Pilot randomised trial of a brief intervention for co-morbid substance misuse in psychiatric inpatient settings

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Running title: Comorbid substance misuse in psychiatric hospitals

Abstract

Objective: This proof of principle study evaluated the effectiveness and feasibility of a brief motivational intervention, delivered in mental health inpatient settings, to improve engagement in treatment for drug and alcohol misuse.

Method: A randomized controlled trial using concealed randomization, blind, independent assessment of outcome at 3 months. Participants were 59 new adult admissions, to 6 acute mental health hospital units in one UK mental health service, with schizophrenia related or bipolar disorder diagnoses, users of community mental health services and also misusing alcohol and/or drugs. Participants were randomised to *Brief Integrated Motivational Intervention (BMI)* with *Treatment As Usual (TAU)*, or TAU alone. The BMI took place over a 2-week period and encouraged participants to explore substance use and its impact on mental health.

Results: 59 inpatients (BMI n=30; TAU n=29) were randomised, the BMI was associated with a 63% relative odds increase in the primary outcome engagement in treatment (OR 1.63 (95% CI 1.01 to 2.65; p=0.047)), at 3 months. Qualitative interviews with staff and participants indicated that the BMI was both feasible and acceptable.

Conclusion

Mental health hospital admissions present an opportunity for brief motivational interventions focussed on substance misuse, and can lead to improvements in engagement.

Keywords: RCT, Hospital admission, dual diagnosis, schizophrenia, substance misuse

Significant Outcomes

- It is both feasible and acceptable for inpatient staff to engage inpatient's in brief motivational interventions focussed on their substance misuse, whilst admitted to psychiatric hospitals. Staff who delivered the intervention found the short burst and targeted style a useful method of engaging inpatients.
- The findings indicate that the brief motivational intervention, delivered during acute psychiatric admission, led to improvements in engagement in substance misuse treatment.
- Whilst this is a challenging group of participants to engage it is clear that it is possible to recruit and retain participants from this client group and primary outcome data were available for 58, highlighting the advantage of a primary outcome measure based on assessment by care coordinators.

Limitations

- This was a pilot feasibility study, which supports the need for a larger trial.
- Specialist "dual diagnosis" staff delivering the intervention alongside inpatient staff provided the latter with an additional level of available expertise, informal in-situ supervision and formed a bridge with care co-ordinators in the community. However, the availability of such a resource is limited in routine services and adds organisational complexity.
- Further research will need to test whether the intervention impacts significantly to reduce subsequent hospital admissions and substance misuse.

Introduction

Hospital admissions may present a natural window of opportunity for inpatients to re-evaluate behaviours that might negatively impact on their health and mental health (1-3). As acute symptoms of mental ill health decline this period may be characterised as a time of contemplation and a window of increased awareness and insight into factors that contributed to becoming mentally unwell and or being admitted into hospital (4,5). Research has shown that, some individuals may "seal over" the experience, in an attempt to reduce emotional distress (6). That is, they may deny or minimize recent mental health symptoms or experiences and precipitating factors, and as a result, lose awareness of the triggers for becoming unwell (6). *Sealing over* the experience of relapse was found to predict low engagement with mental health services six months after discharge for psychiatric inpatients (6). Drug and alcohol misuse in those with severe mental health problems is widespread (7-10). It is associated with poor engagement in treatment (11-13), low motivation to change (14-16), increased psychiatric hospital admissions (e.g. 17), and impacts negatively on the delivery of treatment and management of care during in-patient stays (18). Among this client group poor treatment engagement is a barrier for change and positive treatment outcomes (12,16,19-20).

Of those admitted into psychiatric inpatient facilities 22-44% have been found to have co-existing alcohol or drug problems (18). However, drug or alcohol problems and the role they may have played in precipitating a psychiatric hospital admission are not routinely addressed in such settings. It is recommended that the clinical management strategy of a psychiatric admission should involve inpatient staff who are trained in routine assessment

and treatment of substance misuse providing simple approaches to enhance motivation to change substance use (18). Nonetheless this continues to be a significant gap in service provision, re-admissions are high, outcomes for this group remain poor (21,22). There are equivocal findings in trials of effectiveness of long-term interventions with psychosis and substance misuse (23). However, the evidence for brief motivational-based interventions is encouraging (16,24-28) and shows promise in inpatient settings when delivered by trained therapists (26; 29-30).

Aims of the Study

The current study sought to evaluate whether a psychiatric hospital admission represents a natural window of opportunity for individuals who misuse substances to be routinely offered treatment, by inpatient staff, to re-evaluate drug and alcohol use and become aware of negative impacts on mental health.

