Nurse-led adherence support in hypertension: a randomized controlled trial
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
A nurse-led support intervention, aimed at increasing adherence to medication and reducing blood pressure (BP) in uncontrolled hypertensive patients, was examined. Practice nurses gave participating individuals, in addition to usual care, an adherence support session lasting a maximum of 20 minutes, followed by a shorter reinforcement session (10 minutes) 2 months later.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with hypertension and a latest BP recording of >/= 150 mmHg systolic and/or 90 mmHg diastolic. Individuals who did not control their medication intake (such as some nursing home patients) were excluded from the study, as were patients with secondary hypertension or severe dementia. Also excluded were patients with other reasons for not being approached, such as recent bereavement.

Setting
The setting was primary care and the community. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness and resource use data were gathered from June - December 2001 to December 2002. The price year appears to have been 2002.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that included in the clinical study.

Study sample
Power calculations were performed in the preliminary phase of the study. These showed that for a target difference in adherence of 15 percentage points, a sample of 330 patients was required for 80% power and a 5% significance level. Such a sample size was also adequate to detect significant differences between the groups in terms of BP values. The study investigators contacted a random sample of general practices and, of the 45 practices that replied, 24 refused to
participate. Thus, 21 practices participated in the study. Eligible patients were recruited using a computerised search of practice registers. The practices then contacted an age-gender stratified random sample of the remaining patients (<60 and ≥ 60 years). Of the 837 potentially eligible patients invited to participate, 466 did not respond and 45 refused to participate, thus 326 initially consented. However, 77 dropped out prior to the first appointment and 4 dropped out between run-in and randomisation. Thus, a final study sample of 245 patients was included in the clinical analysis. There were 128 patients (56% men) in the intervention group and 117 (54% men) in the control group. The mean age of the patients was 67.9 (+/- 10.3) years in the intervention group and 68.2 (+/- 9.4) years in the control group. The characteristics of the participating practices were reported.

Study design
This was a prospective, randomised controlled trial that was carried out at 21 general practices in Avon. Patient allocation to the treatment groups was based on computer-generated random numbers supplied by the research team. Baseline adherence was followed for 30 days before randomisation. The length of follow-up was 6 months. The final number of patients who were actually followed was 110 in the intervention group and 94 in the control group. No blinding was used. The authors stated that, owing to the potential for contamination, all practice nurses were made aware of this risk and were strongly recommended not to change their "usual practice" for control patients.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The primary outcome measure was adherence with medications, after controlling for adherence in the baseline period. Adherence was defined as "timing compliance", which was the number of doses taken at 24 (+/- 6) hour intervals for a once-daily regimen or 12 (+/- 3) hours for twice-daily doses, divided by the total number of days and multiplied by 100%. The secondary outcome measures were two less strict measures of adherence ("correct dosing" and "taking compliance"), as well as systolic and diastolic BP. "Correct dosing" was the percentage of days on which the correct number of doses was taken. "Taking compliance" was defined as the percentage of prescribed number of doses taken, which was the equivalent to a "pill count". The baseline comparability of the study groups was not discussed. Regression analyses were carried out to examine the impact of baseline factors on clinical endpoints. Pre-planned sub-group analyses were also performed.

Effectiveness results
No statistically significant difference between the groups was observed in any of the primary or secondary outcome measures.

Timing compliance was 87.2% (+/- 20.1) in the intervention group and 90.2% (+/- 16.2) in the control group. The difference was -1.0% (95% confidence interval, CI: -5.1 - 3.1; p=0.63).

Correct dosing was 90.8% (+/- 16.6) in the intervention group and 92.4% (+/- 15.2) in the control group. The difference was -0.5% (95% CI: -4.2 - 3.1; p=0.77).

Taking compliance was 95.6% (+/- 16.4) in the intervention group and 95.6% (+/- 15.7) in the control group. The difference was -0.6% (95% CI: -3.2 - 4.4; p=0.76).

Systolic BP was 142.9 (+/- 17.6) mmHg in the intervention group and 147.7 (+/- 20.9) mmHg in the control group. The difference was -2.7% (95% CI: -7.2 - 1.8; p=0.24).

Diastolic BP was 80.4 (+/- 10.1) mmHg in the intervention group and 79.9 (+/- 9.7) mmHg in the control group. The difference was 0.2% (95% CI: -1.9 - 2.3; p=0.85).

The sub-group analysis and adjustment for variables that showed any imbalance between groups did not alter the results of the main analysis.

