The RIOTT trial
(Randomised Injectable Opiate Treatment Trial)

Q: Untreatable or just difficult to treat?

Results – confidential conference-level preliminary communication of findings: impact on use of street-heroin

Professor John Strang, Dr Soraya Mayet & Dr Nicola Metrebian
(on behalf of RIOTT research, clinical and related colleagues)

Speakers and scope

- Heroin and injectable-prescribing in the UK (JS)
- Establishing and operating a supervised injecting maintenance clinic (Soraya Mayet)
- The RIOTT trial – design, client characteristics, and retention (Nicola Metrebian)
- The RIOTT trial – main results on reduced/stopped use of street heroin (John Strang)

Declaration - general

- * DH, NTA, Home Office, NACD, WHO, UNODC
- * Diamo, Reckitt-Benkiser, Schering-Plough, Genus-Britannia, GW, Napp, Titan, Catalent, Auralis
- * Phoenix House, Clouds House, Action on Addiction, Society for the Study of Addiction, Lifeline, KCA, …

RIOTT funding support & declarations

- Research Funding
  - Community Fund (Big Lottery) & Action on Addiction & Hedley Foundation
- Clinical Services Funding
  - National Treatment Agency, Department of Health, and Home Office
  - Local DATs & PCTs
- Medications:
  - Diamo, Switzerland; Cardinal, UK; Auralis, UK; also Genus, UK
- Other support
  - The Band Trust – DVD
- Clinical colleagues:
  - Marina House, Maudsley; Darlington; Brighton
- Service users/patients/study subjects:

RIOTT Team & Collaborators

- Investigators/trial coordination
  - Prof John Strang
  - Dr Nicholas Lintzeris
  - Dr Nicola Metrebian

- Local Investigators
  - Dr Deborah Zador / Dr James Bell
  - Dr Tom Carnwath/Dr Soraya Mayet
  - Dr Hugh Williams

- Research staff
  - Vikki Charles
  - Luciana Forzisi
  - Teodora Groshkova
  - Chris Hallam
  - Anthea Martin

- Clinical Trial Pharmacist
  - Glynis Ivin, Maudsley Hospital
  - Godwin Achunine, London clinic

Diamorphine suppliers
- DiaMo Narcotics GmbH, Switzerland
- Auralis, UK

- RIOTT clinical team leaders
  - Rob van der Waal, London
  - Anne McNutt, Darlington
  - Ian Wilson, Brighton

- Trial co-ordination
  - National Addiction Centre, Institute of Psychiatry, KCL

- Statistician
  - Laura Potts, Clinical Trials Unit, Institute of Psychiatry, KCL

- Health Economics
  - Dr Sarah Byford Institute of Psychiatry, KCL
  - Barbara Barrett, Institute of Psychiatry

Randomisation
- Clinical Trials Unit, IoP

- Pathology
  - Dr Andy Marsh & Richard Evers, Kings College Hospital

Sir Humphry Davy Rolleston,
(President of Royal College of Physicians, 1922-1936)

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(President of Royal College of Physicians, 1922-1936)

- The legitimacy and authority of the medical versus law enforcement perspective
- “maintenance” (not termed thus) with injectable morphine or diamorphine (heroin) legitimate medical practice
- Sets UK apart from post-1920s US policy

CHANGES IN THE UK IN THE 1970s

- initial optimism for therapeutic power; growing disillusionment over the years
- The growing status of oral methadone
- The withering of injectable heroin
- Intermediate years of injectable methadone

WHAT INJECTABLE PRODUCTS?

- **Two products:**

- **- heroin ampoules (dry amps) (less than 1%)**

- **methadone ampoules (wet amps) (c 10%, now maybe 1%)**

(historically also morphine by injection)

My starting observations

- The ‘Old British System’ of injectable maintenance and the new supervised treatment are extremely different.
- The evidence base for ‘Old British System’ is extremely weak scientifically (although not necessarily negative).
- The evidence base for ‘Swiss-style’ supervised injectable maintenance (as used in all recent RCTs) is increasingly strong.

Updated Drug Strategy 2002

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Tackling drugs

ISBN 1-84082-918-7

To complement the development of existing services, **heroin should be available on prescription to all those who have a clinical need for it.** The number of people receiving heroin will increase as overall numbers in treatment grow.

The administration of prescribed heroin for those with a clinical need will take place in safe, medically supervised areas with clean needles. Strict and verifiable measures will be in place to ensure there is no risk of seepage into the wider community.

UK Government Drug Strategy, 2002

HM Government

Drugs: protecting families and communities

The 2008 drug strategy

First Edition

"… rolling out the prescription of injectable heroin and methadone to clients who do not respond to other forms of treatment, subject to the findings, due in 2009, of pilots exploring the use of this type of treatment".

(H.M.Government Drug Strategy, 2008)

Unsupervised vs Supervised

- ***‘Old’ (unsupervised)***
- Long history
- But minimal research evidence base
- Internationally isolated
- Mainly for the stable

- ***‘New’ (supervised)***

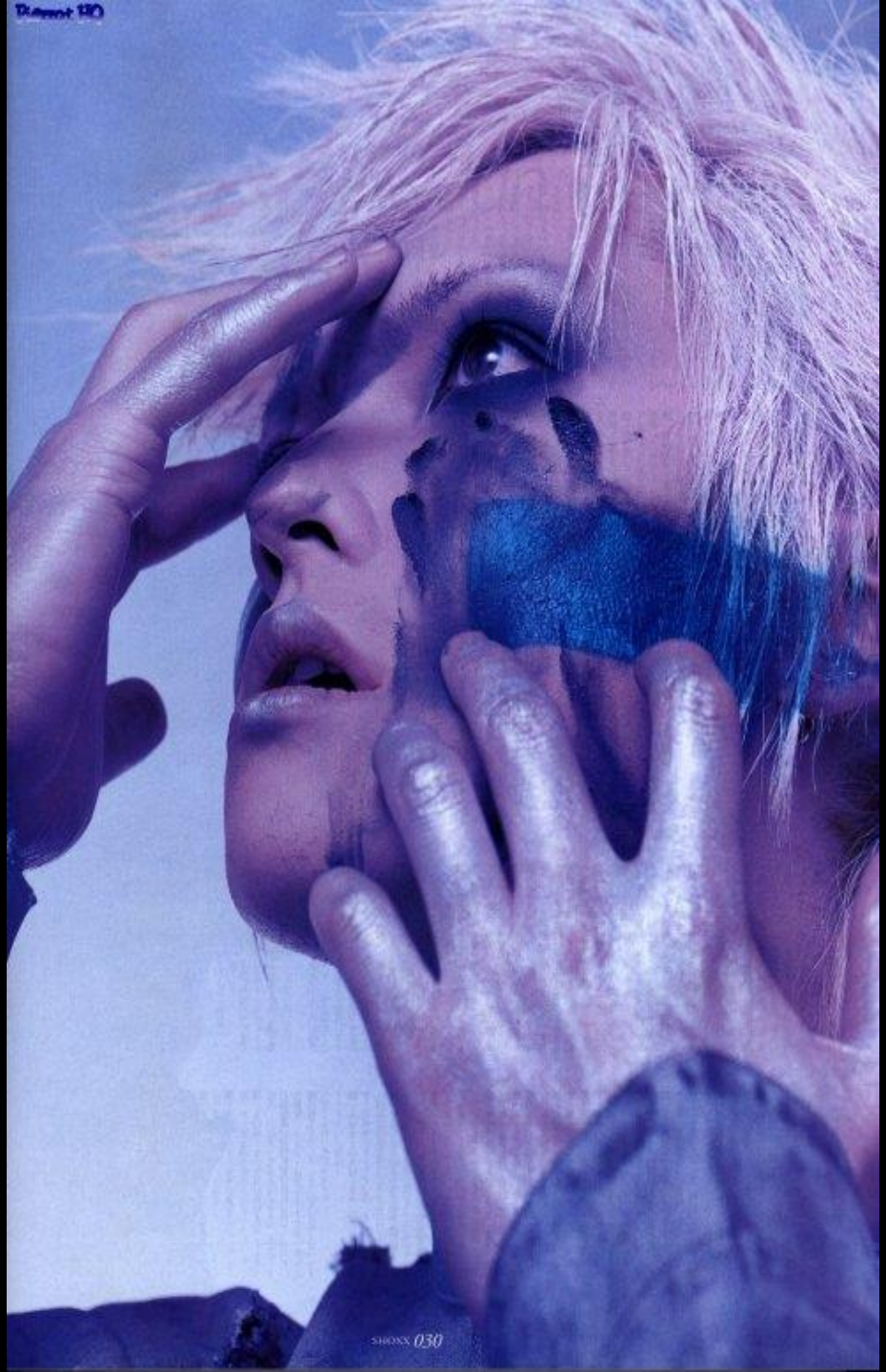
Supervised vs unsupervised

- ***'Old' (unsupervised)***
- Long history
- But minimal research evidence base
- Internationally isolated
- Mainly for the stable

- ***'New' (supervised)***
- Increasingly strong research evidence base
- In line internationally
- Public safety
- Accords with Drug Strategy 2002 & 2008
- For the repeatedly 'failing'

Accumulating body of evidence

- *((Hartnoll et al, 1980, Archives Gen Psych – UK))*
- **Perneger et al, 1998, BMJ – Switzerland**
- **Van den Brink et al, 2003, BMJ – Netherlands**
- *March et al, 2006, JSAT – Spain*
- **Haasen et al, 2007, B J Psych - Germany**
- **Oviedo-Joekes et al (NAOMI), 2009, NEJM - Canada**
- **RIOTT trial, in analyses, England**



To Soraya

Supervised injecting clinics

Characteristics of new clinics

- 7 days per week; under supervision
- no take-home injections / adequate daily doses
- oral take-home supplements
- flexible prescribing - oral take-home conversion on request
- Intensive key work (weekly) & medical (monthly) reviews
- Access to psychosocial services (+ psychology, groups)
- dedicated facility - specific function

Three supervised injecting clinics

London	Darlington	Brighton
☞inner-city area with high levels of deprivation ☞ Large NHS specialist service providing community-based treatment to +400 clients ☞ Opened October 2005 ☞ set within general SMS ☞Capacity 40 IOT	☞ residential area ☞ Large NHS specialist service providing community-based treatment to 320 clients ☞ Opened September 2006 ☞ set within general SMS ☞Capacity 30 IOT	☞ central residential ☞Large NHS specialist service providing community-based treatment to 800 clients ☞Opened September 2007 ☞Stand alone clinic ☞Capacity 30 IOT

Treatment Procedures: injectable heroin

- Diaphin 10gm multidose ampoules
- Auralis 100mg & 500mg ampoules

- Adequate doses of injectable heroin
- Supervision of all doses in 1 – 2 injections per day

- Clients can access oral methadone either on regular basis, or if unable to attend for injected heroin

- Intensive key work (weekly) & medical (monthly) reviews
- Access to psychosocial services (+ psychology, groups)

Treatment Procedures: Injectable Methadone

- 25 & 50mg IM or IV ampoules

- Adequate doses of injectable methadone
- Supervision of all doses – one injection per day

- Clients can access oral methadone either on regular basis, or if unable to attend clinic for injected methadone

- Intensive key work (weekly) & medical (monthly) reviews
- Access to psychosocial services (+ psychology, groups)


OVERDOSE
OVERDOSE

Treatment procedures: Optimised Oral Methadone

- Adequate doses (e.g. >80 mg methadone)
- Supervised dispensing 5 days a week for first 3 months

- Intensive key work (weekly) & medical (monthly) reviews
- Access to psychosocial services (+ psychology, groups)

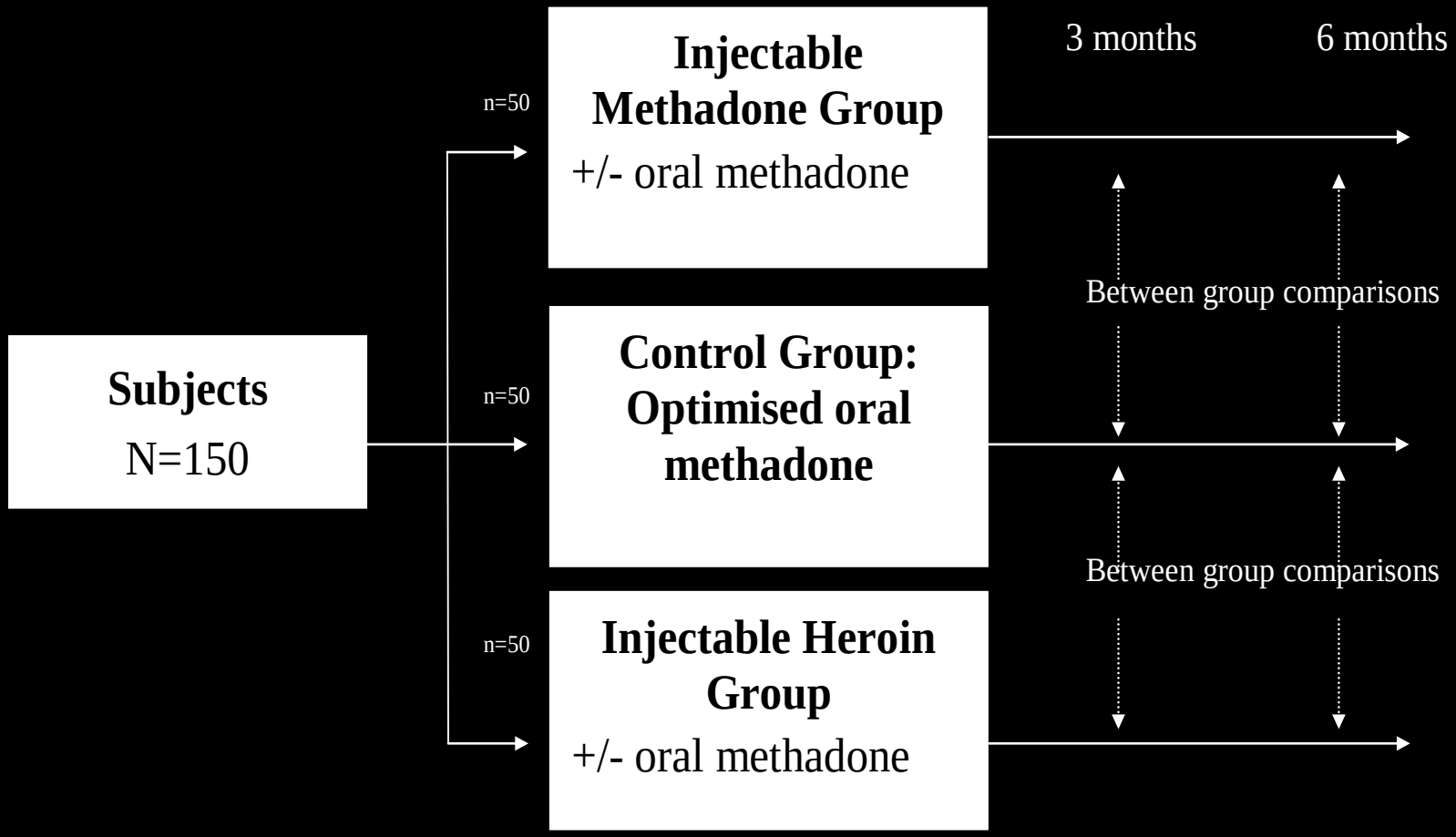
- Subsequent post-trial access to IOT requires 6 months ‘optimised’ treatment: NTA Guidance

What was the aim & design of the trial?