Method

Study design and participants

The study was an open (rater blinded), prospective randomised trial, analysed by intention to treat (31). Intention to treat according to ICH E9 is the principle that participants are analysed on the basis of the group to which they were randomised regardless of the treatment that they actually received. The trial utilised concealed randomisation; blind, independent assessment of outcome at 3-months; characterisation of refusers and drop-outs. Participants were randomised on a 1:1 basis, to one of two experimental conditions: Brief Motivational Intervention (BMI) in addition to Treatment As Usual (TAU); or TAU. Participants recruited were: adults aged 18 years or

above with an ICD-10 diagnosis of schizophrenia, schizoaffective or delusional disorders (F20,22,23,25,28,29); bipolar affective disorders (F31); or recurrent depressive disorder (F33.2) (32), service users of community mental health services; new admissions within the acute phase of severe mental health problems; who were identified as misusing alcohol and/or drugs over the past month based on a minimum score of 3 (abuse/dependent use based on DSM-IV diagnostic criteria for substance-related disorders) on the Clinicians Alcohol/Drugs Use rating scale over the past three months (32) and had a Care Co-ordinator in a Community Mental Heath Team. Participant's capacity to consent was established by the Responsible Clinical Officer. Participants were recruited from inpatient units, within a single UK, National Health Service (NHS) Trust including eleven acute wards and three Psychiatric Intensive Care Units (PICUs), offering a total of 202 beds over a 15-month period. The trial received ethical approval from the West Midlands –The Black Country National Research Ethics Committee (12WM/0369).

The primary hypothesis tested was that *Brief Integrated Motivational Intervention* (BMI) would significantly improve treatment engagement for alcohol and drug misuse compared to treatment as usual (TAU). The secondary hypotheses were that those receiving the BMI would show greater readiness to change substance use behaviour when compared to those receiving treatment as usual and that the BMI would be more cost- effective than the TAU due to reduced service utilisation.

Eligible participants were identified by Research staff based on review of care records. A screening measure was completed with Care Co-ordinators confirming trial eligibility. Within two weeks of admission, once acute symptoms eased, eligible participants were

invited to participate. Written information about the study was provided and written consent obtained. A battery of assessments was administered. Upon completion, participants were randomly allocated to the intervention BMI group (in the context of TAU) or the TAU group (the control group). Just prior to the 3-month data collection meetings were scheduled for completion of follow-up assessment battery by blind researchers. Participants were not paid for study participation.

Sample size

A power calculation was done based on a previous study (27) using the primary outcome measure: Substance Abuse Treatment scale (SATs). Allocating 68 particpants by a 1:1 strategy between the treatment and control conditions (34 participants per group) would have 90% power (1-Beta) to find a difference of 1 point on the SATs scale to be statisticaly significant, using a conventional two sided Alpha of .05. A 1 point difference would be clinically important for participants and mental health services as it would indicate increasing levels of engagement in treatment and addressing substance misuse (eg. a shift from "Pre-engagement" to "Engagement").

Randomisation

The trial used independent central randomisation using a concealed process via e-mail. The researchers were blind to participant treatment group allocation until all baseline, post-treatment and 3-month follow-up quantitative assessments had been completed. Researchers were unblinded once the 3-month data collection had been completed. Participants in the BMI group then completed a qualitative interview.

Trial Interventions

Brief Integrated Motivational Intervention (BMI)

The BMI, a *'Brief Integrated Motivational Intervention'*, was offered in the context of TAU, guided by a manual designed for purpose, based on key ingredients in the two early phases of Cognitive-Behavioural Integrated Treatment (33) strategies from Cognitive therapy for substance use (34) and Motivational approaches (35). BMI promoted a conversational style to build good collaborative relationships with participants working toward a joint goal of "keeping participants from returning to hospital". The BMI provided a 3-step framework. The initial step provided participants with personalised feedback of information gathered in the baseline substance use assessment and highlighted potential impacts on health and mental health. Participants were provided with tailored psychoeducational material. The second step aimed to help participants make decisions. Strategies were aimed at: increasing awareness of perceived "benefits" of use and "costs" associated with continued misuse; re-evaluation of positive beliefs about substances; building awareness of how substance use and mental health interact and maintenance cycles. The third step encouraged participants to contemplate change and develop a change plan based on a self-identified goal and included strategies to cope with setbacks, cravings and urges and develop social support for change. Participants were offered a Peer Mentor during the second step of the intervention aiming to provide ongoing support and solidarity for change.

The BMI was delivered by inpatient unit staff trained as part of the study working alongside staff from a specialist "dual diagnosis" Trust-wide service, the COMPASS Programme (36). The BMI was delivered over a 2 week period for 4-6 sessions lasting 15-30 minutes each . A "booster session" was arranged to be delivered one month after completion. The booster

session aimed to consolidate motivation and transfer the skills from the BMI to the community and was provided by a member of the specialist team and attended by the participant's community-based Care Co-ordinator. Staff training was delivered over two days and supported by a treatment manual. Supervision of the BMI was provided by three of the Investigators. Group, face-to face or telephone supervision were delivered. During supervision, the standard of delivery was regularly monitored and assessed for fidelity and adherence.

Treatment as Usual (TAU)

Treatment as usual was provided by nursing and medical staff on the mental health units in line with inpatient policies, and is regularly monitored by the UK Care Quality Commission. It included assessment and monitoring mental state, provision of medication and stabilisation of mental state.

