

Fact Sheet No.1 : Trials contributing outcome data to NEPOD

Principal investigators	Location	Design	Types of participants	No. of participants reported on by NEPOD ^a
Saunders, Lawford, Young, Jones, McFarland	Brisbane	RCT of naltrexone induced rapid detox under anaesthesia vs. rapid detox under sedation (followed by naltrexone treatment) vs. best conventional control (generally methadone maintenance treatment)	Heroin dependent ^b , and Methadone patients	50 Rapid detox - anaesthesia (n=25) Rapid detox - sedation (n=25) 42 Rapid detox - anaesthesia (n=42)
Bell, Mattick, Bammer, Young	Sydney	Observational study of naltrexone induced rapid detox under sedation (followed by naltrexone treatment)	Heroin dependent, and Methadone patients	15 Rapid detox - sedation (n=15) 15 Rapid detox - sedation (n=15)
Ali, White, Thomas	Adelaide	RCT of naloxone induced rapid detox under anaesthesia vs. conventional inpatient detox (followed by naltrexone treatment)	Heroin dependent	101 Rapid detox - anaesthesia (n=51) Conventional inpatient detox (n=50)
Lintzeris, Bammer, Bell	Melbourne Sydney	RCT of outpatient detox using buprenorphine vs. conventional outpatient detox (followed by choice of post-detox options)	Heroin dependent	114 Buprenorphine outpatient detox (n=58) Conventional outpatient detox (n=56)
Bell, Mattick, Lintzeris	Sydney	RCT of outpatient detox using buprenorphine in specialist vs. GP settings (followed by choice of post-detox options)	Heroin dependent	100 Buprenorphine outpatient detox - GP (n=51) Buprenorphine outpatient detox - specialist (n=49)
Tucker, Ritter, Kutin, Bammer, Jackson, Whelan	Melbourne	RCT of naltrexone treatment with or without 12 weeks counselling	Recently detoxified Heroin dependent	97 Naltrexone treatment (n=97)
Bell, Mattick, Bammer	Sydney	RCT of 3 dose levels of naltrexone treatment (50mg vs .5mg vs .05mg)	Recently detoxified Heroin dependent	20 Naltrexone treatment 50mg (n=20) Naltrexone treatment .5mg (n=21) Naltrexone treatment .05mg (n=20) Nb: the two low dose naltrexone groups were not included in analyses
Mattick, Ali, White	Sydney Adelaide	RCT of buprenorphine vs. methadone maintenance treatment (clinic setting)	Heroin dependent	405 Buprenorphine (n=200) Methadone (n=205)
Ritter, Lintzeris, Kutin, Bammer, Clark	Melbourne	RCT of buprenorphine vs. methadone maintenance treatment (clinic and GP setting)	Heroin dependent, and Methadone patients	92 Buprenorphine (n=50) Methadone (n=42) 61 Buprenorphine (n=29) Methadone (n=32)

Fact Sheet No.1 : Trials contributing outcome data to NEPOD (cont.)

Principal investigators	Location	Design	Types of participants	No. of participants reported on by NEPOD ^a
Ritter, Lintzeris, Kutin, Bammer, Clark	Melbourne	RCT of LAAM vs. methadone maintenance treatment (clinic and GP setting)	Heroin dependent, and Methadone patients	76 LAAM (n=41) Methadone (n=35) 99 LAAM (n=49) Methadone (n=50)
Glasgow, Bell, Mattick, Bammer	Canberra	Single group observational study of naltrexone induced rapid detox under sedation (followed by naltrexone treatment)	Methadone patients	17
White, Ali, Moss	Adelaide	RCT of LAAM vs. methadone maintenance treatment	Methadone patients	66
Ritter, Lintzeris, Mattick, Bell, Hawken	Melbourne Sydney Brisbane Gold Coast	Pilot dosing study of outpatient detoxification (from methadone maintenance treatment) using buprenorphine	Methadone patients	55

Notes.

^a In some instances, the number of participants reported on by NEPOD may differ slightly from the total number recruited. This is due to either essential items of the NEPOD core data set not being available or additional recruitment by a trial once the NEPOD database was locked for analyses.

^b Unless specified otherwise, results in the slide presentation are based on the heroin dependent participants not in treatment at the time of entry into a trial (n=1,070), as shown in bold.

