

Report to the Alcohol Education Research Council

**Two –year follow-up of a randomised trial of Early Warning Signs Relapse
Prevention Training in the treatment of alcohol dependence**

**Gerald A Bennett¹, Peter W Thomas², James Bailey¹, Katherine Graham¹, Eleanor
Davies¹, Jacqueline Withers¹, David S Higgins¹, and
Lorraine Parry¹**

¹Addiction Service, Dorset HealthCare NHS Trust, Bournemouth, Dorset, United
Kingdom

²Dorset Research and Development Support Unit and Institute of Health and Community
Studies, Bournemouth University, Dorset, United Kingdom

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Two –year follow-up of a randomised trial of Early Warning Signs Relapse Prevention Training in the treatment of alcohol dependence

Abstract

Aims Does Early Warning Signs Relapse Prevention Training (EWSRPT) prevent relapse in alcohol dependent persons with history of relapse?

Design: Pragmatic randomised trial comparing (1) Aftercare as Usual (AU) with (2) AU plus 15 individual sessions of EWSRPT . Assessment at entry, and 4, 8, 12 and 24 months later. This study reports the results at final follow-up.

Setting: UK day treatment programme.

Participants: 124 abstinent alcohol dependent patients just completing a 6-week day treatment programme (63% male) who had previously stopped drinking and relapsed at least twice (median 5 relapses): 62 in each condition.

Interventions: AU; eligibility to attend aftercare groups, supportive milieu, and alcohol-free social club. EWSRPT; as AU plus 15 individual sessions of EWSRPT using Gorski's protocol

Measures: Any drinking (primary outcome), any heavy drinking (3 consecutive days consuming >8 units on each day), percent days drinking, percent days heavy drinking, units per drinking day, GGT, and ALT. Measures of non drinking outcomes such as problems resulting from drinking (APQ), quality of life (EQ5D, SF36), mental health (BSI), and cost of health and rehabilitation services used.

Findings: Of the 124 participants, four had died prior to their follow-up date and one had moved abroad. Of the 119 available participants, 102 (86%) were seen face-to-face for a final follow-up interview (51 AU, 51 EWSRPT). Intention to treat analysis found no significant differences between groups on drinking measures in the four months prior to final follow-up or on non-drinking measures. No characteristic of participants on joining the trial were consistently correlated with drinking outcome.

Conclusions: The significant effects of EWSRPT at 12-month follow-up had 'washed out' at final follow-up, but still suggest that its use could be worthwhile.

INTRODUCTION

Many interventions have been shown to help alcohol dependent people cease drinking and begin to live without alcohol (Miller and Wilborne 2002). These changes are often temporary. Many people return to drinking, especially during first few months after stopping. There is a need for effective ways of helping dependent drinkers who have completed treatment to remain abstinent once treatment contact ends. Effective relapse prevention treatments should be capable of being provided by currently available specialist services. Pharmacological treatments with some promise include the opiate antagonist naltrexone (Srisurapanont and Jarusuraisin 2002) and the GABA agonist acamprosate (Garbutt et al 1999). The most influential psychological treatment approach, based on the cognitive-behavioural model of Marlatt (Marlatt and Gordon 1985), focuses on helping patients develop skills to cope with putative 'high risk situations'.

Replications and extensions of Marlatt's original work provide only partial support for key assumptions of this model, calling its rationale into question (Lowman et al 1996). It is unclear to what extent the evidence from treatment studies supports treatments derived from Marlatt's approach. One recent review of the experimental literature (Irvin et al 1999) concluded that the approach was effective; another judged that there was little evidence of effectiveness (Miller and Wilborne 2002). There is no clear evidence that any pharmacological or psychological approach is consistently effective in preventing relapse.

A very different psychological relapse prevention approach is the Early Warning Signs Approach developed by Gorski (1989, 1990) for dependent drinkers who had stopped

drinking and relapsed a number of times. This approach suggests that in the period before resuming drinking people undergo a pattern of changes in their thoughts, feelings, and behaviour, which is characteristic for them. This is said to develop progressively from small changes in feeling and attitude, through increasingly overt changes in behaviour and social functioning, to a state in which drinking becomes very likely. Starting drinking is seen as the end of a process which has occurred for days or weeks, and which may not be apparent to the drinker. Gorski argues that it is much easier to interrupt this unravelling process earlier rather than later - when it may be almost impossible to prevent a resumption of drinking. The treatment involves a series of procedures to help the person (1) become aware of their own habitual warning signs, and associated changes (2) develop and implement plans for managing or coping with each sign or change, so as to interrupt the relapse process and (3) to develop a lifestyle which will help prevent the occurrence of this sequence of changes. There is a clear protocol of about 20 sessions, each of which can be carried out individually in one hour; most involve completing written tasks between sessions. Gorski's approach is widely used in the USA and is supported by published materials including books, patient workbooks (Gorski 1995), videos, and packages for therapists to use in presenting this approach to patients. There is an intensive 6-day training programme for professionals and an accreditation system for graduates of the training: several thousand people have completed this. Thus the approach could be easily disseminated.

This approach was developed for use only with patients who have a history of stopping drinking and subsequently returning to drinking, but has never been subjected to a

randomised controlled trial. In the current state of knowledge the most appropriate evaluation is a simple pragmatic trial designed to answer the question of whether adding this approach to treatment improves the long-term outcome of patients.

The present investigation is a continuation of a study that examined whether providing this type of intervention to alcohol dependent people when they complete a day treatment programme affects their consumption of alcohol during the following year. The initial analysis compared drinking outcomes in participants who received Early Warning Signs Relapse Prevention Therapy (EWSRPT) with those that attended Aftercare as Usual (AU) (Bennett et al submitted for publication). Compared to those in the AU group, the EWSRPT participants were significantly less likely to drink heavily during the follow-up year (74% of AU, 55% of EWSRPT; $P = 0.04$), and had significantly lower frequencies of drinking ($P = 0.05$) and drinking heavily ($P = 0.04$) during that year. They were not, however, significantly more likely to completely abstain from alcohol during this year (17% of AU, 31% of EWSRPT, $P = 0.08$). The difference between the patterns of drinking and heavy drinking of the two condition increased as the follow-up year progressed (Figures 1 and 2), raising the possibility that this might continue to increase thereafter. A longer-term follow-up would be of interest.

The present study carries out such a follow-up by interviewing the participants 24 months after they entered the trial. It aims to establish whether the significant treatment effects that were identified at one year were maintained over the next year. It also offered the

opportunity to examine whether any of the characteristics of participants as they entered the trial were correlated with drinking outcomes.

