS Intervention Group Packing List	V1.0
Location checklist	V1.0

Study Data Flow:


Self-Referrals
Patient response from GP mail out received
Potential Participant Interested
Track response on tracker (DC)
Enter EOI onto online application (DC)
File in relevant CCG eligibility call file (DC)
Potential Participant NOT Interested
Track response on tracker (DC)
Enter EOI onto online application (DC)
File in archive (DC)
Complete eligibility call (TM/TC/RN)
Potential Participant Eligible
Track CRF on participant tracker (DC)
Enter EOI onto online application (DC)
Send out participant baseline pack (DC)
Potential Participant Ineligible
Track CRF on participant tracker (DC)
Enter Eligibility CRF onto online application (DC)
File CRF in the 'Ineligible patients' folder (DC)
Reminder baseline pack to be sent 2 weeks after initial pack if not received (DC)
Baseline pack received
Track consent & baseline QA on participant tracker (DC)
Enter consent & baseline QA onto online application (DC)
Send copy of consent to participant & GP (DC)
Put consent form into 'pending classification' folder (DC)
Baseline Pack not received
Mark as non responder on participant tracker (DC)
Nurse Classification Call (RN)
Eligible Headache Type
* Track CRF on participant tracker 'classification tab' (TM/RN)
Enter CRF onto online application (DC)
File consent in the relevant section of 'Completed classification' file (TM/RN)
* Complete randomisation CRF (TM/RN)
Ineligible Headache Type
*Notify the NMC that a doctor interview is required (TM/TC/RN)
* Dr classifies as Eligible Headache Type
Randomisation
Completed by randomisation team
Intervention Arm
Send intervention pack to participant (DC)
Following CRFs to be returned following the group:
*Intervention Form Facilitator Nurse
Clinical Record Form
Intervention telephone follow up form
When Intervention Form Facilitator Nurse received send relevant GP information (DC)
Control Arm
Send control arm pack to participant (DC)
Send GP notification information (DC)
Follow up questionnaires
at 4 / 8 / 12 months post
* = critical data check

Current Study Documentation:

Case Report Forms:

Current versions of study CRFs can be found in the following location:
M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\9) Data Collection\2. CRFs\Current

CRF Name	Version
CHESS Eligibility Form_Form 1	2.2
CHESS Eligibility Form_Form 2	2.2
CHESS Nurse Classification Form	2.0
CHESS Classification Form_Doctor	2.0
CHESS Randomisation Form	1.0
CHESS Intervention Form Facilitator Nurse	1.1
CHES Intervention Form Facilitator Nurse_Clinical Record Form	2.0
CHESS Intervention Telephone Follow Up Form	1.0
CHESS Adverse Event Form_Initial	1.0
CHESS Adverse Event Form_Follow Up	1.0
CHESS Initial SAE Form	1.1
CHESS Follow Up SAE Form	1.1
CHESS GP Transfer Form	1.1
CHESS Withdrawal Form	1.1
Notification of death Form	1.0
CHESS Self-Referral Form	1.0
CHESS Intervention Attendance Form	1.0

Study Questionnaires:

Current versions of study questionnaires can be found in the following location:
M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\9) Data Collection\1. Questionnaire Packs

Questionnaire Name	Date	Version
CHESS Baseline QA	26.Feb.2019	3.2
CHESS 4 Month QA	26.Feb.2019	3.2
CHESS 4 Month Reminder QA	07.Mar.2019	1.0
CHESS 8 Month QA	26.Feb.2019	3.2
CHESS 8 Month Reminder QA	07.Mar.2019	1.0
CHESS 12 Month QA	26.Feb.2019	3.2
CHESS 12 Month Reminder QA	07.Mar.2019	1.0

Updates to CRFs / Questionnaires:

CHESS do not provide CRFs to sites as data is sent directly between study and participants. Therefore CRF updates should be implemented by the study team on approval of an amendment. The following locations should be updated:

- Q-Pulse
- The M:Drive
- The paper TMF
- The DMP

It is also important to notify the team via email so they are aware that the M:Drive has been updated with new versions just in case paper copies are in circulation and being used.

Systems Access:

Name of system	Use in study	Location	Access granted by	Access controlled by	Checked
M:Drive	Storage of electronic documentation	This PC > Shared (\\ads.warwick.ac.uk) (M:)	Natalie Strickland, Head of Operations	Natalie Strickland, Head of Operations	
CHESSMain Online Application	Data Entry of CRFs / Questionnaires	https://ctu.warwick.ac.uk/CHESSMain/frmLogin.aspx	Kimberley White, System Owner	Kimberley White, System Owner	Quarterly
CHESS Reporting	Study Reporting QA cover letters	https://ctureports.warwick.ac.uk/Reports/Pages/UILogon	Kimberley White, System Owner	Kimberley White, System Owner	Quarterly
CHESS Outlook Resource Account	Should be used for all email correspondence. Emails, including those from participants/public.	Outlook – chess@warwick.ac.uk	Kimberley White, Resource Account Manager	Kimberley White, Resource Account Manager	Quarterly
Participant Tracker (Excel)	Tracking EOI receipt Tracking Study QAs Tracking Classification Interviews Interview Study Tracking Smartphone App Use	M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\9) Data Collection\3. Recruitment	N.A	N.A	N.A

	Re-consent Trackers Data Deletion Tracker Will not be randomised				
PGP Encryption	The following folders are PGP encrypted: CHESS1 Audio Recordings Nurse Classification Interviews Facilitators CHESS Resource Account Vivs Folder Sent summary templates Data	N.A	Kimberley White, Admin	Kimberley White, Admin	Quarterly

