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A randomised trial of early warning signs relapse prevention training in the treatment of alcohol dependence☆

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Abstract

A pragmatic randomised trial examined the effects of Early Warning Signs Relapse Prevention Training (EWSRPT) on drinking in alcohol dependent persons with history of relapse. Participants were 124 abstinent alcohol dependent patients with a history of relapse (median five relapses) who entered the trial as they completed a 6-week day treatment programme. They were randomly allocated to receive either (1) Aftercare as Usual (AU) or (2) AU plus 15 individual sessions of EWSRPT using Gorski's protocol. Assessment carried out at entry to the trial, and 4, 8, and 12 months later, included self-report of drinking, blood tests (gamma glutamyl transferase, GGT; serum alanine amino-transferase, ALT) and measures of functioning (Alcohol Problems Questionnaire, APQ; SF36, Brief Symptom Inventory, BSI; Assessment of Warning-signs of Relapse, AWARE). Intention to treat analysis found no significant differences in continuous abstinence during the follow-up year (17% of 58 AU, 31% of 58 EWSRPT, p=0.08). The EWSRPT participants had a significantly lower probability of drinking heavily (74% of AU, 55% of EWSRPT, p=0.04), and significantly fewer days drinking

☆ The study was carried out at the Sedman Unit, Dorset HealthCare NHS Trust, 16-18 Tower Road, Bournemouth, Dorset, BH1 4LP, United Kingdom.

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(p=0.05) and heavy drinking (p=0.04). These clinically worthwhile effects for a relapse-prone group justify further research into EWSRPT.

Keywords: Alcohol dependence; Relapse prevention; Trial; Warning signs

1. Introduction

Many interventions have been shown to help people who are dependent on alcohol to cease drinking and begin to live without alcohol (Miller & Willborne, 2002). However, the temporary nature of many changes highlights the need for effective ways of helping drinkers to remain abstinent once treatment contact ends. The most influential psychological treatment approach, based on the cognitive-behavioural model of Marlatt (Marlatt & Gordon, 1985), focuses primarily 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, Allen, Stout, & The Relapse Research Group, 1996). Reviews of the outcome literature arrive at differing conclusions about the effectiveness of treatments derived from Marlatt's approach: some (e.g. Irvin, Bowers, Dunn, & Wang, 1999) are very positive, others (e.g. Miller & Wilborne, 2002) are less so.

A rather different psychological approach for dependent drinkers who had stopped drinking and then returned to it a number of times is the early warning signs intervention developed by Gorski (1989, 1990). This 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. The intervention involves a series of procedures to help the person become aware of their own habitual warning signs, and then to interrupt the relapse process by learning how to manage or cope with signs, particularly those early in the sequence. The protocol describes about 20 sessions, each of which can be carried out individually in an hour.

Gorski's (1995) approach is widely used in the USA and is supported by books, patient workbooks, and videos, and could be easily disseminated. Several thousand professionals have completed a 6-day training programme and accreditation system for graduates of this. This intervention has never been subjected to a randomised trial. In the current state of knowledge, the most appropriate evaluation is a simple pragmatic trial designed to ascertain whether adding this approach to treatment improves the long-term outcome of patients. Finding a reduction in relapse would justify the use of the approach, but could not account for the factors responsible for the effect. This current pragmatic study aims to establish whether

providing Gorski's intervention to alcohol dependent people when they complete day treatment reduces their risk of drinking during the following year.

2. Method

2.1. Design

A randomised trial compared (1) Aftercare as Usual (AU) with (2) AU plus Early Warning Signs Relapse Prevention Training (EWSRPT). Participants were assessed at entry to the trial, and 4, 8, and 12 months later. The primary dependent variable is the occurrence of any drinking during the follow-up year. Other variables assessing drinking outcome relate to the frequency and amount of drinking. The design of the trial is depicted in Fig. 1. The Dorset NHS Local Research and Ethics Committee approved the study.

