▶ Randomized trial of standard methadone treatment compared to initiating methadone without counseling: 12-month findings.

Schwartz R.P., Kelly S.M., O'Grady K.E. et al.

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Up to a year after starting methadone treatment US patients offered virtually no counselling for the first four months were still doing as well as those offered regular counselling. But there is a hint that intensive and high quality counselling enabled more to safely leave treatment.

Summary The featured article presents the 12-month follow-up results of a study from which Findings has previously analysed the four-month follow-up results. Both articles are drawn on in this account.

At issue in this US study is whether initial regular counselling improves outcomes from methadone maintenance treatment. US regulations require regular counselling except under special authorisation, and even then counselling must start after 120 days – hence the term 'interim' for this stripped-down provision. Previous studies have shown that compared to waiting for a standard methadone treatment slot, rapid access to interim provision substantially reduces opiate use and crime and many more patients eventually start standard methadone treatment. But these studies left open whether offering rapid access to standard programmes would be even more effective than offering rapid access to interim programmes.

To explore this question two Baltimore methadone clinics randomly assigned new patients were to start (usually within three days) an interim programme, or equally rapidly to start standard or enhanced treatment.

As per regulations, the interim programmes could last only up to 120 days, offered crisis counselling only, required patients to take all methadone doses under supervision at the clinics, and featured at least three tests for illegal drug use.

Patients randomised instead to standard programmes were expected to attend weekly group and/or individual counselling sessions (with some room for adjustment to patient needs), permitted ton taker their methadone at home depending on time in treatment and progress, were subject to more frequent drug testing than in the interim programme, and were able to benefit from care planning and other psychosocial inputs.

At one of the clinics patients were also randomly assigned to a third option – the standard programme plus enriched counselling by a highly regarded counsellor with a low caseload, told to see patients as often as they wanted or the counsellor thought appropriate.

The 230 patients recruited to the study and who started one of the three types of programmes were typically unemployed single black men in their early 40s who used heroin daily. All but a few were followed up by researchers four months later when the interim programmes had to have stopped or been replaced by standard provision. As expected, during this time clinic records showed that the interim patients had received virtually no counselling, standard patients about one session a fortnight, and enhanced patients about one a week. Over the next eight months enhanced patients continued to receive individual counselling most frequently – averaging once every two or three weeks – former interim patients about monthly, and standard patients about one session every six weeks.

Main findings

generally indicative of no differences in outcomes across treatments
Dosing protocols in the three types of programmes did not differ. However, at all assessed time points from one month after starting treatment to 12 months later, patients started in the interim programme averaged the highest doses, next were standard programme patients, while doses averaged the least among patients offered enriched counselling. By the end of the 12-month follow-up doses averaged respectively 92mg, 80mg and 65mg per day, statistically significant differences.

On average interim patients stayed in that stage nearly all the permitted 120 days. Over these four months they were no more likely than other patients to have ceased treatment at the assigned clinic; 92% were still in their original programmes compared to 81% of standard and 89% of enhanced patients. Though still not a statistically significant difference, by 12 months the retention figures had diverged to 61%, 55% and 37% respectively, again meaning that patients who had initiated in the interim programme were most likely to have remained at their clinics.

By the end of the four-month interim period and (with a little 'bounce back') also at the 12-month follow-up, heroin use had declined substantially and cocaine use (far less to begin with) more modestly. Use of both drugs fell to roughly the same degree in all three treatments. Heroin use fell from on average virtually daily to a year later four to seven days a month according the patients' own accounts (the lowest figure was for the interim patients), broadly confirmed by urine tests which were 97% positive at first but fell to 46% to 51% positive. Self-reported drug, legal and family problems all declined too, and to roughly the same degree across the three treatments.

Over the four-month interim period two indicators of criminal activity and one of spending on drugs fell slightly more steeply among interim than standard programme patients. By the 12 month follow-up there remained a statistically significant difference in trends in illegal income, which had fallen steeply from an average $657 a month to just $27 among interim patients, but slightly less steeply (from $475 to $55) among standard programme patients.

No serious medical or other adverse events were considered related to the differences in counselling frequency. By the end of the 12-month follow-up 19% of the interim patients had experienced at least one such event compared to 9% of the standard-programme patients and 15% of those offered enhanced counselling.

The general equivalence of the treatments was broadly replicated when four-month follow-up results for interim patients were compared with those for all remaining study participants assigned to more frequent counselling.

The authors' conclusions

While across the board there was significant improvement, being assigned to standard/enhanced versus interim programmes did not further improve retention, illicit drug use and related problems, or make much difference to criminal activity. There was no evidence that interim patients has been substantially disadvantaged by the four-month period during which only emergency counselling was available and during

which they could not 'earn' take-home doses by providing 'clean' urine tests.

The findings are consistent with other studies at typical US methadone clinics. They strongly suggest that rather than making such services obligatory, opioid agonist treatment regulations should allow for additional services where these are both helpful to and wanted by patients. As well as increasing costs by imposing services that may or may not be needed, mandating these services has the unintended consequence of denying access to more basic treatment which is demonstrably of value to patients and to society. The findings also raise questions over discharging patients simply because they have not attended the required number of counselling sessions.

