

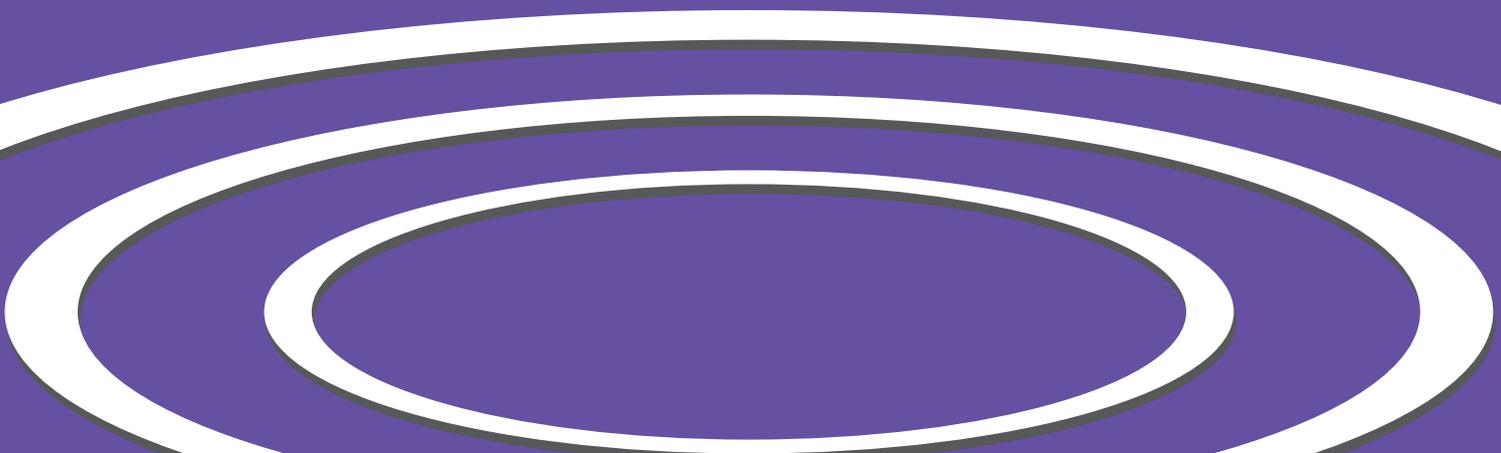


Executive Summary

The effectiveness and cost effectiveness of cognitive behaviour therapy for opiate misusers in methadone maintenance treatment: a multicentre, randomised, controlled trial

(UKCBTMM Study: United Kingdom Cognitive Behaviour Therapy
study in Methadone Maintenance treatment).

Final Report to the funding organisation:
R&D Directorate of the Department of Health as part of the Drug
Misuse Research Initiative
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Disclaimer

This study was funded through the UK Department of Health Drug Misuse Research Initiative and does not necessarily reflect the views of the Department of Health, rather the views of the UKCBTMM Project Group.

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2.1 Background

There is evidence to support the effectiveness of methadone maintenance treatment (MM) from several countries, and it is increasingly applied as a treatment approach in Europe. The quality of provision of adjunctive psychosocial treatments has been shown to be important in the effectiveness of MM. Cognitive behaviour therapy (CBT) has become the leading treatment approach in a variety of psychological disorders. In contrast, relatively little research has been conducted to evaluate the effectiveness, and particularly cost effectiveness, of CBT in substance use disorders. There are several reasons to expect that CBT could make a significant impact on drug misuse and associated problems. CBT has been evaluated as an adjunct to MM. Several RCTs have been undertaken to assess the efficacy of psychotherapy in methadone maintenance treatment. The evidence from these studies, which were exclusively conducted in the US, overall support the efficacy of CBT, although the models of CBT applied varied considerably between studies. One study showed that CBT was more effective than minimal methadone treatment. However, the efficacy and cost effectiveness of CBT in MM in the UK NHS setting is unknown.

