A randomised controlled trial of a Group psychological intervention to increase locus of control for alcohol consumption among Alcohol-misusing Short-term (male) Prisoners (GASP)

Running head: Groups for alcohol misusers in prison

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Abstract

Background and aim: Reducing alcohol misuse by male prisoners is an important global issue. Control of drinking behaviour could be a useful target for intervention in this population and locus of control could be a causal factor in this. We aimed to assess the effect of a clinical psychologist-facilitated group intervention on male prisoners' locus of control of drinking behaviour.

Design: A two-arm, single-site, open, randomised controlled trial.

Setting: A category B, local training prison in South Wales, housing nearly 800 mostly sentenced men.

Participants: Prisoners serving under two years who met inclusion criteria for pre-imprisonment alcohol misuse, alone or with drug misuse. A total of 119 were allocated to the intervention arm and 119 to the control arm; 104 and 87 respectively completed the post-randomisation baseline interview and 68 and 60 completed a second interview about 4 weeks later, respectively after intervention or treatment as usual (TAU) alone.

Intervention: Nine clinical psychologist-facilitated groups in the prison over three weeks. Range of participants per session was 1-7, with 3-5 most usual.

Measures: The primary outcome was Locus of Control of Behaviour (LCB); secondary outcomes included mental state generally (Comprehensive Psychiatric Rating Scale/CPRS) and specifically (Beck Depression Inventory/BDI). An integral process evaluation was conducted.

Findings: LCB scores decreased during the study, but without significant intervention effect (-1.7 (95% CI -5.2 to 1.8), p=0.334). Change among completers in the control group was from a mean score of 37.4 (standard deviation [SD] 10.0) to 33.7 (SD 11.7) and in the intervention group from 37.4 (11.6) to 31.9 (11.8). Secondary outcomes, including change in mental state, did not differ between arms, but 686 (64%) sessions were lost, most because of 'prison issues'.

Conclusions: A clinical psychologist-facilitated group intervention did not have a statistically significant effect on sense of control of drinking behaviour among men with pre-imprisonment alcohol misuse serving under two years in a South Wales prison. The study proved coterminous, however, with 40% prison staff cuts which seem likely to have contributed to the high loss of group sessions and possibly overwhelmed any treatment effect. Intervention completion failures, previously cited as harmful, had no effect here, so the trial should be repeated when prison climate improves.

Declarations of interest: None for any of the authors

Introduction

Alcohol misusers tend to have poor health, die young, harm others[1,2] and be over-represented among prisoners[3]. In Wales over 80% of short-term male prisoners are hazardous drinkers, 40% alcohol dependent[4], making alcohol misuse histories far more prevalent than drug misuse histories. In this earlier study we also showed that alcohol is the only substance misused by about one third of such men and the particular difficulties that such men had accessing treatment. Almost all drug misusers recognised that they had a problem with the substances; about one third of alcohol dependent men had failed to recognise a problem with alcohol while less than 10% of hazardous drinkers recognised difficulties with alcohol. The match between need and accessing help for these alcohol misusers was poor. Accredited prison programmes for drug misusers reduce subsequent re-offending in the UK[5] and the USA[6,7,8] but there are none for alcohol misusers in the UK[9] and we have found none reported in the USA either. Short-term prisoners are at especially high risk of recidivism, but unlikely to get help[10]. There is evidence that brief psychological interventions help alcohol misusers in the general population[11], but they may impact differently in prisons. Among offenders, for example, not completing psychologically informed programmes may yield worse outcomes than never starting[12, 13]. The Welsh Government[14] committed to improving alcohol services; the English Department of Health set a modest target that 15% of dependent drinkers in prison should receive treatment[15]. Evaluation of in-prison interventions for alcohol misusers is thus important.

Few prisoners report getting alcohol in prison[16], so desistance from drinking is not a useful primary outcome measure in this context. Sustaining change in drinking beyond an alcohol free/low environment may depend on changing predisposing traits, with self-perceived sense of personal control[17] and motivation[18] best evidenced. The concept of locus of control captures the extent to which a person perceives that his or her behaviour is under personal, internal control or largely affected by the external environment and chance[19]. Misuse of alcohol, among other health damaging behaviours, has been shown to be associated with a greater sense of external controls dominating, but a sense susceptible to change which may help desistence from drinking[20]. We

therefore chose self-rated locus of control of behaviour (LCB) as our primary outcome[21], as theoretically more valid *and* more measurable in prison than actual alcohol misuse

Our primary research question was: Is male prisoner participation in such groups, supplementing standard prison regime (treatment as usual/TAU), more likely to enhance internalised sense of control than TAU alone? Our secondary questions were whether certain subgroups of men might respond better. Given evidence that interventions with offenders are most likely to be successful when risk and need are high[22,23], were men with higher Alcohol Use Disorders Identification Test (AUDIT)[24] scores or higher health service use in the year before imprisonment more responsive? Given that we had previously found that change in the year before imprisonment in the relationship designated by the prisoner as most important to him affected mental state over time in prison[25], we asked whether this affected intervention outcomes.