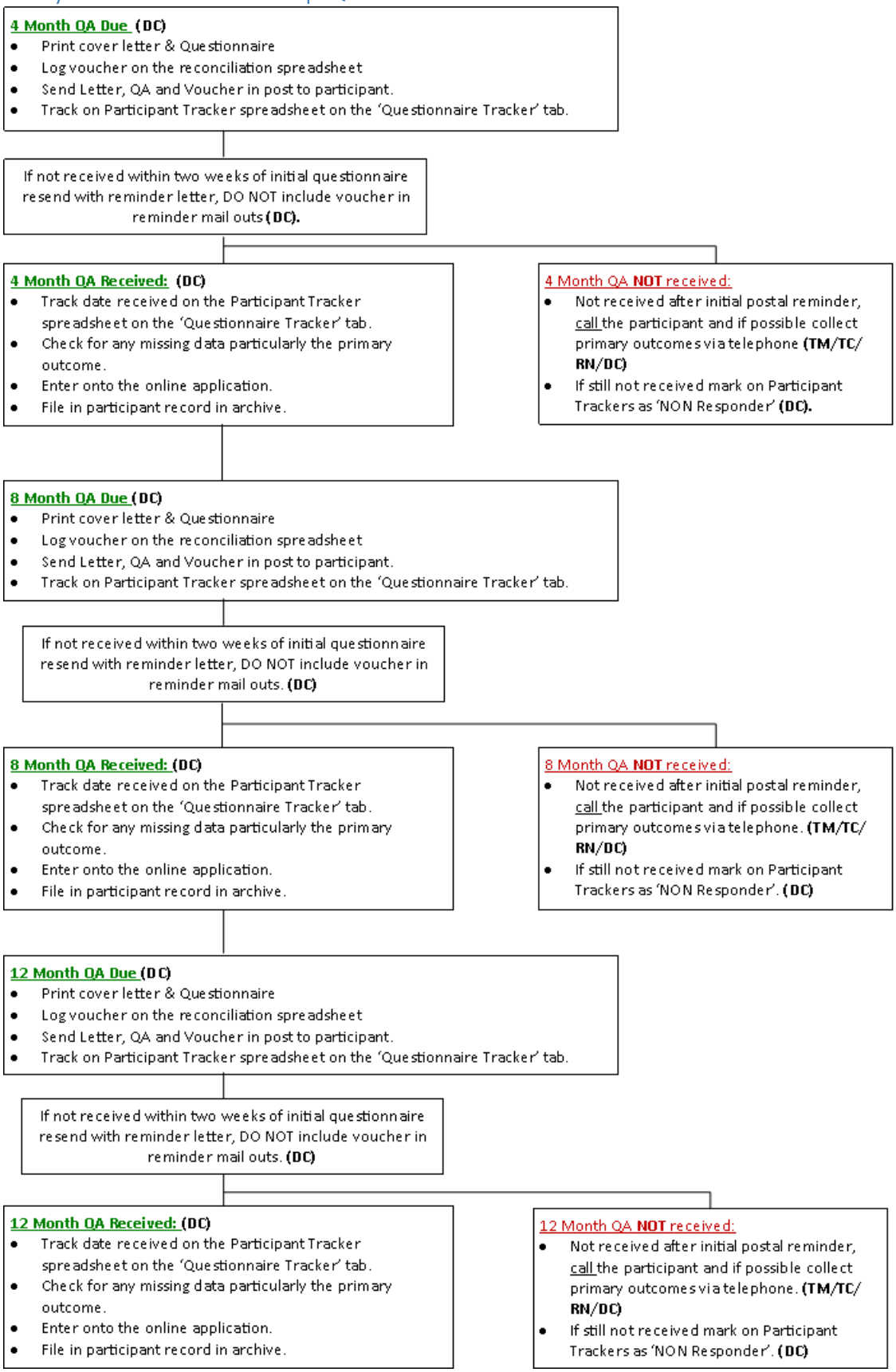
Access to the systems:

Access checks completed quarterly by the Trial Manager, email confirmation of verification to Senior Project Manager, email printed and filed in TMF.

PGP Encryption folder access is check quarterly by the Trial Manager, email confirmed of verification to Senior Project Manager. Screen shot of user access for each folder printed, signed & dated, and filed in the TMF.

Participant Reported Outcome Measures (PROMS) – Questionnaires:

Study Data Flow – Follow Up Questionnaires:



Dispatch and Receipt of study questionnaires:

For details on sending out and tracking receipt of questionnaires please refer to working instructions:

Title of working instruction	Current Version
Sending out 4_8_12 Month QAs with vouchers	V1.0
Sending the second QA reminder	V1.0

The participant tracker where questionnaires are tracked automatically populates the dates when reminder questionnaires are due based on the date the questionnaire was sent. The rule for this is as follows.

- Initial Questionnaire (including high street voucher).
- Questionnaire not received – First Reminder sent two weeks after the date initial QA sent (including study pen).
- Questionnaire not received – Second Reminder sent two weeks after the date first reminder QA sent (short primary outcome only QA).

Missing Data - questionnaires:

Questionnaires should be stamped with the date received which should be initialled in green ink. Once the questionnaire has been tracked the questionnaire should be checked to ensure all questions have been answered. If there are blank questions or data is unclear and therefore requires to be confirmed with the participant the sections should be marked with a post it and the questionnaire should be filed in the relevant tray in the study office cupboard.

Members of the team should attempt to call participants with missing data queries once a week. The calls should be logged on the 'call tracking sheet v1.1' **(location: M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\14) Trial Specific Working Instructions\16.1 Copies of Trial Instruction Docs\Data Management Plan\3)** Call Crib Sheets) which should be kept on the front of the questionnaire.

We will attempt three calls to the participant to collect missing data before leaving a voicemail. Following a voicemail being left no more than three more attempts should be made to contact the participant. No more than six attempts should be made per participant.

Contact made with participant:

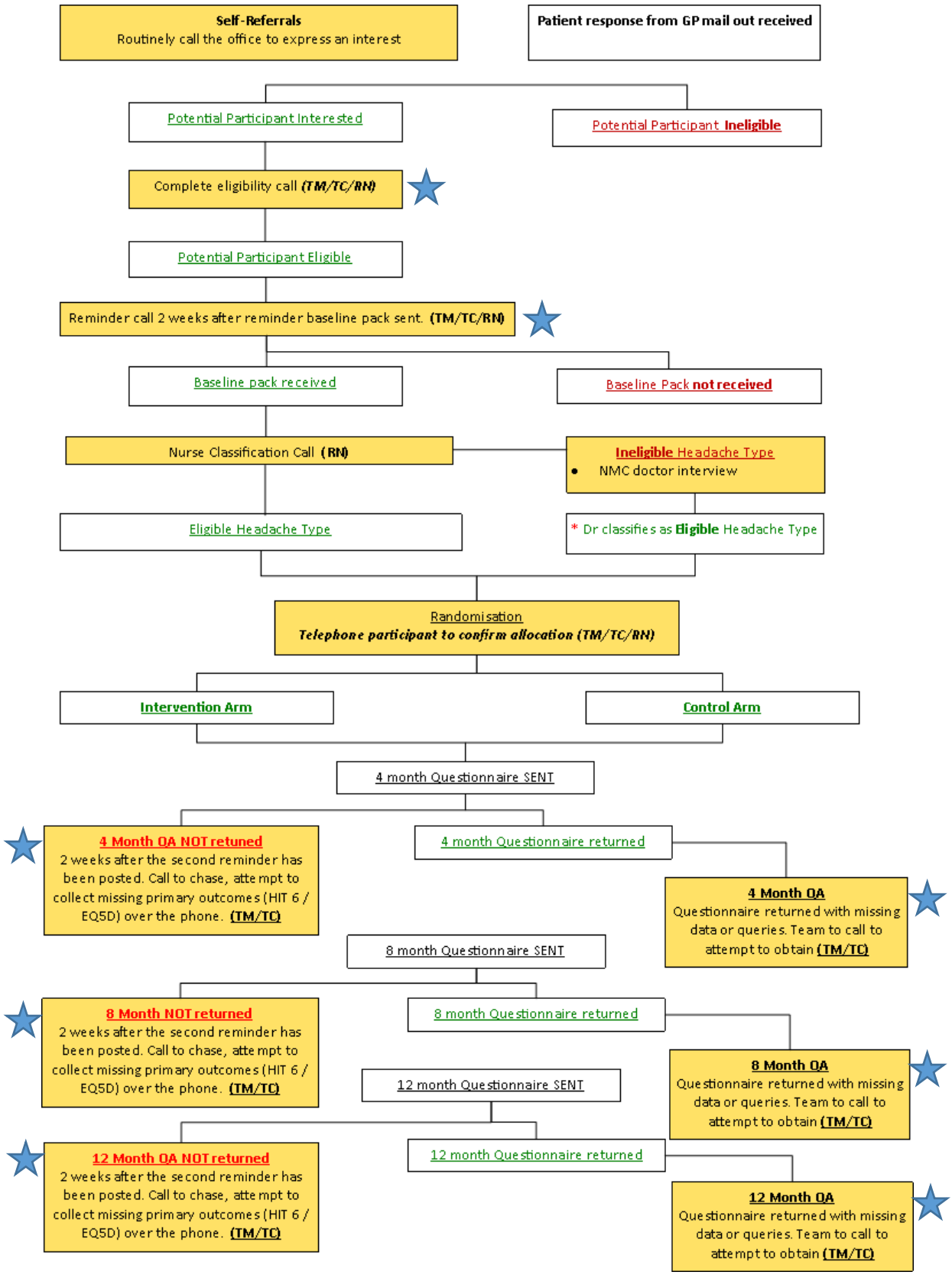
- Confirm missing data.
- Enter participant response in green ink pen.
- Write next to data collected *'data confirmed over phone on <insert date> by <initials>'.*
- The questionnaire can then be put in the relevant data entry tray in the study office cupboard.

