Motivational Interviewing & CBT for people with psychosis and substance misuse: The MIDAS* trial

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*Motivational Intervention for Drug and Alcohol use in Schizophrenia
• Background /rationale for needing intervention studies ✓
• Brief comment on methodological issues
• The Manchester Pilot study
• The MIDAS trial
• Conclusions
Types of evaluation studies for psychological/psychosocial treatments

- Integrated care service delivery models or “structural interventions” combine elements of mental health and substance use approaches into one delivery system and it is the type of system or structure that is evaluated.

- In *client therapy interventions*, specialised single or multiple treatment components have been delivered at either a group or individual level in addition to treatment as usual.
Treatment Approaches

Consensus agreement on 2 key elements (Department of Health, 2002; Ziedonis et al., 2005)

- **Motivation** – Stage matched interventions: need to take account of client’s motivation to address or reduce substances (low motivation common)

- **Integration** – elements of mental health and substance use in one intervention
Treatment elements

- **Motivational Interviewing** effective for variety substance use problems (Dutra et al, 2008)

- **Cognitive Behavioural Therapy**
  - **Psychosis** effective reducing symptoms psychosis (Pilling et al, 2002; Wykes et al 2009)
  - **Substance misuse** effective for drug and alcohol problems (Conrad & Stewart, 2005)
Manchester pilot study

American J Psychiatry 2001

Randomized Controlled Trial of Motivational Interviewing, Cognitive Behavior Therapy, and Family Intervention for Patients With Comorbid Schizophrenia and Substance Use Disorders

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Objective: Comorbidity of substance abuse disorders with schizophrenia is associated with poorer clinical and social outcomes. There are few studies of psychological treatments for this population and little long-term follow-up of their benefits.

Method: Patients with dual diagnosis from a randomised controlled trial of motivational intervention, individual CBT and family intervention were assessed on pre and post treatment.

Results: The integrated treatment program resulted in significantly greater improvement than routine care alone at the end of treatment and 12 months after the beginning of the study. Other benefits of the program included a reduction in positive symptoms and an increase in the percentage of days of abstinence from drugs or alcohol over the 12-month period from baseline to follow-up.

Conclusions: These findings demonstrate the effectiveness of a program of routine care integrated with motivational interviewing, cognitive behavior therapy, and family intervention over routine psychiatric care alone for patients with comorbid schizophrenia and alcohol or drug abuse or dependence.

British J Psychiatry 2003

Cognitive–behavioural therapy and motivational intervention for schizophrenia and substance misuse in 18-month outcomes of a randomised controlled trial

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Background: Comorbid substance misuse in people with schizophrenia is associated with poor clinical and social outcomes. There are few studies of psychological treatments for this population and little long-term follow-up of their benefits.

Aims: To investigate symptom, substance use, functioning and health economy outcomes for patients with schizophrenia and their carers 18 months after a cognitive–behavioural treatment (CBT) programme.

Method: Patients with dual diagnosis from a randomised controlled trial of motivational intervention, individual CBT and family intervention were assessed on pre and post treatment.

Results: The integrated treatment program resulted in significantly greater improvement than routine care alone at the end of treatment and 12 months after the beginning of the study. Other benefits of the program included a reduction in positive symptoms and an increase in the percentage of days of abstinence from drugs or alcohol over the 12-month period from baseline to follow-up.

Conclusions: These findings demonstrate the effectiveness of a program of routine care integrated with motivational interviewing, cognitive behavior therapy, and family intervention over routine psychiatric care alone for patients with comorbid schizophrenia and alcohol or drug abuse or dependence.
Manchester pilot study

- People with diagnosis of schizophrenia in touch with mental health services
- Diagnosis of DSM IV substance misuse or dependence
- At least 10 hours contact with family or significant carer

Random allocation N=36

MI + CBT treatment 9 months  
Treatment as usual
Manchester pilot study: TREATMENT

- Motivational interviewing (first 5 sessions and then integrated)

- Individual CBT (20-24 sessions)

- Family CBT (Between 10-16 sessions)

