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## 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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▶ Efficacy and cost-effectiveness of an adjunctive personalised psychosocial intervention in treatment-resistant maintenance opioid agonist therapy: a pragmatic, open-label, randomised controlled trial.



Marsden J., Stillwell G., James K. et al. Lancet Psychiatry: 2019, 6, p. 391–402.

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Instead of a set programme, a clinic in London tried offering methadone or buprenorphine patients still using heroin or cocaine a selection from a suite of well-supported psychological interventions tailored to the patient and then systematically re-tailored in the light of how they responded. It worked – but did it work well enough, and would the findings be replicated in more typical circumstances?

**SUMMARY** Maintaining patients by prescribing the opioid medications methadone or buprenorphine is the standard first-line treatment for opiate dependence in the UK. However, many patients discontinue treatment, others do not take their medication as directed, continue to use other opioids, or relapse to pre-treatment levels of opioid use. Cocaine use (particularly use of crack cocaine) and co-occurring anxiety and mood disorders are common.

To address such issues supplementary psychosocial interventions have extensively been trialled, but with limited success. The UK's National Institute for Health and Care Excellence (NICE) endorses only contingency management, behavioural couple and family therapies, and 12-step-based groups, while a review concluded that no psychosocial intervention had been found to reliably enhance the effectiveness of opioid maintenance treatments.

However, these supplements have usually taken the form of distinct, manual-driven therapies. Following the manual, typically practitioners offer patients a set progression of interventions, affording little scope for tailoring treatment according to patient preferences and adapting it to how patients are doing.

In contrast, a personalised psychosocial intervention was developed for the featured study. Rather than a set programme, it drew on a 'toolkit' of techniques adapted from manuals and clinical guidelines, at least two of which were selected for each patient based on a 'case formulation'. These are developed during collaborative discussions



## Key points From summary and commentary

A personalised psychosocial intervention was trialled for opioid-dependent patients being prescribed methadone or buprenorphine on a maintenance basis but who were still using heroin or cocaine.

Distinct from most other trials of additional psychosocial therapies, instead of a set programme, in this trial the interventions were selected from a 'toolbox' to match the patient's needs and preferences and adapted in the light of how they responded.

Compared to usual treatment, among patients randomly allocated to this approach there were greater reductions in heroin and cocaine use and improvements in health-related quality of life, making the interventions cost-effective according to some accepted yardsticks. However, these findings which emerged in relatively ideal rather than typical circumstances.

which formulate a working hypothesis of how a disorder is being maintained, focusing on cognitive, emotional, and interpersonal factors. These discussions are usually supplemented by information gathered from standard assessment scales and clinical case conferences. As treatment progresses, patients and therapists review progress, updating the formulation and adapting therapeutic components as required. The featured study was the first to trial such a strategy – common in mental health – in the context of opioid maintenance treatment, specifically to help improve outcomes for patients not responding as well as intended to treatment.

The site of the study was a specialist, publicly funded and provided community addictions service in London. Researchers screened patients to find adults seeking to continue the opioid maintenance they had been in for at least six weeks, who met criteria for opioid or cocaine dependence over the past 12 months, and who were classified as 'non-responders' on the basis of interviews and urine tests revealing opioid or cocaine use in the past 28 days, indicating that the current treatment had failed to entirely suppress these forms of illegal drug use. The question asked by the study was whether for these patients – the bulk of patients in opioid maintenance in the UK - a personalised psychosocial intervention added to usual treatment would prove more effective than usual treatment alone. Primarily this was assessed by the proportion shown by interviews and urine tests not to have used heroin or cocaine over the final four weeks of the 18-20 week trial and therefore to have now become 'responders' to treatment. Missed tests were counted as indicative of heroin and cocaine use. Also assessed was how much overall (ie, not just in treatment costs, but in costs to society as a whole including crime) these gains cost, and whether improvements in the patients' quality of life were gained at below the cost considered by NICE to be a cost-effective use of resources.

Patients who agreed to join the study were randomly assigned to treatment as usual or this plus a personalised psychosocial intervention. They and their clinicians and research staff knew who had been allocated to which. Patients assigned to the intervention were first assessed by a clinical psychologist and an assistant psychologist to agree a case formulation and intervention plan. The extensive measures of psychological health made by the researchers for the purpose of the study were fed into the assessment. Weekly case conferences reviewed the treatment plans.