Unable to contact participant:

- Confirm on the 'call tracking sheet' unable to contact participant, missing data.
- Put the questionnaire in the relevant data entry tray in the study office cupboard.
- When entered the questionnaire should be marked as 'clean – missing data'.

Telephone calls to participants:

Routine phone calls to participants are highlighted in the below flow diagram.



- In the above flow chart **yellow boxes** are routine phone calls to participants.
- **Blue stars** indicate calls which are tracked (details below).

Please note: CHESS is a primary care study where the team at WCTU directly recruit participants. This means there are many ad-hoc calls with participants/members of the public who call the study office directly.

Telephone Call Training:

Telephone call training is provided by the CHESS team usually the TM or another experienced member of the team will sit in a quiet space such as a meeting room and will complete telephone calls on loudspeaker so that both sides of the conversation can be heard. When this has been completed and the trainee feels confident they will make telephone calls on loud speaker so the experienced team member can hear both sides of the call. When the trainer is happy with the quality of the calls and that the scripts are being adhered to they will sign off the trainee on their study specific training log.

Tracking telephone calls:

Type of call	**Location Tracked**
Eligibility call attempts	Call attempts written on the back of the EOI form. Date of call, whether from landline/mobile, whether participant answered, outcome, initials of person completing call.
Eligibility call completed	The date the final call was made (eligible/ineligible/on hold) should be recorded on the Participant Tracker.
Baseline reminder call	As a comment on Participant Tracker in the field where the date the postal reminder was entered.
4 / 8 /12 Month QA **Reminder call**	All call attempts and contact made should be tracked on the call tracking sheet which should be kept with the QA. The call tracking sheet should be filed in the participant archive record when completed. The date when contact was made with participant should be entered onto the Participant Tracker / Questionnaire Tab / Telephone reminder call made. Please include a comment on this field if required to briefly detail conversation with participant.
4 / 8 / 12 Month QA **Missing Data / Primary Outcome Call**	All call attempts and contact made should be tracked on the call tracking sheet which should be kept with the QA. The call tracking sheet should be filed in the participant archive record when completed. This detail is not electronically recorded.

Scripts for telephone calls to participants:

Scripts for the above telephone calls can be found in the following location on the M: Drive

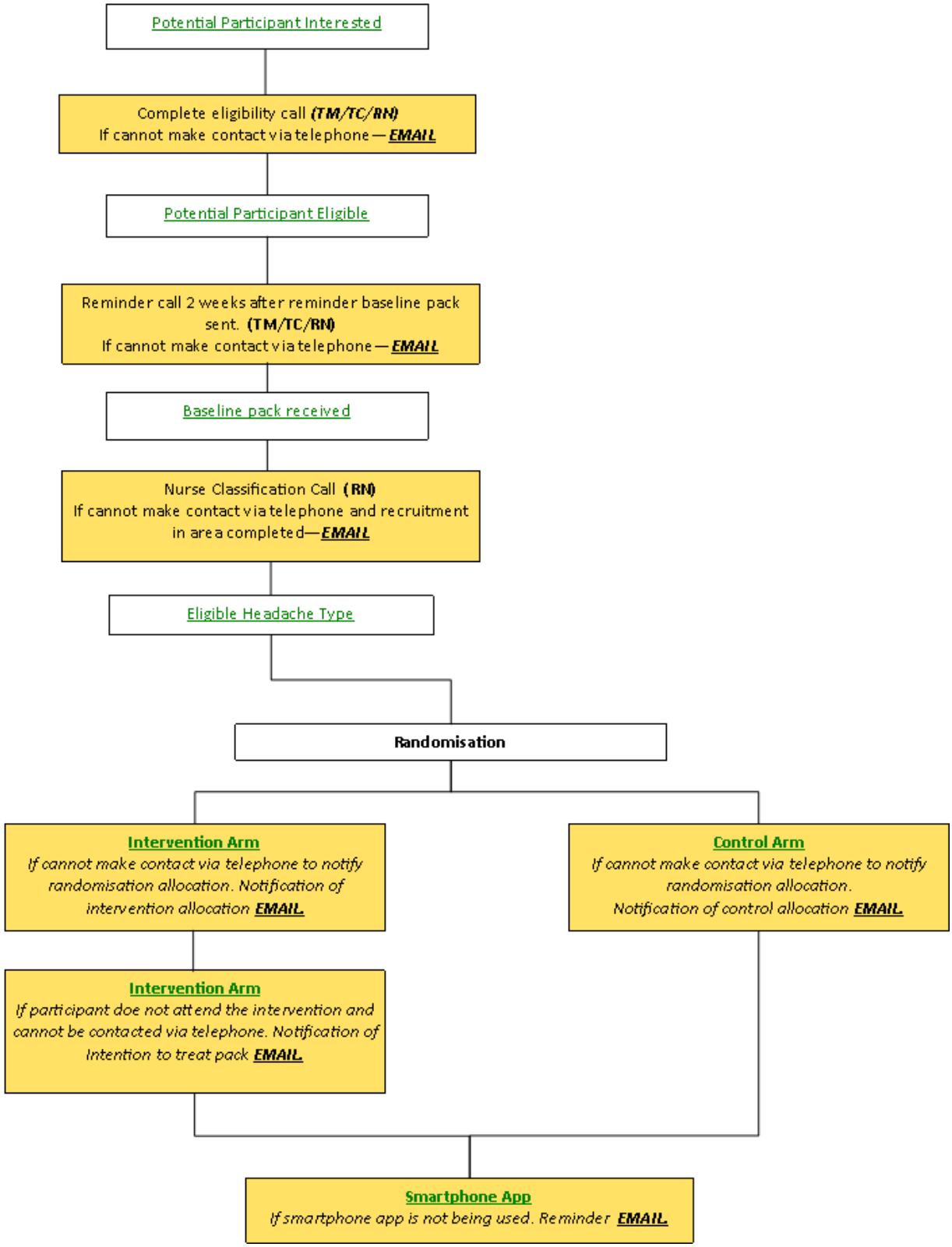
M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\14) Trial Specific Working Instructions\16.1 Copies of Trial Instruction Docs\Data Management Plan\3) Call Crib Sheets

Telephone calls for questionnaires during COVID-19

At the start of lockdown for COVID-19, there were still 63 participants pending questionnaire return. Whilst these had all been sent out, very few had been sent reminders. We will attempt to contact all of the outstanding participants from home following the guidance above and where possible collect all the questionnaire over the phone. If the participant is unwilling, we will then suggest just the primary outcomes.

