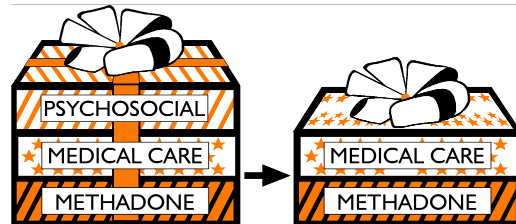
GO Are the drugs enough? Counselling and therapy in substitute prescribing programmes

Specialist programmes which prescribe substitute opiate-type drugs to opiate-dependent patients are supposed to be a securely knotted package of medications, the medical care needed to oversee them, and psychosocial support in the form of counselling and 'talking' therapies. But what happens if you untie the knots and take out the one dispensable element – the psychosocial support? Is most of the talking that goes on in methadone and allied services under the heading of 'counselling' or 'therapy' a waste of time and money, or one way to rehabilitate these services' recovery credentials by helping elevate patients to the point when they can safely leave?

Official guidelines are it seems in no doubt: counselling/therapy is essential; drugs alone are sub-standard treatment. In 2009 the World Health Organization said, "Treatment services should aim to offer onsite, integrated, comprehensive psychosocial support to every patient." Latest UK guidelines on methadone maintenance and allied treatments stipulate the "range and quality of psychosocial interventions" as one of the components which elevate effectiveness in recovery terms. As in the USA, regular counselling may even be legally required.



What happens when you untie the methadone treatment package and dispense with counselling and psychosocial therapies?

The UK guidelines took their lead partly from evidence analysed by Britain's National Institute for Health and Care Excellence (NICE). It is at this level – the level of scientifically credible evidence – that this aspect of the guidelines have been erected on a shaky foundation. In 2007 NICE had commended some social network therapies and the systematic application of rewards and sanctions as adjuncts to maintenance. But other approaches, including cognitive-behavioural therapy, relapse prevention techniques and motivational interviewing, were not recommended, leaving the most commonly implemented (if often only loosely) methods without the backing of this official evidence adjudicator.

NICE's verdict was followed in 2011 by an update of an authoritative Cochrane review of rigorous studies. Surprisingly, it found that adding psychosocial therapy to opiate substitute prescribing plus routine counselling has overall made no difference to retention or substance use. Included among the ineffective supplements was the systematic application of rewards and sanctions, which the earlier NICE report had favoured, deleting yet another psychosocial intervention from the list of effective adjuncts.

Starting without counselling better than starting later or not at all

The studies which led to the Cochrane review's conclusions can be divided into those which tried dispensing with usual counselling only as a means of getting patients more quickly into fully fledged treatment, versus those which extended this stripped-down phase into the treatment itself.

In the first category, trials have taken advantage of US regulations allowing an 'interim' initial phase to methadone programmes of up to 120 days when only crisis counselling is available. Their findings provide the most convincing evidence that at least at the start of treatment, counselling is not routinely required.

The most significant trial was conducted in Baltimore, where two clinics randomly and rapidly assigned new patients (usually within three days) to an interim programme, to a standard methadone programme featuring weekly group and/or individual counselling, or to an enhanced programme which also offered on-demand counselling by a highly regarded counsellor with a low caseload. The 230 patients in the study were typically unemployed single black men in their early 40s who used heroin daily, with on average over 20 years of heroin use and over four years in jail behind them.

Despite this seemingly unpromising population, patients who started their first four months of treatment with virtually no counselling generally did as well as those individually counselled about once a month, and even as well as those counselled once a fortnight by the counsellor handpicked for excellence. This equivalence was sustained for at least eight months after the interim programme had ended. It seems possible that over their decades of heroin use the patients had heard already experienced advice and counselling to which the study's programmes could add little, but what most had never experienced before was being on methadone.

This and similar studies (including some in the UK) reviewed in detail by Findings have shown that subject to sufficient assessment and monitoring to ensure clinical safety, starting prescribing in the absence of regular counselling or other psychosocial supports is preferable to simply leaving patients waiting, even for a few weeks. Patients reduce their drug use, health risks and criminal activity, and more go on to enter the main programme.

Key studies of long-term treatment

Rather than confining low/no counselling to the start of treatment, programmes similar to the US interim arrangements have been trialled as longer term alternatives to more intensive support. For some patients the studies show little more may be needed, and across all patients, evidence of the effectiveness of extra therapy is surprisingly thin – thin, but not non-existent.

Two US trials provided the strongest evidence that counselling methadone patients is not a waste of resources. They were among those analysed in detail in these background notes under the heading "Are cut-down services a viable

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were among those analysed in detail in these background notes under the heading, "Are cut-down services a viable alternative to more comprehensive programmes?"

