DRUG & ALCOHOL FINDINGS *Research analysis*

This entry is our analysis of a study considered particularly relevant to improving outcomes from drug or alcohol interventions in the UK. The original study was not published by Findings; click Title to order a copy. Free reprints may be available from the authors – click prepared e-mail. Links to other documents. Hover over for notes. Click to highlight passage referred to. Unfold extra text The Summary conveys the findings and views expressed in the study. Below is a commentary from Drug and Alcohol Findings.

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A randomized trial of cognitive behavioral therapy in primary care-based buprenorphine.

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Provide psychosocial therapy as well as buprenorphine, or extend treatment to more opioid-dependent patients by not requiring therapy? Across the relatively uncomplicated patients studied at a primary care clinic, this US study found no benefit from cognitive-behavioural therapy, but some patients may need this kind of support to make the most of buprenorphine or methadone treatment.

SUMMARY [In the USA the advent of the buprenorphine/naloxone combination medication (marketed as Suboxone) has helped promote primary-care based treatment of addiction to opioids like heroin. Meant to be dissolved under the tongue, buprenorphine is safer in overdose than methadone but also an effective substitute to illegal opiate-type drugs, and the combination with naloxone helps deter misuse by injection.] Generally primary care practices offer only limited counselling along with buprenorphine, raising the issue of whether more psychosocial support would improve outcomes. In particular, the featured trial conducted at a US hospital's primary care centre investigated whether adding cognitive-behavioural therapy to medical care of patients prescribed Suboxone would further reduce illegal substance use and improve retention in treatment.

Key points
From summary and commentary

US primary care practices which prescribe buprenorphine to opioid-dependent patients generally offer only limited counselling, raising the issue of whether further psychosocial support would improve outcomes.

At a US practice, the randomised study trialled supplementing medical care with cognitive-behavioural therapy.

There was no statistically significant indication that adding these sessions further reduced opioid or cocaine use or improved the treatment completion rate or other outcomes.

Some patients in opiate substitute prescribing programmes have however benefited from extra counselling or therapy. Patients with psychiatric problems may particularly benefit.

Over three years the study recruited 141 opioid-dependent patients seeking treatment at the centre. All were offered 26 weeks (including a two-week induction period) of treatment involving maintenance doses of Suboxone plus a manualised programme of medical care by their doctor. Doses were raised to at least 16mg buprenorphine daily and more if required, averaging nearly 18mg. Three of the weekly doses were administered under supervision by clinic nurses and the remainder provided to patients to take at home. The 15–20-minute consultations with the doctor were weekly for the first two weeks then fortnightly for the next four weeks and monthly thereafter. During these the doctor reviewed the patient's recent drug use, and reviewed and supported the patient's efforts to reduce drug use or remain abstinent. Drug use data available to the doctor, including the results of weekly urine tests, were also used to assess outcomes. Patients were excluded from the trial if also dependent on alcohol, benzodiazepine or cocaine or suffering serious and/or dangerous forms of mental disturbance.

The 141 patients who started the trial were those left after 177 otherwise eligible patients failed to progress to the randomisation phase of the trial, mostly because they lost contact or chose other treatments. Typically they were white men in their early thirties and not in full-time employment. About a third were injecting. They rarely used either alcohol or cocaine. Most had previously been treated for their substance use problems.

Of the 141 patients, 70 were allocated at random to also be offered cognitive-behavioural therapy provided by clinicians trained to be competent in delivering the manual-guided programme, and who underwent weekly supervision based on session recordings. The 50-minute sessions were scheduled weekly over the first 12 weeks of treatment, and focused on coping with craving for drugs and enhancing the patient's decision-making and their ability to resist drug use.

Main findings

Only a minority of patients completed the study and barely more than 50% of the cognitive-behavioural sessions were attended. Both may have made it difficult to establish positive impacts. In the event, regardless of the assumptions made about missing data, there was no statistically significant indication that adding these sessions to medical care further reduced opioid or cocaine use or improved the treatment completion rate or other outcomes; more below.