Research aim

Examine the safety, efficacy and
cost effectiveness of
supervised injectable methadone treatment
& supervised injectable heroin treatment
with
optimised oral methadone treatment

Trial Design



What were our measures of effective treatment?

Primary outcome measure

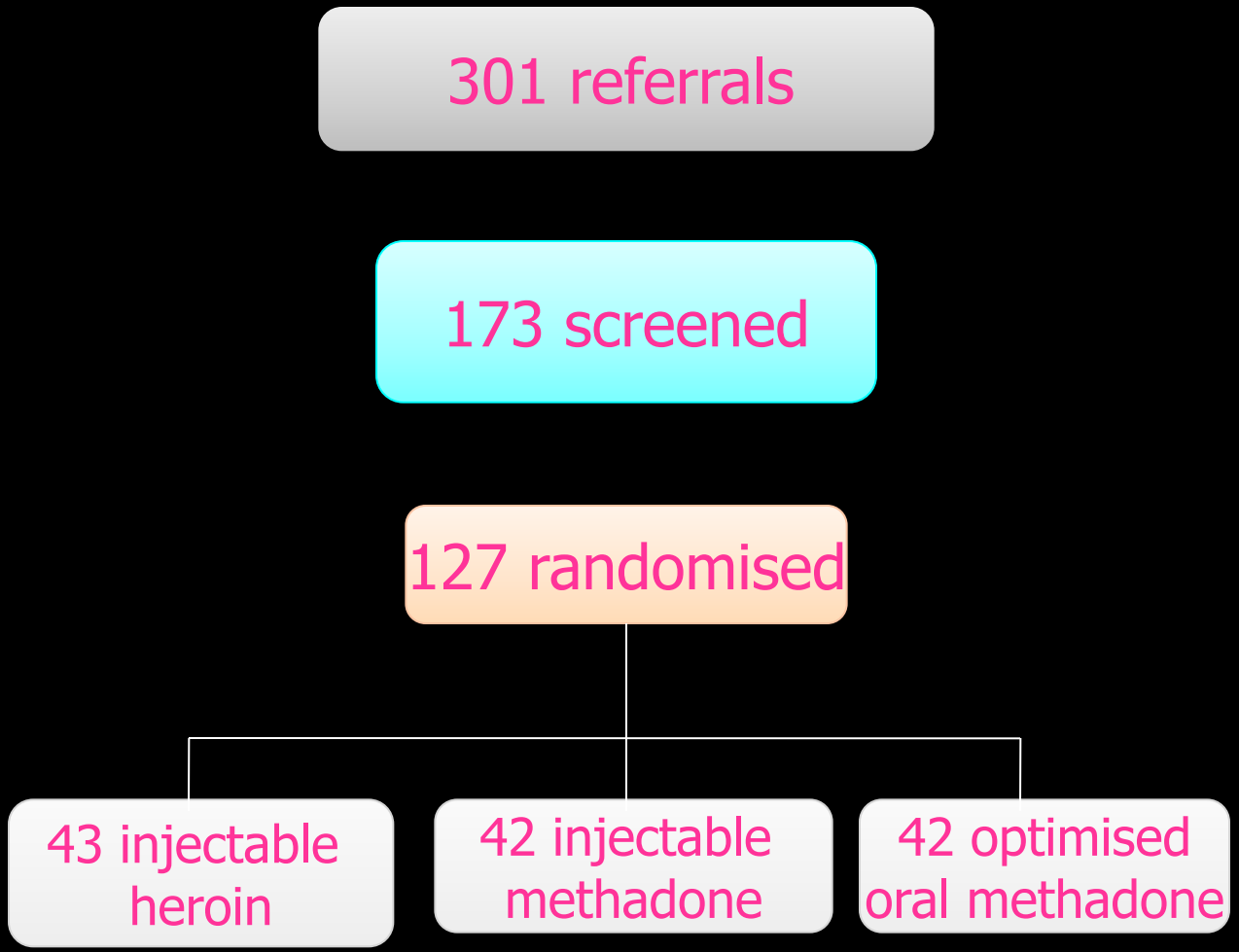
Primary outcome	Measures
Reduction in street heroin use	The proportion of subjects in each group who cease regular street heroin use

Outcome measures

Secondary outcomes	Measures
Other illicit drug use	UDS & self-report
Treatment retention	Clinic records (& self report)
Injecting practices	Frequency, risk & complications
Psychosocial functioning & Quality of Life Measures	SF-36, EQ-5D, OTI
Crime	Self-report (drug related expenditure & criminal activity)
Safety	Adverse events
Patient satisfaction	Semi-structured Q's
Cost effectiveness	Service costs (internal & external)

How many patients did we recruit to RIOTT?

Overall recruitment



Who were the patients in RIOTT?

Who were the patients in RIOTT

Entrenched heroin addicts who have repeatedly been found to fail to benefit from existing treatments

(despite treatment, continuing to inject heroin on all/most days per month)

Patient characteristics at baseline (ITT)

	Oral Methadone n=42	Injectable Methadone n=42	Injectable Heroin n=43	Total n=127
Stratification variables				
Regular cocaine/crack use (>50% in the previous 4 weeks) (Yes percentage)	43%	43%	42%	43%
Already on optimised oral methadone (dose >= 80mg and supervised >= 5/7)	38%	38%	42%	39%

What were the characteristics of a "typical" RIOTT patient ?

Demographics

Male

White

37 years at randomisation

Unemployed

Receiving state benefits

Living alone in rented LA/HA housing

Drug & treatment history

Drug history:

- Started using opiates age 20 years
- Started injecting drugs age 23 years
- Using opiates for 16 years
- Injecting drugs for 13 years

Previous treatment experience:

- First received treatment age 20 years
- Had 4 previous opiate treatments

Previous prison experience:

- Had 6 periods of imprisonment
- (72 % previously been in prison)

Drug use at randomisation

Drug use

Injecting on almost every day

spending £28 a day on street heroin

(100% using heroin)

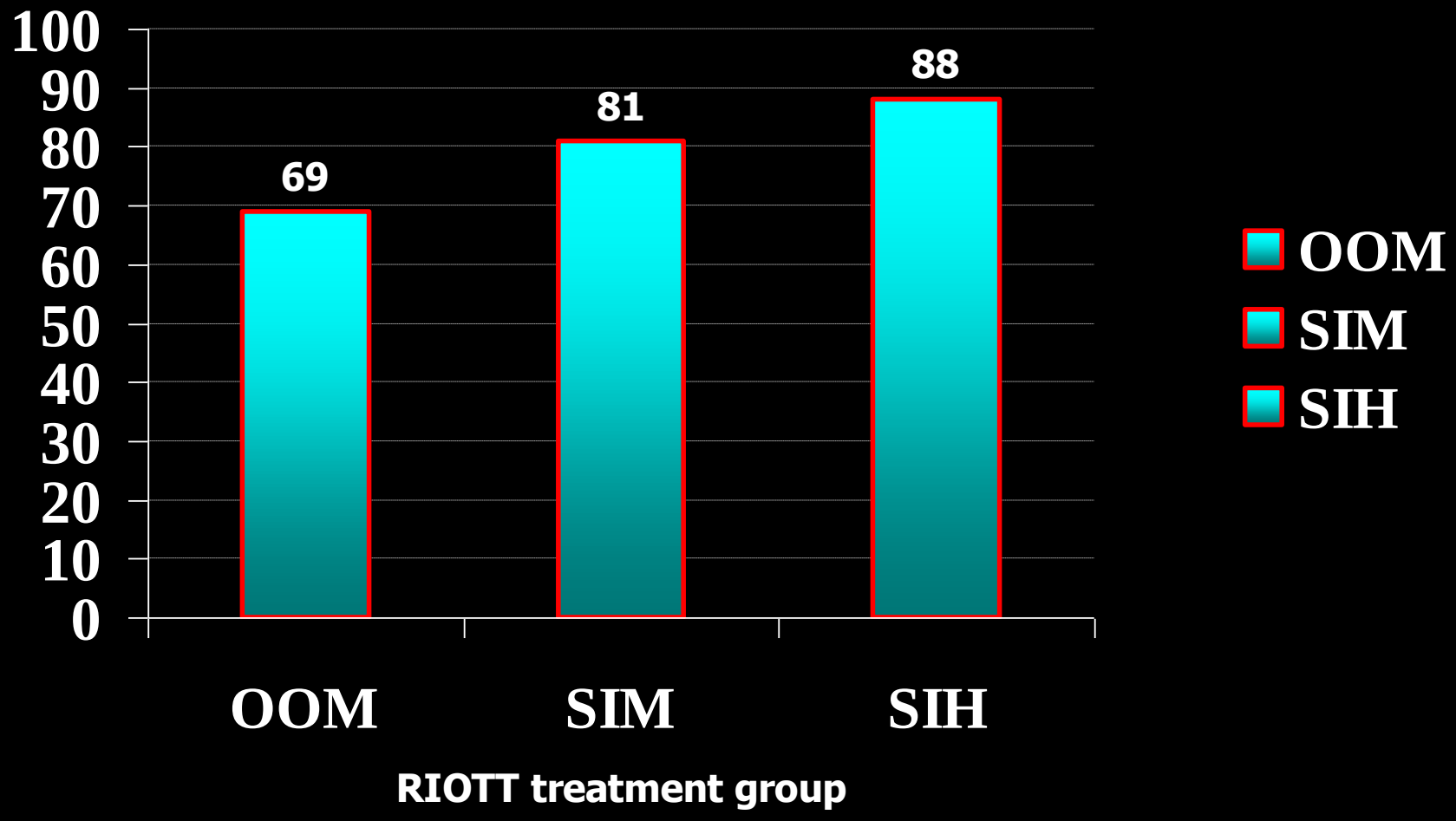
Using crack 13 out of 30 days

Spending £30 a day on crack

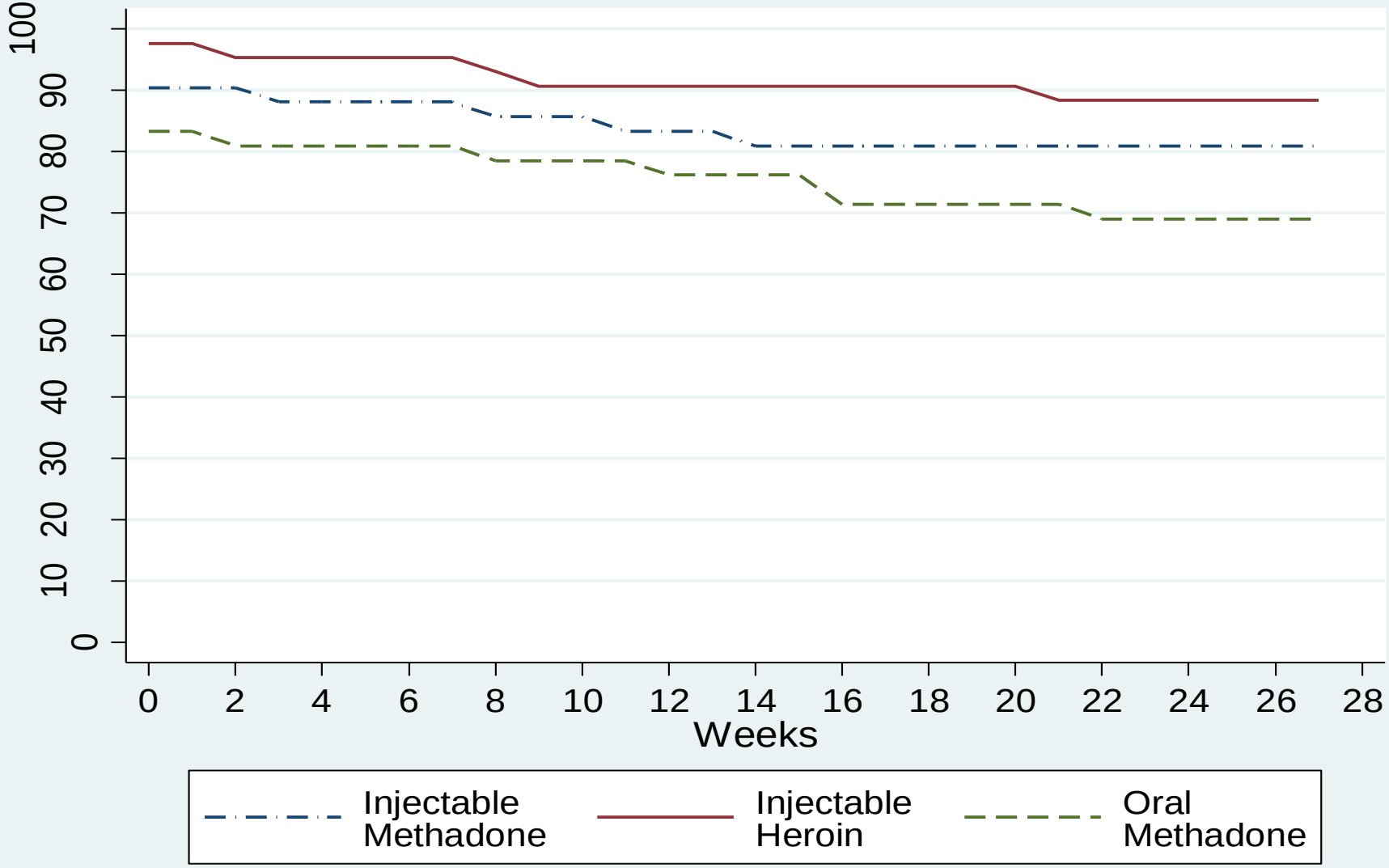
(Over three quarters using crack)

How many patients were retained in treatment?