Method

Ethics approval for the trial was from the NHS Health Research Authority NRES Committee East of England – Essex, incorporating the then National Offender Management Service (NOMS) approval. The trial was registered with ISRCTN (ISRCTN68904585) and the National Institute for Social and Clinical Health Research (NISCHR) portfolio. There was agreement with the governor of the trial prison before ethics application and discussion with him and staff he designated about practical feasibility of the work before and after obtaining ethics approval.

Recruitment and eligibility

Information leaflets and posters about the study were displayed in reception and resettlement (where men access assessments and courses). Screening for inclusion was in two stages. First, the prison records system (P-NOMIS) was examined every six weeks to identify all new receptions in the first two weeks of that period. Those likely to stay in that prison for a minimum of six weeks (see[26]) and a maximum of two years were asked to complete the self-rating alcohol (AUDIT)[24, 27] and drug (Drug

Abuse Screening test [DAST][28]) screens with respect to pre-imprisonment behaviours and especial reference to the month prior to imprisonment. They were also asked to complete the *Locus of Control of Behaviour Scale* (LCB[21]). Consenting men scoring 16+ on the AUDIT and/or 15+ on the DAST and/or clearly experiencing withdrawal symptoms (such as tremors, sweating, hallucinations) were eligible for the trial.

Trial design

A prior feasibility study in the same prison enabled us to develop a brief, motivational, skill-promoting group programme delivered by clinical psychologist/psychology assistant pairs, to estimate sample size for its evaluation and plan recruitment and retention strategies, among ourselves and with prison staff[29].

In this single site, open, parallel randomised trial, eligible men were randomly assigned by a statistician according to research numbers supplied by the recruiting researcher, in a 1:1 ratio, to intervention with TAU or TAU alone. Non-blinded re-assessment of LCB and assessments of mental state[30,31,32] were conducted within a week of randomisation (interview 1) and after the intervention, or equivalent period for the control men, about four weeks later (interview 2). On first interview, men were also asked about pre-prison experiences and on second about within prison experiences.

An integral process evaluation[33] explored *intervention reach* – using prison records to make limited comparisons with eligible but not recruited men on demographics and sentence length; *fidelity* - by checking therapist diaries of each group, written immediately after it, session flipcharts and evidence of task completion, like the City and Guilds Workbook; *exposure* - by counting numbers of groups completed; and *contamination*, by analysing prisoners' second interview reports about their prison experience (TAU) and whether intervention men had talked about the groups outside the sessions, particularly to control men .

Sample size

We calculated that, in order to detect a moderate effect size of 0.5 in the primary outcome (LCB scale) at 80% power (5% significance, two-tailed), 128 participants would be required (64 per trial arm).

Adjusting for possible clustering, given the nature of the intervention (in groups), 14 intervention cycles with an average of 5 men per group completing interview 2 (n=70) would allow, in addition, for a variance inflation factor (VIF) of 1.08 (intra class coefficient [ICC] 0.02); an equivalent VIF was also applied to the control arm, yielding a required total sample size of 140. In our feasibility study, completion rate was 59%, so we further adjusted sample size to allow for 50% drop-out, giving a target of 280 men for randomisation. Since randomisation and intervention were planned in consecutive blocks over 12 months, lower than expected drop-out rates would result in stopping the trial earlier - once the required target sample size was reached.

The setting and treatment as usual (TAU)

The prison is a category B (second highest security of levels A-D) training prison for men awaiting trial or sentencing or serving prison sentences of up to 2 years. At the time of the study it held about 770 men[16].

TAU meant that men had access to all usual facilities, including healthcare, exercise, education, courses or work but, for the duration of their trial cycle, no other group therapies. In practice, in this prison at this time, no group therapy was withheld. In both study arms men were given basic information packs about community substance use treatment services. Intervention men had the opportunity to get City and Guilds accreditation in understanding substance use disorders; TAU men were advised how to do this in the community.

The intervention

The intervention consisted of 9 groups of 50-60 minutes, and 'cell work', over three weeks, four in week 1, three in week 2 and two in week 3. Each was facilitated by an NHS employed clinical psychologist and psychology assistant, trained and experienced in group work. There was a manual with guidance for each session. Therapist pairings, as in real-life practice, were planned to vary between but not within cycles. The plan was to have no more than eight men in each group. In practice, the maximum number was seven. Planned groups were not cancelled on the few occasions

when only one man arrived for the session. Most groups were of 3-5 men. The groups were designed, following evidence-based strategies, to:

1. increase participant motivation to change illicit drug and/or alcohol use[18];

2. increase sense of capacity for personal control over behaviour[17,34,35];

3. provide participants with relapse prevention strategies[36];

4. help participants develop a personal plan for remaining drug free in prison and after release.

In brief, during the first week, focus was on helping men to recognise and record their personal experiences, begin to draw up a personal plan and learn basic anxiety and withdrawal symptom management skills. Week 2 offered further skill development, especially problem solving, meeting with people from relevant prison and community services, relapse prevention and developing the personal plan. Week 3 provided consolidation and formal completion, including signing off personal plans. During the slightly longer group 7, with community services, each participant was offered the opportunity to register for accreditation for a first level City and Guilds qualification '*Employability and Personal Development', Unit 7546-471: Alcohol awareness for the individual*.

