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1 **Title**

2 Chronic Headache Education and Self-management Study (CHESS) – a mixed method feasibility study
3 to inform the design of a randomised controlled trial

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45 **Abstract**

46 Background

47 Self-management support programmes are effective in a range of chronic conditions however there
48 is limited evidence for their use in the treatment of chronic headaches. The aim of this study was to
49 test the feasibility of four key aspects of a planned, future evaluative trial of a new education and self-
50 management intervention for people with chronic headache: 1) recruiting people with chronic
51 headache from primary care; 2) a telephone interview for the classification of chronic headaches; 3)
52 the education and self-management intervention itself; and 4) the most appropriate patient reported
53 outcomes (PROMS).

54

55 Methods

56 Participants were identified and recruited from general practices in the West Midlands of the UK.
57 We developed a nurse-led chronic headache classification interview and assessed agreement with
58 an interview with headache specialists. We developed and tested a group based education and self-
59 management intervention to assess training and delivery receipt using observation, facilitator, and
60 participant feedback. We explored the acceptability and relevance of PROMs using postal
61 questionnaires, interviews and a smartphone app.

62 Results

63 Fourteen practices took part in the study and participant recruitment equated to 1.0/1,000
64 registered patients. Challenges to recruitment were identified. We did 107 paired headache
65 classification interviews. The level of agreement between nurse and doctor interviews was very
66 good. We piloted the intervention in four groups with 18 participants. Qualitative feedback from
67 participants and facilitators helped refine the intervention including shortening the overall
68 intervention and increasing the facilitator training time. Participants completed 131 baseline

69 questionnaires, measurement data quality, reliability and validity for headache-specific and generic
70 measures was acceptable.

71 Conclusion

72 This study indicated that recruiting people with chronic headache from primary care is feasible but
73 challenging, our headache classification interview is fit for purpose, our study intervention is viable,
74 and that our choice of outcome measures is acceptable to participants in a future randomised
75 controlled trial (RCT).

76 Trial Registration: ISRCTN, ISRCTN79708100. Registered 16th December 2015,
77 <http://www.isrctn.com/ISRCTN79708100>

78

79 **Key words**

80 chronic headache, feasibility study, self-management, recruitment, outcome measures, primary care

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96 **Background**

97 Self-management support programmes have an established place in the management of a range of
98 chronic diseases (1), however evidence for self-management programmes for use in chronic
99 headaches disorders is currently limited(2). The National Institute for Health Research (NIHR) funded
100 a programme of work (RP-PG-1212-20018) to develop, and test, a non-pharmacological approach for
101 chronic headache using education and self-management. NIHR programme grants fund research for
102 conditions that cause substantial disease burden and usually consist of ‘an interrelated group of high
103 quality projects focused on a coherent theme, requiring multidisciplinary approaches, including
104 clinical, health economics, statistics, qualitative and behavioural sciences, to ensure that research
105 objectives can be met’. (3) Here we report the findings from a feasibility study we completed as part
106 of our programme of work in preparation for a randomised controlled trial (RCT) evaluating the
107 effectiveness of the intervention.

108 We wanted to test the feasibility of four key aspects prior the planned trial. Firstly, we wanted to test
109 the feasibility of recruiting people with chronic headache from primary care and estimate the
110 population base needed to recruit enough participants for the trial. Nearly a fifth of trials in 2011 were
111 terminated for not meeting sufficient recruitment targets, and therefore unable to answer their
112 research questions meaningfully (4).

113 Secondly, we needed to be able to classify common chronic headaches in participants identified from
114 primary care. Specifically we wanted to test the feasibility of using a telephone classification interview
115 that can be used by a non-headache specialist to classify the common chronic headache disorders:
116 chronic migraine, chronic tension type headache (TTH) and medication overuse headache (MOH).
117 Many people with chronic headache disorders do not have an accurate diagnosis and receive
118 inappropriate treatment of their headaches (5). We wanted the classification interview to allow
119 classification of headache type for both reporting and analysis purposes and to be used as part of the
120 study intervention to allow targeted, individualised, treatment and advice. A systematic review failed

121 to identify a simple classification tool fit for our purpose, we therefore needed to develop and validate
122 a tool which can be used by a non-headache specialist to classify common chronic headache
123 disorders(6).

124 Thirdly, we wanted to test the feasibility of developing and delivering the education and self-
125 management support intervention for the management of common chronic headache disorders and
126 examine the acceptability of the intervention to participants. Evaluations of complex interventions
127 can be undermined by problems of acceptability, compliance and delivery of interventions(7).

128 Finally, we wanted to test the quality, acceptability and appropriateness of patient reported outcome
129 measures (PROMs) for the trial. The selection of appropriate outcomes is crucial to the design of a
130 trial and outcomes need to be relevant to people with chronic headaches(8). A systematic review of
131 the quality and acceptability of patient-reported outcome measure highlighted the paucity of good
132 quality PROM evaluations in this population and the limited focus on measurement relevance and
133 acceptability to end-users, that is, people with headache(9). We therefore wanted to understand
134 which outcomes are important and relevant to people with chronic headache, a population who are
135 often young adults with work and family commitments. Additionally, electronic diaries have shown to
136 be acceptable to participants and may have the advantage of reducing recall effects (10, 11); we
137 wanted to test the feasibility of using a smartphone app to collect weekly data on headache frequency,
138 duration and severity.

139

140 **Methods**

141 This feasibility study was designed to determine what can be done, what should be done and how it
142 can be done well for a future RCT(12). It was a mixed method study to test and evaluate the
143 feasibility of a newly developed education and self-management intervention for chronic headaches,
144 future trial recruitment methods and the most appropriate outcome measures. It included, in
145 addition, an embedded reliability study for the classification of headaches disorders, reported in

146 more detail elsewhere(13). The components of the feasibility study are shown in Figure 1. We did
147 not conduct a full pilot trial but chose to test the feasibility of four crucial components of the main
148 randomised controlled trial due to the complexity and importance of each of these components.
149 The study ran from January 2016 to April 2017.