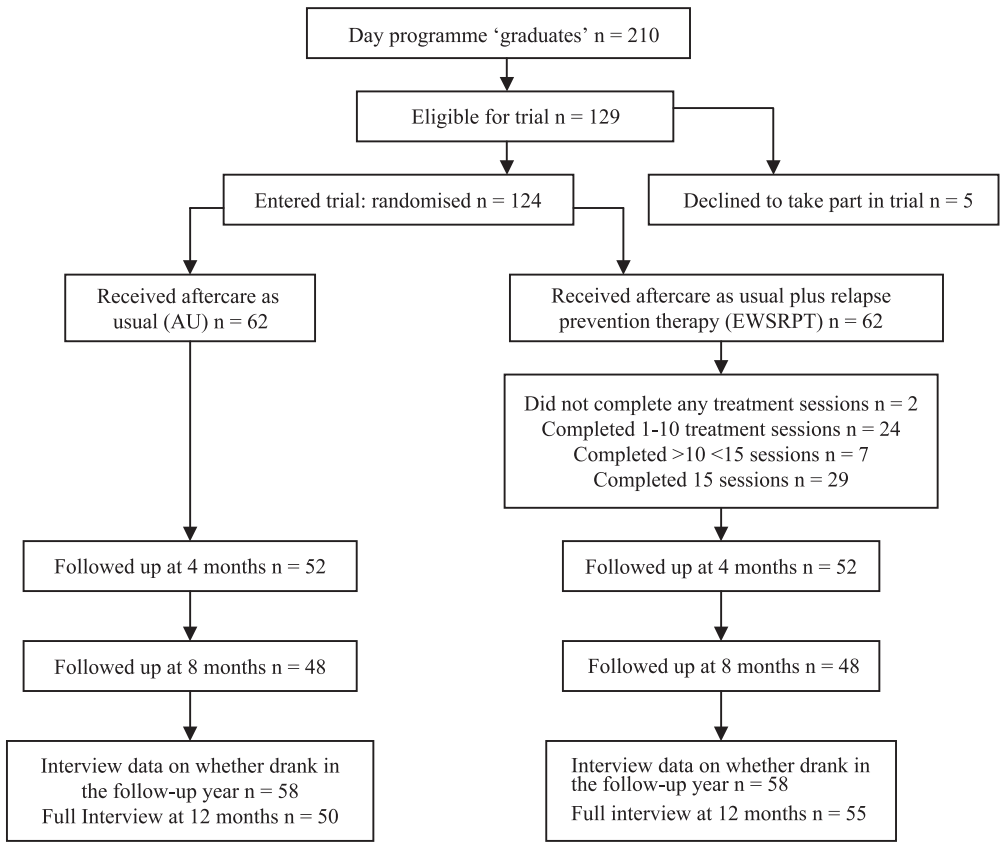

Fig. 1. Recruitment and follow-up of participants in trial.

2.2. Participants

2.2.1. Admission criteria

The criteria for inclusion in the study were: (i) dependence on alcohol (DSM-IV 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 (v) having a goal of abstinence from alcohol and other drugs. The criteria for exclusion from the study were: (vi) having a reading age of less than 10 years; (vii) suffering from a serious mental illness; (viii) having suffered significant brain damage; (ix) having plans to move away from the study area during the following year; (x) being in a major life crisis which required extensive practical help; (xi) dependence on other drugs.

The study recruited 124 participants and 62 were allocated to each condition. Their pretreatment characteristics are summarised in Table 1.

2.2.2. Sample size

The study aimed to recruit sufficient participants to detect a reduction in relapse rate over a 12-month period from 50% to 25% (comparing the two 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). The bases of this calculation were an internal audit of outcome in the day unit, the magnitude of effect seen in a study with a similar client group (Allsop, Saunders, Phillips, & Carr, 1997), and the point of economic break-even calculated in a crude economic analysis.

2.2.3. Recruitment

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

2.3. Setting

The trial was carried out in a 20 place 6-week abstinence-oriented day treatment programme for dependent drinkers (the Sedman Unit) provided by a United Kingdom National Health Service NHS Trust (Dorset HealthCare).