Statistical Methods

Analysis was carried out using SAS version 9.4 (SAS Institute, Cary NC). The analysis method for the primary outcome was a proportional odds model. The proportional odds method used included the pre and post intervention periods (L1SATS and L3STATS), included a cumulative log log link function and multinomial error, linked within a subject with a random intercept term. Denominator degrees of freedom were derived from the number of subjects. Models used maximum Likelihood with adaptive quadrature. The appropriateness of the proportional odds assumption was assessed using the Score Test. Statistical significance was assessed using a conventional two sided Alpha of .05. The secondary outcomes were analysed using analogous generalised mixed models with appropriate link

functions and error structures. The ITT principle was used for all analyses. Missing data was excluded as it would be inappropriate to impute it because it is most plausibly missing not at random.

Cost effectiveness Evaluation

Participant contacts with staff providing the intervention were recorded as well as staff supervision time and these were combined with unit costs (37). Other service use was measured for the three months pre-baseline and over the post-randomisation period using the Client Service Receipt Inventory (38). This recorded use of primary and secondary health and social care services. Sources of data included Client self-report and where data could not be obtained via self-report and/or specific information was required (e.g. medication, appointments, dates of hospital admission) this was gathered via the service electronic medical records. Total service costs were compared at baseline and over the post-randomisation period, the latter adjusting for the baseline costs. The EQ-5D [39] measure was used, which is frequently used to produce quality-adjusted life years (QALYs) as part of economic evaluations (31). Cost data are frequently skewed and a bootstrap model was used which makes no assumption about the underlying cost distribution.

Qualitative Evaluation

Qualitative semi-structured interviews with participants after the 3-month follow-up point sought to assess satisfaction with the treatment received and perceived processes of change, including helpful aspects of the therapeutic process. A sample of therapists was

interviewed using a semi-structured interview, individually and in focus groups. These were recorded, transcribed and thematic analysis conducted, steps were taken to ensure reflexivity (40). That is, attending systematically to the context of knowledge construction by examining concepts critically and aiming to eliminate assumptions and preconceptions affecting interpretation of findings. This was done through group discussions between the analysts, with the wider research team and checking the final findings with some participants (40).

Outcome Measures

Primary Outcome

The primary outcome was engagement with substance misuse treatment whilst inpatient and with community treatment services at 3-month follow-up as reported by Care Co-ordinators/primary clinician, using the *Substance Abuse Treatment Scale* (SATS) (14,32)a widely used measure with reported high validity, reliability, and test-retest reliability (14,32). The Primary Clinicians assessed the level of engagement in substance misuse treatment and progress toward recovery from substance use problems, based primarily on observable behaviours, on an 8-point hierarchical motivational scale. The reporting timeframe was adapted to the previous 3-months.

Secondary Outcome Measures

i) Readiness to change

Current readiness to change alcohol and drug use was assessed using the 19-item *Stages Of Change Readiness And Treatment Eagerness Scale* (SOCRATES). (41).

Motivation to change was measured by the: *Importance-Confidence Ruler* which is a global assessment of motivation and confidence to change assessing two concepts underpinning readiness to change (42); participants were also asked to rate on a scale of 0 to 10 how important it was to change the use of the primary substance and how confident they were that they would succeed.

ii) Drug Use & Alcohol Use

Drug and alcohol use was assessed using a number of complementary measures. The number of days each substance had been used in the past 30 days and the average amount of use of each drug on a using day was assessed using section B of the *Maudsley Addiction Profile* (MAP) (43). The *Clinicians Alcohol/Drugs Use rating scales* (CDUS/CAUS) was used as a screening tool for inclusion, based on DSM-IV diagnostic criteria for substance-related disorders, and reliably used by primary Clinician's to classify severity of substance use amongst people with severe mental health problems (32). The reporting timeframe for the AUDIT both at baseline and post-treatment was adapted to the previous 3-months. The *Severity of Dependence Scale* was used to screen for the severity of drug dependence (44-46). The *Alcohol Use Disorders Identification Test* (AUDIT) a well validated 10-item self-

report questionnaire was used to investigate alcohol consumption (47,48).

iii) Psychological Functioning

Psychological Functioning was assessed using 3 measures: Recovery Style Questionnaire (RSQ) is a 39-item self-report measure designed to assess two concepts of recovery from mental health relapses; 'Integration' (i.e. acknowledgement of, openness and attempts to cope with the mental health problem), and 'Sealing-over' (i.e cognitive and behavioural attempts at avoiding the diagnosis and experience of mental health problems). It reliably enables four recovery styles to be classified based on a continuum (i.e. 'Integration'; 'mixed picture in which integration predominates'; 'mixed picture in which sealing-over predominates' and 'sealing- over'(49)); Insight Scale (IS) reliably assesses changes in levels of insight in terms of perceived need for treatment (50); HADS a 14-item self-report measure found to reliably assess anxiety and depression (51, 52).