All questionnaire data collected during this period of homeworking will be anonymous and stored in a locked cupboard at the Trial Manager's home to be entered as soon as possible. These forms will be transferred back to WCTU at the earliest opportunity.

Emailing participants:



Email templates available are highlighted below in yellow

Please note:

- All emails should be sent from the chess@warwick.ac.uk account.

Please ensure to remove your personal email address from your email signature before sending.

- Participants/public will ad-hoc email the resource account, you can respond accordingly without using a template.
- When forwarding an email to the team if input required, please ensure to remove and identifiable information from the email and refer to the participant by TNO number.
- If a decision is reached of the email from the participant/patient is relating to a trial procedure ensure to print, anonymise and file in the participants archive file.

Email templates to participants:

REC/HRA approved email templates are available for contacting participants from the **CHESS Resource account** and can be found in the following location on the M: Drive

M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\3) Information for Participants\17. Email Templates

Receipt of data into WCTU: Data Entry & Querying

Schedule of return / method of arrival:

The following CRFs are completed by study staff at Warwick CTU.

CRF Name	Version
CHESS Eligibility Form_Form 1	2.2
CHESS Eligibility Form_Form 2	2.2
CHESS Nurse Classification Form	2.0
CHESS Randomisation Form	1.0
CHESS Adverse Event Form_Initial	1.0
CHESS Adverse Event Form_Follow Up	1.0
CHESS Initial SAE Form	1.1
CHESS Follow Up SAE Form	1.1
CHESS GP Transfer Form	1.1
CHESS Withdrawal Form	1.1
Notification of death Form	1.0
CHESS Self-Referral Form	1.0
CHESS Intervention Attendance Form	1.0
CHESS GP Data Collection Form	1.4
CHESS Remote GP Data Collection Form	1.1

The following CRFs are completed by external staff at the National Migraine Centre, a scanned copy is provided via email prior to the wet ink copy being posted to the office.

CRF Name	Version
CHESS Classification Form_Doctor	2.0

CHESS 12 month remote data collection CRF	1.0

The following CRFs are completed by the intervention facilitators once completed they are returned to the study office in the post (no scanned copies provided by email).

CRF Name	Version
CHESS Intervention Form Facilitator Nurse	1.1
CHES Intervention Form Facilitator Nurse_Clinical Record Form	2.0
CHESS Intervention Telephone Follow Up Form	1.0

Receipt of data after completion of randomisation:

Expression of interest forms are sometimes received after randomisation has completed for the study. We should track that these have been received and action accordingly however we do not add the data to the system and record the data deletion as per instructions on page 38.

Smartphone App Data:

Please refer to working instruction '*Smartphone App Tracking'* for instructions on how smartphone app responses should be tracked and how/when the reminders should be sent.

When the smartphone apps have been completed (date 12 months post first completion) the working instruction '*Smartphone App Summaries'* should be used to send out the smartphone app summary data to participants.

Tracking/entering of the CRFs:

Tracking and entering information can be found detailed in the following working instructions:

Title of working instruction	Current Version
Baseline Packs	V1.0
Tracking and Entering Nurse Classification CRFs	V1.0
Referring Pt to the NMC for Doctor Interview	V1.0
Randomisation Process	V1.0
Smartphone App Tracking	V1.0
Sending the second QA reminder	V1.0

Please note: All other CRFs detailed above should be entered when completed, CRFs should be entered by a member of the team who **did not** complete the CRF.

Instructions on tracking/sending study questionnaires is covered in working instruction *'Sending out 4_8_12 Month QAs with vouchers'.* When all reminders have been sent to participants with no response and the telephone call reminders have taken place and the questionnaire has not been completed the participant should be marked on the Participant Tracker as Lost to Follow Up.

Critical On-Receipt Data Checks:

Critical data checks are checks that should be done immediately on receipt of the form, regardless of whether or not any further processing will occur at that time. The required on-receipt critical checks how to document them are outlined in the table below.

CRF Name	Critical Data Check	Person Responsible for check	Escalation process
Nurse Classification Form	**Q2**. Suspected Non-eligible headache	Research Nurse / Trial Coordinator /Trial Manager	If this has been ticked as yes and is a suspected **secondary** cause of headache or a suspected other **primary** headache type then the participant should be referred to the National Migraine Centre for a doctor interview. The participant TNO, Name and contact telephone number should be provided to the NMC representative. The date passed to NMC should be marked at the bottom of the CRF, this should be initialled and dated by the person completing. This should be detailed on the Participant Tracker Excel spreadsheet under the 'Classification Interviews' tab. If there is no need to escalate to the NMC tick the No box in the 'for office use only' section and initial and date to confirm check has been completed.
Doctor Classification Form	**Q2.** Non-eligible headache	Research Nurse / Trial Coordinator / Trial Manager	If the doctor specifies a **non–eligible headache** type this should be flagged to the CI at the earliest opportunity, if there are extensive notes in the additional comments section these should be provided to the CI for review. The action taken from this check should be documented in the 'Office Use Only' section of the CRF, this should be initialled and dated by the person completing. The outcome should also be documented on the Participant Tracked Excel spreadsheet under the 'Classification Interviews' tab.
Randomisation Form	**Q3.** Essential Information required at randomisation	Research Nurse / Trial Coordinator / Trial Manager	This section is the stratification for randomisation and therefore this should be entered exactly as documented on the nurse or doctor classification form whichever is applicable for the randomisation.
Nurse Facilitator	**Q5.** Information	Research Nurse / Trial	The participant should only be given the Chronic Tension Type Headache (CTTH) **or**

Consultation Form	given to participant	Coordinator / Trial Manager	Migraine Leaflet +/- Medication Overuse Leaflet. If the CRF is ticked for both CTTH and Migraine indicates that potentially an incorrect headache classification has taken place. This should be raised with the Senior Research Fellow or CI as appropriate. If an incorrect classification is deemed to have taken place a CAPA should be completed as soon as aware of the incident and the relevant guidance for completing CAPAs should be followed. To show that the form has been reviewed document at the end of the CRF 'check completed by xx' and the date.
Nurse Facilitator Consultation Form	**Q8**. GP Documentation	Research Nurse / Trial Coordinator / Trial Manager	Only one option for GP information should be ticked, if multiple options have been ticked then this should be queried with the person completing the form if the headache classification is not clear. This should be raised with the Senior Research Fellow or CI as appropriate. If an incorrect classification is deemed to have taken place a CAPA should be completed as soon as aware of the incident and the relevant guidance for completing CAPAs should be followed. To show that the form has been reviewed document at the end of the CRF 'check completed by xx' and the date.