2.2 Policy Relevance

There is a need for greater evidence of effectiveness to guide rational commissioning of services, including evaluation of different counselling approaches. To that end this study had certain key features designed to assess cost effectiveness and maximise its generalizability throughout the NHS drug treatment system. This was a pragmatic multicentre trial in which the control condition (Methadone Maintenance Therapy; MMT) was as close as possible to the usual treatment approach in UK clinics, whilst incorporating a degree of standardisation, and exclusion of some patients, necessary to protect internal validity.

2.3 Hypotheses

Primary: CBT is an effective adjunct to standard MMT in reducing illicit drug use. Secondary: CBT is a cost-effective adjunct to standard MMT; CBT plus MMT improves quality of life compared with MMT alone; CBT enhances compliance with MMT; CBT reduces negative outcome expectancies of drug use, enhances coping and self-efficacy compared to standard MMT alone; Coping, self-efficacy, and expectancies are mediating variables in treatment outcome; Addiction

severity and psychiatric co-morbidity are treatment specific prognostic (matching) variables for outcome; Therapist skills and the quality of therapy are positively related to treatment outcome.

2.4 Research Design and Methodology

Design: Pragmatic, randomised, multicentre, parallel group design comparing CBT plus MMT with MMT alone. Outcome assessment 1 year with interim assessment at 6 months.

Setting: 10 community based clinics offering methadone maintenance treatment for opiate misusers in 3 regions in England: North West (Manchester, Bolton, Wigan and Leigh), London (Camden and Islington and South West London), and South East (Brighton).

Inclusion criteria: Male or female; age 18-70; stabilised on oral methadone treatment; ICD-10 diagnosis of opiate dependence; willing to nominate a locator; stable place of residence; living within commuting distance.

Exclusion criteria: Current severe mental illness; severe physical illness; treatment for drug dependence past 3 months; pending imprisonment; severe brain damage or mental impairment.

CBT intervention: Therapists were recruited from existing staff, attended a standardised training programme and received regular CBT supervision and were assessed for accreditation. Therapy was delivered according to a purpose designed CBT manual. Clients randomised to CBT were offered weekly CBT sessions for 50 minutes up to 24 sessions over 6 months. They also attended fortnightly keyworking (MMT) sessions. Core and elective CBT sessions were delivered. Core sessions addressed motivation, coping skills, maladaptive thoughts, attitudes and beliefs. Elective sessions addressed such issues as psychiatric co morbidity. All sessions were tape-recorded. We aim to publish the CBT manual.

MMT intervention: Keyworkers were recruited from existing staff to deliver the MMT intervention. This was as close as possible to usual keyworking, but was manual guided to standardize the intervention. Clients were expected to attend fortnightly keyworking sessions as a minimum.

Outcome measurement: Primary outcome measure: Heroin use (percent days abstinent; amount spent on heroin in past 180 days) (Time Line Follow-Back interview). Secondary outcomes: Addiction

severity (European Addiction Severity Index); Severity of drug dependence (Severity of Dependence Scale); quality of life (Short Form-12; EQ5D); Psychological Symptoms (Brief Symptom Inventory); compliance with methadone treatment (clinic records).

Health economic outcome: Cost of treatments used, other consequences of treatment (health, social, economic, work, criminal justice), quality adjusted life years (based on EQ5D).

Treatment process measures: Coping behaviours (Coping Responses Inventory); Stage of Change (SOCRATES); Self efficacy (Drug Taking Confidence Questionnaire); Outcome expectancies.

2.5 Subjects

842 outpatient opiate misusers were screened, 369 (44% of screened) were eligible, and 60 (16% of eligible) subjects were randomised (29 to CBT, 31 to MMT). The follow-up rate was 82% at 6 months and 88% at 12 months. Main reasons for ineligibility were: low methadone dose/methadone detoxification (29%); not engaged in methadone treatment (28%); unstable housing (24%); severe mental illness (9%); severe physical illness (8%); pending imprisonment (8%). Participating subjects were predominantly male (75%), white (93%), taking heroin by injection (63%).

They had a mean duration of 5 months in methadone treatment at the point of recruitment, and were taking a mean dose of 52mg methadone per day. 65% had received prior opiate treatment, with a mean of 4.6 previous episodes. Subjects were found to be well matched between the two groups at baseline.

