Appendix 16

An overview and summary of the CHESS randomised controlled trial process evaluation

Authors

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Full details of the process evaluation methods are available in the protocol paper (appendix 18). Before the clinical results were revealed we lodged the process evaluation results report, on Warwick Research Archive Portal (WRAP).[2] A separate paper reporting this work is being prepared for publication.

Methods

Data were obtained from trial records, interviews at four months (n = 9, control & n=17 intervention) and 12 months (n = 15, intervention participants), two focus groups with trial staff (11 Nurse facilitators and four AHP facilitators) and feedback from GP practices. We assessed fidelity of all two-day groups (where data were available) assessing audio-recordings of a random three individual sessions (from each group) within the two-days from the eight sessions which focussed on promoting behavioural change and self-management. We assessed both adherence (facilitator adhering to the protocol) and competence (how well was the session facilitated). Score sheets were used rating items within the sessions as being not evident (0), partially evident (1), and evident (2) these were summed, and a percentage produced.

Our process evaluation had the following components: context, reach, recruitment, dose delivered, dose received, intervention fidelity and participant, facilitators and GP experiences of involvement in the trial.[3, 4] We had a separate process evaluation team, working separately from those responsible for recruitment, intervention delivery, and outcome assessment. The process evaluation included the total randomised population (n=736).

Our aims were to assist in; the interpretation of the main results, and future implementation if the intervention proved effective.

Quantitative data was analysed using descriptive statistics and qualitative data analysed using the framework method.[5]

Results

Context, reach, and recruitment

We recruited from 164 general practices, with a median list size of 8,979 (IQR 5,760 to 11,986) across the Midlands and Greater London. We included practices based in all ten deciles of the Index of Multiple Deprivation, median 5 (IQR 2 to 8).[6] Minority ethnic groups made up 27% (SD 23.4) of these practices' populations compared to 14% in England and Wales.[7]

Reasons for not wanting to join the trial were obtained from 85 people who were approached as eligible. The predominant reasons given were that their headaches were not very bad at the time of recruitment or attending the headache self-management programme would take up too much of their time.

Dose delivered and Dose received

We delivered 42 two-day group sessions in a variety of venues proximate to our recruiting practices. Of the 380 participants randomised to the self-management intervention 228 (76%) attended sessions at least one session, 227 (79%) attended both days, and 261 (69%) took part in the one-to-one classification and advice session. Based on our a priori definitions of adherence (partial = day one plus one-to-one session, full = two sessions plus one-to-one) partial and full adherence was achieved by 261 (69%) and 217 (57%) respectively. Group sizes were smaller than originally planned with median actual group size on day one being 6.5 (IQR 5 to 9).

Intervention fidelity

We had 33/42 groups with recordings, with useable data on 90/99 sessions.

The facilitators' overall adherence score was 83% (IQR 67% to 100%) with several components achieving 100%. The two components achieving the lowest scores were 'managing setbacks' 63% (IQR 58% to 77%) and 'unhelpful thinking patterns and finding alternatives' 75% (IQR 72% to 87%).

The facilitators' overall competence score was 70% (IQR 50% to 90%). 'Acceptance of chronic headaches' scored the highest level 90% (IQR 65% to 95%). 'Impact of thoughts,

mood and emotions on headaches' scored 60% (IQR 60% to 80%) and 'communicating better with health professionals' scored 60% (IQR 50% to 80%).

A random 10% sample (n=27) of the case report forms completed as part of the one-to-one sessions were checked for 'completeness' . Overall, the sessions were fully completed, with participants being provided with the appropriate information and support as outlined in the CHESS protocol.

Participants' experiences

Control group (n=9)

Two interviewees were unable to recall the CHESS information they received. Those who recalled the information either felt it was useful as a reminder of what they already knew, provided new knowledge on medications or possible triggers, or they found it normalised or validated their headache experiences. Interviewees noted problems playing the CD and some would have preferred a phone App. Several couldn't find time in the day to devote time to relaxation, but others used it regularly and found it useful.

***Intervention group (n=17) Four-months post randomisation*.**

Participants were asked what they thought about different aspects of the intervention.