- Mental health service treatment as usual
Results: Manchester study
Barrowclough et al, 2001, Haddock et al, 2004

OVERALL, CONTROL SCORES FAIRLY STABLE WHILE TREATMENT GROUP SHOWED IMPROVEMENT

- GAF: significant improvement maintained at 18 months
- Symptoms: PANSS positive significant 12m, negative maintained 18m
- Days in relapse 424 (CBT) vs. 1119 (control) (p=0.06) over 18 mths
- Less substance use in CBT group at 12 months but not significant at 18mths
- Good retention
Motivational issues

• Psychosis & substance use studies recruiting non treatment seeking clients

• low motivation* to change at start of study:

  78% (n = 36) (Barrowclough et al, 2001)

  70- 49% (n = 106) (Baker et al, 2002)

  73% MIDAS study

*precontemplative/contemplative
Therapy challenges/Motivational issues (may increase with duration of dual problems)

- Psychosis > locked into cycle of use
- Service user’s perspective = Multiple problems - role of substances not salient, may have many advantages/ functions
- Engagement/therapy may be difficult: poor relationships with service providers, symptomatic, chaotic lifestyle
- Low self esteem/ low self efficacy for change
- Limited resources for changing “lifestyle balance”
- Substance use/ level of substances “normal” and readily available
“It’s easier to get drugs in here (inpatient psychiatric ward) than it is outside. There’s a menu comes round everyday – you can pick out what you want – weed, speed, crack, whatever you want!”

“There are 4 local dealers. I get texts to let me know when good stuff’s arrived. It’s delivered to the door. They know when I get my DLA”

Local availability and endorsement by cultural norms and peers
Motivational Intervention for Drug and Alcohol use in Schizophrenia

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University of Manchester

University of London

Local NHS trusts
Trial Assumption:

Reduction in substance use will mediate improvement in clinical outcomes: hospitalisations/death, patient psychotic symptomatology and relapse/symptoms exacerbation

Hence prime focus of therapy was substance use reduction
Intervention

- Integrated Motivational Interviewing & CBT (family intervention dropped)

- Offered up to 26 sessions over 1 year (period extended, more emphasis on MI in early stages)

- Assertive outreach approach to appointment scheduling – home based therapy

- Liaison with clinical team (3 meetings with key worker)
Integrated Motivational Interviewing /Cognitive Behaviour Therapy

Motivational phase

• Accepts many patients won’t identify substance use as a key problem

• Aims to facilitate them making links between key concerns & substance use using individual formulations

• Assumes this may often be a slow process with initial focus on engagement
Integrated Motivational Interviewing /Cognitive Behaviour Therapy

Action phase

- Development of change plan (reduction/abstinence) including relapse prevention strategies (CBT)

- Acknowledges need to take account function of substances (eg CBT for affect or symptom management or lifestyle changes)

- Intervention sufficiently flexible to focus on other client led issues where initial attempts to increase motivation for substance reduction unsuccessful
5 therapists

- CBT/psychosis experience
- MI trained
- Weekly supervision
- Independent ratings confirm adherence
Random allocation of 327 patients:

**Inclusion criteria**
- Schizophrenia
- DSM abuse/dep
- Min levels drink/drugs

- Experimental intervention
  - Plus TAU

- Treatment as usual

- End of treatment Assessment (12 months)
- 6 monthly Substance use assessment

- Follow up Assessment (24 months)
- 6 monthly Substance use assessment
Recruitment and Retention*

Approached as potentially eligible = 722

Agreed to be screened = 79%

Met criteria, Consented & Randomised n = 327

6 m  91% (296)

12 m  82% (269)

18 m  80% (260)

24 m  75% (246)

*Available for FU including PANSS and TLFB
Profile Substance Use in

= meeting DSM IV abuse/dependence = any use

1. Alcohol
   64%

2. Cannabis
   30%
   49%

3. *Cocaine
   10% (30)
   19% (57)

4. Amphetamines
   7% (20)
   12% (37)

5. Opiates
   5% (15)
   15% (45)

Poly-substance use in 44% of sample
Demographics/ Clinical characteristics

Age: 39 (sd 10)  Gender: 87% male

Living arrangements: 46% live alone; 30% with partner/family, 24% house share/hostels