Outcome measures

Primary outcome: The Locus of Control of Behaviour Scale (LCB[21]) provides a 17-item self-report rating of beliefs about control over personal behaviour, each measured on a 5-point scale. A high total score indicates belief in being mainly influenced by external factors/fate and a low score personal ability to control one's own behaviour. Original scale development study mean scores for samples of healthy students and nurses were 28.3 (SD 8.5) and 27.9 (SD 8.1) respectively while 'non-neurotic stutterers' and people with agoraphobia had significantly higher scores (31, SD 9.6; 39.4, SD 11.2 respectively)[21]. Failure to decrease overall LCB score in the treated and tested stutterer group was a significant relapse predictor[21]. In our study, LCB was measured before randomisation, about one week later with other baseline measures and about one week after the group cycle was complete (or equivalent period for TAU men).

Secondary outcomes:

The Comprehensive Psychopathological Rating Scale (CPRS[30]) is a semi-structured, sensitive and reliable interview-based measure of 40 reported psychiatric symptoms over the previous 28 days, 25 interviewer-observed signs and a global rating, according to explicit definitions and scale steps.

The Beck Depression Inventory (BDI[31,32]) is a 21 item self-rating questionnaire, with well documented general and prison-based cut-offs indicating clinically important depression[37,38].

The Stages of Change questionnaire[39,40,41] has 32 self-reported items which, regardless of the behavioural problem, indicate change during psychotherapy according to four stages: pre-contemplation, contemplation and action.

In addition, we took simple measures of in-prison behaviour, including drug or alcohol use in prison.

Statistical analyses

Baseline demographic data checks for randomisation balance and drop out bias were completed before outcome analyses. Distributions of primary and secondary outcome measures were examined and transformed, where necessary. All analyses followed intention to treat (ITT) principles with participants remaining in their allocated group irrespective of intervention receipt. Primary analysis used the complete case population: those with LCB scores at the screening interview and immediately following the intervention period. Comparison of the primary outcome used 95% confidence intervals to determine likely intervention effect size, after adjustment for baseline scores as a covariate and clustering in the intervention arm using a linear mixed model with the random effect applied just to the intervention arm[42,43]. Drop out bias was assessed using descriptive baseline data for non-completers. Selected covariates were investigated in the model at individual level (age, previous imprisonment, AUDIT score) and cluster level (group facilitator pair, size of groups, facilitator classification of the group cycle as positive/negative (see online supplement, Table 1), reflecting levels of participant engagement, development of group process and sense of group safety. Two pre-defined

subgroup analyses were conducted, from baseline reports of previous year health service use, with high use an indicator of alcohol related needs and risk, and change in the men's self-designated most important relationship. Subgroup analyses were achieved by the inclusion of an interaction term for the group by treatment arm in the primary analysis model.

As for the primary outcome, analysis of secondary outcomes compared measures at time 2 using a generalised two-level linear model[42,43] for BDI and CRPS scores and two-level ordinal model for Stages of Change (SOC). The clustering effect was found to be negligible for BDI and SOC models (ICC=0) and single level models utilised and presented. Log transformed data were modelled for CPRS and treatment effects therefore interpreted as percentage change. Sensitivity analyses of the primary outcome - LCB scores - took account of missing data, using multiple imputation. A CACE (complier average causal effect) analysis accounted for numbers of groups attended and a binary indicator of intervention completion, defined as missing no more than two consecutive sessions *and*, after missing a session, catching up the missed work. Further sensitivity analysis allowed for primary outcome data collected within and outside the time window specified in the protocol (within one week of the last group session and an equivalent time in the control arm).

Results

Participants

Nearly 3,000 records were examined for sentence length, basic demographics and offence type (Figure 1). Screened and unscreened sentence eligible men were similar in offence category (violent/non-violent), but screened men slightly younger (mean 30.1 years, SD 8.3: 31.9, SD 9.4, $p<0.05$) and more likely to be from Wales (239, 78%) than elsewhere (1204, 74%) ($p<0.05$).
Just over a fifth (176, 21.9%) of the 804 men approached refused participation. Most consenting men screened for alcohol or drug use in the year before imprisonment were eligible for inclusion and were randomised (238, 78%). Of the 128 men who completed the trial, 111 (87%) had AUDIT

scores suggestive of alcohol dependency (15+) and a further five were hazardous drinkers (6-14); 12 were below threshold on the AUDIT. Forty of the men were above threshold for drug misuse according to the DAST, the non- or minimal drinkers among them; a minority of the men thus misused both alcohol and drugs.

There was better retention of men in the intervention (57%) than control (50%) arm. More loss in the control arm (24, 20%) was due to participant refusals/absenteeism than among the intervention men (11, 9%), but with minimal drop-out bias for the primary outcome (see below).

Prison disruptions meant that the trial had to be extended to 16 cycles of the nine-group intervention (from the estimated 14), delivered between July 2014 and August 2016.