METHOD

Design

A randomised trial comparing (1) Aftercare as Usual (AU) with (2) Aftercare as Usual plus Early Warning Signs Relapse Prevention Training (EWSRPT) with assessment at entry to the trial, and 24 months later. The present study is a continuation of assessments that had already been carried out 4, 8 and 12 months after entry (described above)

Participants

Admission criteria The criteria for inclusion in the study were: (i) dependence on alcohol (DSMIV criteria American Psychiatric Association 1994); (ii) having just completed the 6 week day treatment programme; (iii) being abstinent from alcohol; (iv) having experienced at least two relapses (being defined as a return to drinking after at least 3 weeks of voluntary abstinence, achieved with or without professional help, whilst not involuntarily in an institution, e.g. prison); and (iv) having a goal of abstinence from alcohol and other drugs.

The criteria for exclusion from the study were: (v) having a reading age of less than 10 years; (vi) currently suffering from a serious mental illness; (vii) having suffered significant brain damage; (viii) having plans to move away from the study area during the

following year; (ix) being in a major life crisis which required extensive practical help (e.g. becoming homeless); (x) dependence on other drugs.

The study recruited 124 participants and 62 were allocated to each condition.

Sample size The initial 12-month study aimed to recruit sufficient participants to detect a reduction in relapse rate over a 12-month period from 50% to 25% (comparing the 2 arms of the study using the χ^2 test for association with a 5% significance level) with 80% power. This requires 116 participants (58 per group).

Recruitment During the recruitment period the programme produced 210 graduates: 76 were ineligible to take part in the project and 5 were not screened for practical reasons (e.g. the researcher's holidays), leaving 129 potential participants of whom 124 (96%) agreed to participate in the trial. The reasons for ineligibility were (a) insufficient relapse history, 35; (b) already in the project (but had relapsed and returned to treatment), 16; (c) not dependent on alcohol, 11; (d) no abstinence goal, 1; (e) serious mental illness, 3; (f) dependence on other drugs, 4; (g) unavailable for treatment due to practical reasons, 6.

The Dorset NHS Local Research and Ethics Committee approved the study. Potential participants were provided with written information explaining about the nature of the study, their rights to withdraw at any time and confidentiality.

Setting The trial was carried out in a 20-place 6-week day treatment programme (the Sedman Unit) provided by a United Kingdom National Health Service NHS Trust

(Dorset HealthCare) for dependent drinkers who have stopped drinking and wish to remain abstinent. ‘Graduates’ are encouraged to join the aftercare programme. The unit systematically monitors patient outcomes and welcomes clinical research – such as a recent trial of providing patients with a motivational intervention on their first treatment day (Dench and Bennett, 2000).

Interventions In AU participants were eligible to attend the unit for informal contact in a safe milieu; they were welcome to use the same cafeteria and recreational and social facilities as patients in treatment, as well as organized social events, such as barbeques, bowling, fishing trips, and parties. They were encouraged to attend up to three aftercare support groups a week, in which they could discuss their progress and issues that were important to them. They were able to apply to attend structured groups of the 6-week programme, and could also attend an alcohol-free social club in evenings and weekends. All participants were strongly encouraged to use the aftercare services. AU did not offer individual counselling. No programme treatment or aftercare groups offered any elements of EWSRPT listed below; staff agreed not to include any during the course of the study.

EWSRPT was offered in weekly individual sessions based on the sessions in Gorski’s (1995) workbook. Participants were led to carry out procedures, using worksheets from the book, during sessions and completed many of the procedures for homework. The intervention was carried out by one of three research addiction therapists (GB, JW, LP) each of whom had more than 10 years experience in treating dependent drinkers. These

had trained in this approach with its originator (Terence Gorski), and had been formally certified by his organization (CENAPS) as being competent in it following written examinations, submission of a case report using the approach etc. The intervention covered the following procedures, none of which formed part of the 6-week day treatment programme or Aftercare as Usual: (i) life and addiction history (process 5 in Gorski's (1995) Treatment Workbook); (ii) recovery and relapse history; relapse calendar; examination of three most recent attempts at recovery (process 6); (iii) examination of standard warning sign list (process 7); (iv) examination of three outstanding personal warning signs (process 8); (v) sentence completion tasks to examine threats to recovery (process 9); (vi) developing final warning sign list (process 10); (vii) cognitive, behavioural, and emotional management of critical warning signs (processes 11 to 14); and (viii) recovery planning related to warning signs (process 15). The intervention did not include the first phase of Gorski's programme, concerned with stabilisation of the dependent drinker, because the treatment programme had achieved this. This omitted phase consisted of screening, scheduling recovering activities, and carrying out an immediate relapse prevention plan, and an early intervention plan (processes 1 to 4).

At the intake assessment the research assistant invited participants to have their therapy sessions audiotaped and listened to by the three therapists in group mutual supervision. If participants agreed (and all but one did) they signed an informed consent form at their first counselling session and sessions were audio taped. Some audiotapes were transcribed. Weekly peer supervision took place in 60-minute groups as part of quality control to ensure that each patient was receiving treatment according to the protocol.

This involved listening to sections of audiotapes of sessions, reading typed transcripts of sessions, reviewing worksheets completed by patients, and finding solutions to problems and difficulties encountered.

Outcome Measures

Drinking outcome measures (a) Whether the person ever drank alcohol during the 4 months leading up to final 24-month follow-up interview. (b) Whether the person drank alcohol during the second follow-up year (months 12 to 24). (c) Whether the person drank alcohol in the 2 follow-up years (months 1 to 24) (d) Whether the person ever drank alcohol heavily during the 4 months leading up to final follow-up interview, heavy drinking being taken as drinking 9 or more UK units of alcohol (Miller et al 1991) a day for 3 consecutive days. These and measures (e) to (g) below are derived from Time Line Follow Back structured interview, using an adapted version of Form 90 as used in Project MATCH (Project MATCH Research Group (1997). (e) Percentage days drinking in each of the 4 months leading up to final follow-up interview. (f) Percentage days heavy drinking (drinking 9 or more UK units of alcohol a day) in each of the 4 months leading up to final interview. (g) Mean units of alcohol per drinking day in each of the 4 months leading up to final follow-up interview. (h) Blood levels of GGT (gamma glutamyl transferase) and ALT (serum alanine aminotransferase) in samples of capillary blood, measured using a tabletop analyser Reflotron (Boehringer Mannheim) in the final follow-up interview (Conigrave et al 2003).