The first involved 92 US military veterans who on starting methadone treatment had been randomly allocated for 24 weeks either to: no regular counselling (though counsellors did maintain monthly contact); standard counselling – weekly to begin with, then adjusted to the stability of the patient; or standard counselling enhanced with extra services including regular medical and psychiatric care, social work assistance, family therapy and employment help on-site. Patients were typical of the area's caseload: black single men with extensive criminal histories and most of serious psychiatric disorder.

Each step up in psychosocial inputs produced better outcomes over the roughly six months they were operational. The effects were apparent in the proportions of patients who (largely due to regular illicit substance use) met criteria for 'emergency' transfer to usual care: 69% not offered counselling versus 41% of standard care patients, and just 19% in enhanced care. Urinalyses revealed significantly more illicit opiate and cocaine use in the minimal contact patients. When the standard and enhanced groups were compared, improvements were greater in the enhanced group on 14 out of 21 measures and significantly so in respect of employment, drinking, crime, hospitalisation for medical problems, and proportion abstinent from opiates and cocaine, though not in average days of use of these substances or overall drug problems.

Six months after the trial had ended, over which time all patients had reverted to usual care, there remained a lingering statistically significant effect on the proportion abstinent from heroin, contributing to the finding that proportions abstinent from both heroin and cocaine were 29% in the minimal care group but 47–49% in the other two groups. This small study of an atypical set of patients remains the best evidence that supplementing methadone maintenance with extra psychosocial inputs further reduces the key outcome for these treatments – illegal opioid use. But when findings from similar trials were amalgamated, its contribution was outweighed by other studies, leading overall to only a small and possibly chance advantage in proportions abstinent.

For the second study, 353 patients admitted to a US methadone programme were randomly assigned to minimal counselling, standard counselling, or standard counselling enhanced with group therapy and training in relapse-prevention skills. It offered only weak support for extra counselling. Compared to standard care, urinalysis results over the first 18 months of treatment indicated that illegal opiate use was significantly more likely among minimal care patients, but the effect was minor, and enhanced services did not further reduce opiate use. However, these results could only be obtained from patients retained in treatment, and by the end all but a fifth had left. Cocaine use was unaffected by the intensity of support.

Not just methadone; buprenorphine too

Most studies of extra psychosocial inputs have involved methadone maintenance, but it seems added value is hard to find whether the maintenance medication is methadone or buprenorphine.

In a US randomised trial, buprenorphine patients allocated to cognitive-behavioural therapy did no better in reducing drug use and sticking with treatment than those offered a programme approximating usual medical care by their doctors. The findings were all the more remarkable because the therapy was *additional* to rather than instead of medical management. They seemed to confirm the implications of another buprenorphine maintenance study from the same lead researcher which found standard medical management as effective as more intensive medical management – the implication being that "for some patients, a relatively low level of supportive services ... is sufficient for generating abstinence and retention in treatment."

A third US study recruited patients dependent on prescription opioids and stabilised on buprenorphine before attempted detoxification. Those randomly allocated to relatively brief weekly medical management visits versus this plus more extended specialist counselling did equally well in avoiding 'on-top' opioid use during the stabilisation phase.

What we can gather from these studies is that across all methadone or buprenorphine patients in a sample, studies have rarely found consistent and substantial advantages from extra counselling or extra psychosocial therapies. But what of particular sorts of patients – and perhaps it is not the extent or content of counselling or therapy which counts, but some other quality? An affirmative answer to both questions is suggested by a few studies.

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Nuances: does impact depend on patient need and counselling quality?

Perhaps it is no surprise that extra psychosocial inputs have little impact when trials commonly exclude psychologically unstable patients, the very ones some US studies suggest might benefit from psychotherapy. Published in 1983, among these was a randomised trial at a methadone programme in Philadelphia which recruited patients early in treatment who were representative of the entire caseload. Just 1 in 10 were excluded because they might have to move out of the area, though later another 1 in 10 were excluded because they did not attend the first three counselling or therapy sessions.

The conclusion was that patients benefited from being randomly allocated to weekly sessions with professional psychotherapists because these helped ameliorate the psychiatric problems common in the caseload. Benefits were apparent in some ways (but not in substance use) among patients with moderately severe psychiatric problems, but more clear cut for the high-severity patients, who consistently improved more when allocated to professional psychotherapy, including a greater reduction in days of opiate use. Without psychotherapy, among these patients opiate use remained virtually unchanged. Clinical records showed that the two groups of patients with appreciable (moderate or high) psychiatric problems had more drug-positive urines when offered drug counselling alone without psychotherapy and had required higher doses of methadone, typically a response to continuing problems. Unfortunately, the study left open the question of whether extra therapeutic contact accounted for the findings, or the psychotherapeutic nature of that contact.

Later the study was broadly replicated among patients selected for severe psychiatric symptoms attending three more typical US methadone programmes. Many were not interested in the trial, but 123 were sufficiently severe and agreed to be randomly allocated to an extra therapy session a week for 24 weeks of either a form of psychotherapy, or drug counselling of the kind they were already receiving, though a quarter were later excluded from the analysis due to poor initial attendance.