2.4. Interventions

In AU, participants could attend the unit for informal contact, using the same recreational and social facilities as patients in treatment, including social events (e.g. barbeques, fishing

Table 1
Pretreatment characteristics of study participants

	Control		Treatment		Comparison		
	n=62		*n*=62		Index		*p*
(a)	*n*	%	*n*	%	Chi^2	*df*	
Gender							
Male	45	73%	33	53%	4.98	1	0.03
Marital status							
Single	23	37%	28	45%	1.16	2	0.56
Married/separated	18	29%	18	29%			
Divorced	21	34%	16	26%			
Employment status							
Employed	11	18%	7	11%	1.04	1	0.31

(b)	Median	iqr	Median	iqr	*Z*	*p*
Alcohol treatments	2.0	4	2.0	4	−0.30	0.77
Episodes abstinence	5.5	7	5.0	8	−0.26	0.80
Percent days drinking	70.0	52.1	74.1	53.9	−0.26	0.79
GGT (U/L)	21.9	25.0	22.8	34.0	−0.20	0.84
ALT (U/L)	24.8	15.7	23.5	14.1	−0.56	0.58

(c)	Mean	S.D.	Mean	S.D.	*t*	df	*p*
Age	44.3	10.6	41.8	10.6	1.32	122	0.19
SADQ	35.8	12.0	34.7	12.5	0.47	122	0.64
Strauss Bacon index	1.8	1.4	1.7	1.4	0.26	122	0.79
Units/drinking day	28.8	14.9	31.7	17.7	−0.95	122	0.35
BSI GSI score	1.6	0.9	1.8	0.8	−1.13	122	0.26
APQ	13.8	4.5	14.8	3.1	−1.44	122	0.15
AWARE	11.9	6.4	10.6	6.3	1.06	122	0.29
EQ-5D	0.7	0.2	0.7	0.3	0.92	122	0.36
SF36 Physical	66.0	19.0	63.3	23.6	0.68	113	0.50
SF36 Mental	46.5	14.1	45.1	13.3	0.56	113	0.58

trips). They could attend three aftercare support groups a week, in which they could discuss their progress and current personal issues, and an alcohol-free social club in evenings and weekends. All participants were encouraged to use the aftercare services. AU did not offer individual counselling. No programme treatment or aftercare group offered any element of EWSRPT.

EWSRPT was given 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 these for homework. The intervention was carried out by three research addiction therapists (GB, JW, LP), each of whom had more than 10 years experience in treating dependent drinkers. They had trained in this approach with its originator (Terence Gorski), and been formally certified by his organisation (CENAPS) as

being competent in it following written examinations, submission of a case report using the approach, etc. The intervention covered the following procedures, described in Gorski (1995): none formed part of the day treatment programme or AU: (i) life and addiction history; (ii) recovery and relapse history; relapse calendar; review of three most recent attempts at recovery; (iii) review of standard warning sign list; (iv) review of three outstanding personal warning signs; (v) sentence completion tasks to examine threats to recovery; (vi) developing final warning sign list; (vii) cognitive, behavioural, and emotional management of critical warning signs; and (viii) recovery planning related to warning signs. The intervention did not include the first phase of Gorski's programme, concerned with stabilising drinkers, because the treatment programme had achieved this. During weekly hour-long peer supervision groups, carried out to ensure their adherence to the protocol, therapists listened to audiotapes of sessions, read typed transcripts of sessions, reviewed worksheets completed by patients, and attempted to solve problems and difficulties encountered.

2.5. Outcome measures

2.5.1. Drinking outcome measures

(a) Whether the person ever drank alcohol during the 12 months after intake (entering the study): this was defined a priori as the primary outcome measure. (b) Whether the person ever drank alcohol heavily during the 12 months after intake, heavy drinking being taken as drinking 9 or more UK units of alcohol (Miller, Heather, & Hall, 1991) a day for three consecutive days. These and measures (c) 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), conducted at intake (regarding pretreatment baseline of 4 months) and 4, 8, and 12 months afterwards.

Measures (c), (d) and (e) were computed for baseline and each of the 12 months from intake. (c) Percentage days drinking. (d) Percentage days heavy drinking (drinking 9 or more UK units of alcohol a day). (e) Mean units of alcohol per drinking day. (f) Days till first drink (should the person drink). (g) Days to first heavy drink (three consecutive days of drinking >8 units a day—should the person drink). (h) Levels of gamma glutamyl transferase (GGT) and serum alanine aminotransferase (ALT) in samples of capillary blood, measured using a Reflotron analyser (Boehringer Mannheim) at intake, and 4, 8, and 12 months later.