Only 45% of the 71 medical care only patients and 39% of the 70 also offered therapy completed the 24 weeks of treatment. Due to continuing opioid use despite the buprenorphine dose being increased to 24mg, or due to the development of marked psychiatric symptoms, 19 therapy patients had been transferred to alternative treatments for their own protection, and 24 not offered therapy. Most of the other non-completers were removed because they missed medication visits or appointments with their doctors. Completion and protective transfer rates did not significantly differ between the two sets of patients. On average just under seven of the 12 possible cognitive-behavioural therapy sessions were attended.

Given the association between leaving treatment and relapse to illicit opioid use, missing urine tests (about 29% were missing) and patient follow-up data (24% missing) were treated as if the patient has relapsed. However, the pattern of results did not differ significantly when other assumptions were made.

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Whether offered cognitive-behavioural therapy or not, by their own accounts patients rapidly and sustainably reduced non-prescribed opioid use from 5.3 days a week before treatment just 0.8 days during the two-week induction phase and then 0.6 and 0.4 days in successive 12-week periods. These findings were confirmed by urinalysis results. On no measure of opioid use or trends in use did the two sets of patients significantly differ. The same was true of cocaine use.

The authors' conclusions

Supplementing standard medical management with cognitive-behavioural therapy did not further reduce opioid use or promote abstinence among primary care patients being maintained on buprenorphine. Though in other circumstances ancillary psychosocial services have improved outcomes among patients being prescribed opiate substitutes, the findings of the featured study were consistent with earlier research among primary care buprenorphine patients which found no benefits from more extended counselling or more frequent visits to the clinic to obtain medication.

These findings suggest that inability to provide formal psychosocial therapies or extended counselling should not be a barrier to extending buprenorphine-based treatment of opioid dependence in primary care settings. For some patients, a relatively low level of supportive services, like that provided by primary care physicians for other common medical and psychiatric conditions such as diabetes and depression, is sufficient to generate abstinence and retention in treatment, though in this study many had to or chose to leave treatment early.

The study did however exclude patients with other forms of dependence who might have benefited from further psychosocial therapy. Also, the medical management programme might have been harder to improve on than typical primary care practice due to its intensity and delivery by physicians experienced in providing buprenorphine-based treatment.

FINDINGS COMMENTARY Despite this study's findings and their congruence with other findings, the evidence does not enable us to be sure of the effectiveness (and allied to that, the safety) of switching to virtually counselling-free maintenance programmes on a long-term basis, particularly for more severely disturbed patients. The findings do, however, call into question the cost-effectiveness of universally providing extended counselling or structured psychosocial therapy. For many methadone and buprenorphine patients, the impact of entering treatment and being prescribed an opiate-type drug is powerful enough to make further support in the form of counselling or therapy redundant. For policymakers, these findings raise the issue of whether in order to gain harm-reduction and recovery benefits for the greatest number of patients, buprenorphine and methadone treatment should be spread 'thin and wide', or deepened with recovery-oriented interventions for the fewer patients who want and will benefit from these – and to whom we can afford to offer them.

Were the doctors just too good?

Both the authors and a commentator have highlighted the intensity and possibly too the quality of the medical management programme as plausibly accounting for why adding cognitive-behavioural therapy did not improve outcomes. The impact of the weekly therapy may have been overshadowed by these contacts, plus an adequate dose of buprenorphine increased as needed and interacting with clinic nurses three times a week.

Conceivably too, the cognitive-behavioural therapy did help, but in ways not reported, such as mental wellbeing, crime-prevention, health, infection risk, and longer-lasting remission of dependence after prescribing terminated. However, from another account of the study's findings it seems self-reported crime was not further reduced by therapy and nor did these patients experience improved health relative to patients not offered therapy. It is also possible that other forms of support or therapy may have been more effective.