RIOTT- retention in treatment



Retention


100
90
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50
40
30
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10
0
0
2
4
6
8
10
12
14
16
18
20
22
24
26
28
Weeks
Injectable Methadone
Injectable Heroin
Oral Methadone

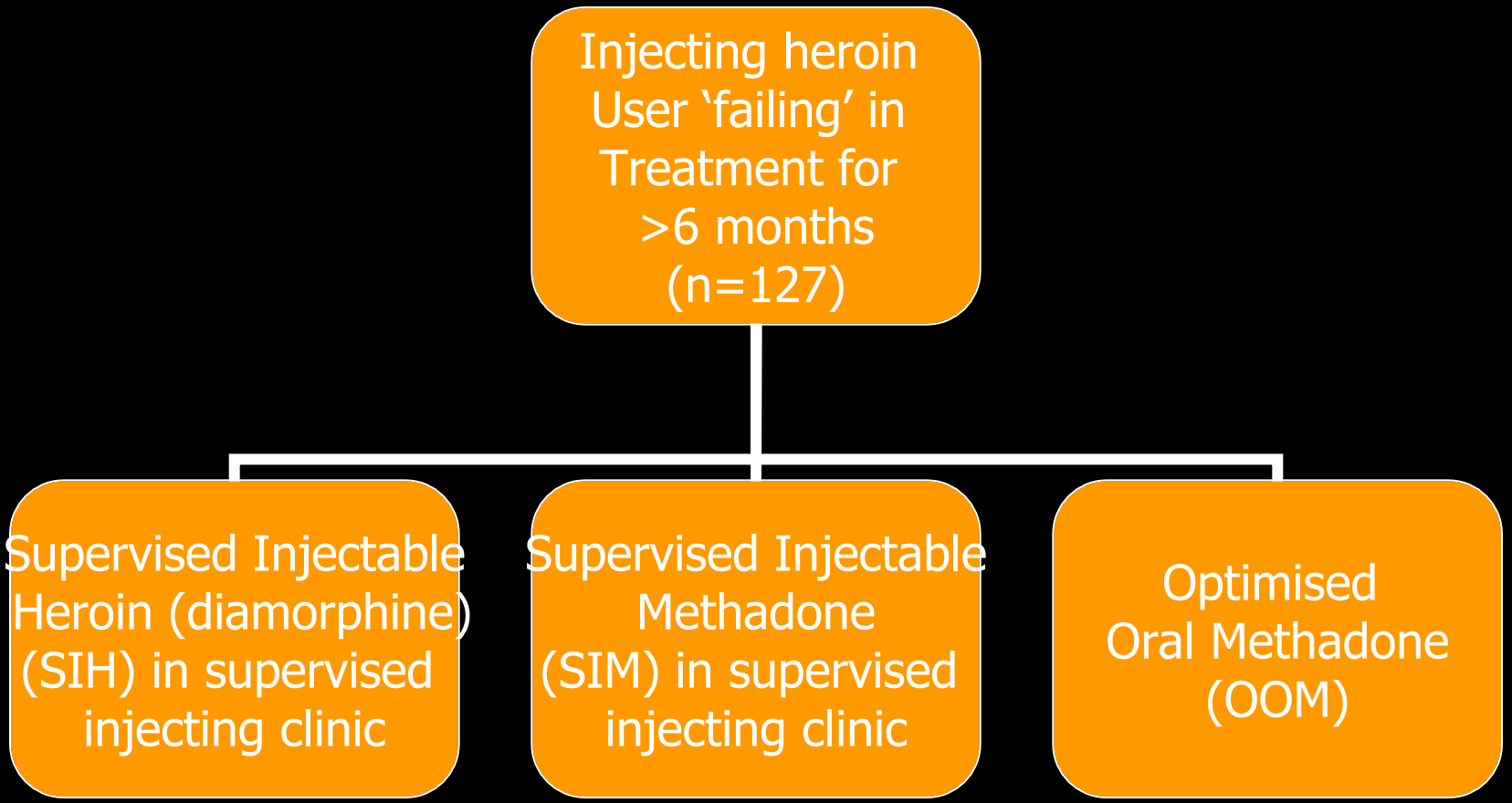
Reason for discontinuing treatment

	Optimsed Oral methadon (n=42)	Injectable Methadon (n=42)	Injectable Heroin (n=43)	Total (n=127)
Never started RIOTTT treatment	8 (19%)	4 (10%)	1 (2%)	13 (10%)
Prison sentence	0	2 (5%)	2 (5%)	4 (3%)
Voluntary discharge	1 (2%)	1 (2%)	1 (2%)	3 (2%)
Homeless and moved location	0	1 (2%)	0	1 (1%)
Medical discharge	1 (2%)	0	1 (2%)	2 (2%)
Disciplinary discharge	1 (2%)	0	0	1 (1%)
Did not attend for 4 weeks after starting treatment	1 (2%)	0	0	1 (2%)
Total	12 (30%)	8 (19%)	5 (12%)	25 (20%)

What were the benefits?

☞ To John

RIOTT research trial design



1: Harm Reduct J. 2006 Sep 27;3:28.

Methodology for the Randomised Injecting Opioid Treatment Trial (RIOTT): evaluating heroin treatment versus optimised oral methadone treatment in the UK.

Lintzeris N, Strang J, Metrebian N, Byford S, Hallam C, Lee S, Zador D; RIOT

Institute of Psychiatry, King's College London, 16 De Crespigny Park, London, SE5 8AF, UK. n.lin

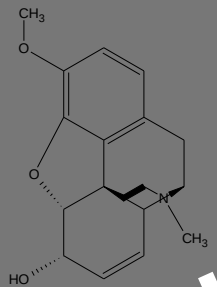
ABSTRACT: Whilst unsupervised injectable methadone and diamorphine treatment h
treatment system for decades, the numbers receiving injectable opioid treatment (
recent years. In contrast, there has been a recent expansion of supervised injecta
conditions in a number of European and North American cities, although the eviden
cost effectiveness of this treatment approach remains equivocal. Recent British cli
should be a second-line treatment for those patients in high-quality oral methadon
regularly inject heroin, and that treatment be initiated in newly-developed supervis
Injectable Opioid Treatment Trial (RIOTT) is a multisite, prospective open-label ran
examining the role of treatment with injected opioids (methadone and heroin) for th
dependence in patients not responding to conventional substitution treatment. Spe
whether efforts should be made to optimise methadone treatment for such patient
supervised dosing, high oral doses, access to psychosocial services), or whether s

Metabolism of "illicit" Heroin

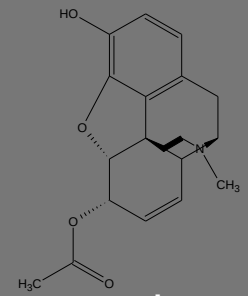
Diamorphine

Noscapine

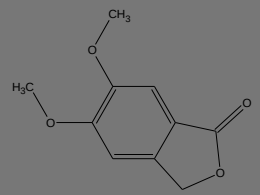
Papaverine



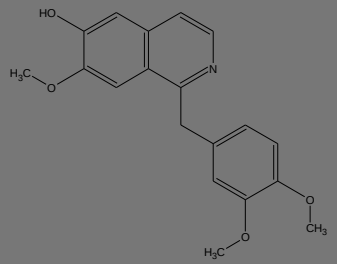
Codeine



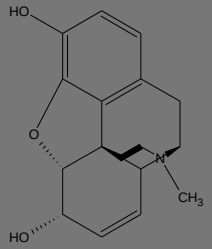
6-Monoacyl morphine



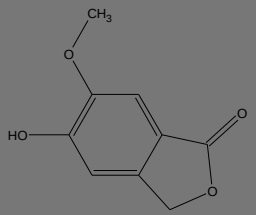
Meconine



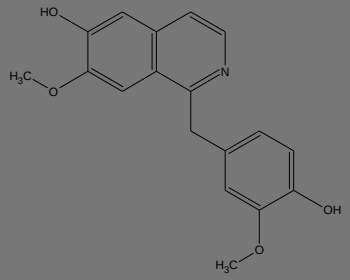
6-Hydroxypapaverine



Morphine



6- Desmethylmeconine



4,6-Dihydroxypapaverine

METHODS AND TECHNIQUES

Validation of techniques to detect illicit heroin use in patients prescribed pharmaceutical heroin for the management of opioid dependence

S. Paterson[1], N. Lintzeris[2,3], T. B. Mitchell[2], R. Cordero[1], L. Nestor[2] & J. Strang[2]

Toxicology Unit, Imperial College London, UK[1] and National Addiction Centre, Institute of Psychiatry, Kings College London, South London and Maudsley Trust, UK[2] and National Drug and Alcohol Research Centre, University of New South Wales, Australia[3]

Correspondence to:
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ABSTRACT

Background The clinical implementation and evaluation of heroin substitution programmes have been confounded by the lack of objective and validated biomarkers for illicit heroin use in patients prescribed pharmaceutical heroin. This study examined the capacity to detect illicit heroin use by gas chromatog-

Target population

Entrenched heroin addicts who have repeatedly been found to fail to benefit from existing treatments

(despite treatment, continuing to inject heroin on all/most days per month)

Treatments to be investigated

Supervised Injectable Heroin (SIH)

Supervised Injectable Methadone (SIM)

Optimised Oral Methadone (OOM)

Quality of evidence

I. Evidence obtained from at least one properly designed randomised controlled trial.

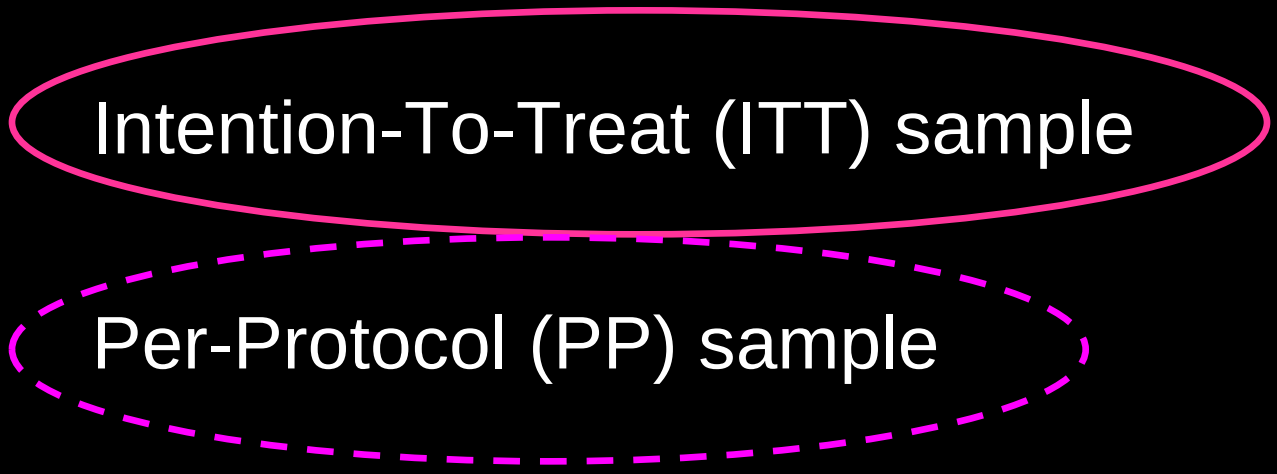
II. - 1 … well-designed controlled trials (not RCT).

II. - 2 … cohort or case-controlled analytical studies (pref. >1 centre/group).

II. - 3 … multiple time series with/without intervention.

III. Opinions of respected authorities, based on clinical experience/descriptive studies, or reports of expert committees.

Sample to be analysed



Primary outcome

Retention in treatment X

Reducing/quitting ‘street heroin’

Other drug use; well-being;

Criminal behaviour ?

Wider recovery

‘responder’ or ‘abstinent’?

Major reduction in frequency of use of ‘street heroin’

Completely abstinent from ‘street heroin’

Which measure of primary outcome?