2.5.2. Nondrinking outcome measures

In each case, higher scores indicate stronger levels of the attribute measured. Measures (i) through (m) were taken at intake and at 12 months follow-up: (j), (k) and (m) were also taken at 4, and 8 months follow-ups. (i) Health-related quality of life was assessed through the SF36 (using Physical and Mental summary scores; Ware, Kosinski, & Keller, 1994), and the EQ5D which produced a single index (The EuroQol Group, 1990). (j) Problems caused by drinking were assessed using the Alcohol Problems Questionnaire (APQ) (Williams & Drummond, 1994), utilising the total of the scores of the first 23 items. (k) Psychopathology was assessed

through the Brief Symptom Inventory (BSI) (Derogatis & Melisaratos, 1983), using the Global Symptoms Index (GSI). (l) Occurrence of warning signs of relapse was assessed by the Assessment of Warning-signs of Relapse (AWARE) questionnaire (Miller & Harris, 2000), scoring items as to whether they had or had not occurred during the previous 4 weeks. (m) Use of healthcare 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 each 4-month period after entering the study. The numbers of aftercare sessions attended by participants during the 12 months were taken from attendance sheets filled in each day at the Unit. (n) The costs of health and rehabilitation services used by participants were assessed 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). Costs of providing EWSRPT were calculated on the same basis.

Measures to describe sample. (o) The degree of dependence on alcohol was assessed using the Severity of Alcohol Dependence Questionnaire (SADQ) (Stockwell, Murphy, & Hodgson, 1983), administered at intake. (p) Social stability was assessed using the Straus Bacon Index (Straus & Bacon, 1951) based on information taken at intake regarding employment, occupation, stability of residence, etc.

2.6. Procedures

2.6.1. 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. Potential participants were provided with written information about the nature of the study, their rights to withdraw at any time and confidentiality. Those choosing to join signed an informed consent form and then underwent intake assessment.

2.6.2. Randomisation

After 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 telephoning the randomisation office. Randomisation was done in variable length blocks to help ensure equal group sizes, using the random number generator in PEPI (Abramson & Gahliner, 1999).

2.6.3. Follow-up

Research assistants attempted to reassess all participants at 4, 8, and 12 months after intake. Follow-ups were carried out in the research centre, the participant's home, or some

other appropriate location (e.g. GP's surgery). Participants who moved to other parts of the UK were visited in their new area. Researchers breathalysed participants at the start of interviews: if the level exceeded 0.05 mg% the interview was rescheduled, but the fact of drinking was noted.

2.7. 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: two-tailed tests were used for comparisons. The person's drinking status (categorised as 'any drinking' or 'no drinking') over the whole year was compared across conditions using the χ^2 test for association and was also summarised using odds ratios with 95% confidence intervals, and the numbers needed to treat statistic (NNT). Whether or not the person drank heavily was dealt with in the same way.

The score distributions for percent days drinking, and percent days heavy drinking, were strongly skewed, with many scores having values of 0. Therefore, for each of these variables participants were divided into four 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 both variables were 0%, 1–4%, 5–19% and 20+%. Comparisons of percent days drinking and percent days heavy drinking between the two conditions were also made by excluding participants with a level of 0%, although here the resulting comparisons are not between randomised groups and the results might be affected by confounding: the Mann–Whitney *U*-test was employed because the score distributions of these variables were highly skewed. Units consumed per drinking day were normally distributed and compared using *t*-tests. The effect size of the EWSRPT compared to AU was calculated using Cohen's *d* for the continuous drinking variables and the odds ratio for categorical variables. The effect sizes were also calculated for all these variables as the correlation coefficient *r*, so as to make them comparable with the results of Irvin et al. (1999) meta-analysis of relapse prevention.

