Headache smartphone app – Development and application in the Chronic Headache Education and Self-management Study (CHESS)

Norman C, Froud R, Matharu M, Mistry D, Nichols V, Potter R, Stewart K, Willis A, Patel S, On behalf of the CHESS team.

Corresponding author Rachel Potter

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Background

As part of the CHESS programme grant we developed an app to allow frequent collection of headache related outcome data on headache frequency, duration and severity. In this section we summarise the work and outcomes.

Methods

Development of the app

The app was developed by Clinvivo Ltd, a University of Warwick spin–out company specialising in electronic data collection. The research team and our patient and public lay advisory group worked with Clinvivo Ltd to design and pilot the app ahead of testing in a large randomised controlled trial.

The research team drew on the existing literature as well as the clinical expertise of the team to draft three questions which aimed to capture the frequency, severity, and duration of headaches. We involved our lay advisory group to ensure the data we proposed to collect and the method of collection were acceptable. Our advisory group members played a key role in helping us refine the questions and provided feedback on the usability and acceptability of the app before its application in the trial. The inclusion of a calendar to show recall period was a suggestion that came from our PPI work.

As part of the app development we considered what processes should be for those participants who may change their device or instal the app on a new device over the duration of the trial. We also thought carefully about the need for reminders and implemented a process for those who failed to download the app and those who had not responded for more than 3 weeks.

Table 1: Final questions for the CHESS app

Questions	Data collected
On how many of the last 7 days (as indicated in green on the calendar) have you had a headache?	**Insert number of headaches**
On those days you had a headache, on average how long did they last?	**Scale**: **0 - 24 hours**
On those days you had a headache on average how severe were they?	**0 (No pain) to 10 (Extremely severe pain)**

Completion of the app

All participants who were eligible to take part in the trial were asked to complete the smartphone app. It was completed weekly for six months from eligibility and then monthly for the remaining six months, providing a total of 12 months data. Instructions on how to download and use the app were sent out with baseline consent packs, which provided a step-by-step guide together with screen shots and a specific enrolment code for people to use with the app. If participants did not have access to a smartphone or did not wish to use the app, a paper version was provided as an alternative.

Data management

The data were collated by Clinvivo Ltd and emailed to the CHESS team daily. Data including date and time outcomes were completed and these data were tracked against each participant's trial number.

Summary results

Initially the app was tested by the research team and by members of the CHESS lay advisory group.[14] The app was subsequently tested with eight participants over an 11 week period. Completion rates varied, but there were no reports of any issues with either downloading or using the app.

Randomised controlled trial

Of the 736 participants randomised to the trial, 679 (92%) opted to respond using the smartphone app and 57 (8%) chose to respond using the paper questionnaire. The proportions opting for app and paper reporting was similar across the two trial arms.

There is evidence of a statistically significant association between the mode of reporting (i.e. app/paper) and whether participants respond or not, with a higher proportion of participants responding using the app compared to paper reporting (Table 2). Here non-responders are defined as participants who did not provide any responses at all.

Table 2: Response rates comparing the App and paper diary

	App (N=679)	**Paper (N=57)**	**P-value**
Non-responders	176 (25.9%)	36 (63.2%)	<0.001
Responders	503 (74.1%)	21 (36.8%)	

Each participant was expected to provide 32 responses in total. The distribution of the completion rates for those responding using the smartphone app varied with 0% completion by 176 participants, 1-12% by 98, 26-50% by 94, 51-75% by 137 and 76-100% by 174. The completion rate of the participants using the smartphone app was low with a median completion rate of 44%.

In total, 33 (4.5%) participants withdrew during the trial and one (0.1%) participant died.

When comparing the characteristics of the participants by mode of reporting, the participants who opted to respond using the smartphone app were on average younger, more educated and employed. Moreover, on average they had greater headache severity (HIT-6), lower emotional function and better quality of life (EQ-5D VAS).

When comparing the non-responders and responders of the app, the responders were on average younger, white, employed with on average lower severity on the days they had a headache/migraine and lower pain not related to headache. Responders reported on average better role preventative quality of life score, better quality of life (EQ-5D VAS) and stronger self-efficacy beliefs (PSEQ).

Feedback

All participants had the opportunity to receive a personalised summary of their data at the end of the 12-month app data collection. They could opt in or out of this when they completed the final study 12-month questionnaire.

Qualitative interviews

Participants who had completed the four-month follow-up questionnaire were invited to take part in a semi-structured interview in which the smartphone app was discussed. A total of 26 participants spoke about the App. Three participants were not aware of the App and the reason for this was unclear. Of the remaining 23, seven found it easy to use and four especially valued the reminder prompts. Two participants specifically spoke about their thought processes around how they decided on their response and how this was challenging at times because it was difficult to recall. Referring to personal diaries made responding easier for some. Technical issues were one of the main barriers to completion. Two participants could not access the App after changing their phone (although another had managed to do this). One had initial problems setting the App up but went on to use it successfully. Four people did not have SMART phones, two used an iPad, one completed the paper version satisfactorily and one had not realised there was a paper version so no data was collected. The two participants using iPads found it unsatisfactory as they were more likely to miss the window for completion due to inconvenient timing or not always being on their devices. Six participants spoke about missing weeks when they had not remembered to complete the app, missed the reminder or were locked out of the system. One person said after missing a few weeks they just gave up.

Discussion & Conclusion

Our app was developed specifically for data collection in the CHESS trial. It was developed to be quick and easy to use with input from our lay members. The overall results suggest frequent data collection using the smartphone app was possible in this population although completion rates were low. The app seemed to appeal more to those that were younger, educated and employed. No differences were observed in the proportions opting for either app or paper in the two arms of the trial. Response rates were greater amongst participants responding using the app compared to paper reporting. Those using the app had greater headache severity (HIT-6), lower emotional function and better quality of life (EQ-5D VAS).

Responders, regardless of method were generally younger, white, and employed. They had lower pain severity when reporting headaches and less unrelated pain. Clinically responders had better quality of life (EQ-5D VAS) and stronger self-efficacy beliefs (PSEQ).

Our feasibility work had highlighted that completion rates were low. As a result, how to use the app was discussed with potential participants early in the recruitment process and the instructions for the app were sent out following the eligibility call with the consent form and baseline questionnaire. This allowed participants time to get used to completing the app prior to randomisation.

Completeness of data and consistency varied. It is unclear if those that were more affected by their chronic headaches may have been less inclined to complete the dairy. It is also unclear if those that were already using some form of headache app may have been less likely to complete this additional app. The results of the qualitative works suggest that tech issues played a big factor in completion rates. It is also likely that the burden of completion may have been too much for some participants, leading to a lack of interest.

We have been reliant on self-report for completion of the app, which can present challenges. In particular, participants were asked to recall on average their headache frequency, severity, and duration over a period of seven days over the first six months, followed by monthly for the remaining six months. Participants in the interviews mentioned needing to refer to paper notes to support them completing the app. We therefore need to be cautious interpreting the results due to recall and accuracy difficulties.

As part of the CHESS programme we developed an app to collect headache frequency, duration, and severity. The app was developed with input from our lay advisory group and tested with participants from our feasibility study before use in the main RCT. Overall completion rates were disappointingly low at 44%. Burden of completion and tech issues are likely to have contributed.

Competing interests

MU and RF are directors and shareholders of Clinvivo Ltd. MU recused himself from any discussions related to the choice of Delphi platform for this study.

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