Coding / Interpretation rules:

Expression of Interest Forms (EOI):

Date of Birth:

To enter the EOI form the date of birth must be entered. The EOI are not always returned with a D.O.B present, to be able to enter the form enter 01/01/1900.

If the date of birth has been left blank, every effort should be made to collect this at the point of eligibility call, or if missed at this time point at the point of classification interview or when next speaking with the participant.

If the date of birth has been left blank and has not been collected at the point of eligibility call and the patient is **ineligible** this should be left as 01/01/1900.

Data Deletion:

Now that the study is in the follow up stage participant identifiable data is to be deleted from the online application. The D.O.B. field has to have an entry in order to be able to count the EOI in the recruitment numbers therefore any deleted records the D.O.B should be entered as 01/01/1901.

Date EOI signed:

The form can be entered without this data, therefore should be left blank.

Adverse Event / SAE CRFs:

AE and SAE forms can be entered for all participants. Those in the control and the intervention arms. For those in the intervention arm the group code will be assigned and can be obtained from the Intervention Group Tracker which can be found in the following location on the M: Drive - ***M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\Intervention***

For control arm participants a group code is not available. A group code is required to enter the CRFs. When this is the case the code should be entered is AAA001 the code is consecutive to find out which number should be assigned

Self-Evident Corrections:

All self-evident corrections should be initialled and dated in a different colour pen to the one used when the form was completed, and if unsure check with Trial Manager or Trial Coordinator in first instance.

The following self-evident corrections apply to the forms detailed in the table below:

Form Name	Version
Expression of Interest Form	2.0
Adverse Event	V1.0
SAE Form	V1.1
Baseline QA	3.2
4 Month QA	3.2
8 Month QA	3.2
12 Month QA	3.2

Nurse Facilitator Consultation Form

Section 2: Total number of days in 4 weeks participant using headache specific treatments:

- Enter as seen, if unable to clarify with nurses completing the form missing values left and saved as unobtainable data

Section 4: Medication Overuse -

- If both 'advised' and 'via self' are ticked, 'via self' overrides and enter 'via self'
- If both 'advised' and 'via support' are ticked, 'via support' overrides and enter 'via support'
- If both 'via self' and 'via support' are ticked, 'via support' overrides and enter 'via support'

Study questionnaires:

Date received:

- If a participant returns two of the same questionnaire (likely to be a response to both the initial and reminder pack) please use the copy which is closest in date to the date the questionnaire was due. The other questionnaire should be superseded.
- If the date completed is empty on the first page, enter as the date received.

Baseline Questionnaire Only:

Section 1: Q2 - What is your ethnic group?

- If more than one answer is selected then select 'Any other' and enter both into the free text box provided.
  For example: British/Italian.

Section 1: Q3 – Which of the following best describes you?

- If more than one answer is selected then select 'other' and enter all answers ticked into the free text box provided.
  For example: Unable to work due to long term sickness / Looking after home/family.
  If answer is 'carer for my….' Enter as 'looking after my family/home'

Section 1: Q4 – How old were you when you left full time education?

If more than one option ticked, use the response indicating the oldest age.

-

Section 5: Q2 (troublesomeness grid)

- If more than one answer has been ticked per row, select the worst case scenario.

For example:

	No pain experienced	Not at all troublesome	Slightly troublesome	Moderately troublesome	Very troublesome	Extremely troublesome
Headache			x	x		

If a participant has selected two (as above) the worst case scenario would be 'moderately troublesome'

The following are applicable to all questionnaires (Baseline / 4 month / 8 month / 12 month):

Section 1 (4/8/12 months)/ Section 2 (baseline) (HIT 6, Primary Outcome):

- If participant has selected two options, enter the worst case scenario.
  For example:

When you have headaches, how often is the pain severe?
□ Never □ Rarely x Sometimes x Very often □Always

If a participant has ticked both 'sometimes' and 'very often', select and enter 'very often'.

Section 2 (4/8/12 months) / Section 3 (baseline) (CHQLQ):

- If participant has selected two options, enter the worst case scenario.

  For example:
  In the past 4 weeks, how often have headaches interfered with how well you dealt with family, friends and others who are close to you? (Select only one response.)

1X None of the time
2X A little bit of the time
3☐ Some of the time
4☐ A good bit of the time
5☐ Most of the time
6☐ All of the time

If a participant has ticked both 'None of the time' and 'A little bit of the time', select and enter 'A little bit of the time.

Section 3 (4/8/12 months) Section 4 (baseline):

Q1 – On how many days over the last 4 weeks have you had a headache/migraine?

- If participant has entered a number over 28 days, enter as 28 days as this is the maximum number of days in 4 weeks.
- If participant has written 'always' or 'everyday' enter as 28

Section 3 (4/8/12 months) Section 4 (baseline):

Q2 – Over the last 4 weeks on how many days have you used pain killers or triptans for your headaches/migraine?

- If participant has entered a number over 28 days, enter as 28 days as this is the maximum number of days in 4 weeks.
- If participant has written 'always' or 'everyday' enter as 28
- If participant has entered N/A, enter as 0
- If a range is given, enter the worst case scenario which is the highest value

Section 3 (4/8/12 months) Section 4 (baseline):

Q3 – On those days you had a headache/migraine, on average how long did they last?

- The maximum number which can be entered is 24.
- If the participant has entered a number higher than 24, the number 24 should be entered.
- If participant has entered a decimal place the number should be rounded up.

Section 3 (4/8/12 months) Section 4 (baseline):

Q4 – On those days you had a headache/migraine on average how severe were they?

- If more than one box has been ticked, enter the worst case scenario (largest number).

For example:

On those days you had a headache/migraine on average how severe were they?

☐	☐	☐	☒	☒	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10

No pain **Extremely severe pain**

If a participant has ticked both 3 and 4 on the scale, select and enter 4 as it is more severe.

Section 3 (4/8/12 months) Section 4 (baseline):
Q5 & 6

- If more than one box has been ticked, enter the worst case scenario.

For example:

In the past seven days how fatigued were you on average?

☐	☐	☒	☒	☐
Not at all	A little bit	Somewhat	Quite a bit	Very much

If a participant has ticked both 'somewhat' and 'quite a bit', select and enter 'quite a bit'.

Section 4 (4/8/12 months)/ Section 5 (baseline): Q1

- If more than one box has been ticked, enter the worst case scenario.

For example:

In the past seven days how would you rate your pain (other than your headache) on average?

☐	☐	☐	☐	☐	☐	☐	☒	☒	☐	☐
0	1	2	3	4	5	6	7	8	9	10

No pain **Worst imaginable pain**

If a participant has ticked both 7 and 8 on the scale, select and enter 8 as it is more severe.