Non drinking outcome measures (i) Health-related quality of life was assessed using two self-completion questionnaires, the SF36 (using the Physical and Mental summary

scores: Ware et al 1994), and the EQ5D which produced a single index of health status (The EuroQol Group, 1990). (j) Problems caused by drinking was assessed using the Alcohol Problems Questionnaire (APQ) (Williams and Drummond, 1994): the study used the total of the scores of the first 23 items, excluding those related to work and marriage, so as to be applicable to all participants. (k) Mental Health was assessed using the Brief Symptom Inventory (BSI) (Derogatis and Melisaratos, 1983), a questionnaire which produces an overall score, the Global Severity Index (GSI). (l) Occurrence of warning signs of relapse was assessed by the Assessment of Warning-signs of Relapse (AWARE) questionnaire measuring the occurrence of proposed common warning signs of relapse (Miller and Harris 2000). Items were scored as to whether they had or had not occurred during the previous 4 weeks. (m) Use of Health Care and Rehabilitation Services was monitored from structured follow-up interviews based on the relevant component of Form 90 (Project MATCH Research Group 1997). Information was collected about use of services during the 4 months leading up to final follow-up interview. All non-drinking outcomes were assessed at the final follow-up interview. (n) The costs of Health and Rehabilitation services used by participants were assessed (in 2002 pounds sterling) by combining information about service utilisation and the costs of service utilised. The agencies, which treated participants (NHS hospital trusts and primary care trusts) or purchased rehabilitation services for them (local authority social service departments) provided costs for each type of service used (in the form of Department of Health reference costs or similarly calculated costs for items where reference costs were not produced).

Measures to describe sample (o) The degree of dependence on alcohol was assessed using the Severity of Alcohol Dependence Questionnaire (SADQ) (Stockwell et al 1983), which was taken at intake. (p) Social Stability was assessed using the Straus Bacon Index (Straus and Bacon, 1951), derived for each participant based on information taken at intake regarding employment, occupation, stability of residence, and marital status. Higher scores indicate greater social stability.

Procedures

Recruitment and intake assessment Patients starting their final treatment week were screened by a research assistant: those eligible were informed about the trial, invited to join, and offered a meeting later in the week for them to tell the researcher of their decision. Participants choosing to join signed an informed consent form and then underwent intake assessment.

Randomisation Following intake assessment participants were randomly allocated to an arm of the study by means of a telephone based randomisation service set up and administered by PWT from a different NHS Trust. The method ensured that group allocation was concealed both from patients and from the researchers until after the researcher had logged the patient into the study by means of a telephone call to the randomisation office. Randomisation was done in variable length blocks to help ensure equal group sizes, using the random number generator in PEPI (Abramson and Gahliner, 1999).

Follow-up

Follow-up - 12 months In the initial study, the research assistants attempted to reassess all participants 4, 8 and 12 months after entering the trial (Bennett et al submitted for publication)

Follow-up -24 Months In the present study research assistants attempted to reassess all participants 24 months after they entered the trial. Great efforts were made to interview participants at the due date or in the following three months. If, despite these concentrated efforts, it was not possible to make contact with the client within that time the researchers continued to try to do this until the end of the project. Follow-ups were carried out in the research centre, the patient's home, or some other appropriate location (e.g. GP's surgery). Patients were breathalysed at the start of each interview: if the level exceeded 0.05mg% the interview was rescheduled, but the fact of drinking was noted. Every effort was made to collect outcome data. This included use of the on-line NHS strategic tracing service, letters, telephone calls, visiting last known address, contacting any relative nominated by the client for this purpose at intake, and contacting the patient's GP. If the patient had moved away from the area but was still in the UK then the research assistant visited them in their new area. Participants were offered £25 for completing a final follow-up interview and were paid on completion. The Dorset NHS Local Research and Ethics Committee approved this payment.

Plan of Statistical Analysis

Patients were analysed in the group to which they were originally randomised (intention-to-treat analysis). Data were analysed using SPSS for Windows Version 11.0. A 5%

significance level was used throughout: 2-tailed tests were used for comparisons. The person's drinking status (categorised as 'any drinking' or 'no drinking') in the 4 months leading up to final interview, during the second follow-up year and during the entire two years of the study was compared at each point across conditions using the χ^2 test for association. Whether or not the person drank heavily was dealt with in the same way. The score distributions for percent days drinking, percent days heavy drinking and units consumed per drinking day were strongly skewed, with many scores having values of 0. Therefore for each of these variables, participants were divided into 4 approximately equally sized groups and these were compared between the experimental conditions using the χ^2 test for linear trend (since the large number with scores of 0 could cause difficulties with the comparison of medians). The categories used for percent days drinking and heavy drinking variables were 0%, 1-13%, 14-47 and 47+%. The categories used for units consumed per drinking day were 0 units, 1-10 units, 11-20 units and 20+ units. GGT, ALT, APQ and the cost of services used during the follow-up year were summarised using medians and inter quartile ranges, and compared between the groups using the Mann-Whitney U test. Scores of EQ5D, SF36, AWARE and BSI at final follow-up were approximately normally distributed and were compared between groups using the independent samples t-test and summarised using means and standard deviations. In order to compare drinking status at 12 months follow up and final follow up the categorical variables (drank, drank heavily in the four months prior to interview) were compared across the two occasions using the McNemar test for the significance of changes, whilst the skewed continuous variables (percent days drinking, percent days heavy drinking) were compared using the Wilcoxon matched pairs signed-ranks test.

Each comparison was performed on the Total follow-up sample and also on the sub samples of that composed of the two treatment conditions.

The pre-trial characteristics of participants who drank during the four months prior to their final interview were compared with those of participants who did not drink then, in order to identify significant correlates of outcome. Similar analyses were carried out examining drinking in the four months prior to the 12 month follow-up. Analyses included the use of Pearson's r , Spearman's ρ , χ^2 , Mann Whitney U tests, or t-tests, depending on the nature of the variable and its distribution. These analyses were carried out on the Total follow-up sample.

RESULTS

Follow-up

Of the 124 participants, four had died prior to their follow-up date and one had moved abroad. Of the 119 available participants, 102 (86%) were seen face-to-face for a final follow-up interview (51 AU, 51 EWSRPT). It was not possible to interview 17 (14% of available participants): 12 could not be located and 5 were located but refused to participate. The recruitment and follow-up of participants is summarised in Figure 3.

Of the 102 participants that were seen face-to-face, 71 (39 AU, 32 EWSRPT) were interviewed within the 6 months following their 2-year follow-up due date (these constitute the 'on-time follow-up' sample). The remaining 31 (12 AU, 19 EWSRPT) were seen more than 6 months after they were due to be interviewed (these constitute the

'late follow-up' sample). A summary of when final follow-up interviews were completed is provided in Table 1.

The 'on-time' and 'late' follow-up samples were combined to create a 'total' follow-up sample i.e. all those 102 participants that had a final follow-up interview. The 18 participants that were not followed-up (excluding those participants that were deceased) constitute the 'not seen' sample.

Comparison of Pre-treatment characteristics

The pre-treatment characteristics of participants in each sample were compared using Chi², Mann Whitney U tests, or t-tests dependent on the nature of the variable and its distribution. The data and results are summarised in Table 2, 3. There were only two significant differences. between samples. The intake AWARE scores for those that were not seen were significantly higher than for those who were seen: one of 17 comparisons was significant at the 0.05 level. The intake ALT measures were significantly lower in participants who were followed up on time compared with all others (seen late or not seen): one of 17 comparisons was significant at the 0.05 level.