Figure 1 about here

Characteristics of the participants

Table 1 confirms that men in the intervention (Int) and control (TAU) arms were similar in measured characteristics at interview 1, including age (about 30 years), offence type (c.42% violent, 9% drug offences), prior experience of imprisonment (c.80%) and lifetime mental health concerns (c.70%). The main indicators of substance dependency were also similar - alcohol (AUDIT Int mean [SD]: 26 [9.8]; TAU: 26 [10.6]) and drug misuse (DAST mean [SD] Int: 11.4 [6.0]; TAU: 12.1 [5.3]). Table 1 also shows that the intervention and control arms had a similar and high (external) locus of control rating at randomisation and first full interview within 7-10 days of that.

Table 1 about here

Primary outcome

Table 2 shows the summary LCB scores for the complete case primary analysis. We considered a complete case analysis to be the most appropriate because data were most likely to have been

missing completely at random, due mainly to operational issues in the prison and not related to any measured characteristics. Intervention group mean LCB scores at the second interview are lower, but this difference is not statistically significant. The level of clustering was small (ICC=0.016), but should be taken into account when designing future studies, as we did here. We fell short of the sample size calculated to allow for clustering, even after running additional cycles, but the observed ICC was lower than that allowed for (0.02); we adjusted for baseline LCB and had a ratio of 1.13:1 in favour of the clustered (intervention) arm, all of which provide additional statistical power.

Table 2 about here

Adjusting for age, previous imprisonment or extent of alcohol problem (AUDIT score), had no effect on these findings (online supplement, table 2). Subgroup analyses, although weakly powered, did not indicate any effect of health service use in the 12 months before imprisonment or of substantial change in most important personal relationship then (online supplement: tables 3a&b, 4a&b respectively). The CACE analysis gave the efficacy per extra session as 0.4 LCB scale points, indicating a small, non-significant internalising effect per session attended (online supplement, table 5). None of the additional analyses, including CACE analysis, allowing for numbers of groups attended or completion/non-completion of the intervention, cross-classified partial cluster modelling to allow for variation in facilitator pairings, or missing data imputation – affected the main result. Only 13 of the 128 post-intervention/equivalent scores were collected outside the 7-day data collection window, again without effect on differences. All these additional analytic checks are detailed in the supplementary online material.

Secondary outcomes

There were no differences in the secondary outcome measures of stages of change or depressive, anxious or schizophrenic symptoms or signs (Table 3). Most men in both intervention (60/68) and control (50/60) arms told researchers that they had used at least one substance in prison in the

three weeks between interviews (60, 80%: 43, 86% respectively). Seventeen intervention men but just one control man completed a personal plan.

Table 3 about here

Process evaluation

Facilitator diaries and flip charts indicated manual fidelity. Sessional engagement was high, evidenced by group rule agreement and flipchart entries; 65 (55%) completed at least one major formal task (e.g. *City & Guilds* workbook). Some men reported sharing group information with cellmates, but not apparently to control men; there was no evidence of contamination between trial arms. Evaluation of men's open descriptions about their experience of imprisonment suggested that this was of a dull, restricted routine and similar between trial arms, reported more fully elsewhere[44].

Retention was lower than expected in both trial arms. Few chose to discontinue groups, but only 385 (36%) of a possible 1071 sessions were attended; 160 (15%) were lost due to men's choice, or personal problems (15, 1%), but 350 (33%) to prison systems issues, including system inflexibility and escort failures or lock downs and 110 (10%) to early release or transfer (no information 51, 5% sessions).

Discussion

Intervention and milieu

We found that study participants changed little during the study. There was no specific benefit of the intervention on locus of control. This may simply mean that the intervention does not work, but absence of mental state change in either study arm was surprising. In an earlier longitudinal, observational study of mental state over a similar period of imprisonment we found improvement[25], consistent with other such studies among people living in ordinary prison conditions[45]. Since 2013,

however, and our earlier study[25], there has been a 40% reduction of staff in this prison[16] and most others throughout Wales and England[46]. Conterminously, suicide rates in English and Welsh prisons reached their highest levels since records began in 1978; self-harm and violence rates also increased[47]. The prevailing prison climate may have overwhelmed any treatment potential.

Our recruitment rate for the trial was better than expected, which fits in part with our good relationship with the prison, developed over years, but our retention rate much lower than predicted from literature or our feasibility study, despite the various measures in place to maximise retention. The latter included agreement with prison staff to hold transfers to another prison until group completion, some flexibility in start time for the groups to allow for special efforts to have men escorted to the group if routine escorts had failed and constant checking that men expected for groups or assessment interviews were on the daily prison transfer lists. Although an occasional incident beyond the control of anyone – such as the cancellation of a complete cycle because a NATO conference was being held close by and the prison was part cleared in case of arrests of protesters - most of the failures could be explained in terms of the prison staff's day to day struggle to fulfil routine duties. There is evidence that it was not only research that was affected in this or other prisons during this period[16,48].

Our systematic literature review of previous RCTs of psychological interventions in prisons found an average 25% participation refusal rate and 76% completion rate[49]. Collectively, in these studies, about 80% of attrition was attributed to 'prison systems issues', including early release, rather higher than in our study (63%), but some of the apparently non-attendance choices by men may have followed from their frustration at the system. Some said so. In any event, prison systems problems are consistently shown as the highest bar to completion of in-prison treatment or research, anywhere[49]. The milieu must be adequate for interventions to have impact.