Results

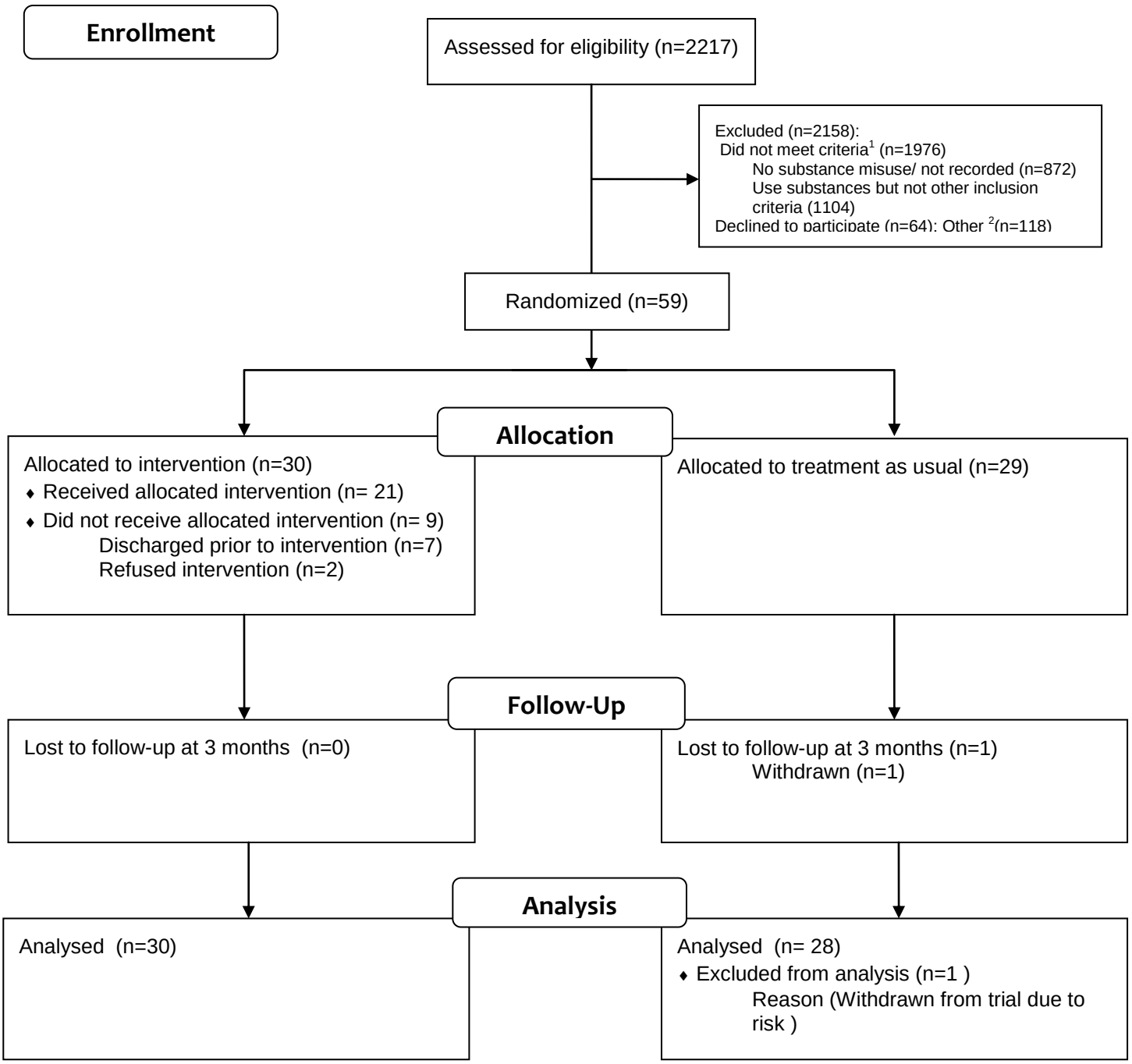
60.67% (1345/2217) of inpatients screened were using substances. However, 1286 did not meet the other study criteria or declined to be involved in the study. 44%, (872/1976) of inpatients were not misusing substances or their substance use was not recorded (Figure 1). Fifty nine inpatients were recruited from 14 wards (Acute n=50; PICU n=9) and randomised to BMI n=30 or TAU n=29. Table 1 shows baseline characteristics of the participants who had a mean age of 38.6 years, with a schizophrenia diagnosis, primarily misusing cannabis,

or alcohol. Inpatients (N=123) were approached regarding involvement in the study, the characteristics of those who consented compared to refusers (n=64) (52%) appeared similar in age, sex and type of mental health team. All participants were followed up for the primary outcome at 3-months, one participant was withdrawn due to risks. Fifty (85%) study participants were interviewed at 3-month follow-up.