The effect of treatment on drinking variables

There was no significant difference between EWSRPT and AU for either the On-time sample or the Total sample on any of the five indices of drinking (any drinking, any heavy drinking, percent days drinking, percent days heavy drinking, units of alcohol consumed per drinking day) for any of the three time periods (during the 4 months

leading up to the final interview, during the second follow-up year, or during the 2 follow-up years). The data and tests are summarised in Tables 4 to 10 and depicted in Figures 4 to 7.

Comparison of drinking status at 12 months and final follow up

There were no significant differences between the occurrence of any drinking in the 4 months prior to the 12 month follow-up and that prior to the final follow-up for the whole sample ($\text{Chi}^2 = 13.7, \text{df} = 1, P = 0.27$), nor within either of the two treatment conditions. There was a significantly lower proportion of heavy drinking in the whole sample at final follow up (29%) than at 12 months (45%; $\text{Chi}^2 = 12.0, \text{df} = 1, P = 0.02$). In AU a significantly higher proportion (52%) drank heavily at final follow-up than at 12 months (31%; $\text{Chi}^2 = 4.8, \text{df} = 1, P = 0.01$); there was no significant difference for EWSRPT ($\text{Chi}^2 = 7.6, \text{df} = 1, P = 0.77$). There were no differences in the frequency of drinking (z for total sample -0.57, $P=0.57$) or heavy drinking (z for total sample -0.12, $P=0.91$) between the 4 months prior to the 12 month follow-up and that for the final follow-up, for either the whole sample or within either of the two treatment conditions.

The effect of treatment on variables other than drinking

There was no significant indication of a treatment effect for either samples on any of the following variables: GGT, ALT, SF36, EQ5D, APQ, AWARE, and BSI. Values and data are summarised in Table 12. The data for the APQ and GSI are depicted in Figures 8 and 9.

The effect of treatment on the cost of the use made of health and rehabilitation services

On-time follow-up sample The median cost (in £2002) for the services used in the 4 months leading up to 2-year follow-up interview was £203.75 (iqr 408.94) for the EWSRPT group and £182.68 (iqr 735.25) for the AU group. The difference was not significant. Values and data are summarised in Table 13

Total follow-up sample The median cost (in £2002) for the services used in the 4 months leading up to final follow-up interview was £165.59 (iqr 444.94) for the EWSRPT group and £165.59 (iqr 725.92) for the AU group. The difference was not significant. Values and data are summarised in Table 13

Comparison between drinking outcomes of On-time follow-up sample and Late follow-up sample

There was no significant difference between the On-time and Late follow-up samples on any of the five indices of drinking (any drinking, any heavy drinking, percent days drinking, percent days heavy drinking and units of alcohol consumed per drinking day) during the 4 months leading up to the final interview. Values and data are summarised in Tables 17, 18 and 19.

Correlates of outcome

The correlates of outcomes were explored for all participants who were followed up, both separately for participants in each of the two treatment conditions and also together as one group. The results for the latter (Total sample) are presented, as there was virtually

no difference between the two subgroups. Each analysis considered the 24 variables listed in Table 14.

Correlates of drinking status: 24 month follow-up interview

Participants who drank during the 4 months leading up to final follow-up had drunk more frequently ($z = -2.95$, $p=0.003$), had drunk heavily more frequently ($z = -2.87$, $p = 0.004$) and had drunk more units per drinking day ($z = -2.10$, $p = 0.04$) in the first 12 months of the study than participants who were abstinent at final follow-up. Values and tests are summarised in Table 14. Similarly, frequency of drinking, frequency of drinking heavily and units consumed per drinking day in the first 12 months of the study are positively correlated with the frequency of drinking in the 4 months leading up to final interview. Values are summarised in Table 16. Participants drinking at final follow-up scored significantly higher on the EQ5D at intake than those who were abstinent at final follow-up ($t = -2.64$, $p = 0.01$). Higher scores indicate higher quality of life. Four of the 48 statistics were significant at the 0.05 level.

Correlates of drinking status: 12 month follow-up interview

Participants drinking in the 4 months leading up to the 12-month interview had significantly more episodes of abstinence before entering the trial than those that did not drink ($z = -1.96$, $p = 0.05$). Values are summarised in Table 14. Men drank significantly more frequently than women in this period ($z = -2.66$, $p = 0.008$). Values are summarised in Table 16. Two of the 40 statistics computed were significant at the 0.05 level.

Correlates of drinking status: Months 12 to 24

Participants that drank at all in the second follow-up year had drunk more frequently ($Z = -3.33$, $p = 0.001$), had drunk heavily more frequently ($z = -2.87$, $p = 0.004$) and had drunk more units per drinking day ($z = -2.64$, $p = 0.008$) during the first 12 months of the study than participants that were abstinent in the second follow-up year. Furthermore, participants who drank during this period had drunk heavily less frequently at baseline ($z = -2.04$, $p = 0.041$) and scored significantly better on the EQ5D at the beginning of the trial ($t = -2.11$, $p = 0.04$) than those that were abstinent. Values are summarised in Table 15. Five of the 48 statistics computed were significant at the 0.05 level.

Correlates of drinking status: Months 0 to 12

Participants that drank at all in the first follow-up year had significantly more episodes of abstinence before entering the trial than those that were abstinent ($z = -2.10$, $p = 0.04$). Values are summarised in Table 15. Furthermore, participants who drank during this period scored significantly better on the EQ5D (indicating higher quality of life) ($t = -1.99$, $p = 0.05$) and had higher GGT blood levels ($z = -2.18$, $p = 0.03$) at the beginning of the trial than those who abstained. Three of the 40 statistics computed were significant at the 0.05 level.

DISCUSSION

The main aim of the study was to establish whether the significant treatment effects identified at one year were maintained over the next year: it failed to find evidence that

this was the case. The significant effects observed over the first follow-up year were based on a larger sample, with greater potential to observe a moderate treatment effect: the smaller follow-up sample had less power to detect a similar effect if it occurred. In the event the levels of drinking in the two groups at final follow-up were almost identical. Such treatment effects as had occurred at 12 months no longer existed.

The secondary aim was to examine potential correlates of drinking outcome. Given that so few pre-treatment characteristics among so many were significantly related to outcome it is difficult to attribute these to anything but chance. No strong or consistent relationships between pre-treatment characteristics and outcome were observed.

When the sample as a whole is considered it is striking how little patterns of drinking changed from 12 months to final follow-up. The drinking status of the total sample during the final four months was reasonable good, with 40% of participants abstinent and 30% drinking but not heavily. The contrast between this picture and the fact that only 17% never drank at all during the whole follow-up period shows that drinking on one occasion did not lead to continued drinking over the remainder of the follow-up period. The information on the utilisation of services by participants illustrates that many drinkers who returned to regular drinking soon attempt to stop again.

