

# York Trials Unit Briefing Note

## Poor recruitment to hazardous drinking study overcome by mass mail out approach

### Background

It is estimated that 20% of those aged 55 years or over consume alcohol at levels hazardous to their health. It is known that hazardous alcohol consumption is associated with a wide range of physical, psychological and social problems including coronary heart disease, hypertension, stroke, liver disease and increased risk of a range of cancers. In addition, alcohol is contraindicated with many medications and interactions are a common occurrence.

However, older people are less likely to seek treatment and many alcohol related presentations are often atypical or masked by co-morbid illness making diagnosis more difficult. As a result, only a small percentage receives any treatment.

Stepped care interventions provide a means of delivering more intensive interventions to those who fail to respond to less intensive interventions and are more in keeping with rational clinical decision making than the blanket use of any one intervention strategy.

In order to evaluate whether stepped care interventions reduce alcohol consumption, improve quality of life and are more cost-effective compared with a minimal intervention, the Aesops study aimed to randomise 500 eligible patients from general practices across various UK centres. This pragmatic multi-centre randomised controlled trial, co-ordinated by York Trials Unit (YTU), is funded by the NIHR Health Technology Assessment Programme.

### What did we do?

Patients aged  $\geq 55$  years in 30 GP practices were screened opportunistically regarding their alcohol consumption using the Alcohol Use Disorders Identification Test (AUDIT). Screening packs were placed in waiting areas and consulting rooms. Patients could complete the form anonymously, or with contact details if interested in helping with the research. Returned questionnaires were scored at YTU and patients who scored 8 or more plus provided their contact details were offered an appointment with the trained practice nurse from their practice.

Consenting patients were randomised to either:

**Minimal intervention:** one 5 minute discussion about the health consequences of continued hazardous alcohol consumption; or

**Stepped care:** three consecutive steps:

Step 1: 20 minute behavioural change counselling session

Step 2: Motivational Enhancement Therapy (MET) for 3 40-minute sessions provided by a trained alcohol therapist

Step 3: Referral to the local specialist alcohol services

Referral to the next step was made only if levels of alcohol consumption remained hazardous.

### Why did we need to change the method?

After 21 months, only 97 patients had been recruited and study closure was a real possibility. However, with the backing of the funders, it was decided to bring on new practices who would send out an AUDIT form and information leaflet to all their patients aged 55 and over, as opposed to opportunistic screening. These practices would also use researchers to provide the interventions and not practice nurses. Current practices were offered the chance to change methods. All the mail out packs were prepared by YTU and forwarded to the practices for addressing.

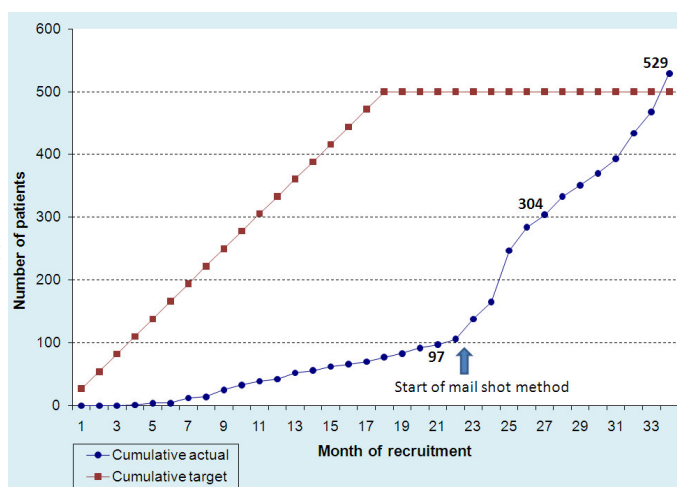
The mail-shot was eventually used in 23 new practices and 5 original practices switched.

### Did it work?

Approximately 13,200 original screening packs were prepared for waiting areas and consulting rooms; in addition, approximately 65,000 mail out envelopes packed. Just over 21,500 completed forms were returned throughout the study. In the remaining 13 months of recruitment 432 patients were recruited, meaning that the study hit target by the end of the revised recruitment period.

See graph below for details.

### Aesops study: Recruitment over study duration



See overleaf for further information on the Aesops study

## Further details on the Aesops trial

*About the researchers:* this work was conducted by the Aesops Trial Team. The study Chief Investigator is Professor Simon Coulton, University of Kent, with support for trial management, data collection and analysis provided by the York Trials Unit.

*For full details see:* Coulton S, Watson J, Bland M, Drummond C, Kaner E, Godfrey C, Hassey A, Morton V, Parrott S, Phillips T, Raistrick D, Rumball D, Tober G. The effectiveness and cost-effectiveness of opportunistic screening and stepped care interventions for older hazardous alcohol users in primary care (AESOPS) - A randomised control trial protocol. BMC Health Services Research 2008; **8**: 129.

## The York Trials Unit

The York Trials Unit (YTU) is based in the **Department of Health Sciences, University of York**, and is dedicated to undertaking and supporting high quality randomised controlled trials (RCTs).

The RCT is the best study design for assessing the effectiveness and efficiency of health care interventions, and rigorous trials are needed to inform best clinical practice and policy. Methodological reviews of RCTs have indicated that many trials have been designed and conducted with insufficient rigour to make their results entirely reliable. It is imperative, therefore, that clinical practice be informed by the results of high quality trials.

We design and manage trials in a range of settings including health services research, the social sciences (education, criminal justice etc.) and clinical trials. The YTU also conducts epidemiological surveys and YTU members conduct systematic reviews.

YTU trials are funded from a range of sources including the Medical Research Council, National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme, charities and pharmaceutical companies.

Our aims are:

- to conduct rigorous trials
- to provide support for trials external to the Unit
- to provide academic leadership for rigorous trial design

Services provided by YTU include:

- Telephone & online randomisation
- Study design & trial co-ordination
- Data management
- Statistical support
- Economic evaluation
- Measurement of quality of life

## Recent Unit Publications

**Cox H, Tilbrook H, Aplin J, Semlyen A, Torgerson DJ, Trehwela A, Watt I.** A randomised controlled trial of yoga for the treatment of chronic low back pain: Results of a pilot study. Complementary Therapies in Clinical Practice 2010: 187-193

**Dennis LA, Brealey S, Rangan A, Rookmoneea M, Watson J.** Managing idiopathic frozen shoulder: a survey of health professionals' current practice and research priorities. Shoulder & Elbow 2010

**Hewitt C, Kumaravel B, Dumville JC, Torgerson DJ.** Assessing the impact of attrition in randomized controlled trials. J Clin Epidemiol 2010; 63(11): 1264-1270

Pearson DAS, McDougall C, Kanaan M, Bowles RA, **Torgerson DJ.** Reducing criminal recidivism: evaluation of Citizenship, an evidence-based probation supervision process. Journal of Experimental Criminology 2010

**Whitehead SJ, Ali S.** Health outcomes in economic evaluation: the QALY and utilities. British Medical Bulletin 2010.

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