150

151 ***Patient and public involvement***

152 Patient and public involvement (PPI) was built into the key stages of the feasibility study to ensure
153 that the research focused on issues that were important and relevant to patients and the public(14).
154 At the start of the study we established a lay advisory group of people with chronic headache to
155 work with collaboratively. We identified members of the group from Universities/User Teaching and
156 Research Action Partnership (UNTRAP) at the University of Warwick and sent out an advert to our
157 three partner headache groups: Migraine Trust, Migraine Action and National Migraine Centre (In
158 2018 Migraine Action merged with Migraine Trust). The CHES Lay Advisory Group specifically
159 supported our application for ethical approval for the study, development of the headache
160 classification interview, development of the study intervention and the choice of patient reported
161 outcome measures.

162

163 **1. Feasibility of recruiting people with chronic headache from primary care**

164 The aim of this part of the study was to test the feasibility of our recruitment procedures and recruit
165 a sample of participants to test the telephone headache classification interview, to pilot the
166 education and self-management intervention, and to test the feasibility and the outcomes
167 measures.

168 *Setting*

169 We aimed to recruit patients with chronic headache registered with general (family) practices in the
170 West Midlands region of the UK. We ran the study in three clinical commissioning groups (CCGs) in
171 the West Midlands which cover urban, small town and semi-rural areas with varying levels of
172 deprivation and ethnic diversity. We initially ran the study in five Clinical Research Network (CRN)
173 West Midlands South 'host practices' with extensive research experience. Subsequently we
174 purposively selected additional practices to maximise diversity and to fill groups for the pilot
175 intervention. We sought feedback via email using a short structured questionnaire from a small
176 sample of General Practitioners (GPs) from the participating practices to explore their experience of
177 taking part in the study.

178 *Participants*

179 The eligibility criteria for the feasibility study were:

180 *Inclusion Criteria:*

- 181 1) Aged ≥ 18 years with chronic headache; defined as headache for 15 or more days per
182 month for at least three months.
- 183 2) Able and willing to comply with the study procedures and provide written consent.
- 184 3) Fluent in written and spoken English.

185

186 *Exclusion Criteria:*

- 187 1) Has an underlying serious psychiatric or psychological disorder that precludes
188 participation in the group intervention.
- 189 2) Known secondary cause of headache other than medication overuse headache; e.g.:
190 primary or secondary brain tumour.
- 191 3) No access to a telephone.
- 192 4) Currently participating in another clinical trial (with an unregistered medicinal product),
193 or less than 90 days have passed since completing participation in such a trial.

194

195 The recruitment process to identify people for the study involved a standardised electronic search
196 for general practice databases using Read-codes (15). Initial scoping work indicated this standard
197 clinical terminology system for coding chronic headache was rarely used, we therefore devised a
198 search strategy to identify patients aged ≥ 18 years who had consulted with headache (migraine, TTH
199 and medication overuse headache) or had been prescribed migraine specific drugs (i.e. triptans,
200 pizotifen) in the preceding 12 months. GPs then screened the list for patients it would be
201 inappropriate to approach e.g. poorly controlled serious mental illness, terminal illness, or known
202 secondary causes of headache other than medication overuse headache

203 Potentially eligible patients were invited to participate in the study by a letter from their GP which
204 also included a patient information leaflet informing them about the study. We also designed a
205 study poster for display in patient waiting areas. People interested in the study were invited to
206 contact the study team and asked the following questions to confirm eligibility:

- 207 1. On average how many days in the month do you get headaches?
- 208 2. How long have you been having your headaches this frequently for?
- 209 3. Has this been for at least the last three months?
- 210 4. Are you currently taking part in a drug trial?

211 Patients who met the eligibility criteria were informed that they would be asked to complete two
212 telephone headache classification calls (one by a nurse the second by a headache specialist doctor)
213 and that they may be invited to attend the education and self-management programme and/or take
214 part in the interview study. Potential participants also had the opportunity to have any questions
215 answered regarding the study.

216 Baseline packs were sent to people who were eligible and interested in the study, they included a
217 consent form, a baseline questionnaire and a freepost return envelope. If necessary, a reminder
218 pack was sent after two weeks. All participants were asked to provide written consent to complete

219 postal questionnaires, a Smartphone App and the two telephone classification interviews. Study
220 entry was marked by receipt of the signed consent form.

221

222 *Sample size*

223 For the suite of work in the feasibility study we initially sought to recruit 170 people with chronic
224 headaches from primary care. The driver for this sample size was to have sufficient data to allow us
225 to assess the inter-rater reliability of the telephone classification interview when done by two raters;
226 namely a nurse, and a doctor experienced in headache management. We assumed level of
227 agreement to be 0.8, a substantial agreement(16). The initial sample size was based on measuring
228 the level of agreement for the classification of migraine (yes/no), TTH (yes/no) and MOH (yes/no).
229 Following our systematic review of diagnostic tools and our classification consensus meeting, the
230 outcomes from the classification changed to measuring the level of agreement in the classification of
231 definite chronic migraine, probable chronic migraine and chronic TTH as well as presence or absence
232 of MOH as a nominal scale. As the analyses changed from three pairwise comparisons to two
233 pairwise comparisons, the multiplicity adjustment also changed hence giving a revised sample size
234 target of 153 paired interviews which was approved by the programme steering committee and the
235 funder(17).

236 An initial pilot search suggested that around 30/1000 people registered with a GP consult for
237 headaches (acute, episodic or chronic) annually. Assuming that a third of these consulters had
238 chronic headaches and a quarter of these joined the feasibility study recruitment rate would be
239 2.5/1000 or 8.3% of those identified as consulting with headaches. Based on an average practice
240 population of 7,000 we estimated we needed 6-10 practices with a combined list size of 64,000
241 people to recruit our sample.

242

243 **2. *Feasibility of a telephone classification interview to classify common headache disorders***

244 We developed a telephone headache classification interview for use by a non-headache specialist to
245 classify chronic headache types for reporting and analysis purposes and that could also be used as
246 part of the study intervention to allow targeted treatment and advice. In brief, we did a systematic
247 literature review to identify any existing tools used to classify or diagnose different headache types
248 which was presented to delegates at a headache classification consensus conference attended by
249 headache specialists and people with chronic headache(6). At the consensus conference delegates
250 agreed what were the important questions to include in the classification interview. The
251 classification interview was not intended to have a rigid interview structure or set questions, instead
252 the person conducting the interview was encouraged to use a logic model to inform their clinical
253 reasoning and decision-making.

