

Service Development or Research: Make Sure You Know Which Game You Are Playing

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Key Messages

- For simple, safe interventions a standard RCT may be unnecessary
- Some form of systematic evaluation is still important

Abstract

Background: Benign headache is a common neurological symptom in both primary care (5% of consultations) and secondary care (20-30% of neurology referrals).

Question: Does a simple patient information sheet improve headache severity, frequency and impact as measured by the HIT-6 score.

Methods: a randomised controlled trial (RCT) in an NHS setting.

Results: the trial terminated early due to incomplete recruitment over a 2 year time period. The information sheet had strong face validity with patients and patient groups but no meaningful conclusions can be drawn because of recruitment problems. 168 patients were randomised from a projected sample size of 220 and only 62 fully completed the trial.

Conclusions: We analysed the reasons for trial failure, and they fall into a number of distinct groups: (1) major service configuration/re-orientation occurred concurrently as the trial was run with 'Choose and Book' and the '18 week targets' being introduced; (2) our aim was a classical evidence-based superiority trial, whereas the PCT aim was demand management; (3) there was a funding and resource shortfall. Our experience generates discussion about appropriate level of evaluation required for service development.

Why this matters to me

Headache is an amazingly common problem, whether viewed through a primary, secondary or public-health perspective. The central issues are: (1) the probability that the headache represents an initial symptom of a brain tumour (patient probability = virtually certain; medical probability = virtually nil); (2) head pain is painful and can interfere with day-to day family and work life; (3) often the causes are trivial but remedial; (4) headache provides the readout for a variety of psycho-social drivers. Given that a large number of clinicians, whatever their practice, are seeing a significant number of patients with headache on a daily basis we initiated this piece of work, to accelerate the treatment of these patients, which we felt could almost be dealt with minimum or no medical contact.

Evidence-base medicine had formed a good part of of our up-bringing, and we felt it only right that the true force of an RCT should be brought to bear on the subject. We therefore lovingly set one up. Sadly, as the piece describes, we were stymied by on-going health-service forces out of our control. The initial data was useful, but the final data too incomplete for meaningful conclusions. Whilst we still think it is important to consider service development from an academic point of view, this does not necessarily have to be as a traditional RCT.

INTRODUCTION

Headache is a common problem in primary care. It accounts for 4.4% of consultations in primary care¹ and accounts consistently for up to 20% of neurology appointments, and in some series may be 30%^{2,3,4}. Comparison of those referred to secondary care to those who are not referred shows that these patients are unlikely to have significant pathology and do not differ in terms of diagnosis⁵. The overwhelming majority of patients are suffering from benign headache syndromes (eg migraine, tension-type headache) which respond to simple measures and appropriate medication.

The neurology department at St. Mary's Hospital, Imperial College Healthcare NHS Trust, Paddington serves a primarily inner city community. In 2004/5 the waiting time for a headache appointment at St. Mary's was 4 months and these patients were considered to be using scarce neurology appointments which patients with other conditions might benefit from. As part of a demand management strategy, the local Primary Care Trust (PCT) brought together representatives from primary care, secondary care and the PCT to consider possible solutions. It was agreed that a mechanism which improved headache treatment in the community could enhance patient quality of life as well as making more appropriate use of available neurology services. There appeared to be two main underlying reasons for the high referral rates: a demand by patients for 'something to be done'; and primary care clinicians lack of confidence in their own diagnostic and management skills. The proposals considered included information and education provision to general practitioners. We felt that we could impact on both of these areas by providing practitioners with information sheets that they could give to patients or use with patients. This would directly empower patients and educate practitioners. We therefore developed an information leaflet for patients. A number of ways of evaluating this intervention were considered, and it was decided to initially test the leaflet itself with patients themselves who were already referred to secondary care. This would allow us to evaluate the leaflet without interfering or influencing patient pathways.

The leaflet would provide information as well as a structured range of treatment options for patients and practitioners to work through. The primary outcome measure would be the change in a dedicated headache score, with secondary outcomes being the use of, and responses to, the headache information sheet. Clearly if the intervention was shown to be of value, it would be appropriate to introduce directly into primary care.