Urine test results

Observations and measurements

Self-report

Types of urinalysis datasets

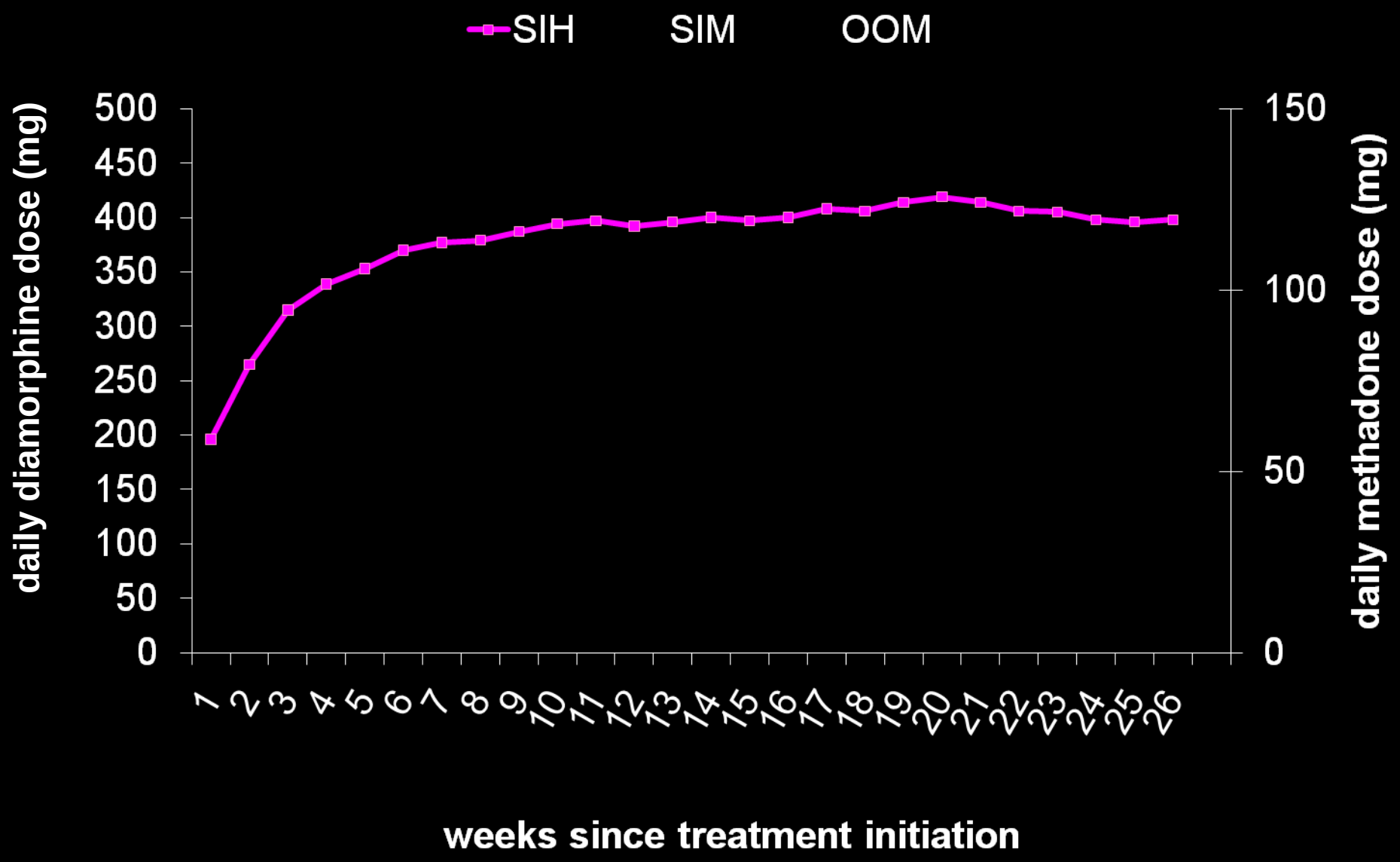
‘raw’ data (actual clinical results)

Data incl. imputations (enables analysis)

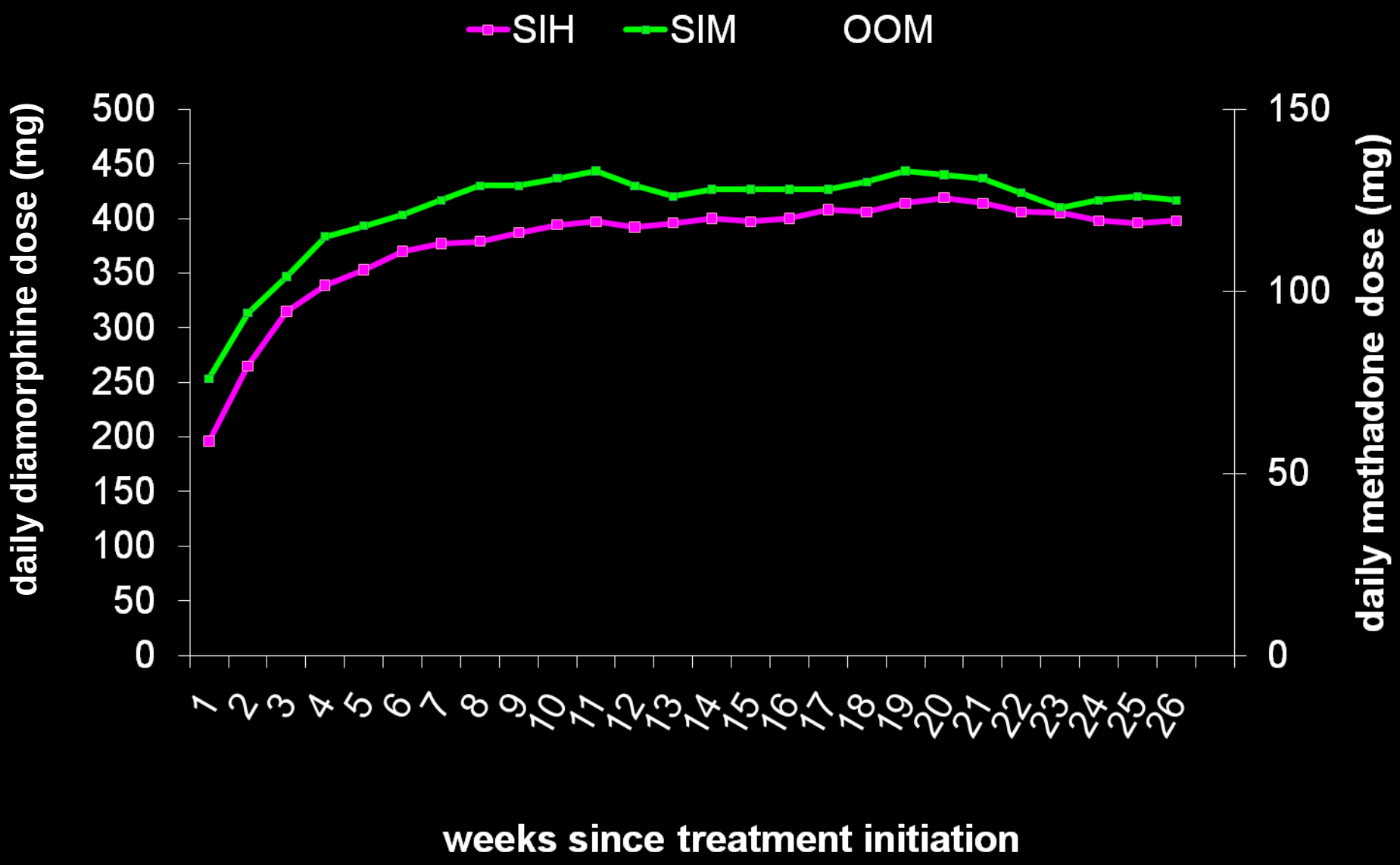
Data incl. imputations adjusted for stratification (ensures no inadvertent bias)

What doses are prescribed and how quickly is the new treatment established?

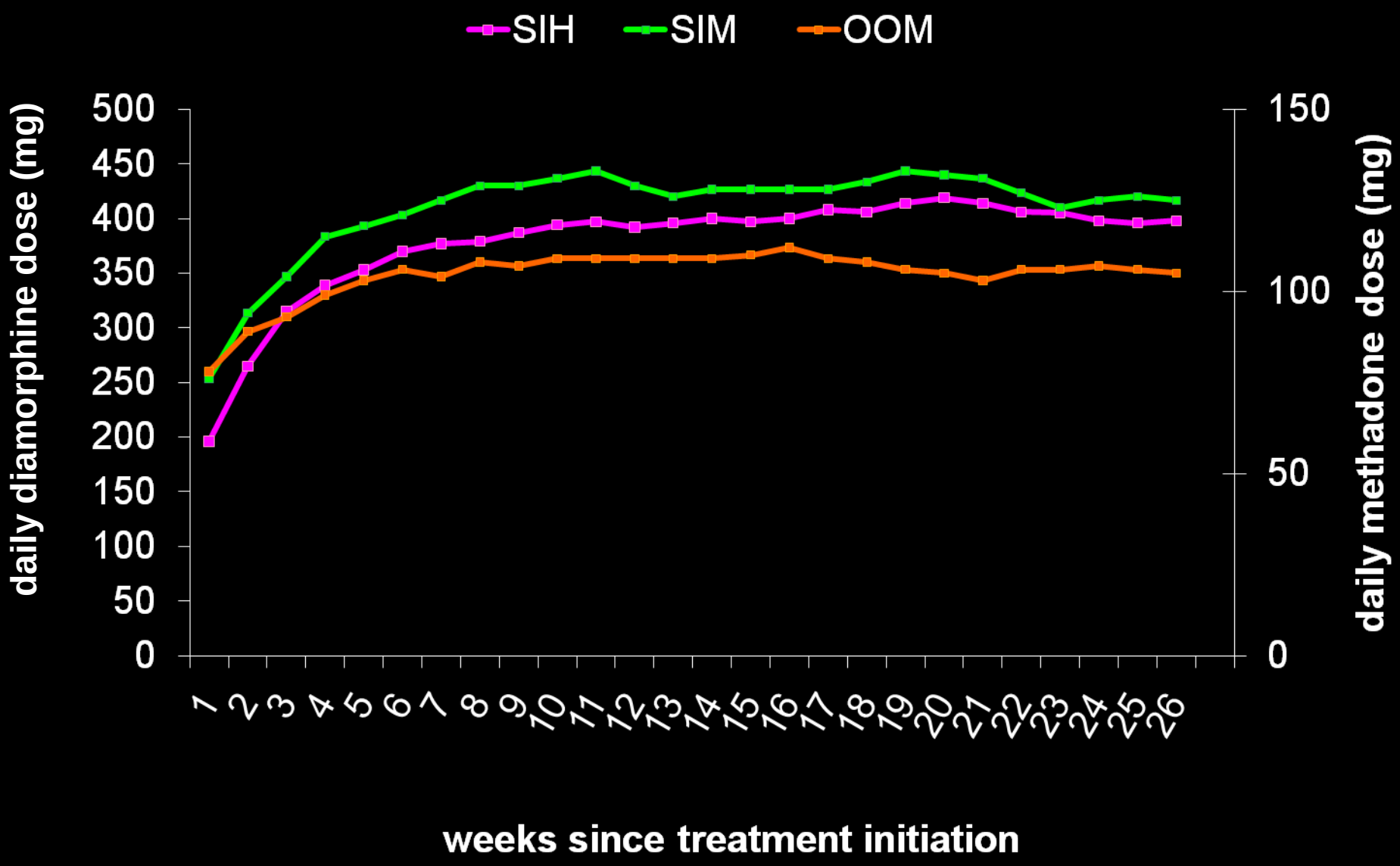
RIOTT- doses for the three groups (OOM, SIM, SIH)



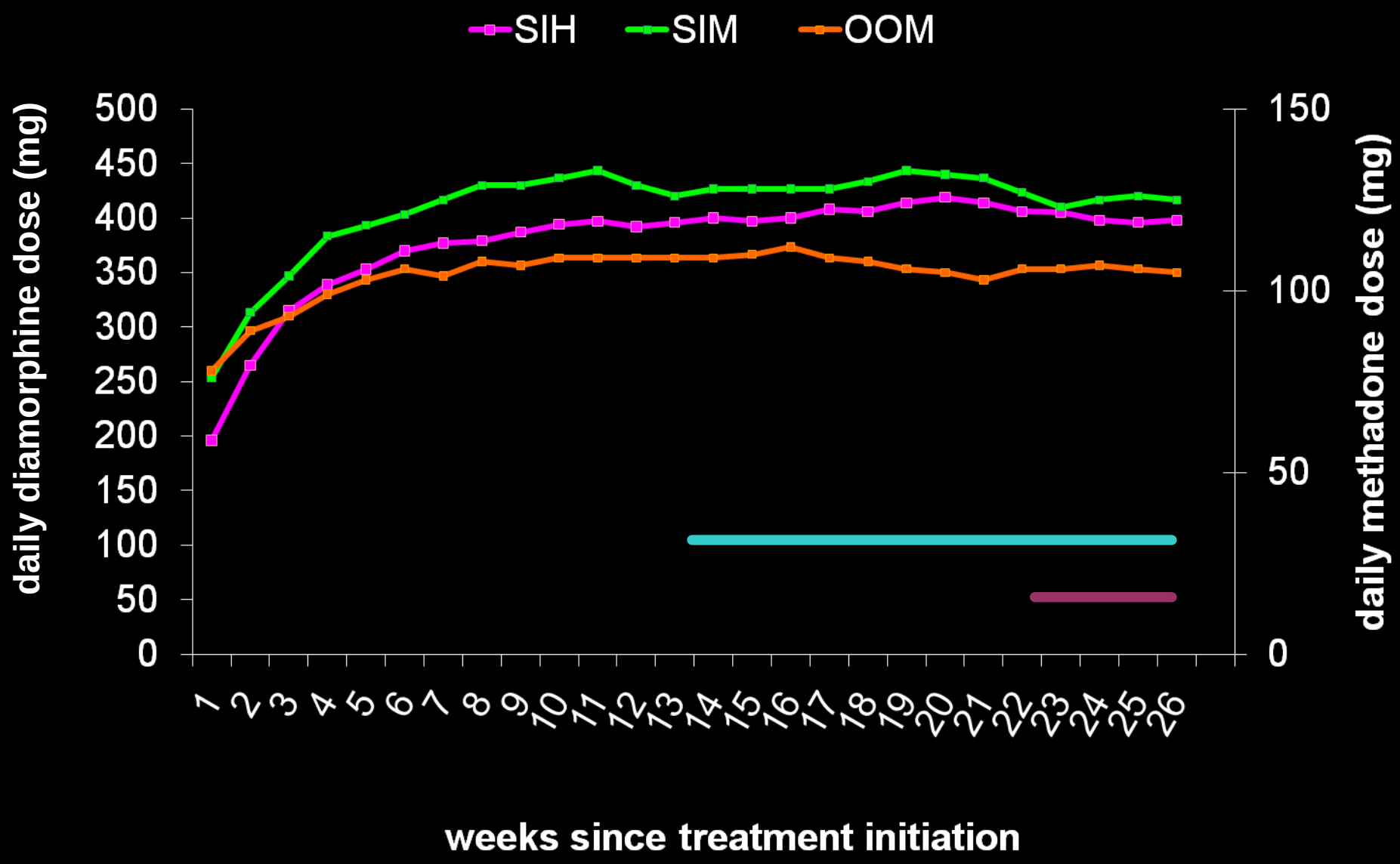
RIOTT- doses for the three groups (OOM, SIM, SIH)