254 We aimed to test the feasibility of training nurses to use the classification interview to classify
255 chronic headache disorders and test the reliability of the tool. To validate the classification interview
256 we trained six nurses, all non-headache experts, to conduct the interviews. The training included a
257 one-day workshop delivered by a neurologist specialised in headache plus time with a member of
258 the study team to practice classification interviews using mock scenarios and a training manual.
259 Participants from the feasibility study were interviewed first by the nurse and later by a doctor from
260 the National Migraine Centre. The doctor classification was the assumed 'gold standard'. Participants
261 were classified into: definite chronic migraine, probable chronic migraine or chronic TTH (with or
262 without medication overuse) or 'other' headache type (other chronic primary headache or
263 suspected secondary headache). We measured level of agreement between the classifications by
264 nurses and doctors by using simple kappa statistics and prevalence-adjusted bias-adjusted kappa
265 (PABAK).

266 The development and evaluation of the telephone headache classification interview is described in
267 detail elsewhere (13).

268 3. ***Feasibility and acceptability of the education and self-management support intervention***
269 ***for chronic headache***

270 We developed the education and self-management intervention using the Medical Research Council
271 (MRC) framework for complex interventions(7). Development was informed by three systematic
272 reviews 1.prognostic factors in chronic headache (18), 2. education and self-management
273 interventions for chronic headache (19) and 3. the lived experiences of chronic headache. We drew
274 from the experience of a previously tested self-management intervention for chronic pain (20) and
275 we did qualitative interviews with people with chronic headache to inform the intervention design.
276 The qualitative interviews were with members of the charity Migraine Action to gain their views on
277 what was important to include in the education and self-management intervention. We held a
278 collaborative intervention design meeting, attended by headache specialist clinicians, headache
279 charity representatives, lay people with chronic headache, psychologists, and researchers.

280 The education and self-management intervention was intended to be delivered in a group format
281 (8-10 per group) facilitated by a nurse and a lay person (with chronic headache). Topics included in
282 the intervention were: understanding headache mechanisms, medication management, mood and
283 headache, recognising unhelpful thought patterns and behaviours, stress management, sleep
284 management, communication and mindfulness. The two and a half day programme used a range of
285 methods including: group discussions, sharing narratives and experiences, problem solving, watching
286 an educational DVD, role play and taster sessions. This was followed by a one to one consultation
287 with a nurse to classify their headache type and discuss medication, lifestyle factors and goal setting,
288 and up to eight weeks of telephone support.

289 The development of the education and self-management interventions is described in detail
290 elsewhere(21).

291 We aimed to test the feasibility of the new intervention by running four groups each with up to 10
292 participants in community settings. We approached people who lived within easy travelling distance

293 of proposed groups; participants provided written consent to attend the group intervention. We
294 wanted to recruit and train two lay people and three nurses to deliver the intervention. The
295 acceptability of the intervention was explored by conducting qualitative interviews with the
296 participants who attended the groups and the facilitators that delivered the groups. Thematic analysis
297 was used to identify common themes across the different components of the intervention.

298

299 **4. Feasibility of the patient reported outcome measures**

300 We proposed that our primary outcome measure for the RCT would be a headache-specific outcome
301 measure collected by postal questionnaire. We initially did a systematic review of the quality and
302 acceptability of patient reported outcome measures for episodic and chronic headache disorders(9),
303 and a qualitative review of the lived experience of chronic headache(22) to understand what
304 outcomes are important to people with chronic headache. This process supported the short-listing
305 of both headache-specific (Migraine-Specific Questionnaire v2.1(MSQv2.1) (23) and the Headache
306 Impact Test 6-item (HIT-6)(24) and generic measures (EuroQoL EQ-5D-5L)(25) and Short-Form 12-
307 item Health Status questionnaire (SF-12)(26) to include in the feasibility study. However, the
308 migraine-specificity of the MSQv2.1 (23) made it unsuitable for use with our chronic headache
309 population. Therefore, with permission from the developers, the target attribute of ‘migraine’ was
310 changed to ‘headache’ and the questionnaire renamed as the ‘Chronic Headache Quality of Life
311 Questionnaire’ (CHQLQv1.0). We evaluated both the acceptability and psychometric performance
312 (data quality, reliability, validity) of the modified measure against the HIT-6, EQ-5D-5L and SF-12 (24-
313 26), providing the first evidence for the performance of the CHQLQ and HIT-6 (24) in a UK population
314 and supporting selection for the RCT. Structured cognitive interviews were also conducted to
315 explore the acceptability and relevance of the measures. Informed by good practice guidance, the
316 interviews explored how responder’s made judgements when completing the PROMs, including
317 aspects such as question comprehension , recall and ease of completion(27, 28). The cognitive

318 interviews and their analysis was carried out by an experienced qualitative team with expertise in
319 this area.

320 *Data collection:*

321 All participants were asked to complete postal questionnaires with the selected measures CHQLQ,
322 HIT-6, SF-12 and EQ-5D-5L at baseline (the point of consent) and at two weeks and 12 weeks after
323 the baseline questionnaire was returned. The study team posted the questionnaire with a covering
324 letter and a freepost return envelope. After one week if the questionnaire had not been received a
325 reminder was sent and, one week following the reminder a telephone call would be made if the
326 questionnaire was not received.

327 A smartphone application (app) compatible with iPhones, iPads and Android devices was designed
328 by Clinvivo Ltd for use in the study. The app asked participants to complete three simple questions
329 regarding the frequency, severity and duration of the headaches they experienced. The questions
330 were developed with the involvement of the CHESS Lay Advisory Group. The app requested the data
331 to be completed weekly for up to 12 weeks and provided notification reminders for those who
332 accepted this option. A small number of participants were approached to test the app; these were
333 all participants who had recently agreed to take part in the study at the time the app was ready for
334 testing.

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341 **Results:**

342 **1. Feasibility of recruiting people with chronic headache from primary care**

343 *Practice recruitment*

344 We recruited 14 general practices with a combined practice population of 128,634 (range 3,300 to
345 16,886), see Figure 2. Feedback from the short structured email questionnaire to GPs indicated that
346 practices were mainly interested in the study because they felt a self-management programme
347 could potentially provide a useful alternative option for the management of patients with frequent
348 headaches.