Intended to be delivered over 12 weeks, the interventions in the 'toolkit' were psychological techniques to facilitate behaviour change:

- all patients were encouraged to select a contingency management programme offering shopping vouchers for either good attendance, recovery activities, or abstinence from drug use;
- additionally, also available were cognitive-behavioural techniques to help cope with craving and modify disorder-maintaining beliefs or to help alleviate depression; or
- 12-step based therapies to promote attendance at self-help groups; or
- methods to engage partners and families in the treatments.

In a motivational interviewing style, the interventions were usually delivered weekly by assistant psychologists who received fortnightly individual clinical supervision and weekly group supervision. The 'usual' psychosocial support to which these interventions were added consisted of fortnightly, half-hour individual appointments with a keyworker for drug counselling.

Of the 348 patients screened for the study between 2013 and 2015, 273 joined and the results for 270 were analysed, 135 each assigned to the different treatments. Over 90% had used non-prescribed opioids in the past four weeks and over 80% crack cocaine. Typically they had been in treatment for six months (two-thirds on methadone) and were unemployed men in their late 30s or 40s assessed as dependent on both opioids and cocaine. The intended end of the trial was 18 weeks after allocation to the treatments (though another two weeks were allowed if needed), when over 9 in 10 of the patients who joined the study were still in treatment.

### Main findings

About 6 in 10 of the participants allocated to the psychosocial interventions attended over a third of the scheduled sessions. On average they attended about five of the 12 scheduled sessions and about nine keyworker appointments, while usual-treatment attended 7.5 appointments. Overall retention in treatment did not significantly lifter.

In the final four weeks of the trial, 16% of those allocated to the psychosocial interventions were classified as 'treatment responders' (no cocaine or heroin use in past four weeks) compared to just 7% of usual-treatment patients, a statistically significant difference. Research interviews indicated that during these four weeks, psychosocial intervention patients spent significantly more days free of opioids (73% v. 57%) and also of crack cocaine (79% v. 67%); both sets of patients had only very rarely used powder cocaine. During the same period, work and social adjustment scores were significantly better in the psychosocial intervention group, though cognitive function and symptoms of depression or anxiety were about the same.

Despite the extra costs associated with the interventions (on average just over £500), patients allocated to the psychosocial interventions imposed a slightly (but not significantly) lower total cost on society, largely due to substantial but not significantly lower average costs associated with the crimes they admitted to having committed during the follow-up period. Use of health and social care services was broadly similar between the groups, though the psychosocial intervention group spent more nights in hospital. Their interview responses also indicated that compared to usual-treatment patients, those allocated to the psychosocial interventions experienced significantly better health-related quality of life once missing scores had been estimated.

Across many simulations varying the figures, on the basis of total social costs, even societies willing to pay very little for an improved response to treatment would generally find the psychosocial interventions more cost-effective than usual treatment. Generally too, the psychosocial interventions would gain quality-adjusted years of life at a cost per year below that considered by NICE to be a cost-effective use of resources. However, this was not consistently the case when instead of total costs including those associated with crime, costs were narrowed down to those imposed on publicly funded health or personal social services, the perspective recommended by NICE. Then usually the psychosocial interventions would not gain an extra quality-adjusted year below a cost-effectiveness threshold of £20,000 per year, and would be only slightly more likely to be cost-effective than usual treatment if the threshold was moved up to £30,000.

#### The authors' conclusions

Compared to typical treatment, at a routine  $\underline{\text{NHS}}$  clinic with patients sifted through minimal exclusion criteria, a team approach with supervised psychology assistants delivering psychosocial interventions tailored to the individual was found both effective and cost-effective at reducing illegal drug use among patients not responding fully to treatment, and a good investment for improving health-related quality of life. While it may not be advisable to offer standardised psychosocial interventions across the board, offering more personalised interventions to patients not responding as desired to treatment seems a more fruitful strategy. That patients can be motivated to engage in a psychosocial intervention was reflected in the proportion (59%) who attended at least a third of the sessions.

Practice implications are that clinicians providing opioid maintenance treatment should assess their patients' response early once the maintenance dose has been achieved. If therapy is not providing clinical benefit, even a basic case formulation will help shed light on why and point to an intervention. Much is also probably to be gained by supplementing usual assessments with standard clinical interview schedules and questionnaires, which provide actionable information and inform the process of selecting change methods. Clinicians should bear in mind that patients' personal preferences are key. Having a 'toolbox' of psychological methods for promoting change gives flexibility and the ability to adapt treatment according to assessments and patients' responses.

supports intensifying psychosocial support in methadone and allied maintenance programmes, the study suggests that it was not the general thesis that was mistaken, but its implementation in the form of inflexible programmes insufficiently tailored to patients' preferences and needs. Take steps to gather the required

information from the patient on their psychological profile, preferences and needs, use this to formulate an understanding of their drug use, develop hypotheses about changing behaviour to be tested using evidence-based practices, keep adapting as necessary, and the desired improvements emerge – a strategy in line with current thinking on psychotherapy in general.