Carrying out long-term follow-ups is a difficult and time-consuming task, even when solid preparations have been made for this venture, as happened in this study. Despite making considerable efforts to do so, only half of those followed up were interviewed

within three months of their 24-month 'anniversary'. There is the possibility that those who were interviewed later differed systematically in some way from those followed up on time, for example that they only chose to be interviewed when they had stopped drinking or were drinking little. The observation that the drinking outcomes of groups of people followed up at different times were so similar might imply that follow-up studies need not take such pains as were taken here to track down and interview hard-to-find participants (who were interviewed last).

The 12 months result of the trial failed to detect the hypothesised relapse prevention effect of the novel intervention: this failed to produce a significant reduction in the recurrence of any drinking (the primary outcome variable). Nevertheless it did detect clinically worthwhile improvements. The EWSRPT produced significant reductions in the occurrence of any heavy drinking during the first follow-up year, in the frequency of drinking and heavy drinking. No significant treatment effect was detected on non-drinking variables. The effects on drinking are particularly important for a population selected for its history of repeatedly failing to make lasting change and also for the context, of having ready access to a range of aftercare support. Producing clinically significant improvements in outcome beyond those of "treatment as usual" is noteworthy, given the severity of the population investigated and the quality of "treatment as usual". The results provide an affirmative answer to the pragmatic question posed in the Introduction - as to whether adding this approach to treatment improves the long-term outcome of treatment. Therefore the results justify the use of EWSRPT with similar patients being treated in similar services, when the aim is to minimise drinking. They

possibly justify adoption where the only acceptable outcome is achieving total abstinence, which is the aim of the approach. The results also suggest that the approach is worthy of further clinical research.

The design of the study precludes the possibility of identifying the mechanism by which the experimental treatment achieved its effects at twelve months. It cannot differentiate between, for example, features that are specific to this approach (e.g. identifying warning signs), and others which may be common to many approaches (e.g. seeing a helper weekly on an individual basis). Since this study has established that this approach is efficacious, there would be value in further controlled research to test the hypothesis that there is specific value in helping people identify and act on their early warning signs of relapse. Finding differential change between the two groups in the measure of warning signs (AWARE) would have lent some support for the hypothesized mode of action of the relapse prevention programme. The logic of the early warning signs approach is that people become better able to identify small warning signs that arise early when things start to go wrong. As a result of this they can act to interrupt the process, and thus avoid experiencing further, possibly more intense warning signs. The lack of differential effect on AWARE scores may result from there being no effect to detect, but it may be due to the fact that this standard list of putative warning signs is not a sensitive index of the occurrence of participants' idiosyncratic patterns of changes. This omnibus measure of 37 experiences is probably too coarse to capture the dozen or so individual signs typically discovered by each patient undergoing EWSRPT. There might be value in constructing more individualised measures.

The significant treatment effects observed at twelve months were confined to measures of drinking. The lack of effects on nondrinking variables (e.g. the APQ) is probably due to the fact that changes in such variables are only moderately linked to changes in drinking. Therefore a fairly strong treatment effect, in reducing the recurrence of drinking, would have been necessary to cause an impact of the experiment on these measures.

The internal validity of the study is strengthened by the high quality of treatment provided (delivered by experienced trained therapists in conditions that ensured adherence to the treatment protocol), the robust independent nature of randomisation, and the high degree of follow-up. The external validity is strengthened by the high level of participation in the study by eligible patients, and the fact that the participants had a range of serious problems in their close relationships and employment status, as well as a high degree of dependence on alcohol, and a history of repeated treatment episodes without sustained benefit. The willingness of patients to participate in the trial and the fairly high engagement of those receiving the relapse prevention treatment suggest that this type of intervention is acceptable and makes sense to service users. EWSRPT seems to be capable of being provided by currently available specialist services, such as the day programme in this case. The therapists in this study were very experienced and had systems to ensure supervision and adherence to the approach. Questions remain about how experienced and skilled therapists need to be in order for them to acquire the skills to carry out this therapy, and about what intensity of training and supervision may be required.

The study could have been strengthened by having independent monitoring of what went on during individual EWSRPT sessions, to demonstrate the extent that therapists followed the protocol. Audiotapes and transcripts of these were only used for this purpose in supervision. Although research assistants who performed the follow-ups were not informed about the condition to which participants had been allocated, it was not possible to blind them to the comments made to them by participants which informed them of this fact.

That the effects on drinking exerted by this hitherto unevaluated approach which were evident at 12 months could not be detected a year or so later does not detract from its potential value. Alcohol dependent people whose attempts to stop drinking last only a few months do not all continue to drink steadily: many stop again, and some of these resume drinking and stop again during a period of two years. They exist in a world with many factors simultaneously stimulate their desires to drink or not to drink, to stay as they are or to use the various sources of formal or informal help available to them. This complex pattern of change may be one reason why the effects of interventions which are not extremely strong are not discernable two years on.

REFERENCES

- Abramson, J.H., & Gahliner, P.M. (1999) *Computer programs for epidemiologists: PEPI Version 3*. Brixton Books: London,
- American Psychiatric Association (1994) *Diagnostic and Statistical Manual of Mental Disorders DSM-IV* American Psychiatric Press: New York
- Bennett, G.A., Withers, J., Thomas, P.W., Higgins, D.S., Bailey, J., Parry, L. and Davies, E. (submitted for publication). A randomised trial of Early Warning Signs Relapse Prevention Training in the treatment of alcohol dependence
- Conigrave, K.M., Davies, P., Haber, P., & Whitfield, J.,B. (2003) Traditional markers of excessive alcohol use. *Addiction*, **98**, 31-43
- Dench, S., & Bennett, G.A.. (2000) The impact of brief motivational intervention at the start of an outpatient day programme for alcohol dependence. *Behavioural and Cognitive Psychotherapy*, **28**, 121-130.
- Derogatis, L.R., & Melisaratos, N. (1983) The brief symptoms inventory: An introductory report. *Acta Psychiatrica Scandinavica*, **13**, 595-605.
- Garbutt, J.C., West, S. L., Carey, T. S., Lohr, K. N., & Crews, F.T. (1999) Pharmacological treatment of alcohol dependence: a review of the evidence. *Journal of the American Medical Association*, **281**, 1318-1325.
- Gorski, T. (1989) The CENAPS model of relapse prevention planning. *Journal of Chemical Dependency Treatment*, **2**, 153-169.
- Gorski, T. (1990)The CENAPS model of relapse prevention: basic principles and procedures. *Journal of Psychoactive Drugs*. **22**, 125-133.
- Gorski, T. (1995) *Relapse Prevention Therapy Workbook: Managing Core*