349 *Participant recruitment*

350 Searches of general practice data bases identified 1827 potential participants (14.2/1,000 of
351 registered patients). GPs excluded 184 (10%) of these as inappropriate to approach. The remaining
352 1634 (1.3% of total list size) were invited to take part in the study. We received 586 (36%) responses,
353 of these 393 (24%) were interested in being contacted by the study team; 193 were not interested in
354 the study. We succeeded in contacting 361/393 (92%) often after numerous attempts to get hold of
355 people; of these potential participants 175 (48% of those contacted, 11% of those 1634 invited)
356 were eligible. We received valid consent forms from 75% (131/175) of eligible participants (8% of
357 those 1634 invited). Forty people failed to respond and four formally withdrew at this stage. We
358 recruited 1.0/1,000 of practice list size.

359 Participants mean age was 49 years (range 21-77, standard deviation, SD, 13.3). There were 108
360 (82%) female participants, 125 (95%) of white ethnicity and 86 (66%) in full or part-time
361 employment. About one third (n=47, 36%) left full time education between age 17 and 19, and
362 another third (n=44, 34%) left full time education after 20 years old (Table 1).

363

364

365

366 **Table 1: Participant demographics**

Feasibility sample (N=131)

Age (years)	N	128
	Mean (sd)	48.9 (13.3)
	Median (IQR)	49 (38.5,58)
	Missing	3
Gender	Male	21 (16 %)
	Female	108 (82 %)
	Missing	2 (2 %)
Ethnicity	White	125 (95 %)
	Black or Black British	2 (2 %)
	Asian or Asian British	1 (1 %)
	Mixed	1 (1 %)
	Other	1 (1 %)
	Missing	1 (1 %)
Employment	Employed (full or part-time including self-employment)	86 (66 %)
	Unemployed and looking for work	0
	At school or in full time education	2 (2 %)
	Unable to work due to long term sickness	3 (2 %)
	Looking after your home/family	11 (8 %)
	Retired from paid work	22 (17 %)
	Other	3 (2 %)
	Missing	4 (3 %)
Age left full time education	Did not receive formal education	0
	≤12	0
	13-16	35 (27 %)
	17-19	47 (36 %)
	≥20	44 (34 %)
	Still in full time education	3 (2 %)
	Other	1 (1 %)
	Missing	1 (1 %)

367

368 **2. Feasibility of the headache classification interview**

369 We trained six research nurses to conduct the telephone classification interviews. Feedback from the
370 training indicated that the nurses felt that the training workshop, opportunity to practice interviews
371 and the training manual prepared them adequately to carry out the classification calls and that they
372 gained confidence the more interviews they completed. Nurses and doctors from the NMC completed

373 111 and 108 headache classifications interviews respectively. There were 107 paired interviews.
374 Median days between interviews was 32 (interquartile range, IQR, 21 to 48 days). Proportion of
375 concordance of agreement between nurses' and doctors' interviews was 0.91, with moderate or very
376 good agreement on PABAK agreement in main and sensitivity analyses respectively. Full details of
377 these analyses are reported elsewhere(13).

378

379 **3. Feasibility of the education and self-management support intervention**

380 We approached 85 participants to pilot the education and self-management programme; we were
381 unable to contact 12 (14%) participants and 46 (54%) participants were unable to attend, reasons
382 included work commitments, dates being unsuitable, home life (including childcare) and holidays
383 (Figure 3), 27 (32%) expressed interest in attending the intervention and of these 18 (21 %) provided
384 written consent to attend a group.

385 We piloted the CHES intervention in four groups and with a total of 18 participants. The attendance
386 at groups ranged from 3-6 participants and 17 participants attended the one-to-one consultation
387 with the nurse. Qualitative interviews were completed with 12 participants using topic guides to
388 explore participants' experience of taking part in the intervention. On the whole the groups were
389 considered acceptable and participants found the educational and self-management components
390 useful and interesting and found the opportunity to meet with other people with chronic headache
391 particularly helpful. Based on participant feedback we removed the half day follow-up session
392 because participants found the time commitment too great and we included the sessions on
393 communication and managing setbacks at the end of day two of the programme.

394 Facilitators gave us feedback in a focus group or interviews with the use of topic guides, including
395 their experiences of delivering the intervention and the training received. They reported that they
396 did not find the two- day training adequate time to cover the delivery of the group intervention and
397 the headache classification and medication information for the one-to-one consultations. It was also

398 difficult for the lay facilitators to commit to delivering the intervention due to existing work and
399 family commitments and unpredictability of their own headaches.

400

401 **4. *Feasibility of the patient reported outcome measures***

402 Participants completed and returned 131 baseline questionnaires; 115 (88%) and 103 (79%)
403 questionnaires were returned at two and 12-week follow up respectively. Measurement data
404 quality, reliability and validity for the headache-specific and generic measures was reached at
405 acceptable standards (29, 30), supporting application of the measures with groups of patients with
406 chronic headache. Participants in the cognitive interviews (n=14) indicated items included in the
407 CHQLQ were comprehensive in scope and particularly welcomed those referring to the emotional
408 impact of headache, and found the measure easy to complete. The lack of recall period for the first
409 three items of the HIT-6 was a concern. The generic measures were considered to be acceptable.
410 In total eight participants downloaded the Smartphone App, participants completed the app for a
411 duration of up to 11 weeks. A telephone call was made to a selection of participants to check they
412 were happy using the app and although participants didn't report difficulties downloading or using
413 the app only one participant completed all 11 weeks of data collection and only four participants
414 completed half or more of the weeks.

415

416 **Discussion:**

417 One of the key objectives for the study was to test the feasibility of recruiting people with chronic
418 headache from primary care and estimate the population base needed to recruit enough
419 participants for the RCT. We successfully recruited 14 general practices to the study and feedback
420 from GPs suggested that an invitation to participate in a randomised controlled trial is likely to be
421 well received by general practices.