The score distributions for GGT, and ALT, and the cost of services used during the follow-up year were strongly skewed and were therefore summarised using the median and interquartile range (iqr), and compared between the groups using the Mann–Whitney *U*-test. Scores of EQ5D, SF36, and AWARE at 12-month follow-up were approximately normally distributed and were compared between groups using the independent samples *t*-test and summarised using means and standard deviations. Scores of the APQ and BSI, which were measured at 4, 8 and 12 months, were approximately normally distributed, and summarised using means and standard deviations. They were analysed using repeated measures analysis of variance, focusing on the main effect for groups and the effect of the interaction between groups and occasions. The distribution of the number of aftercare sessions was highly skewed with many ties (many people with 0 contacts). The data were categorised into four categories containing similar number of patients (0, 1–6, 7–18, 19+

sessions). The categories were compared between the two groups using the χ^2 test for trend. A 'per protocol' analysis compared the two conditions on indices of drinking during the follow-up year, as to whether participants drank or drank heavily, and on their percent days drinking and percent days heavy drinking. This used the same methods as used in the main 'intention to treat' analysis, but only included EWSRPT participants who had attended 10 or more of the 15 sessions (a criterion chosen before the trial to represent a reasonable exposure to the intervention).

3. Results

3.1. Attendance at EWSRPT sessions

Of the 62 participants allocated to EWSRPT, 29 (47%) attended all 15 sessions, 7 (11%) 11 through 14 sessions, 12 (19%) 6 through 10 sessions, 13 (21%) 1 through 5 sessions, and 1 (2%) 0 sessions. The median number of sessions attended was 13.5.

3.2. Comparison of pretreatment characteristics

The only small p-value was in the greater proportion of males in the AU group. Data are summarised in Table 1.

3.3. Follow-up

Of the 124 participants, 105 (85%) were personally followed up at 12 months and provided complete drinking data (55 EWSRPT, 50 AU): 85 (68%) were followed up at all follow-ups (4, 8 and 12 months) and also gave complete data on all other variables. Follow-up interviews provided information about the occurrence of any drinking during the year for 116 (93%) participants (58 in each condition) and about the occurrence of any heavy drinking for 112 (90%) participants (58 EWSRPT, 54 AU). These three samples were examined to see whether there was any significant association between providing information and treatment condition: none was found. Information about drinking frequency and quantity was available for 81% in AU and 89% in EWSRPT (p=0.21: n=105); that for the occurrence of drinking was available for 93% in each group (p=1.0: n=116); that for the occurrence of heavy drinking was available for 93% of EWSRPT and 87% of AU (p=0.45: n=112).

3.4. The effect of treatment on drinking variables

3.4.1. Whether any drinking occurred

Of the 58 EWSRPT patients, 18 (31%) never drank in the follow-up year, as compared to 10 (17%) of the 58 AU patients. The difference in proportions was not significant (χ^2=3.03, df=1, p=0.08). The odds ratio of ever drinking for EWSRPT relative to AU for the year was

0.46 (95% confidence interval, CI, 0.19 to 1.12, p=0.09). The number of patients one would need to treat in order to prevent one relapse during a year (NNT) was 7. The effect size r was 0.16. 'Survival' rates at 3 and 6 months were, respectively, 52% and 40% (AU) and 56% and 42% (EWSRPT).

3.4.2. Whether any heavy drinking occurred

Of the 58 EWSRPT patients, 26 (45%) never drank heavily during the follow-up year, as compared to 14 (26%) of the 54 AU patients. The difference in proportions was significant (χ^2=4.35, df=1, p=0.04). The odds ratio of drinking heavily for EWSRPT relative to AU for the year was 0.43 (CI 0.19 to 0.96, p=0.04). NNT was 5. The effect size r was 0.20. 'Survival' rates at 3 and 6 months were, respectively, 64% and 52% (AU) and 71% and 60% (EWSRPT).

3.4.3. Percent days drinking

Of the 55 EWSRPT participants providing information about drinking frequency, 18 (33%) never drank during the follow-up year, 10 (18%) drank on 1–4% of days, 15 (27%) drank on 5–19% of days, and 12 (22%) drank on more than 19% of days. Of the 50 AU participants providing information about drinking frequency, 10 (20%) never drank during the follow-up year, 8 (16%) drank on 1–4% of days, 12 (24%) drank on 5–19% of days, and 20 (40%) drank on more than 19% of days. There were significantly fewer percentage days drinking for EWSRPT for the year (χ^2=3.94, df=3, p=0.05). The effect size d was 0.34 (CI 0.05 to 0.72), 0.17 expressed as r. A comparison excluding participants with 0% failed to find a significant effect (Z=−0.15, p=0.13).