Locus of Control of Behaviour as an outcome

Internalised locus of control is likely to be an important mediator of stopping alcohol or other substance misuse[17]. Participant LCB scores were initially within the pathological range, supporting the premise that LCB is a worthwhile focus among such men. The absence of significant change in LCB may mean that it is a rather stable abnormal trait among alcohol dependent prisoners. Our feasibility study led to the practical decision to limit the intervention to 9 groups over three weeks, to maintain engagement and allow completion for men being moved between prisons or released early, but would a longer intervention help? Or would a same-length intervention followed by a consolidation period suffice? It is hard to answer these questions, when only about a third of the available sessions were actually taken up and just seven men completed all nine groups. The CACE analysis is perhaps discouraging as this suggested small efficacy per session, but full completion of all nine groups, with attendant 'cell work', may be more important than a sliding scale of group numbers. Again, too, prevailing climate for the groups has to be taken into account. As recorded contemporaneously, and in post-cycle debriefings, the group facilitators often felt that 'control' of the intervention and/or trial was out of their hands in this prison environment – maybe thus, themselves, experiencing a shift towards sense of external controls in this climate.

If such men do merely take longer to internalise the work, then extending the period before re-evaluation may suffice. If, however, they need more active work in order to change, it is essential to overcome practical difficulties in delivering this. As leaving prison is recognised as a high risk period for such men[50], it could be useful anyway to develop transition arrangements between prison and community, with prison and probation staff working closely together. The newly integrated Prison and Probation Service should help this. In this framework, loss of completion through early release, accounting for over 10% of sessions, could be reduced, and extra sessions added, if necessary.

Partial treatment not harmful

McMurran and Theodosi's 2007[12] systematic literature review of 'treatment' outcomes in the criminal justice system is cited in criminological literature as indicating that failing to complete a programme yields worse outcomes than never having started. There are, however, differences between the programmes in this review and GASP; first, they were examining effects of non-clinicians delivering criminal thinking programmes and, secondly, their principal outcome was reoffending. Our intervention was by skilled clinical psychologists, working on a relevant personal trait. Palmer and Humphries[13], however, reported that failing-to-complete also affects some traits adversely. All this has been interpreted as indicating need for extensive supplementary work or even against even trying to intervene if completion seems unlikely. By definition, the latter is often true with short-term prisoners and may contribute to the well-documented failures to offer programmes to this group, who become revolving door prisoners[10]. Our finding reopens the probability that work may be attempted with such prisoners without risk of harm if completion proves impossible, although we advise further confirmation by observing longer-term outcomes too.

Clinical psychologists' roles

Several reports show that 'therapist effect' may be associated with more variation in outcomes than other intervention characteristics, such as therapeutic modality[50,51]. Here, we deliberately varied therapists between cycles, as this will happen in practice. In this study, therapists highlighted differences in their experiences of the cycles - positive and negative. None of these variations, however, seemed to affect outcome. This may simply be because, however, delivered, the intervention was ineffective, but lack of variance could also indicate that the programme is robust in the hands of experienced clinical psychologists, used to working with each other. All group facilitator diaries indicated that, in each cycle of more than two or three sessions, 'group process' occurred. Participating men thus became active in the intervention, often as, in effect, co-therapists, supporting their group peers. Occasionally their input was more toxic, but this was resolved in the group. Thus,

the therapists noted the importance of managing group process as well as delivering specific intervention elements. They used the supervisory facilities available for them at the clinical base, and so group process was consistently managed. This is important as group interventions are generally favoured in prisons.

Strengths, limitations, interpretation and future directions

The prison climate undoubtedly limited delivery of and access to these groups. Nevertheless, a range of sensitivity analyses suggested that the trial was robust methodologically. Although sample size was calculated on best information available beforehand, efficacy per group proved small. Concerns about the risks of harm from non-completion were not sustained, so it would be worth repeating the trial when prison conditions improve, and considering its extension into the community.

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Table 1: General, baseline characteristics of the sample