The study seems to take us a step further along the road away from a usually inconclusive horse-race competition between 'brand name' therapies, towards identifying which mix of a variety of psychosocial active ingredients (the 'toolbox') work best for which patients (1 2). There is, however, another possible interpretation of what drove the outcome improvements. All the patients were encouraged to opt for a variety of contingency management programme, rewarding them with shopping vouchers for engagement or abstinence. Instead of the right therapeutic mix, it could be that the findings primarily represent the well-known effects of these programmes. If that was the case, any gains might well have been found to have evaporated had the trial continued beyond the time when the rewards were on offer, a typical finding in longer term evaluations of contingency management programmes.

Other suggestions from the study are that for the sake of economy – and perhaps also to avoid upsetting a stable apple cart – this extra effort can be restricted to patients not already doing well with more basic care, and that a collaborative approach affording patients a degree of control over the interventions leads to acceptable levels of engagement. These are important implications from a groundbreaking study which seems to point one way towards to a more recovery-oriented opioid maintenance system, in line both with national policy and clinical opinion.

Though in the featured study the interventions and the system to guide and adapt them were structured and may to many drug workers have been unfamiliar, the researchers' practice recommendations were more modest and manageable. Effectively they amounted to advice that clinicians keep tabs on how their patients are doing, try to find out why some are not doing as well as desired, and then adapt treatment to these assessments bearing in mind the patient's preferences. It might be thought that any service which fails to do this is not just failing to provide optimal care, but failing even to provide what in any medical sector would be considered minimally acceptable care. Additional and apparently more optional recommendations are that the assessments use standard clinical interviews or questionnaires or other validated methods, and that the adaptations to treatment be selected from a toolbox of validated psychological change methods.

Delivered in the study by assistant psychologists rather than qualified clinical psychologists, an attractive aspect to the toolbox approach is that the constituent skills could readily be disseminated (through training, monitoring, supervision, ongoing evaluation) across different professional groups, especially keyworkers, the backbone of addictions support and treatment, embedded within the familiar motivational interviewing counselling style. While the therapy is actually happening, the study offers ways to assess its quality and whether it needs adapting, including a very brief scale recording the patient's rating of their therapeutic alliance with the therapist.

Despite this potential, the modesty of the practice recommendations may be a recognition of the current low capacity of opioid maintenance programmes in the UK to systematically implement psychosocial therapies even of a more basic kind than trialled in the study. Among a UK-wide sample of patients prescribed medications for opioid dependence in 2011, 40% said they were not even receiving keyworking or group work. The study's findings offer encouragement for services to try to improve on this and for commissioners to fund these attempts, but these findings emerged from a trial conducted with greater resources and expertise and perhaps too conducted in a more promising clinical setting than typically available. They show what *can* be achieved by this extra effort, not what *will* be in more typical circumstances. If ven then, the extra gains in patient welfare may be considered too modest to warrant the expenditure. These issues are explored further below.

### Is it a good enough investment?

Selecting patients who have used non-prescribed opioids or cocaine in the past 28 days would exclude only a minority, even of those already in treatment for six months. On this basis, the treatments trialled in the study requiring trained staff would be offered to most patients, transforming medication-based treatments into ones substantially based on psychosocial therapies. Despite the cost-effectiveness findings, there must be considerable doubt over whether such an investment is likely in the foreseeable future.

When as recommended by NICE, the focus is narrowed to costs borne by the health and personal social services sectors which would provide the therapies, the featured study did not show they would be considered a good investment in terms of the standard yardstick of improving and extending life for the patients. (Though this was narrowly assessed in health terms, not other quality-of-life components which might have been more responsive to psychological therapy such as loneliness, intimacy, interpersonal or family conflict, social support, and communication.) Only when wider social costs – especially those associated with crime - were included did supplementing opioid maintenance with personalised psychosocial interventions meet criteria for a cost-effective use of resources. The costs of crime which yielded this result are likely to have been related to acquisitive crimes committed to be able to purchase heroin or crack cocaine. Since use of these drugs was reduced by supplementing treatment with psychosocial therapies, it seems the costs of associated crime too were reduced. However, there is a strong argument that the main cost element of these acquisitive crimes - money or goods stolen or defrauded - should not be included in the calculations, since society as a whole (including individuals who gain from crime) suffers no net

There also seems a question over whether interventions were fully costed in. An appendix detailing these costs makes no mention of the costs of data collection by researchers used not only for research purposes, but also to inform the interventions. Not only would these have added to costs, but they may also have improved outcomes, yet not be routinely available. The researchers themselves thought "much is to be gained from the use of clinical scales, which provide actionable information and inform the process of selecting change methods" — information provided to clinicians by the researchers. Additionally, the expertise and experience of the nationally prominent addiction psychologists on the research team who provided clinical supervision and attended case conferences cannot be assumed to be replicated locally.