Fact Sheet No.2 : General description of the interventions evaluated

Detoxification procedure or treatment	Description
Rapid detoxification under anaesthesia	A detoxification program using an opioid antagonist (naloxone or naltrexone) to accelerate acute withdrawal from heroin (or methadone) under anaesthesia. Individuals are unconscious, intubated and ventilated. Symptomatic relief is provided to enable patients to tolerate the procedure. The procedure is used for direct induction onto naltrexone treatment.
Rapid detoxification under sedation	A detoxification program using an opioid antagonist (naloxone or naltrexone) to accelerate acute withdrawal from heroin (or methadone) under sedation. Symptomatic relief is provided to enable patients to tolerate the procedure. The procedure is used for direct induction onto naltrexone treatment.
Buprenorphine outpatient detoxification (from heroin)	A detoxification program using reducing doses of buprenorphine over a five-day period to manage ambulatory withdrawal from heroin.
Buprenorphine outpatient detoxification (from methadone maintenance treatment)	A detoxification program using reducing doses of buprenorphine for up to 16 weeks to manage ambulatory withdrawal from methadone maintenance treatment. Patients are transferred from methadone to buprenorphine, and doses reduced to omg following stabilisation.
Conventional outpatient detoxification	A detoxification program using clonidine and other symptomatic medications (e.g., diazepam, metoclopramide, buscopan) for up to eight days to manage ambulatory withdrawal from heroin.
Conventional inpatient detoxification	A detoxification program using clonidine and other symptomatic medications (e.g., diazepam, metoclopramide, buscopan) for up to eight days to manage inpatient withdrawal from heroin.
Naltrexone Treatment	A form of treatment using the opioid antagonist naltrexone for the prevention of relapse to opioid use in formerly dependent individuals who have already detoxified. One 50mg oral tablet is the usual daily dose.
Methadone Maintenance Treatment	A form of treatment using the opioid agonist methadone as a substitute for heroin and other illicit opioids. An individualised dose of methadone is taken orally on a daily basis.
Buprenorphine Maintenance Treatment	A form of treatment using the partial opioid agonist buprenorphine as a substitute for heroin and other illicit opioids, or an alternative to Methadone Maintenance Treatment. An individualised dose of buprenorphine is taken sublingually on a daily basis (or every second day at a higher dose following stabilisation).
LAAM Maintenance Treatment	A form of treatment using the opioid agonist LAAM as a substitute for heroin and other illicit opioids, or an alternative to Methadone Maintenance Treatment. An individualised dose of LAAM is taken orally every second or third day.

Notes.

For further details regarding the procedures and treatments evaluated by the individual trials refer to the published articles.

Fact Sheet No.3 : The NEPOD core data set

Pre-Treatment (Baseline) Assessment	Outcome Variables
<ol style="list-style-type: none"> 1. Age 2. Sex 3. Illicit drug use in the past 4 weeks OTI^a: number of heroin-free days 4. History of heroin use <i>Age at first use of heroin</i> <i>Age at first habit or regular use of heroin</i> 5. Opioid dependence (not collected for patients initially in methadone treatment) <i>DSM-IV opioid dependence criteria (total score)</i> 6. Methadone dose prior to start of trial (if applicable) 7. Previous D&A treatment history Number of treatment episodes previously started of: <i>Inpatient detoxification</i> <i>Outpatient/ambulatory detoxification</i> <i>Other inpatient or residential treatment/rehabilitation</i> <i>Outpatient counselling</i> <i>Self-help groups</i> <i>Prescribed methadone</i> <i>Total no. of months on prescribed methadone</i> 8. Quality of life <i>AQoL^b</i> <i>SF-36^c</i> 9. Education and employment <i>Highest level of formal education completed</i> <i>Employment status in past 4 weeks</i> 10. Criminal behaviour in past 4 weeks (OTI Crime scale) 11. Total time imprisoned 12. Social Functioning (OTI Social Functioning scale) 13. Depression/psychological functioning (SCL-90-R^d, BSI^e or BDI/BDI-II) 14. Utilisation of non-trial health care services in past 4 weeks 	<p>Short-term outcomes (assessed in the detoxification trials only):</p> <ol style="list-style-type: none"> 1. Whether patients (a) completed the basic intervention, (b) achieved initial 7 days of heroin abstinence, and (c) entered post-detoxification treatment 2. Change in illicit drug use in the past 4 weeks at one month follow-up (OTI Drug scale: number of heroin-free days, Q-scores for each drug class) <p>Primary long-term outcomes (at 3 and 6 month follow-up):</p> <ol style="list-style-type: none"> 3. Change in illicit opioid use in past 4 weeks (OTI Drug scale: number of heroin-free days, Q-score) 4. Retention in treatment (number of days up to 3/6 month follow-up) 5. Change in criminal behaviour in past 4 weeks (OTI Crime scale) <p>Secondary long-term outcome variables (at 3 and 6 month follow-up):</p> <ol style="list-style-type: none"> 6. Change in cost of illicit drug use in past 4 weeks (OTI Drug scale) 7. Change in employment status in past 4 weeks 8. Change in use of other illicit drug types in past 4 weeks (OTI Drug scale: Q-scores) 9. Change in quality of life 10. Abstinence from illicit opioids in past 4 weeks 11. Serious Adverse Events