- Personality and Lifestyle Issues*. Herald House, Independence MO.
- Irvin, J.E., Bowers, C.A., Dunn, M.E., & Wang, M.C. (1999) Efficacy of relapse prevention: a meta-analytic review. *Journal of Consulting and Clinical Psychology*, **67**, 563-70,
- Lowman, C., Allen, J., Stout, R.L., & The Relapse Research Group (1996) Replication and extension of Marlatt's taxonomy of relapse precipitants: overview of procedure and results. *Addiction*. **91**: (Supplement), S51- -S71.
- Marlatt, G.A., & Gordon, J. (1985) *Relapse Prevention*. New York, Guilford Press.
- Miller, WR, and Wilborne, PL. (2002) Mesa Grande: a methodological analysis of clinical trials of treatments for alcohol use disorders. *Addiction*, **97**, 265-277.
- Miller, W.R., Heather, N., & Hall, W.. (1991) Calculating standard drink units: international comparisons. *British Journal of Addiction*, **86**, 43-47.
- Miller, W.R., & Harris, R.J. (2000) A simple scale of Gorski's warning signs for relapse. *Journal of Studies on Alcohol*, **61**, 759-763.
- Project MATCH Research Group. (1997) Matching alcoholism treatments to client heterogeneity: Project MATCH Post treatment drinking outcomes. *Journal of Studies on Alcohol*, **58**, 7-29.
- Srisurapanont, M., & Jarusuraisin, N. (2002) Opioid antagonists for alcohol dependence (Cochrane Review). In: *The Cochrane Library*, Issue 4, Oxford: Update Software.
- Stockwell, T., Murphy, D., & Hodgson, R. (1983) The Severity Of Alcohol Dependence Questionnaire: Its use, reliability and validity. *British Journal of Addiction*, **78**, 45-156.

Straus, R., & Bacon, S.D. (1951) A Study of occupational integration of 2023 male clinic patients. *Quarterly Journal of Studies of Alcoholism*, **12**, 231-260.

The EuroQol Group (1990) EuroQol--a new facility for the measurement of health-related quality of life. *Health Policy*, **16**, 199-208.

Ware J.E., Kosinski, M., & Keller, S.D. (1994). *SF 36 Physical and Mental Health Summary Scales: A User's Manual*. MA: The Health Institute, New England Medical Center.

Williams, B.T., & Drummond, D.C. (1994) The Alcohol Problems Questionnaire: reliability and validity. *Drug and Alcohol Dependence*, **35**, 239-243.

Table 1

Number of final follow-up interviews completed in each follow-up month

Follow-up Month	Frequency	Percent	Cumulative Percent
=<25	25	24.5	24.5
26	14	13.7	38.2
27	10	9.8	48.0
28	7	6.9	54.9
29	9	8.8	63.7
30	6	5.9	69.6
31	3	2.9	72.5
32	4	3.9	76.5
33	4	3.9	80.4
34	5	4.9	85.3
35	2	2.0	87.3
37	4	3.9	91.2
40	2	2.0	93.1
41	3	2.9	96.1
43	1	1.0	97.1
48	1	1.0	98.0
52	1	1.0	99.0
54	1	1.0	100.0

Table 2

Comparisons of pre-treatment characteristics of participants in the 'not seen' follow-up sample and 'total' follow-up sample

	<u>Total Seen</u> n = 102		<u>Not seen</u> n = 18		Index		Comparison P
	n	%	n	%	Chi ²	df	
a)							
gender							
male	64	63%	11	61%	0.02	1	0.90
marital status							
single	44	43%	6	33%	0.41*	1	0.52
married/separated	28	28%	6	33%			
divorced	30	29%	6	33%			
employment status							
employed	14	14%	3	17%	0.11	1	0.74
b)							
	median	iqr	median	iqr	z		P
alcohol treatments	2	4	2.5	5.3	-0.43		0.67
episodes abstinence	5	9	8	6.8	-0.31		0.76
% days drinking	77.5	47.7	82.5	34.6	-0.34		0.74
GGT (U/L)	21.8	23.5	22.0	49.0	-0.19		0.85
ALT (U/L)	24.4	14.2	24.1	17.0	-0.79		0.43
c)							
	mean	sd	mean	sd	F	df	P
age	43.3	10.4	40.0	11.8	1.46	1	0.23
SADQ	34.5	12.4	39.0	11.3	2.04	1	0.16
Strauss Bacon index	1.8	1.4	1.3	1.2	1.9	1	0.17
units /drinking day	30.1	14.2	28.8	25.4	0.11	1	0.74

Continued....

BSI GSI score	0.82	0.63	0.72	0.57	0.31	1	0.58
APQ	14.2	3.8	14.8	4.7	0.33	1	0.58
AWARE	10.7	6.3	15.3	5.3	7.5	1	0.00
EQ-5D	0.72	0.25	0.64	0.33	0.91	1	0.34
SF36 Physical	65.43	21.00	60.59	22.21	0.64	1	0.43
SF36 Mental	46.50	13.73	40.22	12.59	2.61	1	0.11

* Chi² Linear by Linear test

Table 3

Comparisons of pre-treatment characteristics of participants in the 'on-time' follow-up sample and combined 'late' follow-up and 'not seen' sample

	<u>On-time</u> n = 71		<u>Late & Not seen</u> n = 49		Comparison Index		P
	n	%	n	%	Chi ²	df	
a)							
gender							
male	45	63%	30	61%	0.06	1	0.81
marital status							
single	30	42%	20	41%	0.14*	1	0.71
married/separated	21	30%	13	27%			
divorced	20	28%	16	33%			
employment status							
employed	10	14%	7	14%	0.00	1	0.98
b)	median	iqr	median	iqr	z		P
alcohol treatments	2	4	6	8	-1.04		0.30
episodes abstinence	5	9	6	8	-0.05		0.96
% days drinking	77.5	49.2	77.5	44.2	-0.30		0.77
GGT (U/L)	21.9	21.5	21.6	31.6	-1.69		0.09
ALT (U/L)	23.1	13.1	27.3	14.4	-2.01		0.05
c)	mean	sd	mean	sd	F	df	P
age	44.2	10.0	40.8	11.4	3.08	1	0.08
SADQ	35.2	12.1	35.1	12.8	0.00	1	0.98
Strauss Bacon index	1.8	1.4	1.6	1.3	0.75	1	0.39
units /drinking day	29.3	14.0	30.9	19.2	0.27	1	0.61

Continued....