Ethnicity: 84% white

History of psychosis: mean 12 years (sd 9)

History substance use: mean 14 years (sd 9)

ALCOHOL (AUDIT) High DRUGS (DAST) -Moderate problems range

Readiness to change: 72% at pre-action stages
N = 163 randomised to therapy

- Mean number sessions 16.7 (SD 8.3)
- Therapeutic alliance scores (service users & therapist perspectives) were good
Primary outcome – hospital admission in FU period or death from any cause

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>MI/CBT</th>
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<tbody>
<tr>
<td>Deaths</td>
<td>5 (3.1)</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>Admissions</td>
<td>28 (17.6)</td>
<td>36 (22.2)</td>
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<tr>
<td>Negative outcomes</td>
<td>33 (20.3)</td>
<td>38 (23.3)</td>
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Baseline admissions:
- MI-CBT: 46/162 (28.6%)
- Controls: 32/162 (19.8%)
Secondary outcomes: Substance Use

TimeLine Follow Back (TLFB) – last 90 days

Good validity of self report: Hair analysis (drugs); collaterals (mini TLFB and Clinician Rating Scales)

Two outcomes:
- *Severity*: percentage change from baseline in amount per using day (categorical score 1 = abstinent, 5 = large increase)
- *Frequency*: percentage days abstinent
Median % change from baseline in average daily amount of main substance

V. skewed data (thus data were recoded onto a 5 point ordinal scale for analysis)

OR = 0.669; p = 0.017, CI 0.48, 0.93 – repeated measures analysis
**Readiness to Change Questionnaire – 12 months**

Significant increase in motivation at 12 months for MI-CBT, not sustained at 24 months

Significant difference

OR = 2.05; P = 0.004; 95% CIs 1.26, 3.31
Percent days abstinent – main substance – no difference
Secondary outcomes: Symptoms

Positive and Negative Syndrome Schedule (PANSS)
- Total
- Positive symptoms
- Negative Symptoms
- General symptoms
PANSS total score

Assessment point:
- Baseline
- 12 month
- 24 month

Mean PANSS total score for:
- Control
- MiCBT
GAF total score

![Graph showing the mean GAF total score over time for Control and MiCBT groups.](image-url)
Other outcomes...

No effect of MI/CBT on:

• Relapse (yes/no; number relapses)
• Number of admissions
• Self harm
Exploratory analyses

*Were there additional benefits for people using specific substances?*

Problem drinkers (N= 157)
vs the rest (N= 170)

NB fully randomised in stratification
Comparison of treatment effects in alcohol only users compared with all other participants on **percent days abstinent from main substance**

*Difference between MiCBT and Control in percentage of days abstinent*
Conclusions

• MIDAS was successful in recruiting then retaining people with psychosis and substance use in the largest RCT to date

• The sample is representative of people with moderate to severe substance use problems in mental health services

• MI/CBT does result in a reduction in the amount of self reported substance use

• The treatment may be more effective at harm reduction (frequency & amount) for those who use alcohol alone

• MI/CBT does not improve outcome in terms of hospitalisation, relapse, symptom outcomes or functioning
Why did MIDAS not replicate improvements in clinical outcomes of pilot study?

- Earlier study small N, very heterogeneous group, hence findings may have been unreliable

- The absence of FI may have reduced efficacy / the change in inclusion criteria may have resulted in a different sample

- The control group in MIDAS had much better outcomes (less relapses and substantial reduction in substances) than the pilot
  - improvements in standard care?
  - impact of repeated monitoring?
Implications???

- Treatment period too short for patients with longstanding substance and mental health problems, low levels functioning, and little support.

- Advantage in treatment in terms of substance reduction insufficient to translate into clinical gains?

- Was the assumption on which we based the treatment correct?
Implications???

• Treatment period too short for patients with longstanding substance and mental health problems, low levels functioning, and little support.

• Advantage in treatment in terms of substance reduction insufficient to translate into clinical gains?