Section 5 (4/8/12 months) / Section 6 (baseline):
Q1:

- If more than one box has been ticked select the worst case scenario.

For example:

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	x	x	☐

If a participant has ticked both 'yes, limited a lot' and 'yes limited a little', select and enter 'yes limited a lot'

Section 5 (4/8/12 months) / Section 6 (baseline):
Q2, 3 & 5:

- If more than one box is ticked select the worst case scenario

For example:

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Accomplished less than you would like	x	x	☐	☐	☐

If a participant has ticked both 'all of the time' and 'most of the time', select and enter 'all of the time'

Section 6 (4/8/12) Section 7 (baseline):

- If more than one box has been ticked select the worst case scenario.

For example:

MOBILITY

I have no problems in walking about	☐
I have slight problems in walking about	x
I have moderate problems in walking about	x
I have severe problems in walking about	☐
I am unable to walk about	☐

If a participant ticked 'I have slight problems in walking about' and 'I have moderate problems in walking about', select and enter 'I have moderate problems walking about'

- If scale is not completed or slightly different to the written number, disregard scale and enter written number
- Ig a range is given, enter the lowest number as worst case scenario
- If there is a large difference between scale and the written number, enter the lowest as worst case scenario

Section 7 (4/8/12)/ Section 8 (baseline):

- If more than one box has been ticked select the worst case scenario.

For example:

I feel tense or "wound up"

Most of the time x

A lot of the time x

From time to time, occasionally □

Not at all □

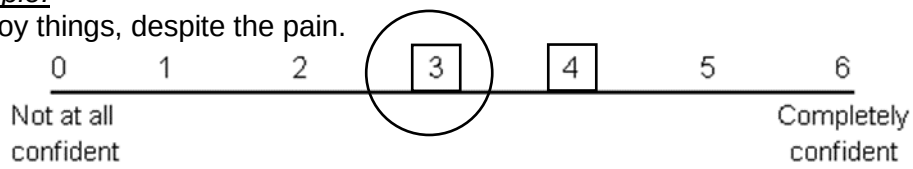
If a participant has ticked 'most of the time' and 'a lot of the time', select and enter 'most of the time' as it is the worst case scenario

Section 8 (4/8/12)/ Section 9 (baseline):

- If more than one number has been circled, select the worst case scenario.

For example:

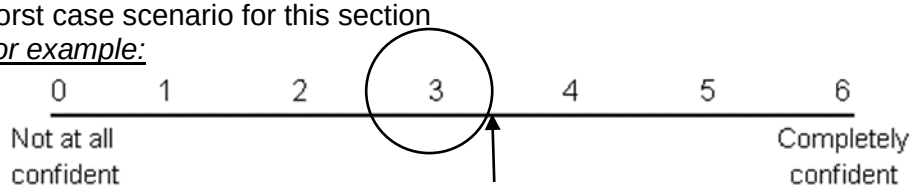
I can enjoy things, despite the pain.



If a participant selects 3 and 4, select and enter 3 as this is the worst case scenario

- If indicated that between numbers, round down to the lowest answer as this is the worst case scenario for this section

For example:



If a participant indicates between 3 and 4, select and enter 3 as this is the worst case scenario.

Section 9 (4/8/12)/ Section 10 (baseline):

- If more than one box has been ticked select the worst case scenario.

For example:

I am doing interesting things in my life

Strongly disagree □

Disagree □

Agree x

Strongly agree x

If a participant selects 'agree' and 'strongly agree', select and enter 'agree' as this is the worst case scenario.

Section 10 (4/8/12)/ Section 11 (baseline):

- If medication table is empty, refer back to Section 4 (4/8/12 months)/ Section 5 (baseline): Q2 – over the last 4 weeks on how many days have you used pain killers or triptans for your headaches/migraine:
    - If ≥ 1 save as unobtainable data
    - If 0 save as clean
- If dose/number of times daily/number of days used is given as a range or 'up to x' take highest value as worst-case scenario
- If number of times daily given as 'every x hours', calculate for 24 hours. E.g. 'every 6h' would be entered as 4.
- If example row with paracetamol is edited, enter as seen
- When dose is given as a multiple, e.g. 'paracetamol 2 x 400mg' enter number with dose:
  E.g. Medication: Paracetamol 400mg, Usual dose: 2
- Any further errors, enter as seen or confirm with health economist

Section 11 (4/8/12)/ Section 12 (baseline):

- If ticked 'No' but further information is given in the table, change to 'yes' and enter
- If the usual dose or number of times daily has a double entry for example 1 – 2 take the worst case scenario which would be the higher number – 2.

Q1.2 –

- If name of hospital not given, enter as 'hospital'
- If Private/NHS not circled but information given, assume and enter as 'NHS'

Q2.2 –

- Ticks in table to be entered as 1 (number of visits)
- GP phone appointment to be entered as a visit

Q3.3 –

- If a cost is given but no tick, change to 'Yes' and enter

Q4.1 –

- If number of days lost given in month, take one month to be 30 days and calculate
- Income lost given as 'N/A' or – or x, enter as 0
- If a range is given, take higher value as worst case scenario
- If half days given, round up to nearest whole number, e.g. if 'half a day' is given enter as 1
- If unemployed or N/A is written, enter as 'No'

Section 12 (4/8/12)/ Section 13 (baseline):

Q 2.2 -

- If ticked but not included number of visits, leave the number of visits entry blank (i.e. missing). There should be a data entry variable indicating whether they ticked yes or no to each resource use variable in the table on page 23.
- If they entered number of visits but no tick, we should assume they forgot to tick and enter a yes for that resource use variable.
- If participant tick that the service has been used and tick in the number of visits box then the number of visits equals 1.

Q4.1 –

- The database only lets whole numbers be entered for income lost, round to the nearest whole number.
  For example:
  £1.50, round up to £2.00
  £1.40 round down to £1.00
- If nothing ticked but 'N.A'/'retired'/'unemployed' written, enter as 'No'
- If number or days lost given as 'all' enter as 120 (4 months x 30 days)

12 Month GP Data Collection:

The GP data collection is tracked on a spreadsheet titled '12 Month Follow Up Data – Sites V2.0' which can be found in the following location:

M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\9) Data Collection\11. 12 month follow up Data Collection

GP Data Collection – WCTU staff

Participants have consented for the study team to have access to their medical records where relating to headache/migraines for the purpose of collecting data on healthcare use and medications. The data collection is completed 12 months post randomisation, and prior to collecting data from a practice consent forms and withdrawals for all participants **must** be checked as they can participate in the study and not consent to medical data being collected.

A tracker for the GP data collection can be found in the following location on the M: Drive –

M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\9) Data Collection\11. 12 month follow up Data Collection

It is an Excel spreadsheet titled *'12 Month Follow Up Data'.*

Any staff completing data collection must have an up to date, valid research passport.