The Intervention

Twenty seven inpatient staff from all wards and six specialist staff were trained to deliver the BMI, 12 inpatient staff and 5 specialist staff actually delivered the MI. Twenty one of the 30 (70%) participants in the BMI group received the intervention. The 9 participants who did not were; discharged prior to the first session (n=5), refused the intervention (n=3) and sent on home leave (n=1). The mean exposure for participants who received the intervention was 3.14 (SD 1.92) sessions, (range1-5 sessions). Mean duration of sessions was 18.3 minutes (SD 4.90). The average total mean duration of the intervention was 57.6 minutes (SD 31.33). The booster session was completed for nine (30%) of these participants. Two participants received a session with a Peer Mentor who aimed to provide ongoing support and solidarity for change. The Peer Mentor provided some low-key social support and a listening ear to help participants feel less isolated and more connected to others during a challenging time and to generally see how they were finding the intervention.

Figure 1: CONSORT Diagram of Trial profile



[1] Did not meet inclusion criteria: No substance misuse/Substance use not recorded (n=872), Use substances but not other inclusion criteria (n=1104) (Inclusion criteria not met due to either, mental health, care co-ordinator unavailable/unallocated, rating unavailable, discharged prior to rating, language, mental health capacity, care being transferred to or from another service. [2]Other: includes previously consented (n=6), previously refused (n=15), previously withdrawn (n=1), discharged before rating (n=30), unable to rate (n=28), discharged before met (n=32), not randomized – withdrawn (n=4), not randomized – discharged (n=2).

Table 1. Baseline Characteristics of Participants

	TAU (n=29)	BMI (n=30)
Age		
Mean (SD)	37.69 (11.11)	39.5 (11.12)
Sex		
Male (%)	25 (86.2)	25 (83.3)
Diagnosis		
Schizophrenia (%)	19 (65.5)	17 (56.7)
Schizoaffective Disorder (%)	2 (6.9)	3 (10)
Psychosis (%)	1(3.4)	0 (0)
Bipolar affective Disorder (%)	7(24.1)	10 (33.3)
Primary Substance		
Alcohol (%)	11 (37.9)	12 (40)
Cannabis (%)	13(44.8)	14 (46.7)
Crack (%)	0 (0)	1 (3.3)
Cocaine (%)	2 (6.9)	0(0)
Methadone (%)	1 (3.4)	0(0)
Legal Highs (%)	2 (6.9)	2 (6.7)
Diamorphine (%)	0 (0)	1(3.3)
Ethnic origin		
White British (%)	15(51.7)	7(23.3)
White Irish (%)	2 (6.9)	4 (13.3)
Asian Indian (%)	2(6.9)	0 (0)
Asian Pakistani (%)	1(3.4)	4(13.3)
Asian Bangladeshi (%)	1(3.6)	0 (0)
Asian Other (%)	1(3.4)	1(3.3)
Black Caribbean (%)	4 (13.8)	8(26.7)
Black African (%)	2 (6.9)	0 (0)
Black Other (%)	0 (0)	1 (3.3)
Mixed Caribbean (%)	0 (0)	5 (16.7)
Mixed African (%)	1(3.4)	0 (0)
Housing status		
Live alone (%)	16 (55.2)	16 (53.3)
With parents or guardian (%)	5 (17.2)	9 (30)
With partner (%)	3(10.3)	0 (0)
Other (%)	5 (17.2)	5 (16.7)

Primary Outcome

Engagement with Substance misuse Treatment

At baseline, for both groups engagement could be described as not having regular contact with an assigned case manager. Both groups had shifted at follow-up, indicating regular contacts with a case manager and discussing substance use and showing evidence of a reduction in use. The effect of randomisation to the BMI group rather than TAU was described using the odds ratio where a value greater than 1 indicates a benefit for the intervention. Two TAU SATs values were missing, one at baseline the other at follow-up. The intervention was associated with a 63% relative odds increase in the SATs score, which is conventionally modestly statistically significant (OR 1.63 (95% CI 1.01 to 2.65; p=0.047)) (see Table 2). In supportive analyses the relationship between actual length of stay in hospital and response to the intervention in relation the primary outcome was examined. There was no interaction between time in hospital and treatment effect.

Table 2. Difference in SATs, Number of substances used, Days Using and HADS at 3-month follow-up by randomised condition, conditional on baseline assessment

Outcome	Odds Ratio¥ (95% CI)	Relative Risk‡ (95% CI)	Difference in means≠ (95% CI)	P Value[2]
SATs	1.63 (1.01 to 2.65)	-	-	0.047*
Number of substances used	0.66 (0.33 to 1.33)	-	-	0.240
Number of days using primary substance	-	1.02 (0.82 to 1.26)	-	0.854
HADS				
Anxiety	-	-	-0.80 (3.93 to 2.34)	0.611
Depression	-	-	-1.89 (-4.51 to 0.74)	0.156
Insight Scale				
Awareness of Symptoms	-	-	0.03 (-0.70 to 0.75)	0.944
Awareness of Illness	-	-	0.25 (-0.42 to 0.93)	0.459
Need for Treatment	-	-	0.09 (-0.65 to 0.84)	0.802
Total	-	-	1.03 (-0.49 to 2.54)	0.178