• Was the assumption on which we based the treatment correct?
Does change in cannabis dose affect outcomes (N= 160)?

Analyses averaged across the 3 time points using GEE using average daily weight of cannabis earlier time points as covariates

Symptoms

- **NOT** related to
  - **PANSS positive scores** (adj coef 0.02, 95%CI -0.24, 0.49)
  - **PANSS Negative scores** (adj coef 0.09, 95%CI -0.25, 0.37)
  - **PANSS General score** (adj coef 0.28, 95%CI -0.15, 0.72)

Functioning

- related to GAF (coef -0.91, 95% CI -1.68, -0.14)
- **NOT** related to readmission or relapse
Whole sample - Is amount of substance use related to outcomes?

Repeated the analyses on whole sample – testing the mediational model …………..

Substance use

\[ a \rightarrow \text{MI-CBT or TAU} \rightarrow \text{Outcomes} \quad b \rightarrow \]

\[ y \]
Whole sample - Is amount of substance use related to outcomes?

there was no effect of reducing substance use on any of the outcomes
Tentative possible conclusions

• In people with existing psychosis, relationship between substance use and poor outcomes may be complex and for some people not attributable to specific effects of substance but to associated factors eg lifestyles, severity of mental health problems, treatment non adherence

Hence
• Reducing substance use per se may have limited impact on clinical outcomes at least for longstanding users. Other issues may need to be addressed to improve outcomes

Or
• Predominantly longstanding psychosis and substance use –possibly irreversible effects or longer periods/abstinence required to show change

• More research is required to identify factors contributing to outcomes in this group if we are to improve treatment options
Integrated motivational interviewing and cognitive behavioural therapy for people with psychosis and comorbid substance misuse: randomised controlled trial

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ABSTRACT

Objectives To evaluate the effectiveness of integrated motivational interviewing and cognitive behavioural therapy in addition to standard care for patients with psychosis and a comorbid substance use problem. Design Two centre, open, rater blinded randomised controlled trial.

Setting Secondary care in the United Kingdom.

Participants 327 patients with a clinical diagnosis of schizophrenia, schizoaffective disorder, or substance misuse disorder and a diagnosis of dependence on or misuse of drugs, alcohol, or both according to the Diagnostic and Statistical Manual of Mental Disorders, fourth edition.

Intervention The intervention was integrated motivational interviewing and cognitive behavioural therapy plus standard care, which was compared with standard care alone.

Phase one of therapy—motivation building—concerns engaging the patient, then exploring and resolving ambivalence for change in substance use. Phase two—action—supports and facilitates change using cognitive behavioural approaches. Up to 26 therapy sessions were delivered over one year.

Main outcome measures The primary outcome was death from any cause or admission to hospital in the 12 months after completion of therapy. Secondary outcomes were frequency and amount of substance use (assessed using secondary outcomes. Treatment had no beneficial effect on hospital admissions or death during follow-up, with 23.3% (8/163) of the therapy group and 20.2% (33/163) of controls deceased or admitted (adjusted odds ratio 1.16, 95% confidence interval 0.68 to 1.99; P=0.579). Therapy had no effect on the frequency of substance use or the perceived negative consequences of misuse, but did have a statistically significant effect on amount used per substance use day (adjusted OR for main substance 1.50, 95% CI 1.08 to 2.09; P=0.016; and all substances 1.48, 95% CI 1.07 to 2.05; P=0.017).

Treatment had a statistically significant effect on readiness to change use at 12 months (adjusted OR 2.05, 95% CI 1.26 to 3.31; P=0.004) that was not maintained at 24 months (0.78, 95% CI 0.48 to 1.28; P=0.328). There were no effects of treatment on clinical outcomes such as relapses, psychotic symptoms, functioning, and self harm.

Conclusions Integrated motivational interviewing and cognitive behavioural therapy for people with psychosis and substance misuse do not improve outcome in terms of hospitalisation, symptom outcomes, or functioning. This approach does reduce the amount of substance used for at least one year after completion of therapy.

Trial registration Current Controlled Trials: ISRCTN14406480.
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