422 Recruitment to the study equated to around one per 1000 of the list size; this is comparable to
423 recruitment rates from general practice for other studies of chronic pain (20, 31, 32). It is, however,

424 substantially less than our pre-study assumptions. The number of people with headaches across our
425 pool of 14 practices was a little under half of that anticipated and the conversion rate of 7.1% from
426 identification to consent was slightly less than pre-study assumptions. The highest identification rate
427 was 18.3/1,000 ranging down to 8.1/1,000 (data not shown) suggesting that whilst there is great
428 variability in coding of headache in practices our initial scoping searches were erroneous. Our
429 conversion rate estimate was slightly optimistic and again there was a wide variability in conversion
430 rate by practice (3.3% to 9.4%, data not shown). Consequently a wide range in recruitment rate
431 (0.6/1,000 to 1.6/1000, data not shown). This means we under-recruited against our original target
432 and will need to recruit participants from over 100 practices for the RCT.

433 Overall we gained much useful information and experience from the recruitment processes for this
434 feasibility study and we have made some important changes to our approach for the main study
435 including allowing self-referral to the study from posters in pharmacies local to participating general
436 practices and word of mouth media exposure. Contacting a largely young working population was
437 challenging often requiring numerous attempts by telephone and email and a flexible approach to
438 contacting people outside usual working hours. Only 75 % of those eligible to take part returned
439 signed consent forms despite chasing.

440 We had also not fully anticipated the challenges of making paired headache classification calls
441 meaning we had data on fewer people than originally planned. Nevertheless we did obtain sufficient
442 data to evaluate the agreement between nurse and doctor interviews. Non-headache specialist
443 nurses were able to use our logic model to classify chronic headaches types and identify medication
444 overuse headache and the level of agreement with interviews by doctors specialised in headache
445 was good, giving us confidence in the classification interview in the RCT.

446 We successfully piloted the intervention in four groups and gained valuable feedback from
447 participants and facilitators. The length of the group intervention was reduced by half a day because
448 participants, found it hard to commit more time due to work and family commitments. Nurse
449 facilitators requested more training in order to feel confident in headache classification and

450 medication advice, and an additional day training has been added in the RCT. The group
451 intervention was originally designed to be facilitated by a health professional and lay person with
452 chronic headache, a model which has previously been successful for the delivery of group
453 interventions for chronic pain (20). Because of the unpredictability of their own headaches it was not
454 possible for the lay facilitators to commit to the role, and in the RCT the intervention will be
455 facilitated by a nurse and an allied health professional. Alongside the RCT we will run a process
456 evaluation to help understand how and if the intervention works. This will include collecting data on
457 group attendance and interviews with a sample of participants and facilitators to explore the
458 experience of delivering and receiving the intervention to inform any future roll out of the
459 programme.

460 The completion and follow up of postal questionnaires was good, and all measures were well
461 completed by responders at all time-points. Acceptable levels of data quality, reliability and validity
462 were found for all measures, supporting their use with groups of people and justifying selection for
463 the RCT. Participants indicated that the modified measure the Chronic Headache Quality of Life
464 Questionnaire was both comprehensive and comprehensible. We were able to test our Smartphone
465 App prior to the RCT in a small sample of participants, completion rates were poorer than
466 anticipated and strategies to improve level of completion will be implemented in the main trial.

467 The advice and support of PPI was integral to the intervention development and other aspects of the
468 feasibility study and the lay advisory group will continue their contribution into the main RCT.

469 The findings from the feasibility study have allowed us to be confident we are selecting the right
470 participants and have a viable intervention, and allowed us to make an informed choice about
471 outcome measures for the RCT. The feasibility study also identified challenges in recruitment of
472 participants with chronic headache from primary care and collecting patient reported outcome
473 measures that we have learnt from before starting the main trail.

474 The CHES RCT (ISRCTN 79708100) which commenced January 2017 will test the effectiveness and
475 cost effectiveness of the group education and self-management intervention compared with a best
476 usual care and a relaxation CD for people living with chronic headaches (ISRCTN 79708100).

477 **Conclusions:**

478 This study has demonstrated that recruiting people with chronic headache from primary care
479 requires a large pool of patients which means recruiting many general practices and a flexible
480 approach to contacting what is largely a young working population. We have developed and
481 evaluated a telephone headache classification interview that can be used by a non-headache
482 specialist to classify chronic headache disorders. We have provided essential evidence in support of
483 a newly modified headache-specific measure, for application alongside established headache-
484 specific and generic measures in this population. Despite our best efforts to involve lay people with
485 chronic headache in the delivery of the intervention it was difficult due to their own person health;
486 from a pragmatic stance the intervention was feasible when delivered by two health care
487 practitioners

488 **Abbreviations**

489	CHES	Chronic Headache Education and Self-management Study
490	CHQLQv1.0	Chronic Headache Quality of Life Questionnaire
491	GP	General Practitioner
492	HIT-6	Headache Impact Test 6-item
493	MSQv2.1	Migraine-Specific Questionnaire v2.1
494	MOH	Medication overuse headache
495	NIHR	National Institute for Health Research
496	PPI	Patient and public involvement
497	PROM	Patient Reported Outcome Measure

498 RCT Randomised Controlled Trial
499 SF-12 Short-Form 12-item Health Status questionnaire (
500 TTH Tension Type Headache
501 UNTRAP User Teaching and Research Action Partnership

502

503 **Declarations**

504 ***Ethics approval and consent to participate***

505 The study received Ethics approval from West Midlands – Black Country Research Ethics Committee
506 (15/WM/0165). Participants provided written consent to take part in the study.

507

508 ***Consent for publication***

509 N/A

510 ***Availability of data and material***

511 The datasets used and/or analysed during the current study are available from the corresponding
512 author on reasonable request.

513 ***Competing interests***

514 MU was Chair of the NICE accreditation advisory committee until March 2017 for which he received
515 a fee. He is chief investigator or co-investigator on multiple previous and current research grants
516 from the UK National Institute for Health Research, Arthritis Research UK and is a co-investigator on
517 grants funded by Arthritis Australia and Australian NHMRC. He has received travel expenses for
518 speaking at conferences from the professional organisations hosting the conferences He is a director
519 and shareholder of Clinvivo Ltd that provides electronic data collection for health services research.
520 Use of Clinvivo’s App for this study was specified in original application for funding. MU has had no
521 subsequent involvement in the tendering and contracting by University of Warwick and no

522 involvement in the service provision by Clinvivo Ltd related to this study. He is part of an academic
523 partnership with Serco Ltd related to return to work initiatives. He is an editor of the NIHR journal
524 series for which he receives a fee.
525 MM has served on the advisory board for Allergan, Medtronic, Novartis and Eli Lilly and has received
526 payment for the development of educational presentations from Medtronic, Allergan and
527 electroCore.
528 SP is a director of Health Psychology Services Ltd which in part provides psychological treatments for
529 those with chronic pain.