In seeking to justify these expenditures, services and commissioners may want to know not just whether the interventions they buy are more effective than routine care, but also more effective than simply increasing patient-clinician contact time without introducing the expertise, interventions and case conferences of the tested interventions. This question cannot be answered by the study. Other studies provide some evidence that contact time can matter, but also that the quality of extra psychosocial inputs can be decisive.

Difficulties in recruiting patients to the study, and a record of fewer than half the intervention sessions attended by those who did join, suggest a less than enthusiastic reception by many patients. Nevertheless, to the research team attendance levels signified a good level of engagement with the interventions, one which may partly have been due to the self-selected nature of the patients. Instead of the intended 368, the study had to make do with 273 because "we verestimated the number of patients who would be interested in taking part". Since their core treatment was not at risk from declining

to join the study, it seems possible that patients particularly interested in engaging in the interventions or controlling their 'on-top' substance use joined, perhaps not typical of those still using heroin or cocaine. In some treatment settings, excluding suicidal patients, those with unresolved medical conditions, or those facing a possible spell in prison, would exclude an appreciable portion of the caseload. Had the interventions been routinely applied across the full range of the still-using caseload, the results might not have differed.

If the patients were selected, so too was the single clinic at which the study was conducted, a community clinic associated with the UK's leading clinical and research addictions centre at King's College London. When an attempt was made to trial cognitive-behavioural therapy at a broader cross-section of English methadone clinics, it foundered partly because the services were overstretched and understaffed and suffered from high staff turnover. Very few staff had been trained in psychological interventions and sometimes even basic individual client keyworking was extremely limited. Just 60 of 369 eligible patients joined the study and typically they attended just four of the 24 extra therapy sessions on offer. Difficulties in engaging clients in the study were attributed partly to a low level of psychological interventions in services, which in turn led to low expectations of clients engaging with these interventions. Worryingly, the researchers discerned a "nihilistic view of psychological intervention and clients' capacity for change among some staff". Despite implementation problems, this randomised trial study did find that cognitive-behavioural therapy was associated with reductions in the severity of addiction and heroin use and improved compliance with prescribed methadone, though none of the findings were statistically significant, so chance fluctuations could not be ruled

A commentary on the featured study raised the issue of whether average medication doses higher than those in the study might have left less scope for extra therapy to further reduce heroin and cocaine use. Recommended methadone and buprenorphine dose ranges in the UK are respectively 60–120 mg and 12–16 mg a day, though some patients will need more. In the featured study doses of methadone averaged around 57 mg and of buprenorphine 11.5 mg, both slightly lower than the recommended minimum, meaning many patients must have been prescribed less than recommended.

#### Guidelines insist on psychosocial support

Notwithstanding patchy evidential support, in many treatment systems across the world psychosocial support is considered indispensable for opioid-addicted patients prescribed heroin substitutes like methadone and buprenorphine. Guidelines insist that "psychosocial interventions are ... a crucial part" of opioid substitution treatment, and regular counselling may be required by the regulations governing the programmes. In their title (Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence), World Health Organization guidelines integrally partner the medication component of the treatment of opioid dependence with what the text recommends should be "comprehensive psychosocial support to every patient". Published in 2017, the UK's own clinical guidelines on treatment for substance use problems also insist that in opioid substitute prescribing programmes, "optimal behaviour change is Inlikely without a good therapeutic alliance and suitable psychosocial interventions" and that "Treatment for drug misuse

should always involve a psychosocial component to help support an individual's recovery." The advice is definite, even if implementation seems to lag a long way behind.

Thanks for their comments on this entry to research author Luke Mitcheson, Consultant Clinical Psychologist and Head of Addictions Psychology and Lead Psychologist for Lambeth Addictions at the South London and Maudsley NHS Foundation Trust in England, and Kevin Ducray, Senior Clinical Psychologist at the Health Service Executive National Drug Treatment Centre in Ireland. Commentators bear no responsibility for the text including the interpretations and any remaining errors.

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