Notes.

All trials conducted pre-treatment assessments. For the trials evaluating detoxification procedures, outcome data were generally collected at the end of a designated withdrawal period and at 1 month follow-up. Trials evaluating maintenance treatments collected outcome data at 3 and 6 month follow-up.

^aOTI = The Opiate Treatment Index

^bAQoL = Australian Quality of Life instrument

^cSF-36 = the Short Form Health Survey

^dSCL-90-R = the Symptom Checklist-90-R

^eBSI = the Brief Symptom Inventory

^fBDI/BDI-II = Beck Depression Inventory/Beck Depression Inventory-II (latest edition of BDI)

Fact Sheet No.4 : Characteristics of the heroin dependent participants (n=1,070)

Variable	Statistic	No. of participants statistic based upon ^a
Sex	66% male	
Mean Age (S.D; range)	30 years (8; 18 - 58)	
Mean Age first used heroin (S.D; range)	20 years (5; 8 - 49)	n=948
Mean Age first heroin habit (S.D; range)	23 years (5; 10 - 43)	n=544
<i>Drug use in the month preceding interview</i>		
	<i>Percent used</i>	
Heroin	100%	
Other opiates	24%	
Alcohol	48%	
Cannabis	62%	
Amphetamines	14%	
Cocaine	10%	
Benzodiazepines	50%	
Hallucinogens	5%	
Inhalants	1%	
Tobacco	94%	
<i>Employment status in the past month</i>		
Unemployed	54%	
Pensioner	9%	
Home duties, other	7%	
Student, part-time/casual work	16%	
Full-time work	13%	
<i>Highest level of education</i>		
Up to Year 10	42%	
Year 11-12	37%	
Tertiary (TAFE, CAE, University)	19%	
<i>Treatment History</i>		
Previously in treatment	82%	n=1054
ever started methadone maintenance	54%	n=1053
ever started inpatient detoxification	50%	n=1030
ever started outpatient counselling	37%	n=1036
ever started outpatient detoxification	36%	n=1040
ever started self-help	30%	n=914
ever started inpatient/residential treatment	19%	n=1039
<i>Psychological functioning^b</i>		
Depression severity (BDI/BDI-II)	12% 'normal' or asymptomatic; 20% mild – moderate; 43% moderate – severe; 26% extremely severe	n=198
Positive 'psychiatric case' (SCL-90-R/BSI)	67% (using Global Severity Index score) 79% (using any-two-dimensions criterion)	n=573

Notes.

^a In some instances, individual trials did not collect the entire NEPOD core data set. The number of cases upon which a statistic is based has been noted in these instances. ^b Several different self-report instruments were used to assess psychological functioning, including the Beck Depression Inventory (BDI, BDI-II), the Symptom Checklist-90-R (SCL-90-R) and, its shorter version, the Brief Symptom Inventory (BSI). The BDI and BDI-II assess the severity of depressive symptoms over the preceding one and two weeks respectively, and were used in two trials involving 198 heroin dependent participants. The SCL-90-R and BSI assess psychological distress and psychopathology over the preceding week, and were used in four trials involving 573 heroin dependent participants. There are nine primary symptom dimensions: somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism, with the Global Severity Index (GSI) based on an average of all nine dimensions. When the SCL-90 or BSI are used to screen for psychiatric disorders, an individual is considered a 'case' if they have a GSI score, or any two primary dimension scores, which are greater than or equal to a T score of 63 (based on normative samples of adult non-patients).