- **Would you recommend this course to others?**

Nearly all interviewees said that they would recommend the intervention. A few said it hadn't been useful for them but might be useful for others. A minority felt their venue was unsatisfactory. Problems identified included lighting, parking, and seating. The majority felt the groups were well run and were positive about the course delivery

- **The Group Experience**

All commented about being in a group, which almost all found a helpful and positive experience. Most valued discussion and sharing within the group. Contributing to the discussions and listening to others gave them new ideas and coping strategies. Some also felt that other people's experiences helped them to consider things from a different perspective. Around half liked the idea that they were with people in the same boat which gave a feeling of a shared experience of living with headaches. Around half spoke of comparing themselves to others within the group especially those who felt that their headaches weren't as bad. Around half said that attending the group had lessened feelings of isolation. A few people

felt that the group was more for those at work, one felt it was more for those who hadn't had headaches for long and one with tension headache noted there was more information about migraines than tension type headache.

Although the group sessions were well received. Some participants noted that the medication overuse headache session was not clear; they felt the facilitators struggled with it and it was a difficult concept to understand. Post study feedback questionnaires from 117 participants mirrored our interview responses

- **Relaxation and mindfulness CDs and DVD**

Interviewees from both arms of the trial commented on the CDs and DVDs. Views were mixed, with some using the relaxation and mindfulness resources and others not seeing any value in them. A number noted that they had no way of playing the discs, with some suggesting that technology has moved on, and that an App would have been better.

- **Smartphone App**

Interview participants reported this was easy to use but there were problems re-connecting with a new phone, forgetting to complete it if busy, and not being able to use the App on different devices.

- **One-to-one nurse sessions**

All felt that they had got something out of the one to one session with the nurse. Most valued the chance to discuss their medication, a few using this discussion as a springboard to see their GP to discuss possible changes. Some said they were confused about their headache classification. Several felt they had a mix of TTH and Migraine although their classification was given as migraine. Several liked the opportunity to talk about medication overuse headaches. A few spoke about the goals they set, although none had achieved their goals. One person felt that the support for goal setting was inadequate, and one felt this session wasn't useful as they had had the same conversation with other clinicians already.

- **Headache Diaries**

Most interviewees felt that the diaries were useful to identify patterns of headache frequency, duration, medication usage or possible triggers. Seeing these patterns written down made them reflect on their headaches and medication. Some said they didn't realise they had had that many headaches and that it was easy to lose track. Sometimes the frequency of medications was underestimated.

Telephone support

Around half of those who commented on the telephone calls felt they didn't need them, although they found it useful as a catch up on how they were doing. A few valued not being 'just left' after finishing the group and one-to-one contact.

Facilitator experiences

Facilitators said that more role play might have been beneficial during training, delays between training and delivering groups were problematic and they needed to do more preparation before each session than they had anticipated.

Facilitators found some sessions more challenging than others to deliver; acceptance, impact of thoughts mood and emotions on headaches, mindfulness and relaxation for headaches, medication management, and managing setbacks. They found that the medication overuse headache session was a difficult to deliver.

The nurses reported that during the one-to-one sessions that some participants were unhappy with their headache classification. Some believing it did not describe their headache and others did not believe the classification.

Impact – from 12 month interviews (N=15)

Responses were mixed, with some people seeking support to change medications and change how they think about their headaches and others who hadn't changed anything. Some were appreciative of the research, that their headaches were being taken seriously. Those who reported changing little following CHESS cited changes in family commitments, work, health issues and just general life as ongoing issues meaning that headaches whilst an ongoing problem were overlooked.

Conclusion

The process evaluation suggests that the CHESS study reached a diverse population across different geographical settings. Attendance reached our predefined dose, but many participants were not exposed to the intervention. The interventions were delivered with fidelity and generally well received with some sessions liked more than others. There is evidence participants valued the group and one-to-one aspects of the intervention giving them the opportunity to explore and review their headaches and its management. The process evaluation provides no clear explanation as to why the clinical outcome was negative.

Word count 1614

References

1. Nichols VP, Ellard DR, Griffiths FE, Underwood M, Taylor SJ, Patel S. The CHESS trial: protocol for the process evaluation of a randomised trial of an education and self-management intervention for people with chronic headache. Trials. 2019;20(1):323.

2. Ellard DR, Nichols V, Taylor S, Griffiths F. CHESS Process Evaluation Results Report (Vers 1).2020 13.01.2021. Available from: http://wrap.warwick.ac.uk/145633/.

3. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ. 2015;350:h1258.

4. Steckler A, Linnan L. Process Evaluation for Public health Interventions and research. San Fransisco: Jossey-Bass; 2002.

5. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. The qualitative researcher's companion. 2002;573(2002):305-29.

6. Gov.UK. English indices of deprivation 2015. 2015. Available from: https://www.gov.uk/government/statistics/english-indices-of-deprivation-2015.

7. Office of National Statistics. 2011 Census2011 23/02/2021. Available from: https://www.ons.gov.uk/census/2011census.