Effectiveness of nurse-led brief alcohol intervention: a cluster randomized controlled trial

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
The study examined a nurse-led brief intervention aimed at reducing excessive alcohol consumption. The intervention took 5 to 10 minutes and involved nurses giving structured advice on alcohol. Specifically, standard drink units, recommended low-risk consumption levels, the benefits of cutting down on drinking, tips on helping patients reduce consumption, advice on how to set goals, determine action and review progress, and a self-help booklet/diary for patients to take away.

Type of intervention
Information and education in health.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients aged 16 years and older who were drinking at risk levels, defined as a cut-off point of 8+ for men and 7+ for women using the AUDIT (Alcohol Use Disorders Identification Test) questionnaire. Patients were excluded if they were under 16 years of age, had current major physical or psychiatric illness, were severely alcohol dependent, or had severe brain damage or mental impairment.

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

Dates to which data relate
The effectiveness and resource use data were gathered between August 2000 and June 2003. Costs were expressed using 2001/02 prices.

Source of effectiveness data
The effectiveness data were 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 effectiveness study.

Study sample
Power calculations were performed in the preliminary phase of the study using data from a published clinical trial. These suggested that the required number of practices was 76, assuming an average number of 5 patients per practice and using 80% power and a two-tailed significance level of 5% to detect a difference in the main clinical measure.
initial number of eligible general practices was 369, of which 183 were in the intervention group and 186 in the control group. After excluding practices that were not contacted (43 and 49, respectively, for the intervention and control groups), declined participation (96 and 84), withdrew (22 for both), or did not recruit any patients (6 and 3), the final sample of practices comprised 21 units in the intervention group and 19 units in the control group. The majority were group practices (80%) in urban settings (55%) with an average of 3 (±/− 8) GPs per practice.

Of the 515 patients initially approached for AUDIT screening, 3% declined participation. Screening data were collected for 498 patients. Of these, the final number of eligible patients (8+ for men and 7+ points for women using the AUDIT questionnaire) was 127. There were 67 patients (51% female) in the intervention group and 60 (48% female) in the control group. The mean age was 42.7 (±/− 15.5) years in the intervention group and 45.7 (±/− 14.9) years in the control group. The authors reported the refusal rates and main reasons for declining participation.

**Study design**
This was a prospective, pragmatic, cluster-randomised clinical trial that was carried out in five health authority areas in the north-east of England. The unit of randomisation was the general practice. Randomisation was carried out using computer-generated random allocation of practices. The length of follow-up was 1 year, but clinical outcomes were also evaluated at 6 months. The number of patients available at the 12-month follow-up was 36 in the intervention group and 42 in the control group. Patients, nurses and health researchers were blinded to treatment allocation.

**Analysis of effectiveness**
The authors stated that the analysis of the clinical study was conducted on an intention to treat basis. The clinical end points used in the effectiveness analysis were:

- AUDIT score (10 questions about alcohol use in terms of quantity/frequency/intensity, alcohol dependence symptoms and alcohol-related problems),
- the mean number of drinks per drinking day (alcohol timeline followback),
- Drinking Problems Index (DPI; a 17-item tool designed to assess drinking problems in older adults and covering adverse consequences from drinking, excessive consumption, dependence symptoms, and escapist drinking), and
- health-related quality of life (SF-12; a 12-item questionnaire that generated an abbreviated health profile of health).

The intervention and control clusters differed significantly in the average number of GPs per practice (mean of 4 in the intervention group and 3 in the control group) and number of hours worked by nurses (29.1 versus 23.6, respectively). At baseline, the study groups were similar with respect to sociodemographic factors and alcohol consumption at baseline. However, patients who refused to participate were statistically significantly younger (36.4 years) than patients who were enrolled (44.1 years).

**Effectiveness results**
There was a statistically significant reduction in AUDIT score in both groups compared with baseline consumption, (p=0.046).

There were no statistically significant differences between the two groups in any clinical end point. However, AUDIT scores, standard drink units per week and the DPI scores significantly fell between baseline and follow-up in the intervention group, while only standard drink units per week fell significantly in the control group during the 1-year follow-up period.

**Clinical conclusions**
The effectiveness analysis showed that the nurse-led brief alcohol intervention was as effective as usual care in terms of statistical significance.
Measure of benefits used in the economic analysis
No summary benefit measure was used as the two interventions were equally effective, as shown in the effectiveness analysis. In effect, a cost-minimisation analysis was performed.