RIOTT- doses for the three groups (OOM, SIM, SIH)



RIOTT- doses for the three groups (OOM, SIM, SIH)



To begin at the end

Four important conclusions, as I see them

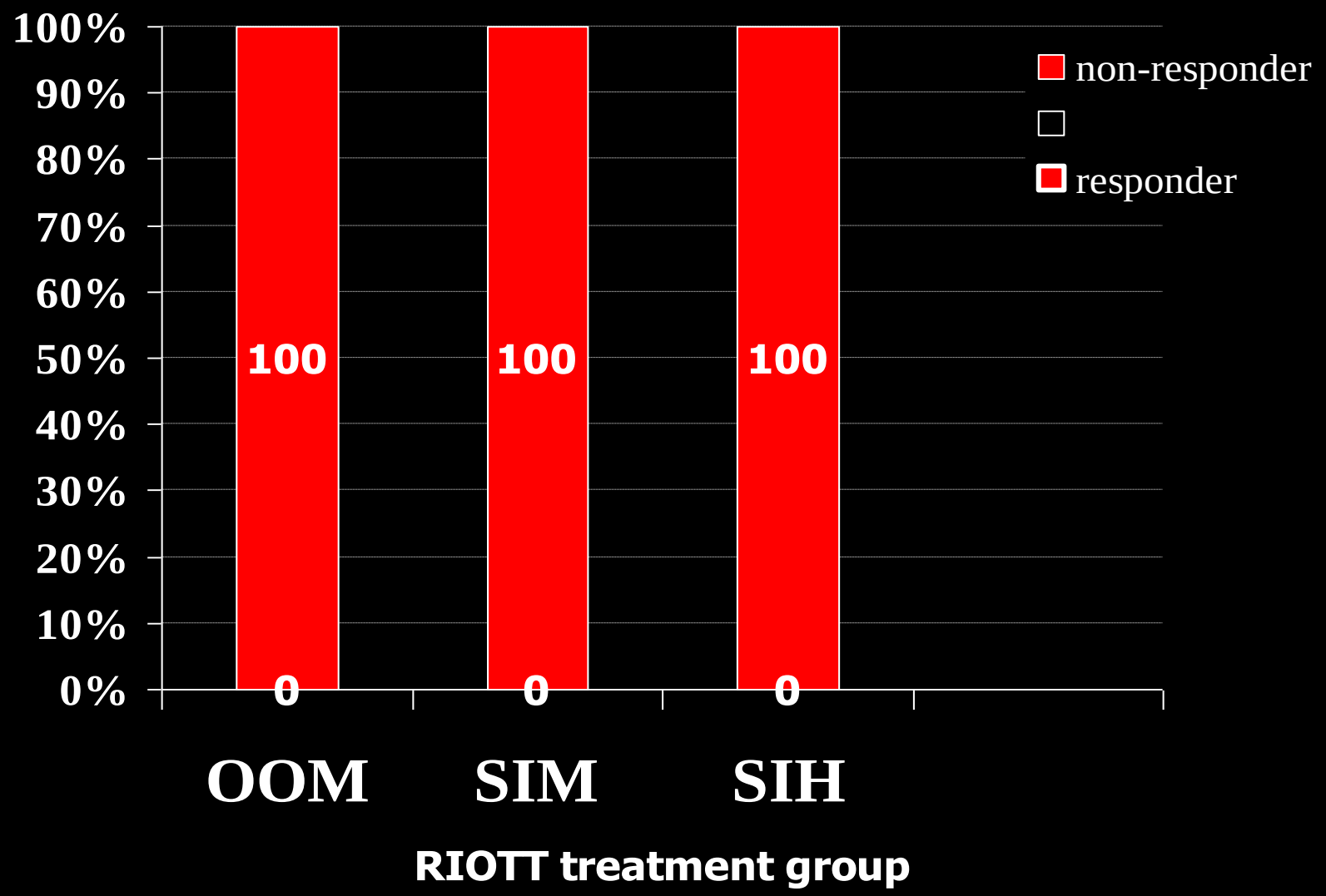
- **SIH (heroin) group strongest achievement**
- **SIM (inj methadone) better than control group**
- **OOM (optimised oral) – notable benefit**
- **Rapid onset of benefit and gain**

So what are the main findings on

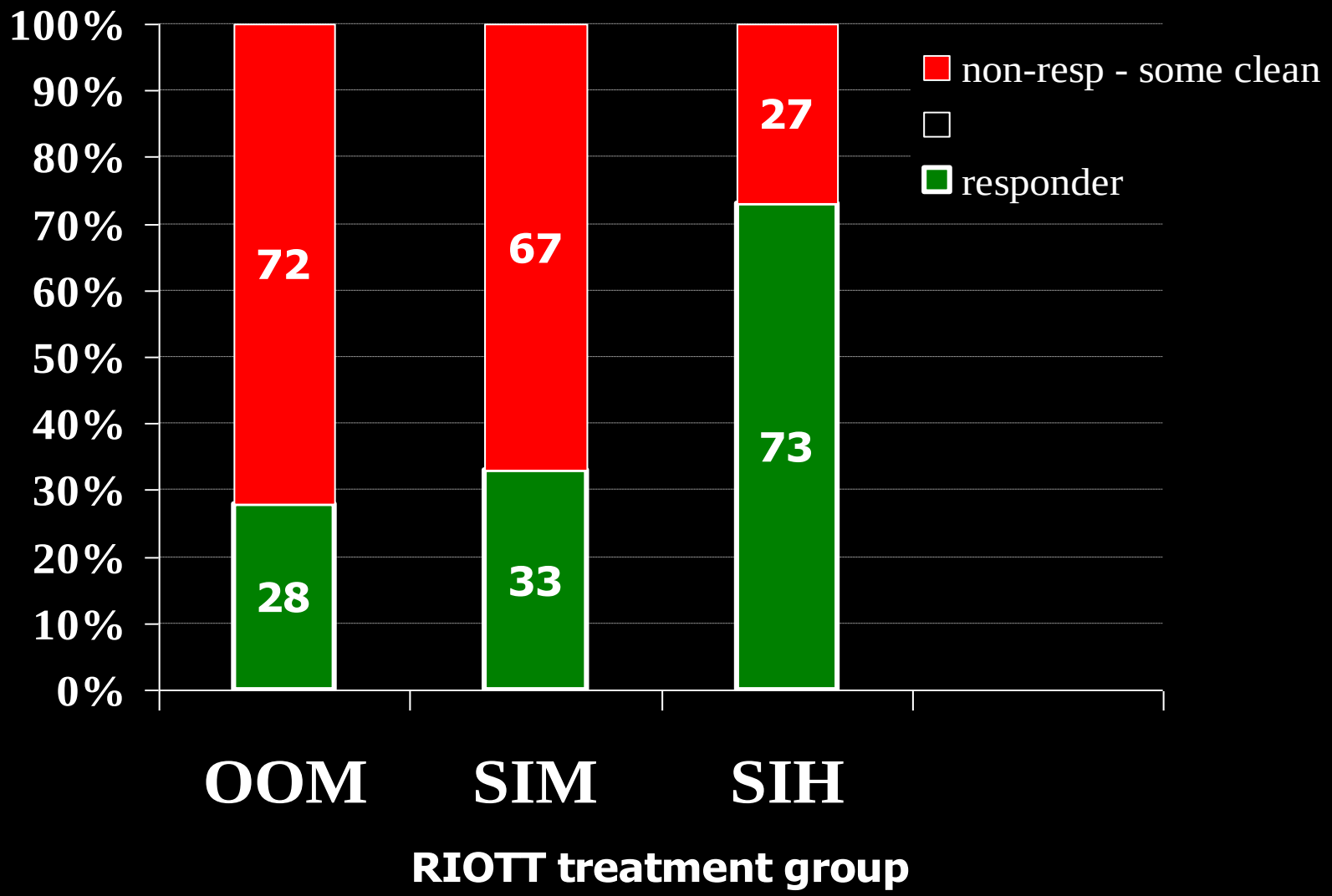
(i) ‘responder’ (reduced use of street-heroin)?

(ii) ‘abstinent from street-heroin’?

RIOTT - data on ‘responders’ and ‘non-responders’ – broken down as % - at baseline (OOM, SIM, SIH)



RIOTT - data on ‘responders’ and ‘non-responders’ – broken down as % - at Months 4-6 (OOM, SIM, SIH)



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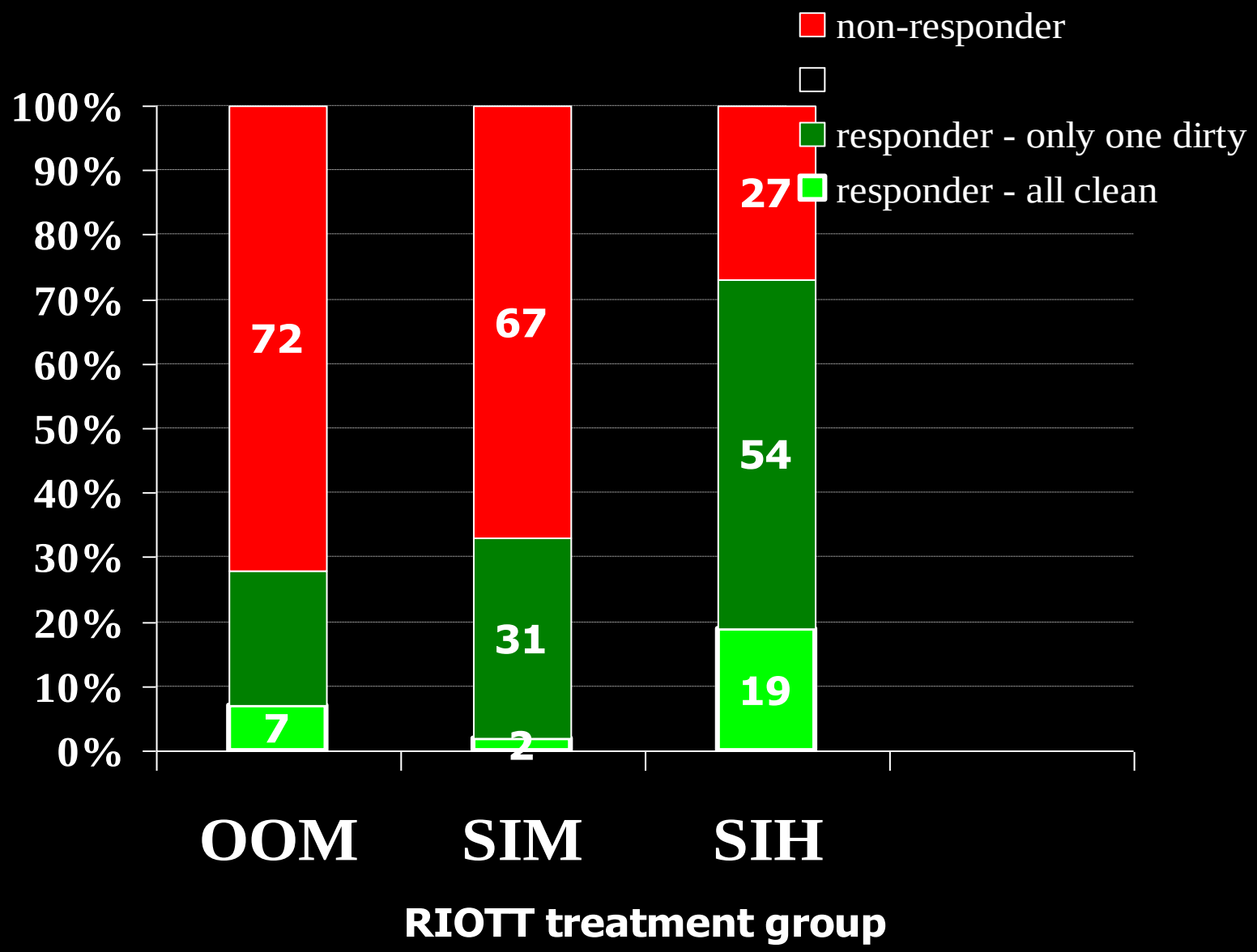