METHODS

The team developed a best practice information leaflet on benign headache syndromes. This fitted on 2 sides of an A4 sheet and was eventually printed on high quality paper (*attached as Appendix*). The content was initially developed by the team and altered following comments from patients in primary care, patients with headache waiting to be seen in secondary care, patient groups, managers and other healthcare professionals. Headache patients were generally supportive and welcomed the information provided. The information was kept fairly simple – migraine and tension headache were described briefly, reassurance was given that serious causes were extremely rare, information was provided on analgesic overuse headache and that headache may also be caused by sinus, eye and neck and back problems.

A randomised controlled trial was designed to evaluate the use and impact of the information sheet. Initially patient letters were screened by a consultant neurologist for symptoms that could indicate more serious underlying pathology. Those that passed through the screening were randomised to either receiving the information sheet or not. The sheet was sent out several weeks before the outpatient appointment in order to give patients time to consider the information and undertake any interventions suggested if appropriate. All patients were sent an initial questionnaire which collected information on headache frequency and severity and impact on quality of life using validated questionnaires. Patients who attended their clinic visit were given a similar questionnaire to complete with additional questions on their responses to the information sheet and its contents, eg how useful the information was and whether recipients had acted upon it. The Frequency, severity and impact of headache were assessed using Headache Impact Test (HIT-6)^{6,7,8}. Anxiety and depression were also measured using the Hospital Anxiety and Depression score (HAD). The primary outcome measure for the study was the headache frequency score. Sample size was calculated assuming 10% of control group would have a spontaneous improvement in their symptoms over the 16 week wait (consistent with figures from other studies). To detect an improvement in a further 20% due to the intervention (90% power and $\alpha = 5\%$) due to the intervention, 92 subjects were required in each group. The neurology clinic had a current clinic non-attendance rate of 16%, so to allow for this, and non-participation, we aimed to recruit approximately 220 people.

RESULTS

168 patients were randomised 50:50 to the control and intervention arms over a 24 month period. Block randomisation was used to determine

allocation. Questionnaires were returned by 114 patients. Of these 62 had completed both the initial and follow up questionnaires – 28% of the desired sample size. Patients reported varying levels of engagement with the information sheet with individuals selecting specific information and advice to try in an attempt to relieve their symptoms.

Demographics

The vast majority of those returning questionnaires were women – 70% of those returning both questionnaires and 73% of those returning only one questionnaire. The modal age group of those returning both questionnaires was 40-49 years. The proportion of men returning both (30%) or only one (27%) questionnaire was similar. Patients returning at least one questionnaire ranged in age from 14 to 77 years. Those aged between 31 and 51 years of age had the highest proportion of return of both questionnaires (66%). Those aged under 31 had the lowest proportion of paired questionnaire returns (24%).

Symptoms

Of those completing the initial questionnaire (n=102) 85 completed the question on number of days with headache, with 31 of these patients (36%) reporting between 22 and 30 days of headache in the previous month. Similar results were seen in those completing the final questionnaire (n=74). Of the 67 answering the question, 24 (36%) reported 22-30 affected days in the previous month. In the initial group there was a correlation (Pearson correlation 0.437) between the HIT-6 score and the number of days of headache. This was not seen in the final group. There was no significant correlation between the number of headache days and the HAD.

Inter and intra-group comparisons

Comparison between the control and intervention groups, using the Mann Whitney U test, demonstrated no significant difference in accessing any of the therapies suggested on the information sheet (as measured by the second questionnaire). Comparing the HIT and HAD scores between the first and second questionnaire in each group there was no significant difference in either score in the control group. In the intervention group there was a significant beneficial difference in the HIT scores with a mean difference of 2.6 (p=0.05, 95% CI 0.877 to 4.361)

DISCUSSION

We are here essentially reporting a failed attempt at conducting an RCT. That is, only a third of the desired sample size was achieved, although the initial questionnaire return was 168/220. It is particularly disappointing because from the data we have collated there appeared to be a beneficial effect from the intervention, although we will never now know its validity. In the discussion below we reflect

on whether there are larger lessons to learn from our experience. We would not be the first group to stumble because of difficulty in receiving funding or recruiting patients or to be sidelined by contemporaneous changes in clinical practice that make a study difficult or obsolete, but an added dimension in this case was perhaps an inadequate appreciation of the difference between *health services development and research*.