When completing data collection from a practice using the EMIS system please use the working instruction titled 'CHESS 12 Month Follow Up Data Collection – EMIS' and when collection data from a System One practice use the working instruction titled 'CHESS Medication Reports – System One'. Both of these can be found in the following location on the M: Drive - **M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\14) Trial Specific Working Instructions\16.1 Copies of Trial Instruction Docs\Data Management Plan\2) Working Instructions**

When completing data collection the CRF '12 Month Data Collection CRF_V1.4_21.06.2019' should be used, this can be found in the following location on the M: Drive -

M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\9) Data Collection\11. 12 month follow up Data Collection\12 Month Data CRF

When returned to the office this should be stored in the CHESS office cupboard until ready to be entered onto the online application.

The electronic medication reports should be saved on the M: Drive in the following location: **M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\9) Data Collection\11. 12 month follow up Data Collection** in a folder with the sites name. The medication information should then be copied over onto the '*Master list of medications'* which is kept in a file with the same name, in the same location as the medication reports.

GP Data Collection – Remote data collection

For practices where two or less participants have consented we have a letter and CRF to send to the practice to request they complete the data collection CRF. The date the letter and CRF are sent should be recorded on the Excel spreadsheet titled *'12 Month Follow Up Data'.*

Due to lockdown and COVID-19, we are now unable to visit any practices, and all remaining GP data collection will be done remotely. Practices are contacted and asked if they are willing to complete the form, and then a time is arranged for the PID of each participant to be given over the phone. The date the email is sent and the PID is given should be recorded on the Excel spreadsheet titled '12 Month Follow Up Data'. A member of staff at the practice will then complete the Remote Data Collection CRF and scan to email to chess@warwick.ac.uk and checked upon receipt. All electronic CRFs received will be saved to the M:Drive (Location: M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\9) Data Collection\11. 12 month follow up Data Collection).

We are currently still in the process of sending out the first remote data collection CRFs and will update the DMP in time when we know how well this process is working. We appreciate that there could be difficulties in practices completing the CRF or not returning at all. We will review the processes at the end of January 2020 and update the DMP accordingly.

Data Checking:

% checking that will be carried out:

- When a new member of staff is trained to complete data entry 100% of the first ten forms they enter will be checked. Triggers for further training are documented below.

- A 10% data check of all data entered in a month will be completed at the end of each month, the statistician will email to the TC/TM a list of forms to be checked.

Who will do the checking and when:

- Data checking will be completed by an available member of the team who has not entered the forms. In most instances this will be the TC or TM.

- Regular monthly data checks will be completed by the TC or TM, in the absence of the TC/TM the Quality Assurance team may be asked to assist.

- The results of the data check are saved in the following location on the M Drive - **M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\9) Data Collection\7. Data Checking**

- A working instruction for the completion of the monthly data check can be found in the following location on the M: Drive - **M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\14) Trial Specific Working Instructions\16.1 Copies of Trial Instruction Docs\Data Management Plan\2) Working Instructions**

Triggers for further training:

- A 5% error rate or above would trigger a further 10% sample to be checked, if the error rate is 5% or greater again then this would be a trigger for retraining.
- If retraining required then a 100% check of all data entered would be required.

Suggested items for training:

- If the error rate is consistently 5% or higher as detailed above the TC/TM will provide additional training on the relevant CRF.

- 100% of the first forms will be checked to ensure an acceptable error rate.

Training plan:

- Training will include CTU induction plan, sign off all relevant SOPs and include being trained by the relevant member of the team on entry of each study CRF as per the study data flow in figure one.

Competency sign off:

Competency sign off will be documented on the study specific training log in personal development folders, this will be when the error rate is an acceptable level for the first forms entered. This should be signed off by the TC/TM

Data Cleaning:

The study statistician will perform validation checks of the data on the database prior to DMC meetings and also before the final data lock. These checks will include range checks, date checks, missingness and querying any outliers or unusual looking data.

The study statistician will perform validation checks of the data on the database prior to DMC meetings and also before the final data lock. These checks will include range checks, date checks, missingness and querying any outliers or unusual looking data.

Once the checks are completed, the study statistician will provide a list of queries to the Trial Co-ordinator/Trial Manager to resolve. The TC/TM will keep a log of the queries and, once they have been resolved, the study statistician will be notified. The data on the database with the resolved queries can then be locked for analysis.

Medications

Medications that are reported by participants were reviewed by Professor Martin Underwood and Professor Manjit Matharu for drugs used to treat headache attacks or used for migraine/headache prophylaxis either within licensed indication or used off-licence for this purpose. This included drugs used outside of NICE guidance Drugs and drugs without a product licence for use in the UK.

A consensus approach was used for which drugs to include. Those drugs that were not an obvious misspelling of a drug used for headache treatment of other drugs not falling within groups of drugs used to treat migraine were excluded from classification

Drugs were classified in to two levels of drug group and type (prophylaxis/treatment) All relevant medications were therefore standardised on the 'medications master sheet '(**Location: M:\WMS\CTU\Rehabilitation\ CHESS\2) MAIN RCT\14) Trial Specific Working Instructions\16.1) Copies of Trial instruction Docs/Data Management Plan)** which will be used for analysis and not directly match what is entered onto the online application.

Quality Control:

CHESS Education and Self-management Intervention:

Quality control of the CHESS study intervention took place as per the QC protocol which can be found in the following location on the M: Drive - **M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\Intervention\6. QA Protocol**

Shilpa Patel (Senior Research Fellow) is responsible for the QC of the study intervention.

Data Deletion:

Deletion of identifiable data.

In the following instances patient/participant identifiable data should be deleted from the study records both the online application and paper records.

1. Patient returned expression of interest form – never answered the phone to complete eligibility call.

2. Patient was sent baseline pack – never received completed consent form back at study office *'pending consent'.*

3. Patient returned incomplete consent form – unable to make contact to confirm the missing details.

4. Patient returned the consent form – too late to be randomised to local group.

5. Patient returned the consent form – changed mind and no longer wishes to take part in the study.

6. Patient returned consent form – never answered the phone to complete nurse telephone classification interview.

7. Patient returned consent form – was classified by the nurse/NMC too late to be randomised for their local group and could no longer participate.

8. Withdrawal – participant no longer wishes to be in the study following randomisation.

For **situations 1 - 6** above there are letters which should be sent to the patient to confirm that their data will be destroyed from the study records. The letter templates can be found in the following location on the M: Drive:

M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\3) Information for Participants\21. Letters of Acknowledgement

The letter should be sent to the participant, the participants records will then be kept on file for **one month** from the date the letter is sent to ensure the relevant details are available should the patient call the office with any queries/complaints. Following this one month period if no contact has been received then the records should be deleted as described below.

For **number 7** in the list above participants who are classified too late to be randomised to their local group should always be offered an alternative group. If they are unable to attend an alternative group they should still be provided with the classification information following the interview. They should be notified via telephone that as there are no further groups they will not continue with the study and be randomised and thanked for their time to date. This call should be logged on the Participant Tracker under the 'Will not be rando' tab. The GP

should also receive a copy of the headache classification information with an accompanying note to explain that the patient will not be randomised.

