



Executive Summary

Pilot UK-Injectable Methadone Trial (Pilot UK-INJECT)

Final Report, February 2003

Report prepared by:
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Introduction

Oral methadone maintenance is the standard treatment for opioid dependence and has proved to be effective. Some opiate dependent injecting drug users (OD-IDUs), despite repeated treatment with oral methadone, fail to make any health and social gains and continue to inject illicit drugs and participate in criminal activity. These OD-IDUs have been clinically identified as potentially benefiting from receiving injectable methadone.

There is little consensus of opinion on how best to manage these treatment resistant OD-IDUs and the effectiveness of prescribing injectable methadone remains untested in the UK or elsewhere. Injectable methadone is three times costlier than oral methadone treatment, and would need to have advantage over oral methadone to justify its use.

Aims & objectives of the pilot study

This report describes the results of a pilot feasibility study for a multi-centre randomised controlled trial to compare the outcomes and costs of offering and prescribing injectable versus oral methadone to a selected group of OD-IDUs, in the treatment of opioid dependence.

The objectives of the pilot study included: a) identify the number of patients potentially eligible for a randomised controlled trial; b) assess the feasibility of recruiting and randomising OD-IDUs to the trial; c) assess recruitment rates; d) develop data collection forms and procedures; e) observe compliance with follow-up at six months; f) assess the reliability of researchers and clinic staff to record data; g) determine the feasibility of obtaining follow-up data; h) assess the feasibility for collation and checking of data; i) determine whether the primary outcome measure relates to other outcome measures; j) assess the feasibility of procedures for trial co-ordination and monitoring; k) assess clinic staffs' compliance with the study protocol; l) assess the feasibility of implementing supervised injectable methadone treatment; and m) identify any practical problems

Methods

Design This was a multi-site randomised controlled trial conducted between December 2000 and November 2001. OD-IDUs enrolled at five drug treatment centres were screened to determine numbers of

eligible patients interested in participating in the trial. Those from three of the centres were further assessed to confirm eligibility and invited to participate in the pilot trial.

Recruitment & sample The study aimed to recruit between 40-60 patients at three centres over four months. The target population were treatment resistant, entrenched OD-IDUs presenting for treatment. A two stage screening process was established. During usual patient assessment, those who were potentially eligible for the trial were identified and if interested, they were referred for a full eligibility assessment.

Treatment Consenting patients were randomised to receive either the offer and prescription of injectable methadone or oral methadone and followed-up for six months. The consumption of oral and injectable methadone was supervised daily (Monday – Friday with weekend takehome) for the first three months in treatment.

Data collection Data collection forms were developed to collect outcome data (illicit drug use, HIV risk behaviour, health and social functioning), other measures at baseline, service delivery measures, and cost data. Follow-up assessments were conducted at two and six months.

Results

Patient screening and recruitment

Over a seven month period 903 OD-DUs presenting to five clinics were screened for eligibility for the trial. Eleven per cent (101) of OD-DUs presenting to the five clinics were identified as potentially eligible.

Sixty per cent of OD-DUs failed to fulfil items on the eligibility criteria around injecting: (60% (541) had not injected at least once a day in the four weeks prior to screening; 60% (543) had not injected for nine out of the previous 12 months, and 59 % (532) had not been injecting for a minimum of three years). Also, 54 per cent (486) had not previously received oral methadone treatment continuously for at least six months.

At the five treatment centres, 32 per cent of potentially eligible patients were interested in participating in the trial.

At the three participating treatment centres, 19 patients were randomised to the trial – two per cent (19/765) of patients screened and 22 per cent (19/88) of potentially eligible patients.

Treatment received

Of the 19 patients randomised, 11 were allocated to receive oral methadone and eight to receive injectable methadone. One patient allocated to injectable methadone chose to receive oral methadone.

Outcome measures

Proportion of patients followed up at 2 and 6 months.

Three patients dropped out after randomisation. Fourteen patients were successfully followed-up at two months and 12 at six months.

Completeness of data obtained Researchers and clinic staff reliably recorded data.

Compliance with trial protocol The trial protocol was well adhered to. There was only one violation of trial protocol.

Supervised injectable methadone

Suitable rooms to be used as injecting rooms had to be identified and extra resources were needed to equip rooms for this purpose.

The great majority of patients attended for supervision every day and returned their used ampoules. Patients took between 5 and 15 minutes to inject but the length of time for supervision ranged between 30 – 60 minutes. Clinic staff reported that patients were not injecting safely. No serious adverse events were recorded.

Conclusions

Recruitment of newly presenting opiate dependent drug users into the trial proved not feasible

The study was unable to recruit a sufficient number of OD-DUs presenting for treatment.

Trial eligibility criteria excluded the majority of patients presenting for treatment

The majority of OD-DUs presenting to treatment were either not injecting, injecting infrequently or had only recently started injecting. A high proportion had either never received oral methadone treatment, or had received it for less than six months. The target population does not appear to be presenting to treatment.

Conducting multi-site RCT proven to be feasible

Viable procedures were developed for screening and randomisation. The screening procedures were successful but monitoring them was time consuming. The randomisation procedure was successfully conducted by an experienced team independent of the treatment staff and research team.

Good procedures for data collection, and the collation and checking of data were developed. Follow-up rates would be higher if three patients had not dropped out immediately after randomisation. Data were reliably recorded by researchers and clinic staff.

Compliance with the study protocol was good. Each site recruited a clinical coordinator to manage the clinical aspects of the trial. There was good adherence to the trial protocol.

The trial was well organised and managed. The management of the trial was conducted by a research team independent of the treatment sites.

Implementing supervised consumption of injectable methadone proven to be feasible

An injecting room was established and clinic staff were able to supervise patients injecting their ampoules. However, supervising injecting was time consuming, needs extra resources and may restrict access to treatment for some drug users. There were no existing guidelines for supervising injecting.

UK-INJECT multi-disciplinary group is a viable collaborative treatment research grouping

UK-INJECT comprises a group of academics, consultant addiction psychiatrists, and experts in clinical trials and health economists who are in a good position to undertake research on drug treatment effectiveness.

Recommendations

An injectable trial with modified research design

Modify eligibility criteria

The eligibility criteria including previous treatment and current injecting frequency could be modified to include those new to treatment and those with shorter injecting careers or those injecting less frequently. The target population should be recruited from OD-DUs currently receiving oral methadone treatment. A further pilot study should be conducted to assess the feasibility of recruiting from this population.

Provide adequate resources to conduct a two-stage screening process A two stage screening process should be adopted.

Reduce the likelihood of drop-out Future studies should consider using a cross-over design instead of a usual RCT. Patients should be randomised after they have completed their dose assessment and when treatment commences.

Appoint two named clinical co-ordinators at each site Each site would need two named clinical coordinators to undertake the clinical aspects of the trial and supervise injecting.

Further related studies

Practicalities and benefits of supervised injection

Future research should assess the cost effectiveness of supervising oral and injectable methadone (and heroin) and produce guidelines on the supervision of injectable prescriptions.

Survey of drug users presenting to UK drug clinics

Insufficient information is known about drug users presenting to drug treatment services. Research should be conducted to identify the characteristics and treatment needs of drug users presenting to treatment services in the UK. ■