

# **AESOPS: a randomised controlled trial of the clinical effectiveness and cost-effectiveness of opportunistic screening and stepped care interventions for older hazardous alcohol users in primary care**

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## **Scientific summary**

### **Alcohol: Evaluating Stepped care in Older Populations Study (AESOPS)**

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# Scientific summary

## Background

There is clear evidence of the detrimental impact of hazardous alcohol consumption on the physical and mental health of the population. Estimates suggest that hazardous alcohol consumption annually accounts for 150,000 hospital admissions and between 15,000 and 22,000 deaths in the UK. In the older population, hazardous alcohol consumption is associated with a wide range of physical, psychological and social problems. There is evidence of an association between increased alcohol consumption and increased risk of coronary heart disease, hypertension, haemorrhagic and ischaemic stroke, increased rates of alcohol-related liver disease and increased risk of a range of cancers. Alcohol has been identified as one of the three main risk factors for falls. Excessive alcohol consumption in older age can also contribute to the onset of dementia and other age-related cognitive deficits and is implicated in one-third of all suicides in the older population.

## Objectives

To compare the clinical effectiveness and cost-effectiveness of a stepped care intervention against a minimal intervention in the treatment of older hazardous alcohol users in primary care.

## Design

A multicentre, pragmatic, two-armed randomised controlled trial with an economic evaluation. Randomisation was performed by a remote service. Treating nurses, therapists and participants were aware of allocation result, and outcome assessment was average drinks per day (ADD) derived from the extended Alcohol Use Disorders Identification Test – Consumption (3-item) (AUDIT-C).

## Setting

General practices in primary care in England and Scotland.

## Participants

Participants were eligible to participate in the study if they were aged  $\geq 55$  years and scored  $\geq 8$  on the Alcohol Use Disorders Identification Test (AUDIT). Following screening, a total of 529 participants were randomised in the study.

## Interventions

Participants in the minimal intervention group received a 5-minute brief advice intervention with the practice nurse or research nurse involving feedback of the results of the screening and discussion regarding the health consequences of continued hazardous alcohol consumption. Those in the stepped care arm initially received a 20-minute session of behavioural change counselling (step 1), with referral to step 2 (motivational enhancement therapy) and step 3 (local specialist alcohol services) if indicated. Sessions were recorded to ensure treatment fidelity.

## Main outcome measures

The primary outcome was ADD derived from the extended AUDIT-C at 12 months. Secondary outcomes were alcohol-related problems assessed using the Drinking Problems Index (DPI) at 6 and 12 months; ADD (derived from the extended AUDIT-C) at 6 months; extended AUDIT-C score at 6 and 12 months; health-related quality of life (HRQoL) at 6 and 12 months; quality-adjusted life-years (QALYs) (for cost–utility analysis derived from European Quality of Life-5 Dimensions); and health and social care resource use associated with the two groups.

## Results

Both groups reduced alcohol consumption between baseline and 12 months. There were no significant differences in ADD between the treatment groups at 12 months. Stepped care had a marginally higher ADD [1.129; standard deviation (SD) 0.037] than minimal intervention (1.104; SD 0.037), but not significantly so. At months 6 and 12, the stepped care group had a lower DPI score than the minimal intervention group, but the difference was not statistically significant at the 5% level. At month 6, the stepped care group had a lower ADD than the minimal intervention group, but this difference was not statistically significant. The stepped care group had a lower mental component score [measured using the Short Form Questionnaire-12 items (SF-12)] than the minimal intervention group at month 6 and month 12. The stepped care group also had a lower physical component score at month 6 and month 12. These differences were not significant at the 5% level.

The cost-effectiveness results indicated that the overall average cost per patient, taking into account health and social care resource use, was £488 (SD £826) in the stepped care group and £482 (SD £826) in the minimal intervention group at month 6. The mean QALY gains were slightly greater in the stepped care group than in the minimal intervention group, with a mean difference of 0.0058 [95% confidence interval (CI) –0.0018 to 0.0133], generating an incremental cost-effectiveness ratio (ICER) of £1100 per QALY gained. At month 12, participants in the stepped care group incurred fewer costs, with a mean difference of –£194 (95% CI –£585 to £198), and had gained 0.0117 more QALYs (95% CI –0.0084 to 0.0318) than the control group. From an economic perspective the minimal intervention, therefore, was dominated by stepped care. Given thresholds of £20,000–30,000 per additional QALY gained, the probability that stepped care is more cost-effective is 81–86% at the 6-month follow-up and 93.5–93.8% at 12 months.

A sensitivity analysis that excluded extreme cases altered the average costs of interventions; the ICERs were £8496 per QALY at 6 months and £4224 per QALY at 12 months. The probability that stepped care is more cost-effective ranges between 80% and 88% at 6 months, and between 87% and 90% at 12 months, using the £20,000–30,000 per QALY gained threshold.

The prevalence of hazardous alcohol consumption in those aged  $\geq 55$  years had been estimated at 15% in the general population. Screening results from this study found this to be only 7.5%. Fidelity process rating identified significant differences between the minimal and step 1 interventions, indicating that the two types of intervention were distinct. There were no significant differences in the rating scores between practice or research nurses with different levels of experience (specialist vs non-specialist practitioners).

## Conclusions

Stepped care does not confer an advantage over minimal intervention in terms of reduction in alcohol consumption at 12 months post intervention when compared with a 5-minute brief (minimal) intervention. Our cost-effectiveness analysis examining QALY gains suggested that the stepped care intervention is more likely to generate greater health benefits and achieves better value for money compared with minimal

intervention, but caution is required given the uncertainty surrounding the estimates and the absence of a statistically significant difference in effectiveness outcomes.

### **Implications for health care**

There is no evidence that a stepped care approach reduces alcohol consumption in terms of ADD among older hazardous alcohol users after 12 months, or improves AUDIT score, alcohol-related problems or quality of life after 6 or 12 months.

### **Recommendations for future research**

The experience of conducting this study alongside the results obtained has prompted a number of suggestions for future research:

- What factors facilitate or hinder the conduct of research in primary care settings?
- What is the clinical effectiveness and cost-effectiveness of community-based screening and self-directed ultra-brief interventions for hazardous alcohol users compared with screening alone?
- What is the clinical effectiveness and cost-effectiveness of motivational enhancement therapy for opportunistically identified, non-treatment-seeking harmful alcohol users delivered in primary care?
- What are the longer-term clinical and economic impacts of stepped care interventions?

### **Study registration**

This trial is registered as ISRCTN52557360.

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### **Publication**

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