530

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535 ***Authors' contributions***

536 KW: acquisition and interpretation of data, study management and drafting of the manuscript

537 RP: study concept and design, acquisition and interpretation of data and drafting the manuscript

538 SP: study concept and design, acquisition and interpretation of data and critical revision of
539 manuscript

540 VN: study design, acquisition and interpretation of data and critical revision of manuscript

541 KH: study concept and design, interpretation of data and critical revision of manuscript

542 SWH: study concept and design, analysis and interpretation of data and critical revision of
543 manuscript

544 DM: study design, and analysis and interpretation of data and critical revision of manuscript

545 DC: study concept and design, interpretation of data and drafting of manuscript

546 SJT: study concept and design, interpretation of data and critical revision of manuscript

547 MU: project lead, study concept and design, interpretation of data and critical revision of manuscript

548 MM: study concept and design, interpretation of data and critical revision of manuscript

549

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References

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558 1. Taylor SJC, Pinnock H, Epiphaniou E, Pearce G, Parke HL, Schwappach A, et al. Health
559 Services and Delivery Research. A rapid synthesis of the evidence on interventions supporting self-
560 management for people with long-term conditions: PRISMS - Practical systematic Review of Self-
561 Management Support for long-term conditions. Southampton (UK): NIHR Journals Library

562 2014.

563 2. Carville S, Padhi S, Reason T, Underwood M. Diagnosis and management of headaches in
564 young people and adults: summary of NICE guidance. *BMJ*. 2012;345:e5765.

565 3. National Institute for Health Research Programme Grants for Applied Research 2018
566 [Available from: [https://www.nihr.ac.uk/funding-and-support/funding-for-research-studies/funding-
567 programmes/programme-grants-for-applied-research/](https://www.nihr.ac.uk/funding-and-support/funding-for-research-studies/funding-programmes/programme-grants-for-applied-research/)].

568 4. Carlisle B, Kimmelman J, Ramsay T, MacKinnon N. Unsuccessful trial accrual and human
569 subjects protections: an empirical analysis of recently closed trials. *Clinical trials (London, England)*.
570 2015;12(1):77-83.

571 5. Kernick D, Stapley S, Hamilton W. GPs' classification of headache: is primary headache
572 underdiagnosed? *The British journal of general practice : the journal of the Royal College of General
573 Practitioners*. 2008;58(547):102-4.

574 6. Potter R, Probyn K, Bernstein C, Pincus T, Underwood M, Matharu M. Diagnostic and
575 classification tools for chronic headache disorders: A systematic review. *Cephalalgia : an
576 international journal of headache*. 2018;333102418806864.

577 7. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating
578 complex interventions: the new Medical Research Council guidance. *BMJ (Clinical research ed)*.
579 2008;337.

580 8. Jafree DJ, Zakrzewska JM, Bhatia S, Venda Nova C. Accuracy of the painDETECT screening
581 questionnaire for detection of neuropathic components in hospital-based patients with orofacial
582 pain: a prospective cohort study. *The journal of headache and pain*. 2018;19(1):103.

583 9. Haywood KL, Mars TS, Potter R, Patel S, Matharu M, Underwood M. Assessing the impact of
584 headaches and the outcomes of treatment: A systematic review of patient-reported outcome
585 measures (PROMs). *Cephalalgia : an international journal of headache*. 2017;333102417731348.

586 10. Burton C, Weller D, Sharpe M. Are electronic diaries useful for symptoms research? A
587 systematic review. *Journal of psychosomatic research*. 2007;62(5):553-61.

- 588 11. Bolger N, Davis A, Rafaeli E. Diary methods: capturing life as it is lived. *Annual review of*
589 *psychology*. 2003;54:579-616.
- 590 12. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010
591 statement: extension to randomised pilot and feasibility trials. *BMJ (Clinical research ed)*. 2016;355.
- 592 13. Potter R, Hee SW, Griffiths F, Dodd K, Hoverd E, Underwood, et al. Development and
593 validation of a telephone classification interview for common chronic headache disorders. *The*
594 *Journal of Headache and Pain*
- 595 2019;20(2).
- 596 14. Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S, et al. GRIPP2 reporting
597 checklists: tools to improve reporting of patient and public involvement in research. *BMJ (Clinical*
598 *research ed)*. 2017;358.
- 599 15. Klasser GD, Manfredini D, Goulet JP, De Laat A. Oro-facial pain and temporomandibular
600 disorders classification systems: A critical appraisal and future directions. *Journal of Oral*
601 *Rehabilitation*.45(3):258-68.
- 602 16. Landis JR, Koch GG. The measurement of observer agreement for categorical data.
603 *Biometrics*. 1977;33(1):159-74.
- 604 17. Donner A, Eliasziw M. A goodness-of-fit approach to inference procedures for the kappa
605 statistic: confidence interval construction, significance-testing and sample size estimation. *Statistics*
606 *in medicine*. 1992;11(11):1511-9.
- 607 18. Probyn K, Bowers H, Caldwell F, Mistry D, Underwood M, Matharu M, et al. Prognostic
608 factors for chronic headache: A systematic review. *Neurology*. 2017;89(3):291-301.
- 609 19. Probyn K, Bowers H, Mistry D, Caldwell F, Underwood M, Patel S, et al. Non-pharmacological
610 self-management for people living with migraine or tension-type headache: a systematic review
611 including analysis of intervention components. *BMJ open*. 2017;7(8):e016670.
- 612 20. Taylor SJC, Carnes D, Homer K, Kahan BC, Hounsborne N, Eldridge S, et al. Novel Three-Day,
613 Community-Based, Nonpharmacological Group Intervention for Chronic Musculoskeletal Pain
614 (COPERS): A Randomised Clinical Trial. *PLOS Medicine*. 2016;13(6):e1002040.
- 615 21. Patel S, Sandhu H, Pincus T, Taylor SJ, Underwood M, Matharu M. Development of an
616 education and self-management intervention for chronic headache – CHES trial (Chronic Headache
617 Education and Self-management Study). *Journal of Headache and Pain*. 2018 (submitted).
- 618 22. Nichols VP, Ellard DR, Griffiths FE, Kamal A, Underwood M, Taylor SJC. The lived experience
619 of chronic headache: a systematic review and synthesis of the qualitative literature. *BMJ open*.
620 2017;7(12).
- 621 23. McKenna SP, Doward LC, Davey KM. The Development and Psychometric Properties of the
622 MSQOL: A Migraine-Specific Quality-of-Life Instrument. *Clinical drug investigation*. 1998;15(5):413-
623 23.
- 624 24. Kosinski M, Bayliss MS, Bjorner JB, Ware JE, Jr., Garber WH, Batenhorst A, et al. A six-item
625 short-form survey for measuring headache impact: the HIT-6. *Quality of life research : an*
626 *international journal of quality of life aspects of treatment, care and rehabilitation*. 2003;12(8):963-
627 74.
- 628 25. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and
629 preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of life research : an*
630 *international journal of quality of life aspects of treatment, care and rehabilitation*.
631 2011;20(10):1727-36.
- 632 26. Jenkinson C, Layte R. Development and testing of the UK SF-12 (short form health survey).
633 *Journal of health services research & policy*. 1997;2(1):14-8.
- 634 27. Haywood KL, de Wit M, Staniszewska S, Morel T, Salek S. Developing Patient-Reported and
635 Relevant Outcome Measures. In: Facey KM, Ploug Hansen H, Single ANV, editors. *Patient*
636 *Involvement in Health Technology Assessment*. Singapore: Springer Singapore; 2017. p. 103-20.