[2]two-tailed; *p<0.05; ¥ Mixed proportional odds model; ǂ Poisson mixed model; ≠ Gaussian mixed model

Secondary Outcome Measures

Readiness to change

For the secondary outcome, readiness to change, both groups remained in the 'low' readiness to change category for alcohol and drugs at follow-up. No overall statistical analysis was carried out for this readiness to change data, due to missing data and the scores for alcohol and drug use could not be meaningfully combined. Assessment of motivation to change indicated that both groups at baseline similarly rated the Importance to change their substance use (BMI=6.77(SD 3.23); TAU=7.19(SD 3.58)) and Confidence to

be able to change (BMI=8.12(SD 2.30); TAU=7.50(SD 2.94)). There was very little variation between Importance (BMI=7.08(SD 3.74); TAU=6.89(SD 3.30)) and Confidence (BMI=8.15(SD 2.19); TAU=8.02(SD 2.83)) scores across time and between groups.

Substance Use

Number of days Substances Used

The number of days in the past 30 in which the primary substance consumed was available for 50 subjects at baseline and follow up. Both groups reduced number of days they used by more than half (Table 3). There was no evidence of an effect of randomised treatment on the number of days using the primary substance (Relative Risk 1.02 (95% CI 0.82 to 1.26; p=0.85)) (Table 2).

Table 3. Substance Use in past 30 days at baseline and follow up

	BMI		**TAU**	
	Baseline (n=30)	**Follow-up (n=26)**	**Baseline (n=29)**	**Follow-up (n=24)**
Number of Substances				
None	0	10	0	5
One	14	10	18	16
Two	12	6	7	3
Three	4	0	3	0
Four	0	0	1	0
Number of days used				
Mean (SD)	21.48 (11.00)	9.25 (10.82)	21.23 (9.68)	9.31 (11.86)

In supportive analysis the amount of substance used was explored. At 3-month follow-up, 15 participants reported not having used any substances in the past 30 days; 10 of whom were in the BMI group compared to 5 in TAU (Table 3). The number of substances used by the BMI group reduced on average by 0.34 or about a third of a substance when compared to the TAU group (Table 2). However the effect was not significant (OR 0.66 (95% CI 0.33 to 1.33; p=0.24)).

Severity & Impact of Substance Use

Mean baseline scores for the primary substance used for both groups, as rated by the Care Co-ordinator, was categorised as 'abuse' in the previous three months (Table 4). Mean AUDIT scores for the TAU and BMI group met the 'possible dependence' category at baseline. At 3-month follow-up these mean scores were lower and were within the 'increasing risk category'. Mean SDS scores across time and groups were all above a score of 4 which suggested a continued 'level of dependence'.

Table 4. Severity & impact of Primary substance at baseline & 3 month follow up

	TAU		**BMI**	
	Baseline	**Follow-up**	**Baseline**	**Follow-up**
Alcohol (CAUS)	N=11	N=11	N=12	N=12
Mean (SD)	3.27 (0.65)	2.18 (.98)	3.42 (0.67)	2.25 (1.22)
Drugs (CDUS)	N=18	N=17	N=18	N=18
Mean (SD)	3.28 (0.46)	2.41 (1.06)	3.33 (0.49)	1.89 (0.90)
Alcohol Use (AUDIT)	N=11	N=11	N=12	N=9
Mean (SD)	20.00 (8.14)	13.09 (7.92)	22.00 (7.76)	15.11 (7.71)
Drug Use (SDS)	N=18	N=13	N=18	N=14
Mean (SD)	5.11 (4.93)	5.31 (3.68)	4.56 (4.23)	4.64 (4.18)

Psychological Functioning

Anxiety & Depression

Analysis of the difference in the HADS Anxiety and Depression Scores by randomised group, accounting for baseline values, indicated no evidence of a treatment effect on HADS Anxiety (Difference in means -0.80(95% CI 3.93 to 2.34; p=0.611)). The HADS Depression, although not significant, was in line with a modest effect on that outcome suggesting that the TAU had higher depression scores (Difference in means -1.89 (95% CI -4.51 to 0.74; p=0.156)) (Table 2).

Style of Recovery from Mental Health Problems

Baseline mean scores on the RSQ descriptively classified the TAU group as adopting a 'mixed picture in which integration predominates' style of recovery from mental health problems (66.54 (SD 15.28)), and the BMI group as adopting an 'integration' style (71.14 (SD 13.37)). At 3-month follow-up both groups were classified as 'integration' (TAU=70.74 (SD 70.74); BMI=71.15(SD 18.97), suggesting that both groups had an acknowledgement of and were making attempts to cope with their mental health problems. Due to the amount of missing data no further analysis was conducted.