For **number 8** participants who wish to completely withdraw from the study **and** request for their data to be deleted. These requests need to be sent to the Information Data Compliance (IDC) Team as 'a right to erasure' request. The request should be emailed to infocompliance@warwick.ac.uk. The IDC team will liaise with the requester and WCTU to ascertain whether we can comply with the request

Process for deleting data:

To be completed one month after letters notifying patients of data deletion have been sent. When data is deleted from the online application this should be documented in a study file note and recorded on the participant tracker under the tab 'Data Deletion notifications'.

When redacting participant personal information please use a specific redacting pen.

Data should be deleted from the following forms:

Form	Data Fields	Deleted/ Redacted	Location
Expression of interest form.	Identifiable data fields including: Title / First Name / Surname House name or number / street name / town or city / postcode / email / landline Tel number / mobile Tel number / date of birth	Redacted	Online application. Paper record to be destroyed (shredded or removed via confidential waste).
Consent form	Name & signature.	Redacted	Paper record to be destroyed (shredded or removed via confidential waste).
Eligibility CRF	Initials	Redacted	Paper record to be destroyed (shredded or removed via confidential waste).
Baseline CRF	All data provided	Deleted	Online application & paper record to be destroyed (shredded or removed via confidential waste).
Nurse/ Doctor Classification CRF	Initials	Initials should be redacted	Online application & Paper record to be destroyed (shredded or removed via confidential waste).

Online Application:

- To be requested by the system owner (trial manager).

- Place a request with the programmers to remove identifiable data **only** from the online application. The TNO number and a record of the forms completed should remain for reporting purposes, for example to record an EOI form was received delete the personal data only and not the complete record.

- The requests will be acknowledged via an email receipt from the IT helpdesk these receipts should be saved on the M: Drive in the following location: **M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\9) Data Collection\12. Data Cleaning\Data Clean Requests to programmers**

- Similarly when the IT Helpdesk sends a receipt to confirm the data deletion request has been actioned this should also be saved in the above location on the M: Drive.

Paper Records:

Once confirmation is received from IT Helpdesk that the data has been deleted from the online application the paper records should be redacted or destroyed as detailed

- **Expression of Interest Forms**: Paper record to be destroyed (shredded or removed via confidential waste).

- **Consent Forms:** Paper record to be destroyed (shredded or removed via confidential waste). When the forms have been destroyed a file note should be created to detail the date the data was redacted/destroyed confirming the reason and referencing the relevant section of the data management plan.

All other anonymised CRFs should be kept on record once redacted and the information has been removed from the CHESS application.

If randomisation never took place the baseline data should be destroyed and removed from the online application so that no data can be analysed for the study.

Data Lock:

Following TMG on 21st November 2019 it was agreed that the target to complete data entry by was July 2020. The data clean will follow in August 2020; with the aim of a data lock taking place at the beginning of September 2020.

Procedures for dealing with identifiable data:

Encryption Controls:

The following folders on the M: Drive are encrypted using PGP. Currently the Trial Manager has admin access to these. Access is reviewed on a quarterly basis is signed/verified by the Trial Manager printed and saved in the study TMF.

Folder Name	Folder contents	Folder Location
CHESS1	Audio recordings from group interventions	M:\WMS\CTU\Rehabilitation
Nurse Classification Interview Transcripts	Feasibility study nurse telephone classification interview recordings.	M:\WMS\CTU\Rehabilitation\CHESS\1) Feasibility Study\11. Data Collection\Nurse Classification Interview Transcripts
Facilitators	Main RCT Facilitator details including research passports/CVs/GCP, etc.	M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\Intervention\1. Facilitators
CHESS Resource Account Access	Names and email address of staff who have access to the CHESS Resource Outlook account.	M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\7) Monitoring\9.6 Internal QA Monitoring\CHESS Resource Account Access
Smartphone App Summary/Sent Summary Templates	Smartphone App summaries sent to participant. Includes TNO and results from smartphone app completion.	M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\3) Information for Participants\22. Smartphone APP Summary\Sent Summary Templates
Data	Names/Addresses of randomisation participants used to complete mail merge to send out the GDPR Transparency Statement.	M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\9) Data Collection\Data

Pseudonymisation:

All study participants are assigned a unique study identifier which is three letters followed by three numbers e.g. CTU001. The letters are unique to the GP practice. TNOs are generated by the programming team prior to mail outs from GP practices full details can be obtained from the programming FRS.

Physical access:

Study data is stored in two separate locations.

Pseudonymised data is stored in the WCTU archive room in a locked study cupboard.

Identifiable data is stored in the locked cupboards of the study office (currently T0.14) at WCTU.

On the CHESS online application is both identifiable data as well as study data, the study team are compliant with the unit policies for clear screens and desks.

Email deletion:

To be confirmed.

Redaction procedures:

Any identifiable data received on either a study CRF, Questionnaire or other paper format should be redacted using a specific redaction pen. This should be checked by a colleague once redacted to confirm that the details cannot be seen.

If the paper document, for example a printed email does not have the TNO on please ensure to add this in green ink pen.

Data Transfer / Sharing:

To be confirmed, pending data sharing agreement with QMUL.

Data Storage / Filing:

To be confirmed, pending data from QMUL.

Document Name	Location to be filed	Security	File Naming Conventions	Order	Responsibilities	Timelines
Expression of Interest – Green / Interested	Locked cupboard – T0.14					
Expression of Interest – Red / Not Interested	Archive Room					
Eligibility Form 1	Archive Room					
Eligibility Form 2	Archive Room					
Consent Form – Main RCT	Locked Cupboard – T0.14					
Consent Form – Interview Study	Locked Cupboard – T0.14					
Nurse Classification Form	Archive Room					
Doctor Classification Form	Archive Room					
Randomisation Form	Archive Room					
AE Form Initial	Archive Room					
AE Form Reminder	Archive Room					

SAE Form Initial	Archive Room					
SAE Form Reminder	Archive Room					
GP Transfer Form	Archive Room					
Withdrawal Form	Archive Room					
Notification of Death Form	Archive Room					
Self-Referral Form	Archive Room					
Intervention Attendance Form	Archive Room					
Intervention Attendance Form – Clinical Record	Archive Room					
Intervention Telephone Follow Up Form	Archive Room					
Baseline Questionnaire	Archive Room					
4 Month Questionnaire	Archive Room					
8 Month Questionnaire	Archive Room					
12 Month Questionnaire	Archive Room					

Safety Reporting and Non-compliance:

Safety Reporting:

Non-compliance:

For the reporting of Non-compliance please refer to working instruction 13) Non-compliance process which can be found in the following location on the M: Drive - **M:\WMS\CTU\Rehabilitation\CHESS\2) MAIN RCT\14) Trial Specific Working Instructions\16.1 Copies of Trial Instruction Docs\Data Management Plan\2) Working Instructions**

The process for reporting non-compliance can be seen in the flow diagram below:

In the first instance the Trial Manager is responsible for identifying and reporting Non-compliance. In the Trial Managers absence this should be covered by the study Trial Coordinator / Team.