On nearly every measure, by the final follow-up psychotherapy patients were doing better than those allocated to extra drug counselling, though usually the differences were modest. After the initial impacts of being on methadone had evened out, patients allocated to psychotherapy evidenced somewhat better psychiatric adjustment and a more

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evened out, patients allocated to psychotherapy evidenced somewhat better psychiatric adjustment and a move towards a more conventional and law-abiding lifestyle. However, in some respects the effects were not as substantial as in the earlier study and were not seen at the initial follow-up, perhaps partly because both groups of patients were offered an extra therapy session a week. This was intended to eliminate concerns that the earlier findings might have reflected the amount of therapeutic contact rather than its type. Given the relative findings of the two studies, it seems these concerns might have been at least partly justified. Though this concern was addressed by the second study, the highly (self-)selected participants raised another concern – that the findings would not be replicated across a typical caseload.

The hand-picked, expertly supervised professional psychotherapists employed by these studies can perhaps be expected to be experts at forging therapeutic relationships with troubled individuals, raising the issue of the quality of the interaction with patients. If counselling was truly ineffective, quality would be irrelevant, but that is not what is found. As described in these background notes, the quality of counselling seemed decisive at a US methadone clinic where patients were allocated in a virtually random fashion to four drug counsellors. Two were moderately effective, the third very effective, and the fourth not effective at all. The most effective counsellor was able to bring his clients to a point over a six-month period where their drug use and unemployment were significantly reduced when compared with the prior six months, while at the same time reducing their use of both methadone and psychoactive medications. By contrast, the clients of the least effective counsellor showed increased unemployment, drug use and criminal activity, and needed more methadone and medications. When the case notes were examined, it became clear that the most effective counsellor was distinguished from the rest by their ability to help clients anticipate problems and develop ways of dealing with them in advance.

The quality of counselling seemed decisive at a US methadone clinic

Another US study started off investigating methadone dose, but found that when tailored to the individual it made no difference. What did make a big difference to retention and illegal substance use (the two were related) was which of 13 counsellors the patient had (essentially at random) been assigned to. Of the counsellors with appreciable numbers of patients, the patients of one averaged around 20% of urine tests indicative of opiate use and 24% cocaine, while at the other end of the range, another counsellor recorded corresponding figures of 60% and 57%.

Spread methadone programmes thin and wide?

Sometimes denigrated as 'merely' substituting one drug for another, findings on the impact of extra support are a testament to the power of routine methadone and buprenorphine maintenance. For patients who previously had to offend several times a day to sustain the roller-coaster of repeated daily heroin injections, a legal supply of a more normalising, smoother and longer acting drug like oral methadone, is in itself typically a quick-acting and powerful intervention. Adding a specific programme of counselling or psychological therapy seems less important than the basics identified in UK guidelines: a structured treatment with clear objectives, involving an adequate dose of methadone, long-term treatment with no hurry to withdraw, and an accepting, non-judgmental therapeutic alliance.

It may be important to note that even counselling-free substitute prescribing programmes are not devoid of potentially therapeutic and stabilising human contacts, especially if they require daily or near-daily supervised consumption. The attitudes and inputs of reception staff, doctors, nurses and others may determine whether someone wants to keep coming to the service, and retention is the key factor in impacts on substance use. Human beings too react to the symbolism and meaning they attribute to a service or object as well as to the thing itself. In the case of substitute prescribing programmes, the therapeutic and affirming value of having someone care enough to provide a medication to a person society has written off should not be underestimated.

Inevitably there are exceptions, among whom may be the psychologically unstable patients often excluded from trials and who do seem to benefit from extra therapy, and the (in the UK) minority of patients in a position to engage in family or couples therapy. And with such limited research, it is not possible definitely to conclude that extra psychosocial support is on average *in*effective – just that generally it cannot be shown to have been effective.

With this evidence base, we cannot be sure of the effectiveness (and allied to that, the safety) of switching to virtually counselling-free programmes on a long-term basis. Shaun Shelly, an expert in addictions at the University of Cape Town, has pointed out that effective psychosocial inputs might be expected to affect recovery indicators like quality of life perhaps more than substance use, to help sustain recovery more than to make a short-term impact, and to help more troubled patients in particular. It could be too, he suggested, that the typical offer of more drug counselling or cognitive-behavioural therapy misses the mark by not addressing the "character healing" or "capacity building" and "self-renewal" needed to solidify recovery. On all these counts, the research is particularly lacking.

Such findings as we do have, however, raise the issue discussed in the Effectiveness Bank's Drug Treatment Matrix of whether in order to gain harm-reduction and recovery benefits for the greatest number of patients, methadone 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.

Thanks for their comments on this hot topic to Shaun Shelly of the University of Pretoria in South Africa. Commentators bear no responsibility for the text including the interpretations and any remaining errors.

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