Insight in Mental Health problems

Awareness of symptoms and of illness mean scores indicated 'poor insight' over time in both TAU groups at baseline and follow-up. Need for treatment mean scores increased over time for both groups suggesting 'good insight' into need for treatment. The difference in

means implied a benefit for the intervention. Whilst there were no significant differences all values pointed toward a benefit from the BMI (see Table 2).

Cost effectiveness Evaluation

For the secondary outcome of cost-effectiveness, service use in the period prior to baseline was relatively similar between the two groups. All participants were inpatients during the baseline period and all but one were also inpatients during the post-randomisation period (one participant in the BMI group went on home leave on the day of randomisation). Although we do not test for differences for individual services it was observed that during the post-randomisation period there was a greater number of participants in contact with psychiatrists in the BMI group (BMI n=19; TAU n=13) and more participants in contact with assertive outreach teams (BMI n=7; TAU n=1). At baseline, the number of days in hospital was similar between the groups (BMI=13.4 (SD 7.9); TAU=14.5 (SD 9.7). During the post-randomisation period inpatient days were slightly higher in the BMI group (BMI=45.3 (SD 35.1); TAU=35.8 (SD 30.8). The mean cost of delivering the intervention was £72 (SD £66). The total mean cost of services used post-randomisation by the TAU and BMI group were £15,698 (SD £12,632) and £18,651 (SD £15,580) respectively. Adjusting for baseline costs, the BMI group had costs that were on average £3279 higher post-randomisation than the TAU group (95% CI, -£3933 to £10,876). One participant in the BMI group was an outlier in number of days of inpatient care during the post-randomisation period. When they were removed the mean cost for the BMI group was £16,825 (SD £12,159) The EQ5D-5L scores were similar between the two groups.

Qualitative Evaluation

Two focus groups (n=7) and five individual interviews were conducted with staff who delivered the BMI. Twenty-one participants who received the intervention were interviewed at follow-up. Qualitative data revealed that participants and staff found the BMI both feasible and acceptable when delivered as part of routine care on inpatient wards. Whilst most participants reported on positive non-specific factors of the intervention; such as 'staff giving time' and 'going out of their way', several participants identified that the intervention allowed them to recognise the amount of substances they were using, the pros and cons/effects of their use on them or their mental health, as well as developing new coping strategies and techniques. For inpatient staff and the specialist practitioners the targeted, motivational style of the intervention and the brevity of the sessions were found to be useful to engage patients in discussions about their substance use. There were mixed views about the timing of the intervention and how well it worked when inpatients were acutely unwell; other issues included the practicalities of joint working between inpatient and community-based staff; and conflict with duties on the ward.

Discussion

The intervention was associated with an improvement in engagement in treatment, the primary outcome, which was modestly statistically significant providing some support for the principal hypothesis in line with findings in out-patient settings (e.g. 27). During the post-randomisation period there were greater rates of contacts with psychiatrists and assertive outreach teams among inpatients who received the intervention. A shift was

observed from irregular to regular contacts with care co-ordinators, discussing substance use. Both groups fell into the 'low' readiness to change category at follow-up and there was no significant difference in the reduction in the number of days on which the primary substance was used between groups. However, both groups reported a reduction by more than half in the number of days they used their primary substance over the past 30 days at 3-month follow-up. These changes in substance use noted in both groups, are not an uncommon findings in studies evaluating motivational based interventions. A number of explanations have been offered including the natural fluctuations in co-existing mental health and substance misuse and the period before an admission being associated with greater amounts of substance use resulting in relative improvement that may not necessarily reflect longer term improvements; also it has been suggested that the baseline assessment of both groups may have a motivational effect (e.g. 53-55). Some exploratory non-significant findings that warrant investigation in a larger trial are reductions in the number of substances used. A study by Baker and colleagues carried out in inpatient settings similarly found that brief motivational interventions had the potential to have a modest, short-term impact on poly-drug use (56). Tobacco smoking was not assessed in the current study; however, this would be an important consideration within future research due to its prevalence and impacts in this population.

The study aimed to assess the feasibility and acceptability of delivering a brief integrated motivational intervention to inpatients as part of routine care on the wards. The recruitment rate in the current study was 50%, which was expected among this group of service users who have been historically described as 'difficult to engage' (11-14, 27). However, 85% of participants were retained in the study at follow-up and 70% of

participants engaged in the BMI with a good level of exposure to it. Inpatients described the intervention as helpful enabling them to: have an opportunity to talk to inpatient staff, recognise the amount of substances they were using and the effects of their use on them including their mental health. Developing new coping strategies and techniques was also helpful. This study indicates that it is feasible and acceptable to engage and retain inpatients, with severe mental health problems from a diverse range of ethnic origins, who are poorly engaged in treatment and misusing a range of substances in a brief intervention for substance misuse, whilst they are on a psychiatric wards. There was improved awareness in both groups over time of the need for mental health treatment and a positive shift to a more integrating style of recovery from mental health problems which has been associated with improved engagement in treatment over time (6). The intervention was relatively low-cost and no significant differences were observed in costs between the two groups. The rate of substance use in the inpatient sample was 61%. However, despite the reported rates prevalence of substance misuse amongst those with severe mental health problems in the literature and in the current study, a number of inpatients in the current study were unable to be included for a number of reasons. Key factors appeared to be whether information about substance use was reported and how it was reported and the stringent study inclusion criteria needed due to the nature of a randomised controlled trial. These factors have important implications for clinical practice and a further trial. Some of the eligible inpatients who refused to participate were poorly engaged with services and with their inpatient care and treatment; some were reluctant or suspicious of engaging in a research study to discuss their substance use. Future research might also consider strategies to increase the participation rate among eligible inpatients, including payment for participation and intervening earlier on during an admission.