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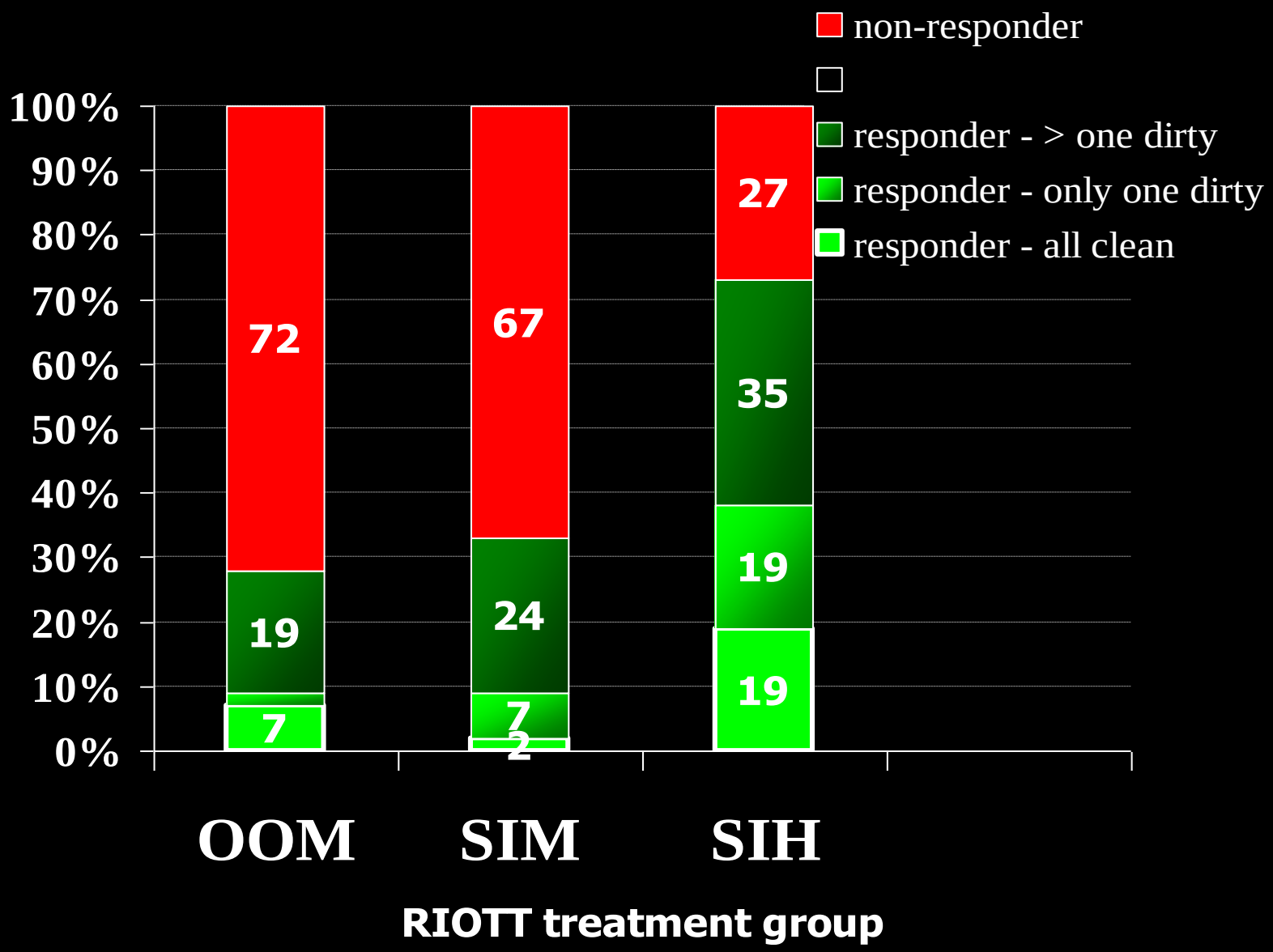
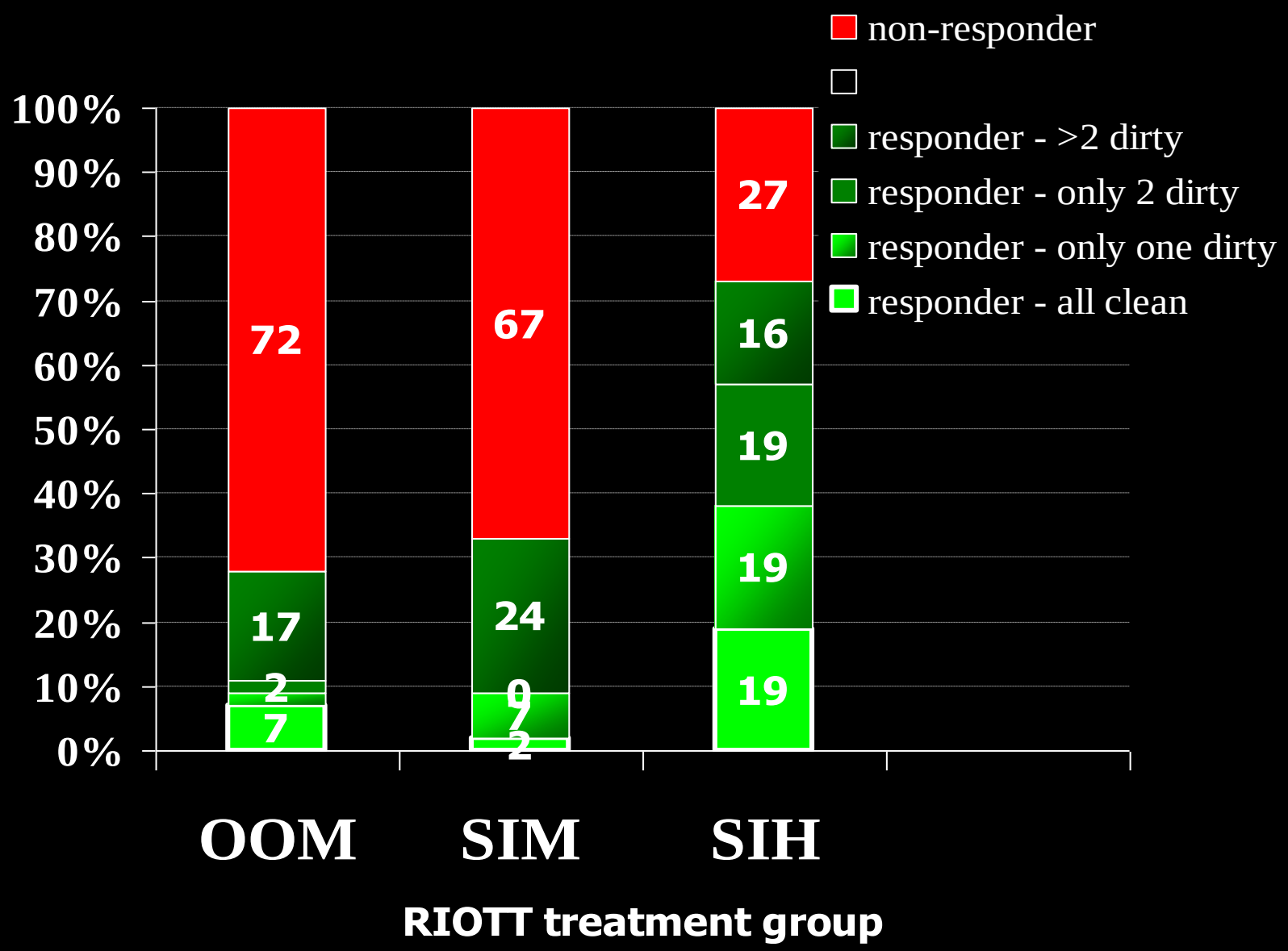


RIOTT - data on ‘responders’ and ‘non-responders’ – broken down as % - at Months 4-6 (OOM, SIM, SIH)



So how substantial a benefit are we talking about?

Odds ratios for >50% 'heroin-abstinent' urines at 6/12 (ITT)

Factors	Category	Odds ratio	95% CI	p-value
Treatment	SIH vs OOM	8.2	(2.9, 23.2)	<0.001
	SIM vs OOM	1.8	(0.7, 4.8)	0.25
	SIH vs SIM	4.6	(1.7, 12.2)	0.002

Odds ratios for completely 'heroin-abstinent' urines at 6/12 (ITT)

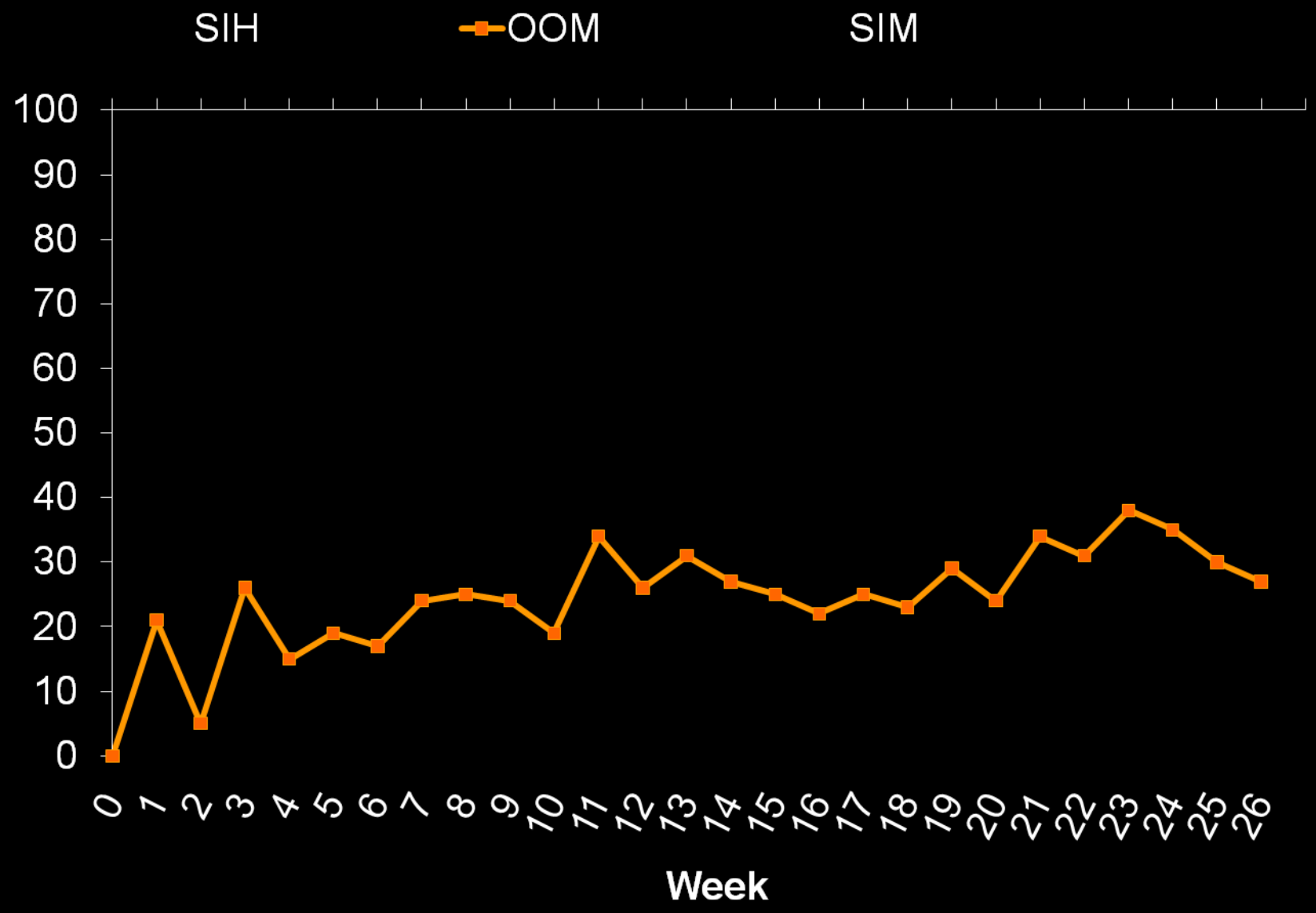
Factors	Category	Odds ratio	95% CI	p-value
Treatment	**SIH vs OOM**	6.11	(1.93,20.44)	0.003
	SIM vs OOM	2.31	(0.62, 8.54)	0.210
	SIH vs SIM	2.65	(0.95, 7.38)	0.063

The NNT calculation: (Number-Needed-to-Treat)

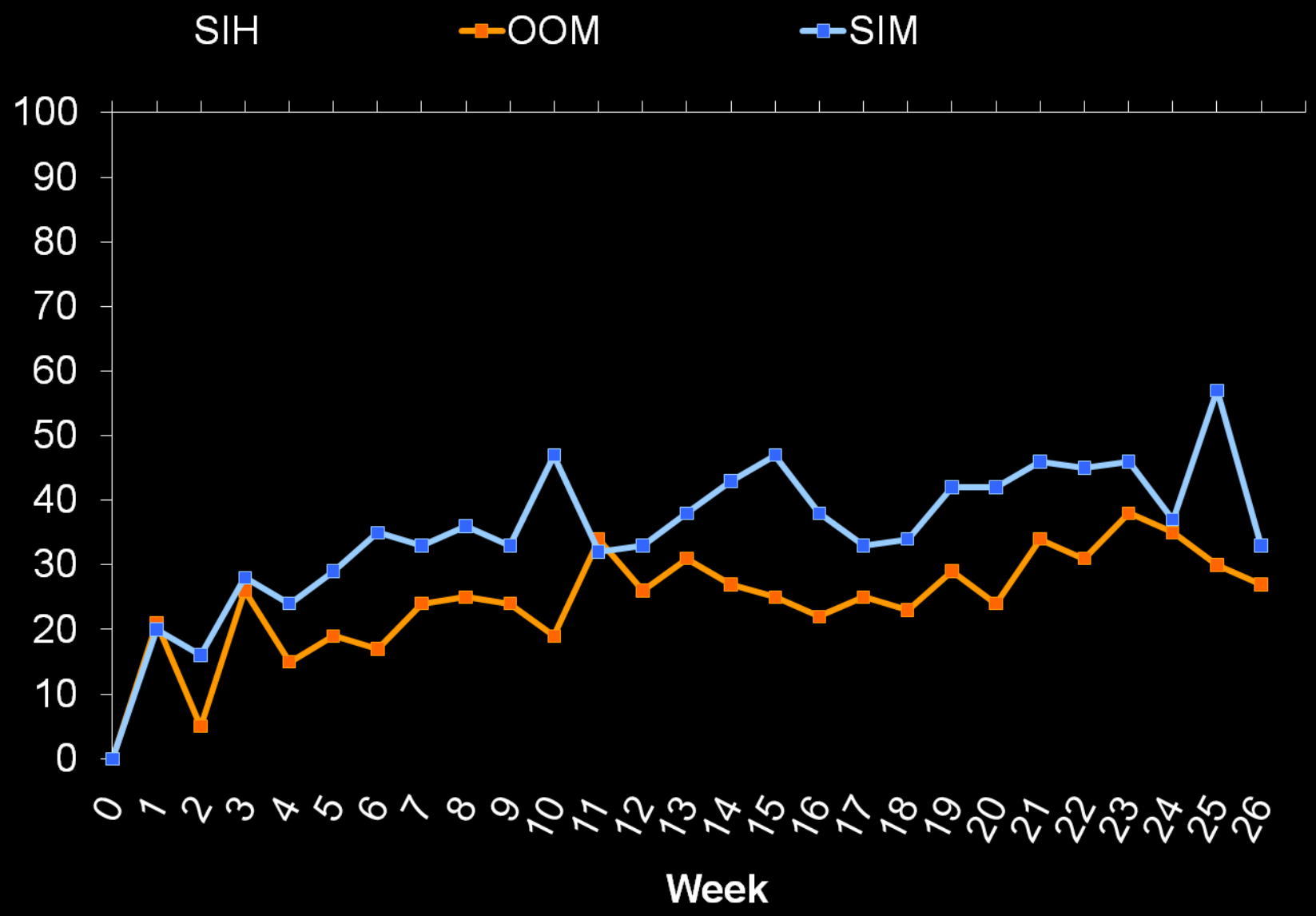
NNT	**SIH vs OOM**	2.1
	SIM vs OOM	9.1
	SIH vs SIM	2.8

How quickly does this marked advantage show itself?