2.6 Results

Implementation: Significant difficulties were encountered in implementation of the trial. These included: Low baseline levels of CBT trained staff; low rates of subject eligibility and willingness to participate, particularly in certain sites; poor engagement in, and drop out from, standard methadone treatment; delay in obtaining treatment costs for the trial interventions; high turnover of staff; delays in therapists obtaining training accreditation; attrition of therapists in both CBT and MMT due to high staff turnover and motivational issues; low level of client engagement in CBT.

Treatment outcome: No statistically significant differences were found on the primary or secondary

outcome measures between the two groups in terms of differences in changes from baseline. There was a trend for CBT to show advantages over MMT on several outcome measures with standardised effect sizes comparable with our predictions (0.3) in relation to reductions in EASI score and heroin use, and increased compliance with prescribed methadone use in the CBT compared with the MMT group. CBT subjects attended fewer CBT sessions than planned (mean=2.6; median=4).

Cost effectiveness: The results confirmed earlier findings that the costs of treatment are outweighed by resource savings. However, the reductions were smaller than in some other studies, most likely because subjects were recruited into the study on average 5 months into methadone treatment. Although CBT showed a mean cost saving advantage of £7,000 per patient over MMT alone, there were no significant cost differences between the groups. A simulated Incremental Cost Effectiveness Ratio showed that, at a threshold value of £30,000 per QALY, the probability that CBT is preferred over MMT alone is 74%. Sensitivity analyses did not show any significant differences from the planned health economic analysis.

Process measures: Some of the process measures showed effects of CBT in the predicted direction, albeit the results were not statistically significant. These included increased ability to consider alternative coping responses and increased problem solving. There was also a non-significant reduction in negative coping responses such as cognitive avoidance, emotional discharge, and resignation. There was a significant increase in self efficacy in the CBT group.

Secondary hypotheses: Contrary to expectations there was a significant increase in quality of life in the MMT compared to the CBT group on SF12 in relation to physical problems. It is possible that the CBT group became more introspective as a result of CBT and therefore more sensitive to physical sensations. Or it may be the case that the CBT group had an increase in physical symptoms as a consequence of their relative reduction in illicit heroin use.

2.7 Conclusions

Implementation: Recruitment into the trial was considerably lower than in previous published research using a similar trial design in the US. This might be accounted for by several factors including: differences in the US and UK treatment systems; delays in obtaining treatment costs; lower level of client

eligibility; lower baseline level of psychosocial services in UK methadone treatment which may have affected staff and client expectations of CBT treatment; and considerable variation in methadone treatment across the sites with those offering a low threshold, flexible engagement policy having poor treatment retention and low study recruitment. Low methadone dose was a major reason for exclusion, as was disengagement from treatment. Several of the centres were not geared or resourced to hosting research trials, or were overloaded with research studies competing for similar subjects. It is also important to note that in comparison to previous studies, this was a pragmatic clinical trial conducted in typical clinical settings, with a limited number of existing CBT trained staff. Because the study required the establishment of a new CBT service in each of the sites as well as conducting an evaluation this cause considerable delay in implementation and diversion of research resources to carry out clinical implementation. However, on the positive side we were able to recruit the planned number of services and staff to participate, and we were able to implement CBT in the final group of clinical centres.

Study findings: In relation to treatment outcome, there was no significant difference between CBT and MMT on any of the outcome measures, although there was a tendency for CBT to show some advantages over MMT. In relation to cost effectiveness, again there were no significant differences between the groups. Both treatments resulted in considerable cost savings relative to treatment costs. The CBT showed a mean cost saving of £7,000 per patient over MMT but this was not statistically significant. An incremental cost effectiveness ratio however showed that CBT would be preferred to MMT 74% of the time by policy makers. The reasons for the negative findings are likely to be several: low statistical power - we had planned to recruit 220 subjects but in the end managed to recruit only 60. This points to the potential for type II error, particularly as the standardised effect sizes were close to those predicted on the main outcome measures. It is also possible that the CBT treatment was not effective. Subjects received lower “doses” of CBT than intended (planned=24, actual median=4). It is also possible that the CBT therapists were not sufficiently trained or competent to implement effective CBT. This was mitigated against by several factors including standard intensive training, a standard manual, regular supervision, and accreditation by an independent expert rater who rated tape recorded sessions. Further research on this data will examine the extent to which CBT was delivered according to the protocol, based on the taped sessions.