3.4.4. Units of alcohol consumed per drinking day

There was no significant effect on units per drinking day, based on the participants who drank during the period. Mean daily units (S.D., n) consumed over the whole year were for EWSRPT 21.4 (16.4, 37) and AU 23.1 (13.3, 40): t=0.49, 75 df, p=0.63.

3.4.5. Percent days heavy drinking

Of the 55 EWSRPT participants providing information about frequency of heavy drinking, 22 (40%) never drank heavily during the follow-up year, 8 (15%) drank heavily on 1–4% of days, 15 (27%) drank heavily on 5–19% of days, and 10 (18%) drank heavily on more than 19% of days. Of the 50 AU participants providing information about frequency of heavy drinking, 11 (22%) never drank heavily during the follow-up year, 7 (14%) drank heavily on 1–4% of days, 18 (36%) drank heavily on 5–19% of days, and 14 (28%) drank heavily on more than 19% of days. There were significantly fewer percentage days heavy drinking for EWSRPT for the year (χ^2=4.18, df=3, p=0.04). The effect size d was 0.31 (CI 0.08 to 0.69), 0.15 expressed as r. A comparison excluding participants with 0% failed to find a significant effect (Z=−1.33, p=0.18).

3.4.6. GGT and ALT

Data are summarised in Table 2. No comparison was significant.

Table 2
Measures of characteristics other than drinking: scores during the follow-up year

		4 months			8 months			12 months		
		n	Mean	S.D.	*n*	Mean	S.D.	*n*	Mean	S.D.
APQ	Treatment	51	4.78	5.01	48	3.75	4.60	53	4.32	5.03
	Control	52	4.56	5.05	45	3.51	4.31	50	5.96	5.47
BSI GSI score	Treatment	48	0.96	0.84	47	0.84	0.74	52	0.98	0.88
	Control	49	1.06	0.97	46	0.81	0.80	48	1.17	0.89
EQ5D	Treatment	nt[a]			nt			52	0.71	0.28
	Control	nt			nt			50	0.63	0.30
SF36 Physical	Treatment	nt			nt			52	63.21	17.89
	Control	nt			nt			50	64.29	20.84
SF36 Mental	Treatment	nt			nt			52	46.61	8.39
	Control	nt			nt			50	40.66	9.04
AWARE	Treatment	nt			nt			51	9.84	7.28
	Control	nt			nt			50	12.48	7.33
		n	Median	iqr	*n*	Median	iqr	*n*	Median	iqr
GGT	Treatment	46	22.0	27.9	41	18.0	22.2	43	25.5	0.8
	Control	48	19.1	23.5	43	24.4	28.4	43	29.8	49.0
ALT	Treatment	46	22.7	16.5	41	19.6	8.5	43	23.5	16.5
	Control	48	25.8	21.3	43	25.0	14.1	43	28.1	26.0

[a] nt=measure not taken at this point.

3.4.7. '*Per protocol*' *analysis of drinking data*

Of EWSRPT participants, 39 attended 10 or more sessions. No drinking during the follow-up year was reported by 14 (39%) of the 36 EWSRPT participants and 10 (17%) of the AU group—a significant difference (χ^2=4.70, 1 *df*, p=0.03; OR 0.36, CI 0.14 to 0.92, NNT 5). No heavy drinking was reported by 19 (53%) of EWSRPT and 14 (26%) of AU (χ^2=5.62, 1 *df*, p=0.02; OR 0.35, CI 0.15 to 0.84, p=0.02; NNT 4). The EWSRPT group also had significantly fewer percent drinking days (χ^2=7.33, 1 *df*, p=0.007) and fewer percent heavy drinking days (χ^2=7.25, 1 *df*, p=0.007).