637 28. Hak T, Veer Kvd, Jansen H. The Three-Step Test-Interview (TSTI): An observation-based
638 method for pretesting self-completion questionnaires. 2008. 2008;2(3):8 %J Survey Research
639 Methods.

640 29. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, et al. Quality criteria
641 were proposed for measurement properties of health status questionnaires. Journal of clinical
642 epidemiology. 2007;60(1):34-42.

643 30. Streiner D, Norman G, Cairney J. Health Measurement Scales: A practical guide to their
644 development and use Fifth ed. Oxford: Oxford University Press; 2014.

645 31. United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial:
646 effectiveness of physical treatments for back pain in primary care. BMJ (Clinical research ed).
647 2004;329(7479):1377.

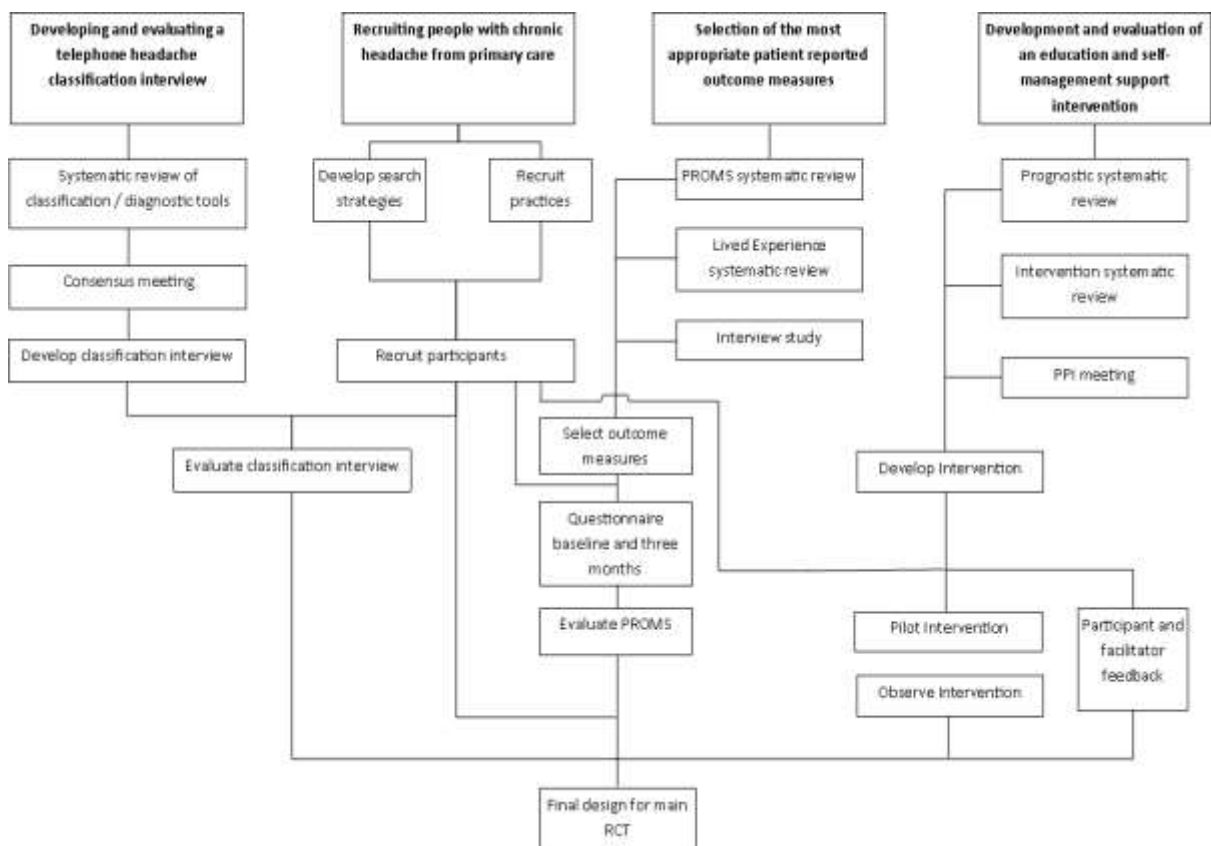
648 32. Lamb SE, Hansen Z, Lall R, Castelnuovo E, Withers EJ, Nichols V, et al. Group cognitive
649 behavioural treatment for low-back pain in primary care: a randomised controlled trial and cost-
650 effectiveness analysis. Lancet (London, England). 2010;375(9718):916-23.