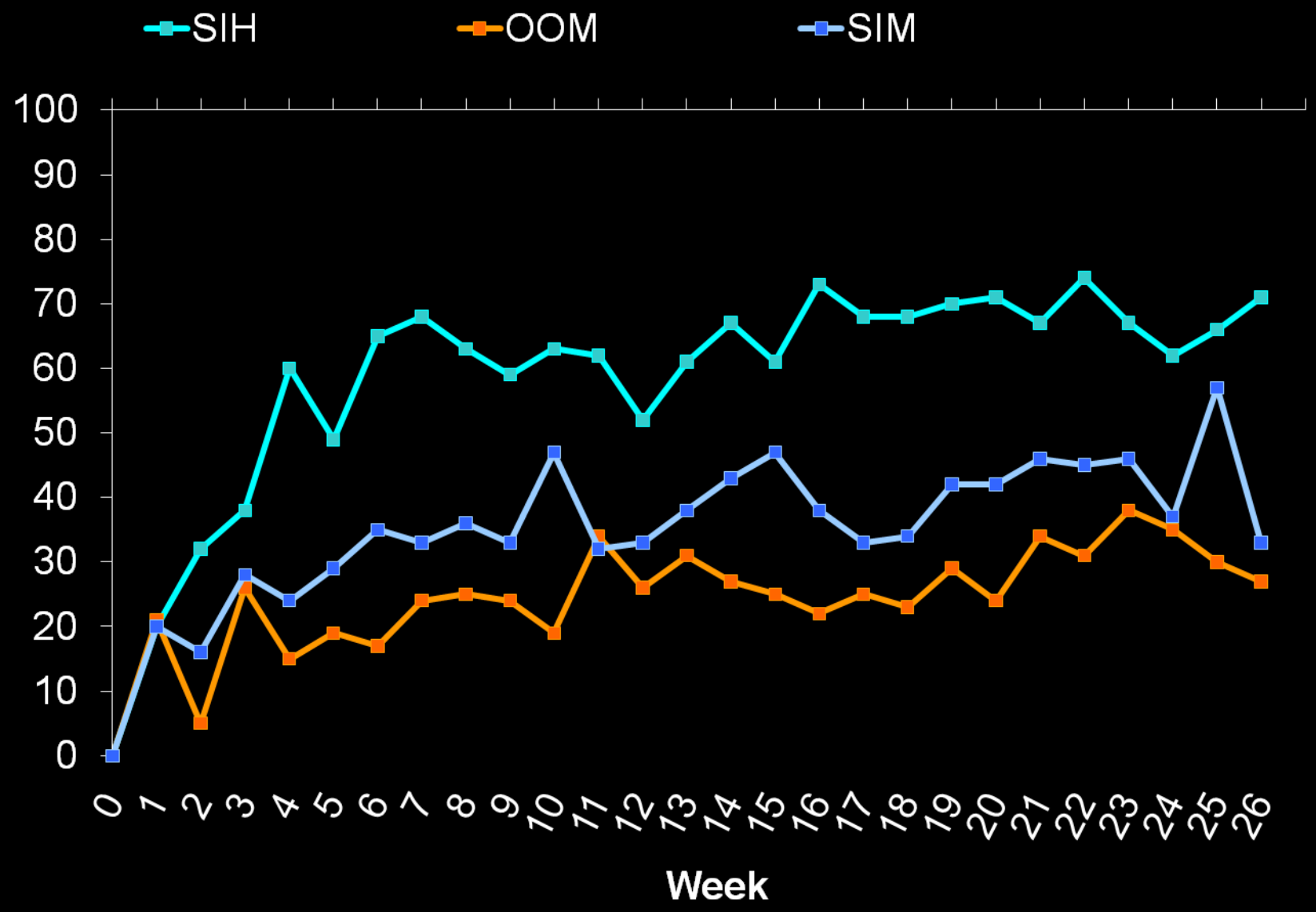
Percentage of participants not using illicit heroin by week (ITT sample)



Percentage of participants not using illicit heroin by week (ITT sample)

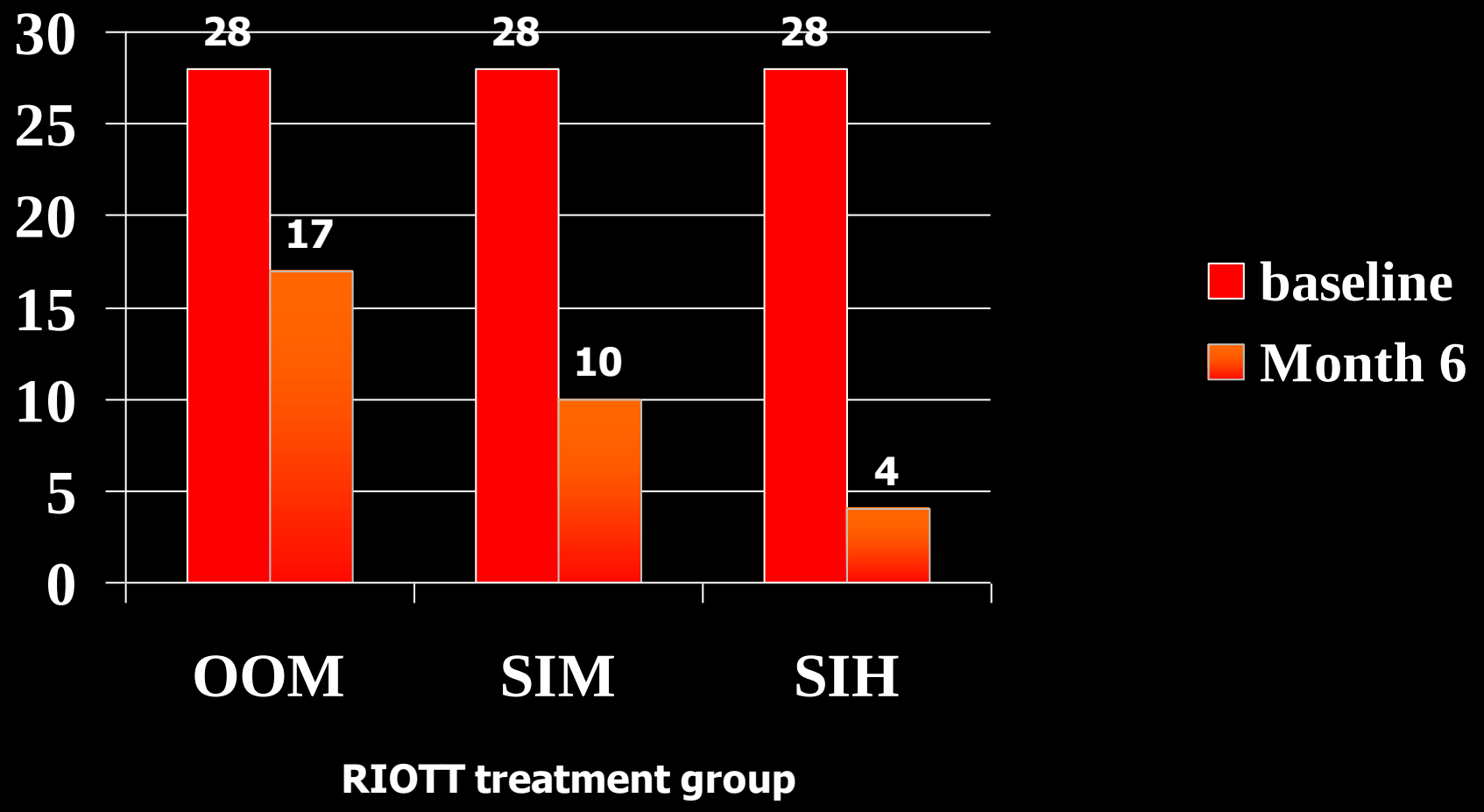


Percentage of participants not using illicit heroin by week (ITT sample)



And what extra can we discern from the self-report data?

RIOTT- self-report ‘heroin-using’ days/month – baseline & 6/12 (OOM, SIM, SIH)