3.5. The effect of treatment on variables other than drinking

There was no significant indication of a treatment effect on any of the following variables, each followed by the p values for, respectively, treatment×occasion interaction and treatment main effect: APQ (0.42, 0.62); BSI (0.45, 0.78); EQ5D (0.22, 0.51); AWARE (0.32, 0.11); and SF36 Physical (0.91, 0.91). For SF36 Mental, there was no significant treatment main effect (p=0.06), but there was a significant interaction effect (p=0.02). *T*-tests between SF36 Mental Component scores for the two groups found that the mean scores at intake did not differ significantly, but the scores at 12 months were significantly higher for EWSRPT (t=98.7, p=0.001). Scores are summarised in Table 2. Participants in EWSRPT attended significantly more aftercare sessions for the whole year (median of 16, IQR=48.5) than those in AU (median of 6, IQR=29.0; χ^2=10.0, 1 *df*, p=0.0002).

The median cost (in £2002) for the services used over the follow-up year was £582.27 (iqr 1353.59) for the EWSRPT group if the cost of EWSRPT itself was not included or £1050.49 (iqr 1435.53) if it was included. The median cost for the AU group was £822.43 (iqr 2033.37). The difference was not significant if either the EWSRPT costs were (Z=1.11, p=0.27) or were not (Z=0.86, p=0.39) included.

4. Discussion

The trial failed to detect the hypothesised relapse prevention effect of EWSRPT, which did not produce a significant reduction in the recurrence of any drinking (the primary outcome variable). Nevertheless, it did detect clinically worthwhile improvements in the form of significant reductions in the occurrence of any heavy drinking, and in the frequency of drinking and of heavy drinking. Producing such improvements in outcome beyond those of "aftercare as usual" is 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 good quality aftercare. 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. They 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 EWSRPT achieved its effects. There would be value in further controlled research to test the hypothesis that there is specific value in people learning to identify and act on their early warning signs. Finding differential change between the two groups in the measure of warning signs (AWARE) would have lent some support for the hypothesised mode of action of the relapse prevention programme. The lack of differential effect may result from there being no effect to detect, but it may be that this standard list of 37 experiences is an insufficiently sensitive index to detect change in the dozen or so individual signs typically discovered by patients in EWSRPT. The sequence of the components of the EWSRPT intervention meant that participants who only attended 10 sessions received help to discover and recognise their idiosyncratic pattern of warning signs but not skills to interrupt the sequence of changes. Increasing awareness may be necessary to produce change in persons with a history of relapse. How far skill building is also necessary is an important issue for the theory and practice and is worthy of further investigation.

The two groups differed significantly in only one characteristic, their proportions of men and women. This was not taken into account in the analyses reported because it is assumed all differences in outcome between the groups are due to the different treatments that they are subjected to as a result of random allocation. The internal validity of the study is strengthened by having EWSRPT 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 undergone multiple treatments without sustained benefit. Patients' willingness to participate in the trial and the fairly high engagement of those receiving EWSRPT suggest that this is acceptable to them. Questions remain about how experienced and skilled therapists need to be in order to deliver this therapy effectively, and about the intensity of training and supervision that may be required. The effectiveness of EWSRPT may be affected by the treatment context in which it is offered. It may exert a stronger treatment effect following less intensive interventions than that provided here, or for agencies with less intensive aftercare services.

One limitation was the lack of independent monitoring of what occurred during individual EWSRPT sessions, to assess the extent that therapists followed the protocol. Research assistants who followed up participants were not informed which condition they had been allocated to, but it was impossible to prevent them hearing participants' comments that informed them of this fact. The sample size required for the trial was derived from power calculations that had been based on two assumptions that turned out to be inconsistent with the results. The 12-month relapse rate in the AU group was 83% (95% CI; 71%, 90%), appreciably larger than the rate of 50% that was assumed in the calculation. The reduction in the relapse rate was 14% (95% CI; −2%, 29%) rather than the 25% specified in the calculation. Thus the study had less power to detect the more moderate effect observed. The effect sizes for the 12-month effects (expressed as r) varied between 0.15 and 0.20 (equivalent to d values of 0.3 to 0.4). These moderate effect sizes compare favourably with the mean r value of 0.09 emerging for 12-month follow-ups of relapse prevention treatment from Irvin et al.'s (1999) meta-analysis.

The results of this study justify the use of EWSRPT in contexts similar to that of this trial, serving similar patients. They also suggest the need for further studies to establish the extent to which the hypothesised mechanism of action accounts for its effects, and also to test whether strengthening the programme's section on managing warning signs would improve outcomes.

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