Academic enthusiasm

Although this project was initiated by the PCT and some funding had been suggested, it became clear ultimately that funding would probably not be available to run the project. Considerable preparatory work had already been done when that was declared. Perhaps at this stage we should have stopped (maybe just sufficed with a pilot study) but we decided to apply for funding to a local primary care network which necessitated writing the project as a formal research proposal and applying for ethical approval. We then had to attend the ethics committee for interview where our information sheet and questionnaires were commented on and changes requested. We were favourably reviewed by the research network but did not receive funding. The PCT then agreed to fund the administrative costs. The three academic members of the team continued the work largely in their own time, until interim analysis showed that the numbers of patients completing the study were too small to show significant changes. Throughout we responded as academics do – we adapted to each new hurdle and filled in more forms!

Changes in service organisation

The project was significantly derailed by changes in mechanisms of primary-secondary care referral and also by the 18 week wait directive. The 18 week wait directive reduced the time period between when patient referral and first visit to a consultant which also reduced the time for us to send questionnaires and allow patients to respond to these. Choose and Book made it very difficult to identify the target population as appointments were made directly by practitioners with letters attached later and not easily accessible.

Different cultures

The initial aims of our project were modest and we developed a well received user-friendly information sheet with simple information about common headaches. This was achieved because of the expertise of the academic practitioners in the group. On any risk-benefit analysis we were unlikely to do harm, the cost of producing and distributing the information sheets to general practitioners would have been minimal and distributing them as a service to help inform practitioners and patients

might have had some impact. Requests for further supplies would have been as useful an outcome as any.

However in retrospect each professional group involved in the project had different underlying assumptions and traditions. These were never openly declared or considered within the group. As academically trained practitioners our instinct was that proper evaluation of service development should be carried out. We regularly bemoan government or health care organisations changes when they have no evidence base. We were enthusiastic about the idea of directly empowering patients. It is unclear whether the Trust or PCT really knew what they were getting: they were interested in demand management and perhaps less by the mechanisms by which this might be achieved. What a RCT really involved, the timescales required to achieve it and whether it would be helpful for Trust and PCT was not discussed.

There were some ideas expressed by the non-clinical members of the group that we did not challenge and which influenced the path taken. We could have recruited practices to use the leaflet and evaluated use and outcomes. Despite existing evidence that significant pathology is rare in this population there was a nervousness on the part of Trusts about altering existing referral pathways without first evaluating the impact of the change. The spectre of 'a missed brain tumour' was never really addressed. Interfering with general practitioner referral and access to secondary care was considered inappropriate. At this stage the caution expressed by management fitted well with our academic proposal to do a proper randomised controlled trial.

The question then arises of what sort of evaluation is appropriate when considering developments and what are the criteria by which we can judge these? We continue to believe that proper evaluation is required and that RCTS are the gold standard. Realistically perhaps observational methods using multiple different measurements and action research methods are more feasible. This is not a new suggestion but it does feel uncomfortable to suggest that something less than the best is good enough.

CONCLUSION

Service configuration and referrals to secondary care remains a hot topic for primary and secondary care providers and PCTs. Many practitioners will now be involved in practice based commissioning and services are regularly considered for review and re-organisation. These decisions are rarely evidence based, but decisions are based on what is judged good practice and often pragmatic decisions. Interventions do need to be evaluated, the history of medicine is littered with seemingly logical

interventions that caused more harm than good but perhaps a *sense of proportion* is also required when evaluating very simple measures, highly unlikely to cause harm, which are perhaps no-more than good clinical practice. We would advise academically trained practitioners to be cautious when invited into the world of service development and to continually ask themselves what game they are playing and whether or not they know the rules.

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