Limitations of research: The interpretation of the results is limited by the small sample size and potential for type II error, and the lower than planned uptake of CBT sessions. While the treatment centres involved in the study are relatively typical of UK drug treatment services, the sample is only a small proportion of all clients attending methadone treatment, and therefore may not be representative. Also several clients were excluded for reasons given above. Nevertheless we expect that the clients who entered the study are likely to be representative of those who would volunteer for adjunctive CBT if it was offered more widely in the NHS. We also feel that the staff who took part in the study were typical of available staff in the services who would volunteer to be trained for this work should it become more widely implemented. We also believe that the pragmatic nature of the trial is an additional strength compared to previous efficacy trials carried out in academic centres. This increases the study’s policy relevance.

Implications for research: In terms of future research we feel that it is important to carry out efficacy research before doing effectiveness research. Future studies of this type would benefit from carrying out research on established treatment interventions rather than implementing the services and research at the same time. Once CBT services are more established in the UK a more definitive trial could be conducted. Complex studies of this nature need formal piloting before proceeding to implementation of the main trial. We need a better system for treatment cost funding for centrally funded clinical trials. Delays in obtaining treatment costs caused significant problems with staff training and recruitment and implementation of the trial. We also recommend the development of a network of research active addiction treatment centres in the UK to facilitate trials of this nature. The NIMHE model may provide some useful pointers. Finally, this study advises some caution in interpreting research evidence from the US in relation to its applicability to the UK treatment setting. We have identified several important differences between this and previous US research which suggest caution is called for. This also points to the need for more research specifically in the UK on the effectiveness of addiction treatment to guide clinical policy.

Implications for clinical practice: We found that practice in relation to standard methadone treatment varied considerably across the sites involved in this study. Several of the treatment clinics involved in this study were providing methadone treatment in a less than optimal way as suggested by the existing evidence base. Mostly this appeared to be a measure

of the services being under pressure to attract as many patients as possible into treatment, whilst at the same time trying to provide a high quality service. Most of the services were overstretched, understaffed and with a high staff turnover. We believe that these problems need to be addressed by supporting services to improve quality possibly at the expense of quantity. There were very few staff in the service who had been trained to provide psychological interventions, including CBT, which has implications for workforce development. The baseline level of individual client keyworking was extremely low in some programmes. However, in spite of this we managed to train the target number of staff to the accreditation standard, which shows that it is possible to implement a CBT programme in the NHS setting. We also had difficulties in engaging clients in CBT. We think this was partly due to a low baseline level of psychological interventions in existing treatment services, and hence a low level of expectation of clients engaging, and perhaps a reluctance of some clients to become involved in more intensive treatment than usual, or to address psychological issues which had often not been previously identified in routine clinical care. There was also a nihilistic view of psychological intervention and clients' capacity for change amongst some staff in this setting, which will require some major work to change, including appropriate training to bring about a necessary cultural shift.

Implications for policy: This study found that the background methadone treatment was not optimal in many of the centres involved. We believe it is a priority for policy makers to provide the necessary resources to improve the quality and comprehensiveness of methadone treatment in line with existing evidence. While adjunctive psychological interventions should clearly be part of this, there are other aspects of methadone treatment that should be improved, including adequate resources for individual client work, support and supervision. Several of the services were struggling with high caseloads, limited resources, and a high staff turnover. Some clients appeared confused by flexible drop-in arrangements and a lack of clarity on the terms of engagement. There appears to be an over-reliance on maximising the number of clients in treatment and lowering the threshold and terms of engagement for clients, at the expense of the quality of care. We found low baseline levels of training in psychological interventions in the services studied. We feel that policy should be developed to increase the psychological skills of the drug treatment workforce. ■