Whether for the patients in the featured study, any substantial dose either of therapy or medical contact was needed is called into question by the rapidity of their improvement. Within the first two weeks of treatment, opioid use had plummeted to on average under a day a week – a typical reaction to the advent of substitute prescribing, which left little room for further improvement. In turn this is likely to have been a testament to the motivation of patients prepared to join the study, which most prospective participants had refused. Notably, this rapid reduction in opioid use was seen at a time when all the patients were still in treatment. Exclusion of patients with complicating conditions may have meant that those who joined the study were quickly able to take advantage of the opportunity it provided. However, this does not seem to have been a particularly promising caseload. At least two-thirds had tried prior treatments and presumably not responded well or sustainably, and three-quarters were without full-time employment. Their attendance records and the need for many to be removed from the study also suggest a set of patients not particularly easy to treat.

Related studies testify to the power of substitute prescribing

Allied with the motivation of patients, the results testify to the power of providing adequate doses of substitute opiate-type drugs, enabling patients to experience the opiate effects they have come to feel they need without having to engage in illegal use. Partnered with regular, well structured and expert medical care, substitute prescribing is in itself an intervention hard to better. Other related studies among similar patients generally support this conclusion.

A prior study of primary care buprenorphine patients from the same research stable had found that nearly doubling the amount of time patients spent being counselled did not further reduce substance use or extend retention in treatment, leading to the same conclusion as the featured study – that on average, only standard medical care was needed to extract whatever benefits there were going to be from the treatment. As in the featured study, in this study too, during the two-week induction phase opiate use had already plummeted to almost the level it would remain during the next 24 weeks of the study. Accounting for the findings, the lead author explained that "the medication, in and of itself, is so effective, so you would really need to have a large magnitude of difference in services to demonstrate any benefit over what the medication is able to provide".

An earlier pilot study from the same author had suggested the contrary – that adding drug counselling to medical care *did* improve outcomes among buprenorphine patients – but numbers were so small that differences were not statistically significant, suggesting this an anamolous finding. Later a study similar to the featured study tested the impact of adding cognitive-behavioural therapy to buprenorphine maintenance, but allocated patients to therapy dependent on the availability of the therapist rather than at random. Therapy patients were also required to attend the clinic three times a week to take their medication, while non-therapy patients were given their drugs weekly to take at home. Even at the low daily doses in this study – averaging 12–13mg a day – no statistically significant advantage was gained by

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Though the featured report discounted this comparison, its findings were in line with a synthesis of findings from trials of supplementing opiate substitute prescribing with psychosocial therapies, most of which involved methadone patients. Overall and in respect of the type of therapy tested in the featured study, no statistically significant advantage was gained for therapy patients in reducing illegal opiate use, extending retention, or improved psychological health.

Some may benefit even if on average no differences

An Effectiveness Bank hot topic has addressed the issue of whether extra counselling and therapy augment the benefits of substitute prescribing programmes. It notes that UK and US guidelines insist that substitute prescribing without counselling or therapy is substandard treatment, but that the evidence supporting this position is thin. However, this evidence normally relates to averages across a caseload, not whether individuals within those caseloads might suffer from a blanket denial of psychosocial support.

Even across a caseload, some studies have found substantial benefits from extra psychosocial inputs, of which the most convincing was a US study whose patients were typically black single men with extensive criminal histories and experience of serious psychiatric disorders. Psychiatric severity may have been the key in this study, and certainly seemed the key in a study at a methadone programme in Philadelphia which recruited the full range of patients seen at the clinic and randomly allocated some to weekly sessions with professional psychotherapists. Benefits were most clear-cut for the patients with the most severe psychiatric problems, who consistently recorded greater improvements when allocated to professional psychotherapy, including a further reduction in days of opiate use. Without psychotherapy, among these patients opiate use remained virtually unchanged.

Patients dependent on cocaine as well as opioids were excluded from the featured study and from similar primary-care based buprenorphine maintenance studies, but were the focus of a US trial of offering methadone maintenance patients group cognitive-behavioural therapy. Compared to methadone treatment alone, the therapy substantially reduced cocaine use. Once both programmes had ended, it was also more effective than providing vouchers with a monetary value in response to cocaine-free urine tests.

This draft entry is currently subject to consultation and correction by the study authors and other experts.

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