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652

653 **Figures**

654 Figure 1 Components of the Feasibility Study



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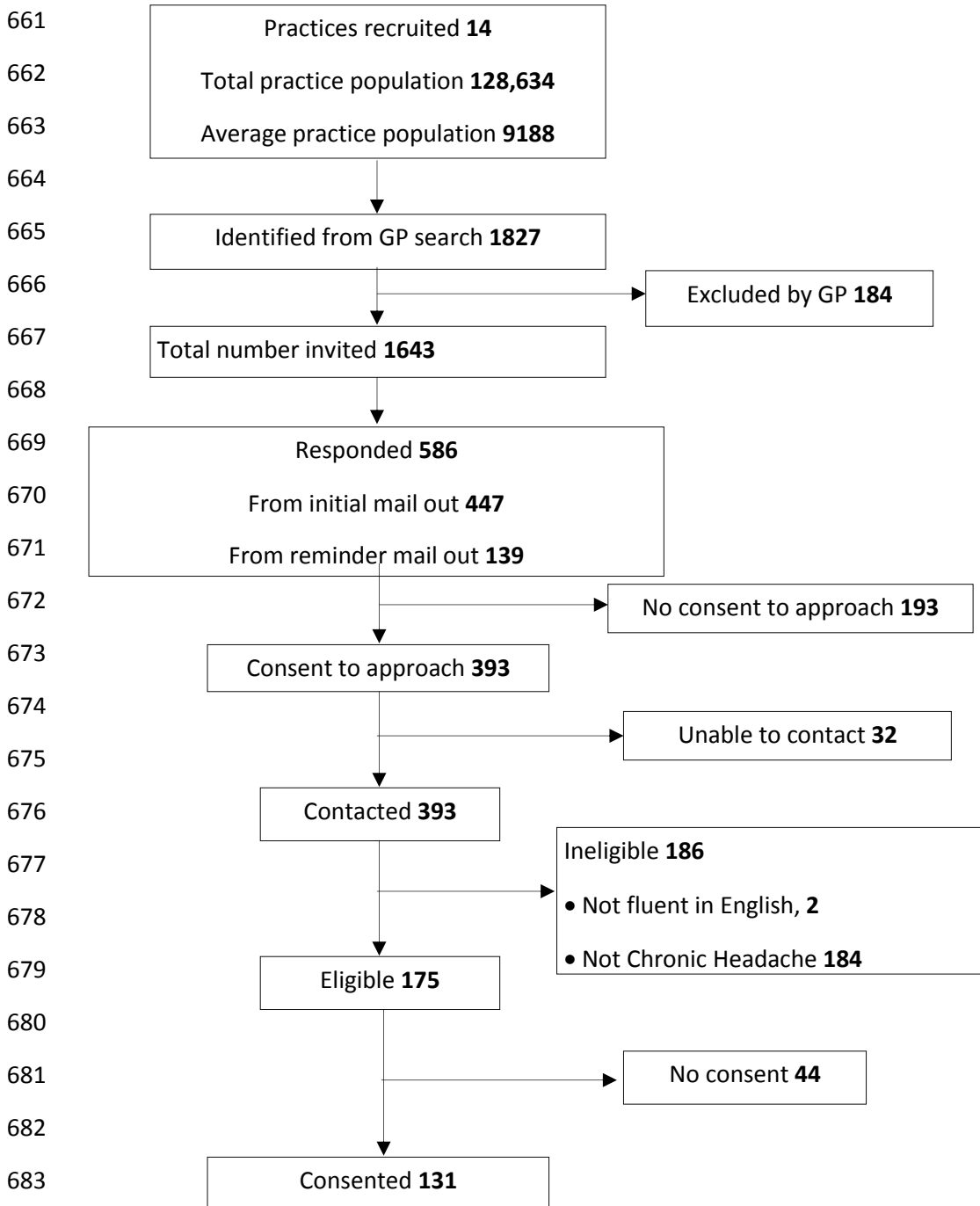
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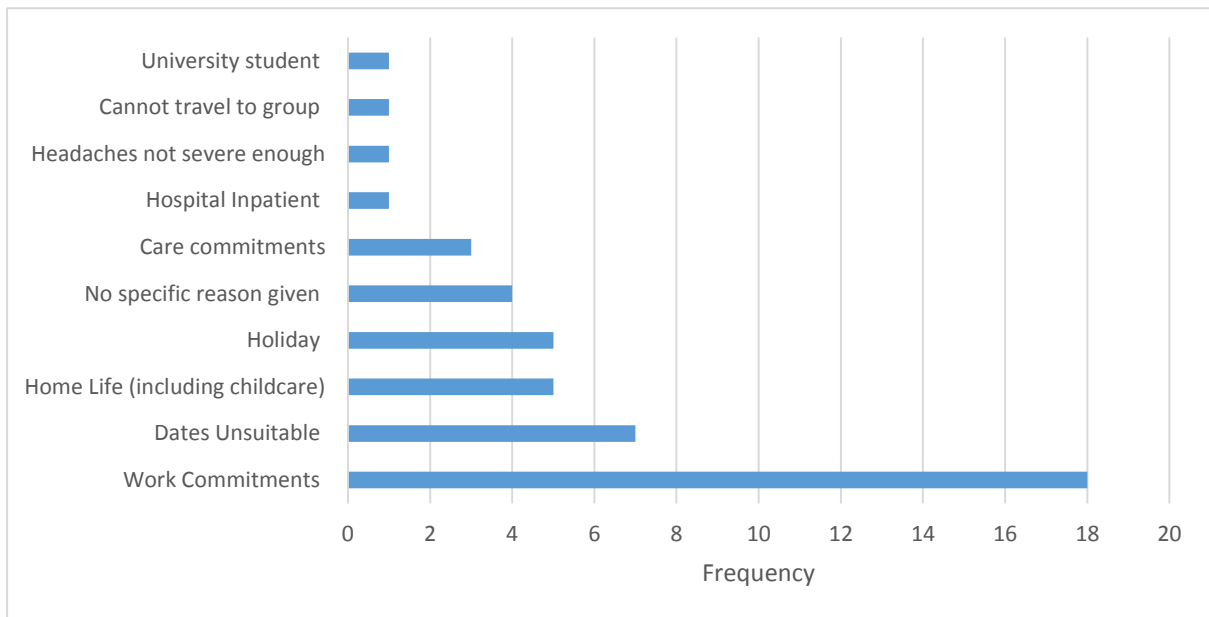
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660 Figure 2 Practice and participant recruitment consort chart



691 Figure 3 Reasons participants were unable to attend the group intervention

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