Characteristic	Control men	Intervention men	Totals
LCB[1] screening score mean [SD]	38.0 (10.9) [n=118]	37.7 (9.7) [n=119]	37.9 (10.3) [n=237]
LCB score I week after randomisation mean [SD]	36.1 (11.8) [n=87]	36.2 (11.3) [n=102]	36.2 (11.5) [n=189]
	Control men (n=87)*	**Intervention men (n=104)***	**Totals (n=191)**
Age in years	29.9 (7.7)	30.5 (8.1)	30.2 (7.9)
Most important relationship			
Other relative	29 (28.2)	26 (29.9)	55 (28.9)
Parent	35 (34.0)	34 (39.1)	69 (36.3)
Partner	24 (23.3)	16 (18.4)	40 (21.1)
Other	15 (14.6)	11 (12.6)	26 (13.7)
Change in most important relationship in year prior to imprisonment			
Negative	23 (27.4)	36 (38.3)	59 (33.1)
Positive	11 (13.1)	9 (9.6)	20 (11.2)
No change	49 (58.3)	46 (48.9)	95 (53.4)
Don't know	1 (1.2)	3 (3.2)	4 (2.2)
Parental behaviour			
Criminal behaviour	35 (41.2)	45 (45.0)	80 (43.5)
Alcohol abuse	40 (47.1)	51 (50.5)	91 (48.9)
Drug abuse	27 (31.8)	20 (19.8)	47 (25.3)
Mental illness	28 (32.9)	36 (35.6)	64 (34.4)
Abuse history			
Any form of abuse	35 (40.2)	33 (32.0)	68 (35.8)
Emotional	31 (35.6)	29 (28.2)	60 (31.6)
Physical violence	25 (28.7)	21 (20.4)	46 (24.2)
Sexual	12 (13.8)	6 (5.8)	18 (9.5)
Type of offence			
interpersonal violence	32 (37.2)	47 (46.1)	79 (42.0)
drugs/alcohol offence only	8 (9.3)	9 (8.8)	17 (9.0)
other	46 (53.5)	46 (45.1)	92 (48.9)
Any prior imprisonment	71 (81.6)	83 (79.8)	154 (80.6)
Five years or more of life in prison to date	28 (43.8)	35 (43.8)	63 (33.0)
Physical health concerns current	16 (18.4)	31 (29.8)	47 (24.6)
Admitted as a hospital inpatient at least once in year prior to this imprisonment	34 (39.1)	37 (35.6)	71 (37.2)
Mental health concerns ever	58 (67.4)	76 (73.1)	134 (70.5)
Mental health treatment in year before imprisonment	26 (29.9)	22 (21.6)	48 (25.4)
Beck Depression Inventory score (21 or above)[2]	45 (51.7)	51 (50.5)	96 (51.1)

*The numbers are lower than the total number randomised because of drop-out of participants – see Figure 1 for details; figures in each category do not necessarily add up to the totals retained (87 control group men, 104 intervention group men) because of missing data.

1 Locus of Control of Behaviour

2 indicative of clinically significant depression

Table 2: Primary analysis of locus of control of behaviour scores over time, comparing the intervention and treatment as usual

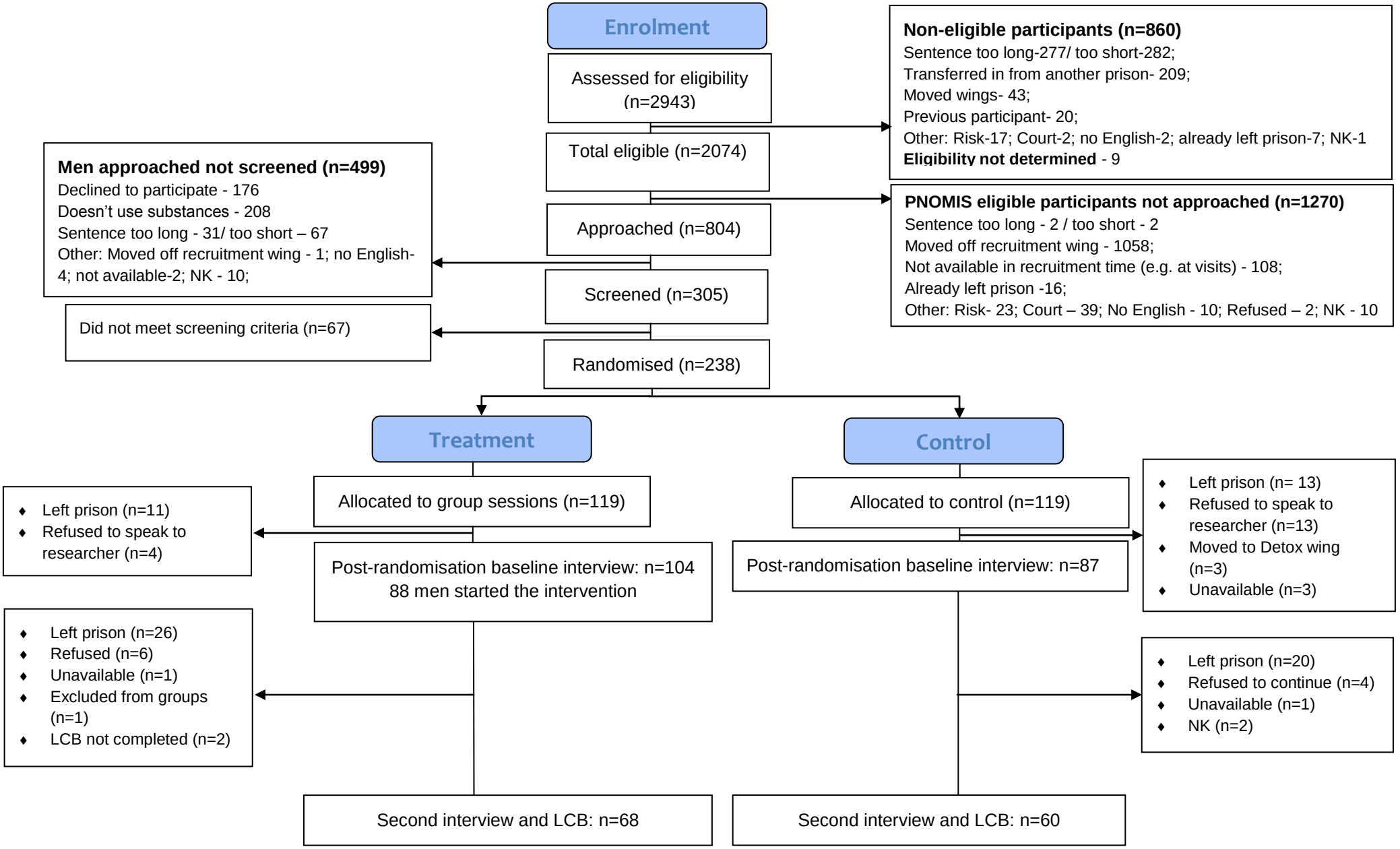
	Control Group (n=60)		Intervention Group (n=68)		Intervention effect (95% CI)	p-value	ICC
	Baseline Mean (SD)	second interview Mean (SD)	Baseline Mean (SD)	second interview (post-intervention) Mean (SD)			
LCB	37.4 (10.0)	33.7 (11.7)	37.4 (11.6)	31.9 (11.8)	-1.7 (-5.1 to 1.6)	0.329	0.016