However, even the most frequently counselled group in the study were seen on average once a week. More intensive or different forms of counselling and other forms of support might have made more of a difference. Possibly too, some counsellors were actually beneficial, but across all patients their impacts were neutralised by less effective staff. Perhaps also patients must achieve a level of stability before counselling helps, or methadone itself at the doses prescribed at the clinics has such a powerful impact that modest levels of counselling could not create additional improvement.

FINDINGS Together with this study, 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.

What this study adds is that in this seemingly unpromising population with on average over 20 years of heroin use and over four years in jail behind them, patients who started their first four months of treatment virtually without counselling can do as well as those individually counselled about once a month, and even as well as those counselled once a fortnight by a counsellor handpicked for excellence, and this equivalence can be sustained for at least eight months after the interim programme has ended.

Long-term solution?

Rather than just a short-term introduction to facilitate rapid access, for some patients, little more may be needed and programmes similar to the US interim arrangements can form a longer term alternative to more intensive support. Across all patients, evidence of the effectiveness of extra therapy is surprisingly thin.

These findings challenge guidelines and regulations which commonly see offering drugs alone as sub-standard treatment. For example, in 2009 the World Health Organization said "Treatment services should aim to offer onsite, integrated, comprehensive psychosocial support to every patient". UK guidelines also support psychosocial adjuncts to methadone, taking their lead partly from evidence analysed by Britain's National Institute for Health and Clinical Excellence (NICE). In 2007, NICE 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 health service advisory body.

NICE's verdict was followed in 2011 by an update of an authoritative review of rigorous studies, which found that adding psychosocial therapy to opiate substitute prescribing plus routine counselling has overall made no significant difference to retention or substance use. 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.

It is important to remember that these analyses were considering the impact of therapies over and above counselling, not counselling itself, though they are suggestive that the dose of 'talking therapies' is not a critical factor. That verdict does however apply to *formal* therapies, and the featured study's findings to *formal* counselling. Even without these scheduled talking sessions, methadone treatment is far from a 'contactless' endeavour. In the featured study (and other studies of US interim arrangements), every day of the week over the entire interim period, interim patients had to attend the clinic to take their methadone under supervision – more staff contact than many British patients experience.

Also the difference counselling makes will depend on the quality and nature of that counselling and also on the quality and nature of the counsellor. Perfunctory brief encounters focused on dose, prescribing and dispensing arrangements, attendance records, and regulatory and disciplinary issues are unlikely to accelerate recovery, yet are characteristic of the keyworking service offered by some British criminal justice teams to offenders on opiate substitute prescribing programmes.

Maybe good counselling helps patients *leave* treatment

Guidance for Britain on how to foster recovery in methadone maintenance and allied treatments makes it clear that it would be unacceptable to leave patients on minimal programmes without regular reviews probing for and seizing opportunities to further improve welfare and progress recovery from addiction, including ways to solidify recovery sufficiently for patients to safely leave treatment. In turn this raises the issue of whether more intensive counselling, even if it seems to add little to the powerful effect of *entering* methadone treatment, might help patients get sufficiently on their feet for more to *leave* and leave earlier.

High quality and relatively intensive counselling in the featured study was focused on the 27 patients at one of the clinics allocated to one of the clinic's "best counselors". Their patients managed about as well as the others despite significantly lower doses of methadone and despite many more – nearly two thirds versus just over a third of interim patients – leaving the clinic within a year. What happened to these patients specifically is not reported, but under a third of the leavers across all three programmes were in any kind of treatment at the last follow-up. Here there may be a hint that expert and intensive counselling, though it may not improve in-treatment outcomes, may decrease the patient's reliance on methadone and on treatment, making it possible for more to leave safely earlier.

A further hint comes from the review which found no statistically significant differences between methadone programmes with and without extra therapy. However, the direction of the differences was that with therapy more patients left, but while in treatment, more managed to do at least for a time without illicit opiate-type drugs.

In the featured study an alternative explanation for the findings is that counsellors at the clinics were unduly concerned to limit methadone doses and that this counteracted any benefit from their counselling. Interim patients free to seek increases from nurses (perhaps more pro-medication) gained those increases, and then maintained this differential over the next eight months.

Even if when averaged across all patients, counselling and therapy seem to make little difference, inevitably there are exceptions, among whom may be the psychologically unstable patients often excluded from trials, and the (in the UK) minority of patients in a position to engage in family or couples therapy. Some studies have found that multiply problematic clients benefit from regular counselling and well targeted ancillary services. Without these they suffer repeated crises, perhaps in the end requiring more intensive and expensive intervention than would otherwise have been needed.

Powerful substitute

Sometimes denigrated as 'merely' substituting one drug for another, these findings are a testament to the power of routine methadone (the same applies to buprenorphine) maintenance. The impact of a legal supply of a more 'normalising', smoother and longer acting drug like oral methadone on patients, many of whom previously had to offend several times a day to sustain the roller-coaster of repeated daily heroin injections, is in itself typically rapid and powerful. Adding a specific programme of psychological therapy or more intensive counselling seems less important than the basics identified in the UK recovery guidance cited above: a structured treatment with clear objectives, involving an adequate dose of methadone, long-term treatment with no hurry to withdraw, and a therapeutic alliance built on an accepting, non-judgmental stance by the clinician. Cost-effectiveness is probably maximised by making more intensive and extensive services available for those who feel they need them, or where such services seem advisable.

For more on these issues see this Findings hot topic on counselling in methadone programmes.

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