BSI GSI score	0.83	0.65	0.77	0.59	0.24	1	0.62
APQ	14.4	3.8	14.7	4.1	0.70	1	0.40
AWARE	10.6	6.6	12.4	6.0	2.25	1	0.14
EQ-5D	0.72	0.24	0.69	0.28	0.29	1	0.59
SF36 Physical	66.45	21.50	62.32	20.50	1.02	1	0.32
SF36 Mental	46.21	13.44	44.95	14.19	0.23	1	0.64

* Chi² Linear by Linear test

Table 4

The occurrence of drinking in the 4 months leading up to final interview

	<u>EWSRPT</u>		<u>AU</u>		<u>Chi²</u>	<u>P</u>
	n	%	n	%		
On-time follow-up sample (n = 71)						
never drank	13	41	18	46	0.22	0.64
ever drank	19	59	21	54		
Total follow-up sample (n = 102)						
never drank	21	41	22	43	0.04	0.84
ever drank	30	59	29	57		

Table 5

The occurrence of heavy drinking (3 consecutive days of consuming >8 units each day)

in the 4 months leading up to interview

	<u>EWSRPT</u>		<u>AU</u>		<u>Chi²</u>	<u>P</u>
	n	%	n	%		
On-time follow-up sample (n = 70)						
never drank heavily	22	69	26	69	0.00	0.98
ever drank heavily	10	31	12	31		
Total follow-up sample (n = 101)						
never drank heavily	36	71	35	70	0.00	0.95
ever drank heavily	15	29	15	30		

Table 6

The occurrence of drinking during the 2nd follow-up year (months 12 – 24)

	<u>EWSRPT</u>		<u>AU</u>		<u>Chi²</u>	<u>P</u>
	n	%	n	%		
On-time follow-up sample (n = 71)						
never drank	8	25	14	36	0.98	0.32
ever drank	24	75	25	64		
Total follow-up sample (n = 102)						
never drank	13	26	16	31	0.43	0.51
ever drank	38	75	35	69		

Table 7

The occurrence of drinking during the entire 2-year follow-up period (months 1 – 24)

	<u>EWSRPT</u>		<u>AU</u>		<u>Chi²</u>	<u>P</u>
	n	%	n	%		
On-time follow-up sample (n = 71)						
never drank	5	16	7	18	0.07	0.80
ever drank	27	84	32	82		
Total follow-up sample (n = 102)						
never drank	10	20	8	16	0.27	0.60
ever drank	41	80	43	84		

Table 8

The frequency of drinking during the 4 months leading up to 2-year interview

	<u>EWSRPT</u>		<u>AU</u>		<u>Chi²*</u>	<u>P</u>
Percent days drinking	n	%	n	%		
On-time follow-up sample (n = 70)						
0% days	13	41	18	47	0.08	0.78
1-13% days	6	19	7	18		
14-47% days	7	22	4	11		
47+% days	6	19	9	24		
Total follow-up sample (n = 102)						
0% days	21	41	22	44	0.12	0.73
1-13% days	10	20	8	16		
14-47% days	12	24	7	14		
47+% days	8	16	13	26		

*Chi²- Linear by Linear

Table 9

The frequency of heavy drinking during the 4 months leading up to 2-year interview

	<u>EWSRPT</u>		<u>AU</u>		<u>Chi^{2*}</u>	<u>P</u>
Percent days heavy drinking	n	%	n	%		
On-time follow-up sample (n = 70)						
0% days	20	63	21	55	0.23	0.64
1-13% days	2	6	6	16		
14-47% days	6	19	3	8		
47+% days	4	13	8	21		
Total follow-up sample (n = 102)						
0% days	31	61	28	56	0.25	0.61
1-13% days	5	10	8	16		
14-47% days	9	18	4	8		
47+% days	6	12	10	20		

*Chi²- Linear by Linear

Table 10

The amount of alcohol consumed on drinking days during the 4 months leading up to 2-year interview

	<u>EWSRPT</u>		<u>AU</u>		<u>Chi^{2*}</u>	<u>P</u>
Units per drinking day	n	%	n	%		
On-time follow-up sample (n = 70)						
0 units	13	41	18	47	0.60	0.44
1-10 units	9	28	10	26		
11-19 units	5	16	7	18		
20+ units	5	16	3	8		
Total follow-up sample (n = 101)						
0 units	21	41	22	44	0.62	0.43
1-10 units	12	24	14	28		
11-19 units	7	14	7	14		
20+ units	11	22	7	14		

*Chi²- Linear by Linear

Table 11

Blood levels of GGT and ALT

	<u>EWSRPT</u>		<u>AU</u>			
On-time follow-up sample (n = 57)						
	median	iqr	median	iqr	z	P
GGT	18.2	97.6	20.2	25.8	-0.05	0.96
ALT	20.5	31.1	20.4	13.3	-0.26	0.79
Total follow-up sample (n = 82)						
GGT	18.1	41.2	21.6	24.3	-0.71	0.48
ALT	20.5	19.7	20.1	17.9	-0.23	0.78

Table 12

Comparisons of variables other than drinking at final interview

	<u>EWSRPT</u>		<u>AU</u>		Comparison Index		
	mean	sd	mean	sd	t	df	P
On-time follow-up sample							
SF36 Physical	63.97	23.39	67.08	19.38	0.64	67	0.53
SF36 Mental	47.44	17.69	49.30	17.77	0.43	67	0.67
GSI	1.02	0.80	0.98	0.89	-0.22	67	0.83
AWARE	10.4	6.8	11.7	7.5	0.74	68	0.46
EQ-5D	0.64	0.29	0.64	0.29	0.00	68	1.00
	median	iqr	median	iqr	z		P
APQ	1.5	9.0	2.0	9.3	-0.16		0.87
Total follow-up sample							
	mean	sd	mean	sd	t	df	P
SF36 Physical	68.00	21.42	66.00	19.79	-0.48	97	0.63
SF36 Mental	50.12	17.56	49.19	17.27	-0.27	97	0.79
GSI	0.96	0.74	0.95	0.85	-0.02	95	0.98
AWARE	10.0	6.4	11.1	7.2	0.78	98	0.44
EQ-5D	0.66	0.30	0.64	0.30	-0.40	97	0.70
	median	iqr	median	iqr	z		P
APQ	1.0	9.0	2.0	8.0	-0.24		0.81

Table 13

Comparisons of cost of the use made of health and rehabilitation services

	<u>EWSRPT</u>		<u>AU</u>		z	P
	median	iqr	median	iqr		
On-time follow-up sample						
Total Cost £	209.17	559.52	174.14	891.83	-0.45	0.65
Total follow-up sample						
Total Cost £	165.59	444.94	165.59	725.92	-0.45	0.96

Table 14

Correlates of outcome: Drink/No drink in the 4 months leading up to 24 month and 12 month interview