Table 3: Analysis of secondary outcome measures at second interview (post-intervention or equivalent 4 week period)

	Control group Follow-up scores		Intervention group Follow-up scores		Effect 95% (CI)	p-value	
Stages of Change	**n**	**%***	**n**	**%**	**Threshold**		
Precontemplation	18	36.0	16	25.4	-0.6 (-1.1 to -0.02)		
Contemplation	24	48.0	31	49.2	1.6 (1.0 to 2.3)		
Action	8	16.0	16	25.4	ref.		
					OR = 1.7 (0.84 to 3.45)	0.139	
Beck Depression Scale Global score	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**Effect 95% (CI)**	**p-value**	
	60	17.9 (11.2)	67	16.0 (9.9)	-1.8 (-5.5 to 1.8)	0.324	
Comprehensive Psychopathological Rating Scale* (CPRS)	**n**	**Median (IQR)**	**n**	**Median (IQR)**	**Effect adjusted for clustering 95% (CI)**	**p-value**	**ICC**
anxiety	60	2.0 (1.0, 4.0)	70	2.0 (1.0, 4.0)	-0.0 (-0.3 to 0.3)	0.887	0.183
depression	60	3.0 (1.0, 4.8)	70	2.0 (1.0, 4.0)	-0.0 (-0.3 to 0.3)	0.996	0.006
schizophrenia	59	1.0 (0, 2.0)	68	1.0 (0, 2.0)	-0.1 (-0.7 to 0.5)	0.726	0.067

*for log transformed data the intervention effect is interpreted as percentage change

Selection and flow of participants in the GASP trial: final consort flow diagram



Online supplement

Table 1: Group facilitator characterisation of the GASP group cycles

Positively experienced groups, with engagement and some sustained group process	**Negatively experienced groups, with little sustained group process, disrupted process or process deriving from dysfunctional control on the part of the men, the prison system or both**
1. Good	2. Lost[1]
4. Process-wise[2]	3. High Expressed Emotion
6. Safe but frustrating	5. Risky[3]
7. Fragmented and chaotic, but generally positive	9. Exhausting and emotionally draining
8. Rewarding and committed	10. Macho-misogynist
11. Locus of control cycle[4]	12. Disrupted cycle[5]
13. The asylum cycle	15. The aborted cycle
14. the extended family cycle[6]	
16. Managing the dynamic	

1. Did not take place for reasons outside of the control of the prison staff or researchers, but men had been randomly assigned, so it is listed here
2. Facilitators particularly aware of process details, including their differing roles
3. Particularly distressed, chaotic men, with facilitators occasionally feeling unsafe and prison unable to offer much support
4. The difficult prison climate was very intrusive, but the men appeared to use the group work to exert actual personal control of some situations
5. Started well, but broken by failures to get the men to the groups – groups process never quite recovered
6. Unusual because the group fortuitously reunited brothers who had not seen each other for years – they bonded and were inclusive of other members

Table 2: Primary outcome adjusted for selected baseline covariates at individual and cluster level

	Intervention effect adjusted for clustering and covariate* (95% CI)	p-value	ICC group	ICC facilitator pair
Individual level factors				
Age (years)	-1.6 (-5.1 to 1.9)	0.360	0	n/a
Previous experience of prison (yes)	-1.7 (-5.3 to 1.8)	0.321	0.099	n/a
AUDIT score	-1.6 (-5.3 to 2.0)	0.365	0	n/a
Cluster level factors				
Facilitator pair	-1.7 (-5.2 to 1.8)	0.334	0	0
Size of groups	-2.1 (-7.3 to 3.2)	0.425	0	n/a
Cycle classification	-1.7 (-5.2 to 1.9)	0.348	0.506	n/a

*Covariates added one at a time in three separate models

Table 3a: Mean (SD) LCB by resource use

	n	Control group Mean(SD) LCB		n	Intervention group Mean (SD) LCB		n	Total Mean (SD) LCB	
		Baseline	Follow-up		Baseline	Follow-up		Baseline	Follow-up
Low resource use (total cost <£1500)	32	35.8 (10.3)	32.4 (9.4)	49	36.5 (10.0)	32.1 (10.8)	81	36.2 (10.1)	32.2 (10.2)
High resource use (total cost ≥ £1500)	16	40.4 (11.9)	39.6 (13.7)	9	46.1 (14.5)	38.0 (11.0)	25	42.5 (12.9)	39.1 (12.6)