Clinical conclusions
The effectiveness analysis showed that the clinical outcomes for the two groups were comparable.
Measure of benefits used in the economic analysis
No summary benefit measure was used in the economic analysis because no statistically significant difference between the groups was observed. In effect, a cost-minimisation analysis was carried out.

Direct costs
The cost analysis was undertaken from the perspective of provider institutions in the primary care sector. The economic evaluation considered only nurse time, which was estimated from the sample of patients included in the clinical trial. The costs came from typical National Health Service sources (Personal Social Services Research Unit) in 2002, which might have been the price year. The unit cost was presented separately from the quantity of resource used. Discounting was not relevant because of the short time horizon of the analysis.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs were not considered.

Currency
UK pounds sterling (€).

Sensitivity analysis
A simple one-way sensitivity analysis was performed to determine the effect of changing the duration of the nurse appointment to a more realistic level. Thus, a shorter duration was used.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The projected costs for the primary care sector per consultation were 9.50 for the intervention and 5.08 for usual care.

The sensitivity analysis showed that using a shorter duration for a nurse appointment for the first consultation led to a cost of 6.60 in the intervention group.

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant since a cost-minimisation analysis was carried out.

Authors' conclusions
The nurse-led support intervention did not increase adherence to medication and did not result in significant improvements in blood pressure (BP) in uncontrolled hypertensive patients. Further, the nurse-led support intervention was more expensive than usual care. However, the authors noted that adherence was already very high among patients participating in the trial.

CRD COMMENTARY - Selection of comparators
The selection of the comparator was appropriate as it reflected usual care in the authors' setting, and it was clearly
described. The rationale for the choice of the nurse-led support intervention was reported. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a clinical trial, which was appropriate for the study question. The methods of sample selection and randomisation were reported. The potential impact of selection bias was limited. Reasons for patient refusal and loss to follow-up were provided for most patients. However, the design was open-label and the authors noted the potential for contamination. The comparability of the patients at enrolment was not discussed clearly, although the two groups of participating individuals appear to have been well balanced. To control for the impact of confounding factors, statistical analyses were performed to examine the impact of baseline differences on the clinical results. A sub-group analysis was also performed. The evidence came from multiple centres and no strict enrolment criteria were used to select the patients. Thus, the study sample appears to have been representative of the patient population. Power calculations were performed, but a sample of patients smaller than that planned in the preliminary phase was included in the final analysis. The robustness of the analysis was enhanced by the use of intention to treat in the assessment of clinical data.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-minimisation analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The authors stated explicitly which perspective was adopted in the analysis and only the extra cost associated with nurse visits was included in the analysis. The impact of the intervention on other direct medical costs was not investigated. Resource consumption was estimated from the clinical trial. However, a sensitivity analysis was carried out to examine the scenario with a shorter nurse visit, in order to reflect real-world treatment patterns (which might be more resource-consuming in the setting of a clinical trial). The source of the cost data was reported and was consistent with the perspective adopted. The price year was not explicitly stated, but it could be derived from the source of the cost data.

Other issues
The authors stated that their findings were not consistent with the widespread belief that adherence with BP-lowering medication is only about 50 to 60%. However, the results of the analysis were not compared with those from other published studies. The issue of the generalisability of the study results to other settings was not addressed and limited sensitivity analyses were performed. This reduces the external validity of the analysis. The authors noted that the patients’ adherence with antihypertensive medication was very high in both groups at study entry, which might reflect a population of very compliant patients. Therefore, caution is required when extrapolating the results of the analysis to populations of patients with lower levels of adherence.

Implications of the study
The study results did not support the introduction of a nurse-led support intervention among hypertensive patients. The authors stated that the findings of their study could be used for future power calculations in studies that use timing compliance as the main outcome. Future studies should investigate the epidemiology of adherence in treated hypertensive people in the UK.

Source of funding
Funded as part of a Medical Research Council Training Fellowship in Health Services Research.

Bibliographic details
Schroeder K, Fahey T, Hollinghurst S, Peters T J. Nurse-led adherence support in hypertension: a randomized
controlled trial. Family Practice 2005; 22(2): 144-151

**PubMedID**
15655101

**DOI**
10.1093/fampra/cmh717

**Other publications of related interest**

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Aged; Antihypertensive Agents /therapeutic use; Blood Pressure /drug effects; Confidence Intervals; Female; Humans; Hypertension /drug therapy; Male; Nursing Care /methods; Patient Compliance

**AccessionNumber**
22005000650

**Date bibliographic record published**
31/12/2005

**Date abstract record published**
31/12/2005