Variable	Index	24 Months		12 Months	
		Value	P	Value	P
Pre-treatment Characteristics					
Gender	χ^2	0.18	0.67	2.70	0.10
Age	t	0.57	0.57	-1.08	0.28
SADQ	t	0.35	0.72	0.07	0.94
Marital Status	χ^{2**}	0.47	0.49	0.87	0.35
Employment Status	χ^2	0.40	0.52	0.55	0.46
Straus Bacon	t	0.92	0.36		
No of abstinence with help	Z	-0.70	0.49	-0.78	0.44
No. of abstinence	Z	-1.23	0.22	-1.96	0.05*
GGT	Z	-1.52	0.13	-1.59	0.11
ALT	Z	-0.60	0.55	-1.55	0.12
APQ	t	0.17	0.87	0.08	0.53
AWARE	t	1.11	0.27	0.63	0.53
SF36 Mental	t	-0.43	0.66	-0.62	0.53
SF36 Physical	t	-1.37	0.18	-1.44	0.15
GSI	t	0.93	0.36	0.52	0.61
EQ5D	t	-2.64	0.01*	-1.37	0.17
%days drinking Baseline	Z	-1.64	0.10	-1.08	0.28
% days heavy drinking Baseline	Z	-1.81	0.07	-1.00	0.32
Units per drinking day Baseline	t	1.17	0.25	-0.15	0.88
Total use of aftercare	Z	-1.01	0.31	N/a	N/a
12 Month drinking outcomes					
% days drinking First 12 months	Z	-2.95	0.003*	N/a	N/a
% days heavy drinking First 12 months	Z	-2.87	0.004*	N/a	N/a
Units per drinking day First 12 months	Z	-2.10	0.04*	N/a	N/a

* statistically significant

**Chi² Linear by Linear

Table 15

Correlates of outcome: Drink/No drink in Months 12-24 and months 0-12

Variable	Index	24 Months		12 Months	
		Value	P	Value	P
Pre-treatment Characteristics					
Gender	χ^2	4.76	0.029*	3.26	0.07
Age	t	1.09	0.28	-0.59	0.59
SADQ	t	0.64	0.53	0.07	0.95
Marital Status	χ^{2**}	0.070	0.79	1.45	0.23
Employment Status	χ^2	1.66	0.20	0.00	1.00
Straus Bacon	t	1.22	0.23		
No of abstinence with help	Z	-0.83	0.41	-0.96	0.34
No. of abstinence	Z	-1.52	0.13	-2.10	0.04*
GGT	Z	-0.65	0.52	-2.18	0.03*
ALT	Z	-0.91	0.36	-1.07	0.29
APQ	t	-0.41	0.69	-0.92	0.36
AWARE	t	0.52	0.61	0.40	0.69
SF36 Mental	t	0.19	0.85	-0.69	0.49
SF36 Physical	t	-1.71	0.09	-1.63	0.11
GSI	t	0.76	0.45	0.97	0.34
EQ5D	t	-2.11	0.04*	-1.99	0.05*
%days drinking Baseline	Z	-1.81	0.07	-1.41	0.16
% days heavy drinking Baseline	Z	-2.04	0.041*	-1.66	0.09
Units per drinking day Baseline	t	1.51	0.14	-0.65	0.52
Total use of aftercare	Z	-0.97	0.332	N/a	N/a
12 Month drinking outcomes					
% days drinking First 12 months	Z	-3.33	0.001*	N/a	N/a
% days heavy drinking First 12 months	Z	-2.91	0.004*	N/a	N/a
Units per drinking day First 12 months	Z	-2.64	0.008*	N/a	N/a

*statistically significant

**Chi² Linear by Linear

Table 16**Correlates of outcome: Percentage days drinking in the 4 months leading up to final interview**

Variable	Index	24 Months		12 Months	
		Value	P	Value	P
Pre-treatment Characteristics					
Gender	Z	-1.08	0.28	-2.66	0.008*
Age	r ¹	-0.09	0.38	0.04	0.66
SADQ	r ¹	0.04	0.71	0.07	0.53
Marital Status	χ ^{2**}	4.17	0.13	1.55	0.46
Employment Status	Z	-0.59	0.55	-0.64	0.52
Straus Bacon	r ¹	-0.15	0.15	0.01	0.91
No of abstinence with help	p ²	0.17	0.09	0.13	0.19
No. of abstinence	p ²	0.17	0.08	0.20	0.04*
GGT	p ²	0.14	0.18	0.11	0.29
ALT	p ²	0.00	0.96	0.06	0.59
APQ	r ¹	0.14	0.18	0.13	0.19
AWARE	r ¹	0.03	0.74	0.01	0.94
SF36 Mental	r ¹	0.03	0.81	0.07	0.49
SF36 Physical	r ¹	0.09	0.41	0.19	0.07
GSI	r ¹	-0.01	0.96	-0.41	0.70
EQ5D	r ¹	0.14	0.18	0.03	0.77
%days drinking	p ²	-0.07	0.47	0.03	0.78
Baseline					
% days heavy drinking	p ²	-0.06	0.52	-0.00	0.99
Baseline					
Units per drinking day	r ¹	0.05	0.65	0.01	0.96
Baseline					
Total use of aftercare	p ²	-0.17	0.08	N/a	N/a
12 Month drinking outcomes					
% days drinking First 12 months	p ²	0.40	0.000*	N/a	N/a
% days heavy drinking First 12 months	p ²	0.41	0.000*	N/a	N/a
Units per drinking day First 12 months	p ²	0.28	0.006*	N/a	N/a

*statistically significant

**Chi² Kruskal wallis¹ Pearsons r² Spearmans p

Table 17

Comparison of drinking status of participants followed up On-time and those followed up Later : whether or not they drank or drank heavily during 4 months prior to final interview

The occurrence of any drinking in the 4 months leading up to final interview

	On time		Late follow-up		<u>Chi²</u>	<u>P</u>
	n	%	n	%		
never drank	31	44	12	39	0.22	0.64
ever drank	40	56	19	61		

The occurrence of heavy drinking (3 consecutive days of consuming >8 units each day) in the 4 months leading up to final interview

ever drank heavily	48	69	23	74	0.33	0.57
ever drank heavily	22	31	8	26		

Table 18

Comparison of drinking status of participants followed up On-time and those followed up Late : frequency of drinking and heavy drinking

	<u>On time</u>		<u>Late</u>		<u>Chi²*</u>	<u>P</u>
	n	%	n	%		
Percent days drinking						
0% days	31	44	12	39	0.20	0.66
1-13% days	13	19	5	16		
14-47% days	11	16	8	26		
47+% days	15	21	6	19		
Percent days heavy drinking						
0% days	41	59	18	58	0.10	0.75
1-13% days	8	11	5	16		
14-47% days	9	13	4	13		
47+% days	12	17	4	13		

Table 19

Comparison of drinking status of participants followed up On-time and those followed up Late : units of alcohol consumed per drinking day

	<u>On-time</u>		<u>Late</u>		<u>Chi^{2*}</u>	<u>P</u>
	n	%	n	%		
Units per drinking day						
0 units	31	44	12	39	2.23	0.14
1-10 units	19	27	7	23		
11-19 units	12	17	2	6		
20+ units	8	11	10	32		