Direct costs
The analysis of the costs considered the viewpoint of the NHS and the patients. The categories of costs included were those related to GP consultations, nurse consultations, Accident and Emergency Department attendances, inpatient stays and outpatient visits, time related to travelling to and waiting at surgeries and hospitals, time spent in appointments and transport costs. Details of the calculation of the intervention costs were reported. The patients also reported the number and length of absences from work and other out-of-pocket expenses related to property damage or accidents for a 1-year period pre- and post-intervention. The unit costs and the quantities of resources used were not presented separately, although information on resources used was provided for most items. The quantities of resources used were based on self-reported data. NHS costs were derived from typical sources, such as Unit Costs of Health and Social Care. Discounting was not relevant as the costs were incurred during 1 year. The costs were expressed using 2001/02 prices.

Statistical analysis of costs
A bootstrap approach was used to calculate confidence intervals (CIs) around the mean costs.

Indirect Costs
The indirect costs were not considered.

Currency
UK pounds sterling (€).

Sensitivity analysis
No sensitivity analysis was carried out.

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

Cost results
The total health care costs per patient over a 1-year timeframe were 291.73 (+/- 359.04) (95% CI: 179.44 to 470.57) in the intervention group and 392.06 (+/- 970.52) (95% CI: 149.16 to 790.71) in the control group. The difference in costs did not reach statistical significance.

The patient costs were 0.48 (+/- 0.88) (95% CI: 0 to 1.12) in the intervention group and 2.12 (+/- 5.18) (95% CI: 0 to 6.22) in the control group.

The patients' travel did not differ between the groups. No patients reported the occurrence of expenditure related to accidents, or the payment of higher motor vehicle or household insurance premiums as a result of accidents.

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

Authors' conclusions
There were no statistically significant differences in outcomes between the intervention and control groups, although this might have been due to a lack of sufficient power to detect an effect of the brief alcohol intervention. The authors stated that the magnitude of differences in clinical outcomes suggest some clinically significant impact of the intervention. Health care resource consumption was similar between the groups.

**CRD COMMENTARY - Selection of comparators**
The rationale for the selection of the comparator was clear since it reflected the current pattern in primary care. You should decide whether this is a valid comparator 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 method of randomisation was described and should have reduced the impact of selection bias, especially the cluster design which should have prevented contamination across trial groups. The approach used to select the sample of participating patients was reported, and the reasons for the loss of patients over the study period were stated. Reasons why practices refused to participate were also reported. The study groups were comparable at baseline and the comparability of participants and non-participants was evaluated. The analysis of the clinical study was conducted on an intention to treat basis, which represents a strong characteristic of the analysis given the observed loss to follow-up. A justification for the size of the sample was provided, but it was unclear whether the clinical outcomes might have been different over a longer timeframe. A further strength of the analysis was the blinded design, which should have reduced the possibility of assessment bias. The multi-centre design enhances the validity of the analysis. However, it was pointed out that a substantial number of practices withdrew without recruiting any patients. The aspects of poor recruitment and retention of nurses should be considered when evaluating the robustness of the clinical analysis.

**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 analysis of the costs was consistent with the viewpoints of the NHS and the patients. Some information on the unit costs and quantities of resources used was provided, which will help if repeating the analysis in other settings. Resource consumption was obtained prospectively from the same patients as those used in the effectiveness analysis, which is a positive feature of the study. However, the cost estimates were specific to the study setting and the impact of using alternative economic estimates was not investigated. The price year was reported, which enhances the possibility of reflating the costs in other time periods. Statistical tests were carried out only to assess the significance of the cost comparison.

**Other issues**
The authors did not compare their findings with those from other studies, presumably because of the lack of published economic evaluations of nurse-led brief alcohol interventions. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not carried out, thus limiting the external validity of the study. The authors highlighted the fact that the results of the analysis should be treated with caution since it is unclear whether the lack of statistically significant differences between the groups was due to true comparability or to a lack of adequate power in the trial to detect an effect of the brief alcohol intervention.

**Implications of the study**
The study results do not support the routine use of nurse screening and brief alcohol intervention, although the analysis indicated a great uncertainty in terms of the clinical and economic impact of the intervention. Further research should explore the nurses' reasons for inconsistent delivery of alcohol-related interventions in general practices. The authors noted that the cost-effectiveness of the nurse-led brief alcohol intervention should be further investigated in a larger
clinical trial.

Source of funding
Funded through the NHS Executive (Northern & Yorkshire) Research and Development Regionally Commissioned Project Grant.

Bibliographic details

PubMedID
16671972

DOI
10.1111/j.1365-2648.2006.03836.x

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Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Alcoholism /nursing; Cluster Analysis; Cost-Benefit Analysis /methods; Family Practice /methods; Female; Health Care Costs; Humans; Male; Middle Aged; Patient Education as Topic /economics /methods; Quality of Life; Treatment Outcome

AccessionNumber
22006005096

Date bibliographic record published
31/05/2007

Date abstract record published
31/05/2007