Table 3b: Effect of Resource use

	Effect adjusted for clustering (95% CI)	p-value	ICC
Intervention Control	-4.9 (-12.2 to 2.4) reference	0.183	0
Low resource users High resource users	-4.5 (-9.8 to 0.9) reference	0.098	0
High resource*Intervention	4.3 (-3.9 to 12.5)	0.297	0

Table 4a: Mean (SD) LCB by relationship status

	n	Control group Mean(SD) LCB		n	Intervention group Mean (SD) LCB		n	Total Mean (SD) LCB	
		Baseline	Follow-up		Baseline	Follow-up		Baseline	Follow-up
Positive relationship change	8	38.6 (11.4)	30.0 (7.9)	3	30.0 (9.1)	25.3 (5.0)	11	36.2 (10.0)	28.7 (7.3)
Negative relationship change	14	38.0 (11.4)	34.1 (11.9)	24	39.8 (11.7)	34.3 (11.8)	38	39.1 (11.4)	34.3 (11.7)
No change/don't know	35	36.4 (9.9)	33.1 (11.5)	35	36.5 (12.3)	30.0 (12.6)	70	36.4 (11.1)	31.7 (12.4)

Table 4b: Effect of relationship change

	Effect adjusted for clustering (95% CI)	p-value	ICC
Intervention Control	-3.3 (-8.0 to 0.8) reference	0.165	0
Positive change Negative change No change	-0.2 (-6.2 to 5.9) -4.7 (12.1 to 2.8) reference	0.958 0.218	0
Positive change* intervention arm Negative change * intervention arm Reference	2.4 (-5.4 to 10.3) 3.0 (-10.7 to 16.7)	0.542 0.664	0

Table 5: CACE analysis for session attendance, efficacy per session and for completers compared to non completers

Type of analysis	Adjusted between-group mean difference LCB*	95% C.I. (adjusted for clustering)	p-value
Efficacy per session	-0.4	(-1.2 to 0.4)	0.326
Efficacy for completion	-3.2	(-9.6 to 3.2)	0.330

* Intervention minus control. † Completers are defined as missing no more than two consecutive sessions and, after missing a session, having caught up the work missed in the next session attended

Tables 6 and 7 Further analytic considerations

A reviewer raised the question of analysing the subsample of men who completed as well as all randomised men, via a per-protocol analysis, but we consider that doing this would run the risk of bias. A CACE analysis is preferred and recommended by CONSORT for clinical trial analysis and reporting. Further, imputation and systematic sensitivity analysis is superior to pragmatic analysis and the recommendations of the NIHR (Carpenter, JR; Kenward, MG; (2007) *Missing data in randomised controlled trials: a practical guide*. Health Technology Assessment Methodology Programme, Birmingham, p.199. https://researchonline.lshtm.ac.uk/id/eprint/4018500)

The results of the imputation analysis are given below. Limitations on space in the main paper precluded adding all the detail.

The treatment effect for the imputed dataset did not differ from the primary analysis and did not change the conclusions of the study.

Table 6: LCB at follow-up for the pooled multiple imputation

Primary outcome	Intervention effect and 95% CI	p-value
Imputed LCB m=50	-1.4 (-4.9 to 2.2)	0.450

In order to assess the possibility of a non random drop out process, mean baseline LCB data in the complete cases and those who were missing follow-up LCB scores were compared. Mean baseline LCB scores do not differ, however, there was increased dropout in the control arm. This indicates the missing data could be 'missing completely at random' (MCAR) or more likely 'missing at random' (MAR). If data are missing completely at random the complete case primary analysis is unbiased and the best estimate of the true treatment effect. If the data are missing at random then imputation may provide a less biased estimate of treatment effect.

To assess the sensitivity of the imputation to a 'missing not at random' process, a sensitivity analysis was carried out with increasing and decreasing increments added to the imputed data. In this way it is simulated that those dropping out of the study had increasingly larger mean LCB or increasingly smaller mean LCB than those remaining in the study. Table B and Figure A give the results of this analysis and indicate that the results are stable with respect to non random dropout. Only implausibly large increments in mean LCB score in the missing cohort would affect the primary results.

Table 7: Sensitivity of the missing data analysis

Primary outcome	Intervention effect and 95% CI	p-value
Missing mean LCB -15	-1.8 (-5.3 to 1.7)	0.312
Missing mean LCB -10	-1.7 (-5.1 to 1.8)	0.353
Missing mean LCB -5	-1.5 (-5.0 to 2.0)	0.399
Missing mean LCB +5	-1.2 (-4.8 to 2.4)	0.504
Missing mean LCB +10	-1.1 (-4.8 to 2.6)	0.562
Missing mean LCB +15	-1.0 (-4.7 to 2.8)	0.621

Figure A: Plot of sensitivity analysis for imputation carried out under the assumption of MAR