Unlike previous studies (26; 29-30), the current study utilised routine inpatient staff to deliver the intervention. They reported that the short burst and targeted style of the intervention was a useful method of engaging inpatients in discussions about drug and alcohol use. However, they felt that the timing (i.e. when such an intervention is delivered) was important due to the mental state of inpatients on acute wards. Similarly participants felt that sometimes they did not have the "headspace" and so the timing of the intervention appears important. The qualitative findings highlight that a shift in the clinical management strategy on wards would be needed for such brief interventions to become embedded into routine practice (57, 58). The literature on inpatient psychiatric treatment has highlighted the need for *'protected time'* for staff to deliver therapeutic interventions as a routine part of their inpatient work (59-61).

Specialist "dual diagnosis" staff delivering the intervention alongside routine inpatient staff provided an additional level of available expertise and informal supervision in-situ. However, the availability of such a specialist resource is limited and adds another layer of organisational complexity. None-the-less, the recommendations from other studies for co-morbid severe mental health and substance misuse problems are that brief interventions are best provided within the context of a comprehensive package of ongoing integrated treatment (e.g. 27,62) and the specialist staff were able to form a bridge with care co-ordinators in the community. In future trials the BMI may benefit from evaluation as part of a comprehensive package of integrated treatment so that positive changes in engagement can be built upon in community services post-discharge.

This proof of principle study attempted to test the BMI, method and measures in an inpatient setting and there are aspects that would require refinement for further studies. There were recruitment challenges; the original protocol aimed for recruitment of 68 participants, in the event we recruited 59. Whilst a challenging group of participants to engage, it is clear that it is possible to recruit and retain participants from this client group and primary outcome data were available for 58 highlighting the advantage of a primary outcome based on an assessment by care coordinators. However, although these primary Clinicians would have been blind at the baseline and two-week ratings, potentially they were not at the 3-month rating for those in the intervention arm. This is a limitation of the study that may have introduced bias. In addition, a rating of this nature, provided by the Primary Clinician working with the client might be influenced by the therapeutic alliance. Measuring motivation to change raised a number of challenges, including the sensitivity of the measures to differentiate between those who are abstinent or have made changes in substance use compared to those who are pre-contemplators. The low uptake of Peer mentors requires further consideration in future research. The low number of female inpatients included in the study may well reflect that co-existing severe mental health and substance misuse is more common among men and less prevalent among females. It is also questionable whether an improvement in costs and health-related quality of life over a 3-month time period would be found. A future trial should include a sufficiently long follow-up to explore cost changes over a prolonged period. In particular, long enough to detect differences in readmission rates and assess changes in substance misuse. However, this pilot feasibility study suggests that an acute psychiatric hospital admission may present a "teachable moment" similar to that identified in physical health settings (1, 63); that is a

natural window of opportunity for inpatient staff to routinely engage inpatients in brief motivational interventions focussed on alcohol and drug use. The intervention is feasible and represents a simple, low-cost, and easy to implement approach, however, timing is key.

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Declaration of Interests & Competing interests

The authors' declare that they have no competing interests. All authors have completed the Unified Competing Interest form (available on request from the corresponding author) and declare that (1) [HG, AC, MB, EG, NF, PMc, LC, KW, CS and AR] have support for the submitted work; (2) [HG, AC, MB, EG, NF, PMc, LC, KW, CS and AR] have no relationships with any companies that might have an interest in the submitted work in the previous 3 years; (3) their spouses, partners, or children have no financial relationships that may be

relevant to the submitted work; and (4) [HG, AC, MB, EG, NF, PMc, LC, KW, CS and AR] have no non-financial interests that may be relevant to the submitted work. The statistical analyses were performed by Professor Nick Freemantle Department of Primary Care and Population Health, UCL Medical School (Nicholas.Freemantle@ucl.ac.uk) and Professor Paul McCrone Health Service and Population Research Department, Institute of Psychiatry, Kings College London (paul.mccrone@kcl.ac.uk). Trial Registration: NIHR CRN/UKCRN:13978 date of registration - 06.02.13; ISRCTN43548483 date of registration - 4/17/2014

Authors' contribution

HG, AC, MB, EG, NF, PMc, LC, KW, CS and AR, have made substantive intellectual contributions to the study. All authors read and approved the final manuscript.

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