Other outcomes

Retention in treatment

Other drug use

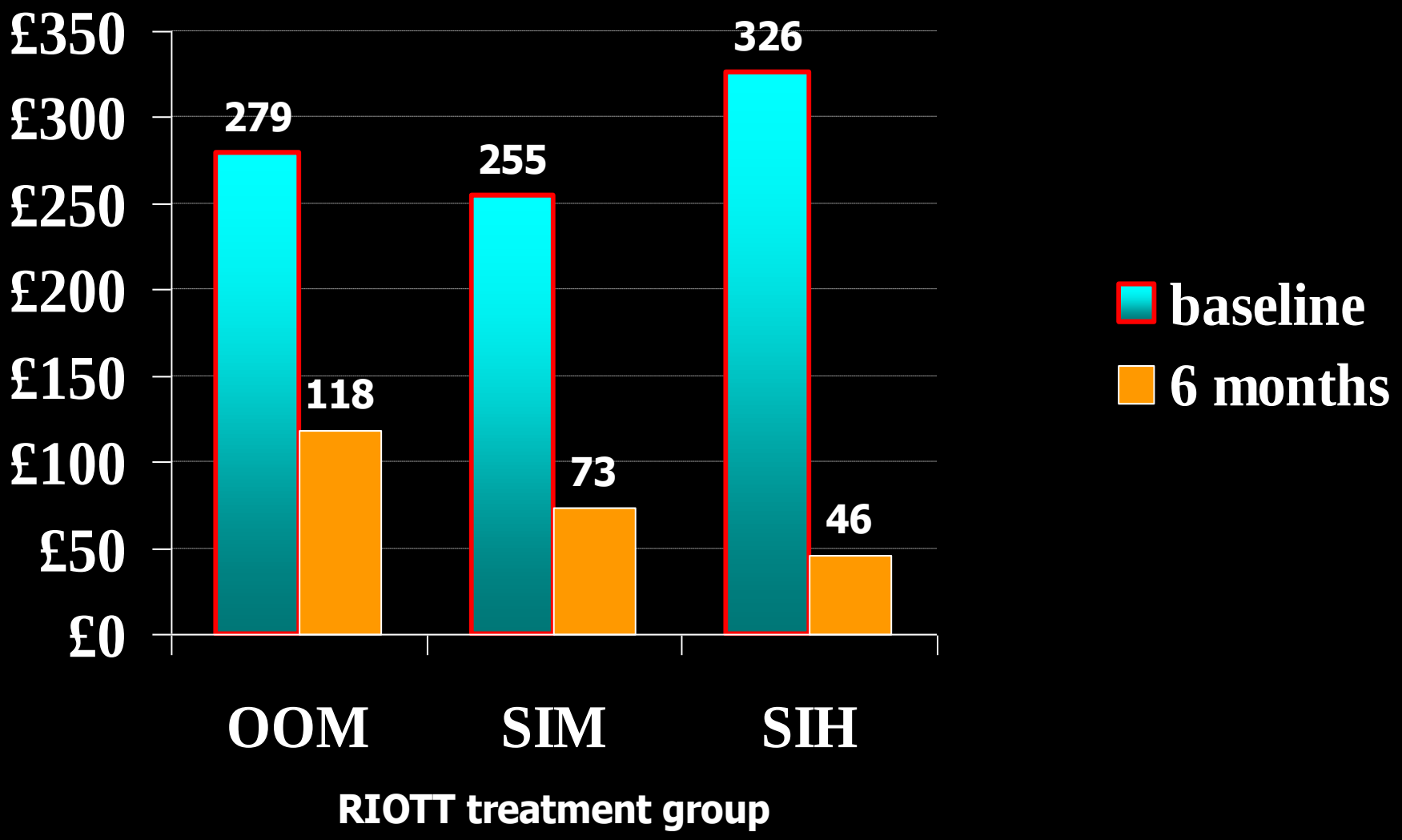
Well-being

Serious Adverse events

Criminal behaviour

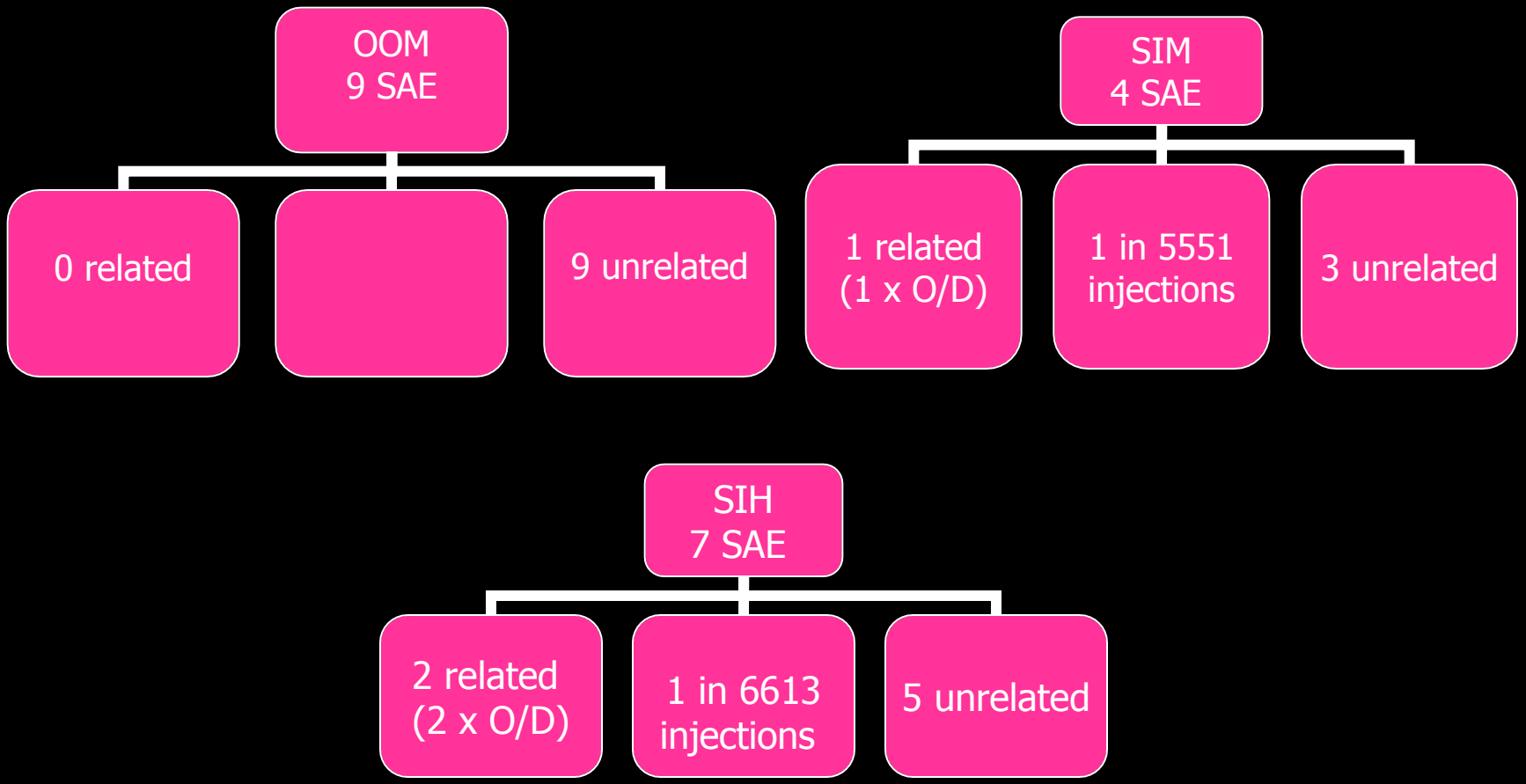
How much money was spent on buying street drugs?

RIOTT- mean weekly spending on street drugs



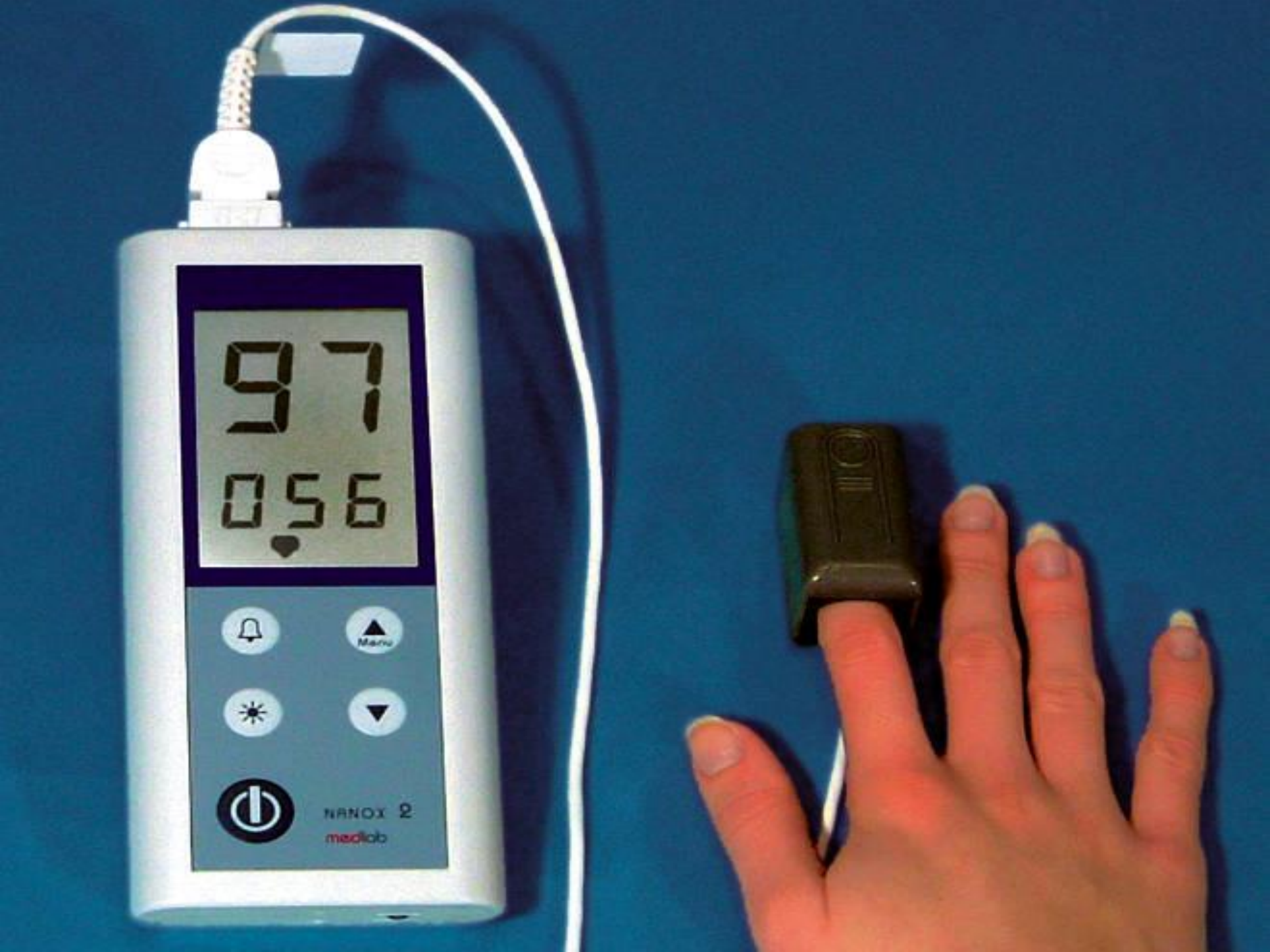
How much crack were patients using ?

Serious Adverse Events

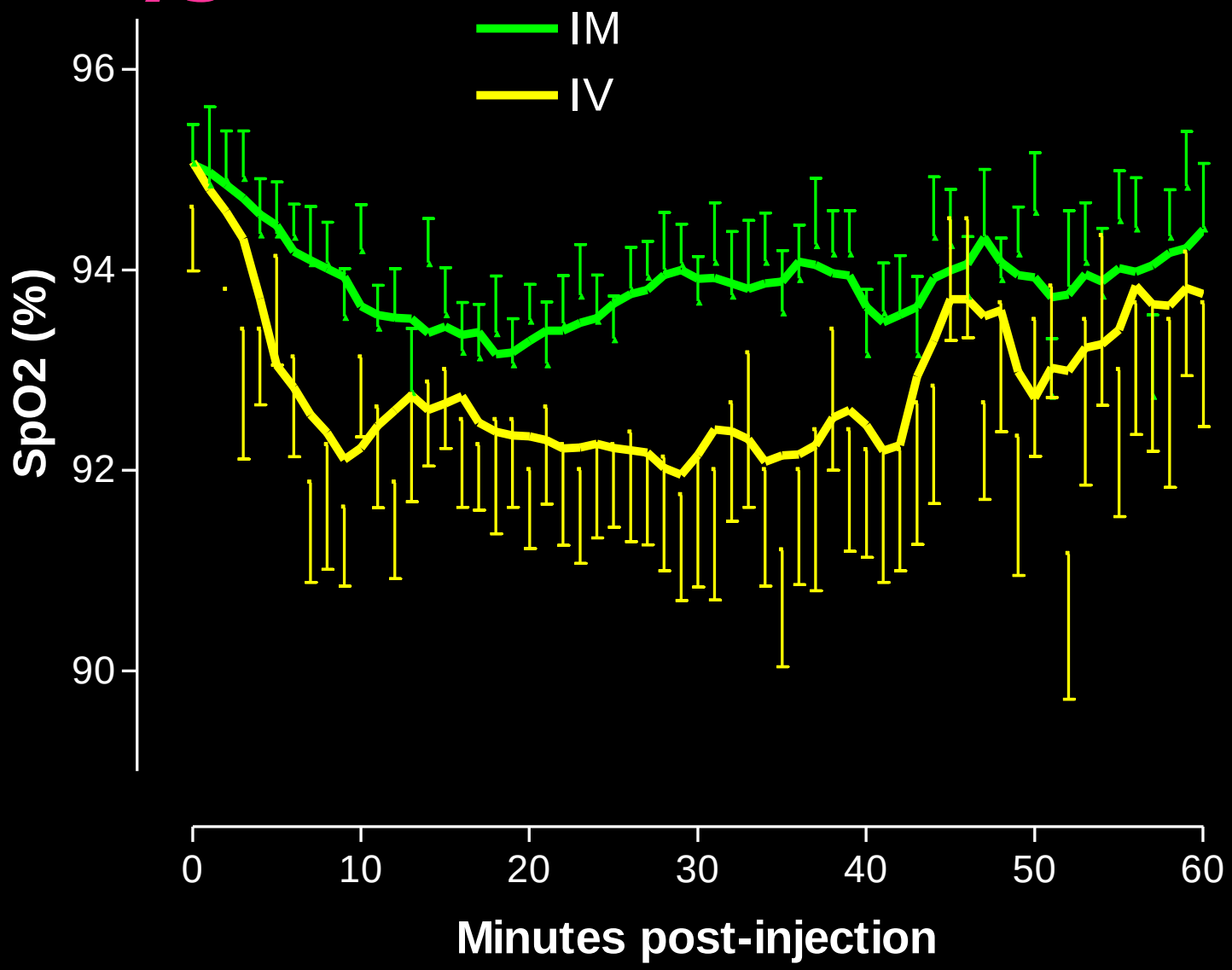


How real an issue? SAEs

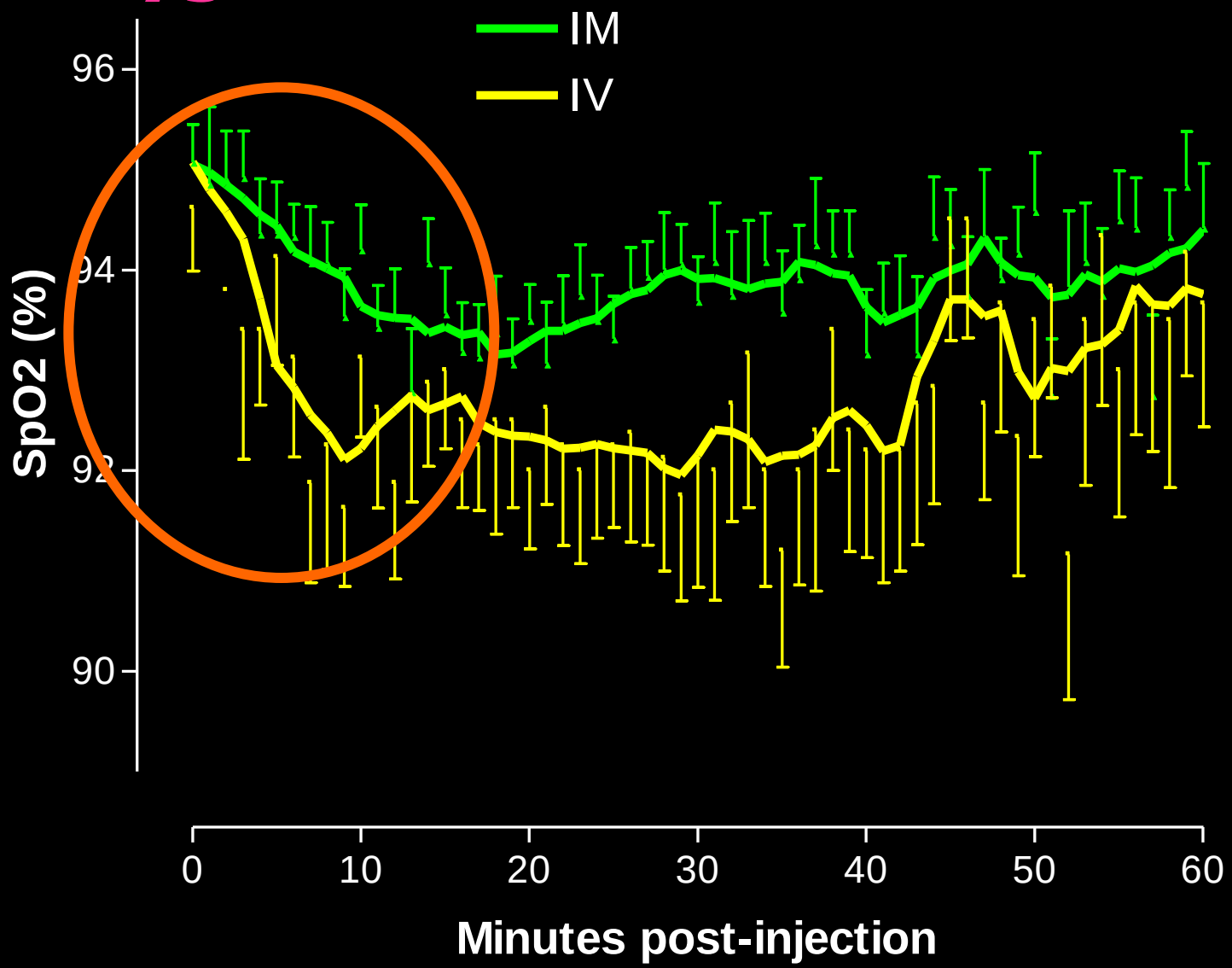
- Injected diamorphine –
  - 2 x rapid overdose requiring emergency naloxone as well as oxygen (incl. unconscious and unrousable)
- Injected methadone –
  - 1 x rapid overdose requiring emergency naloxone plus oxygen


97
056
Menu
NANOX 2
medlab

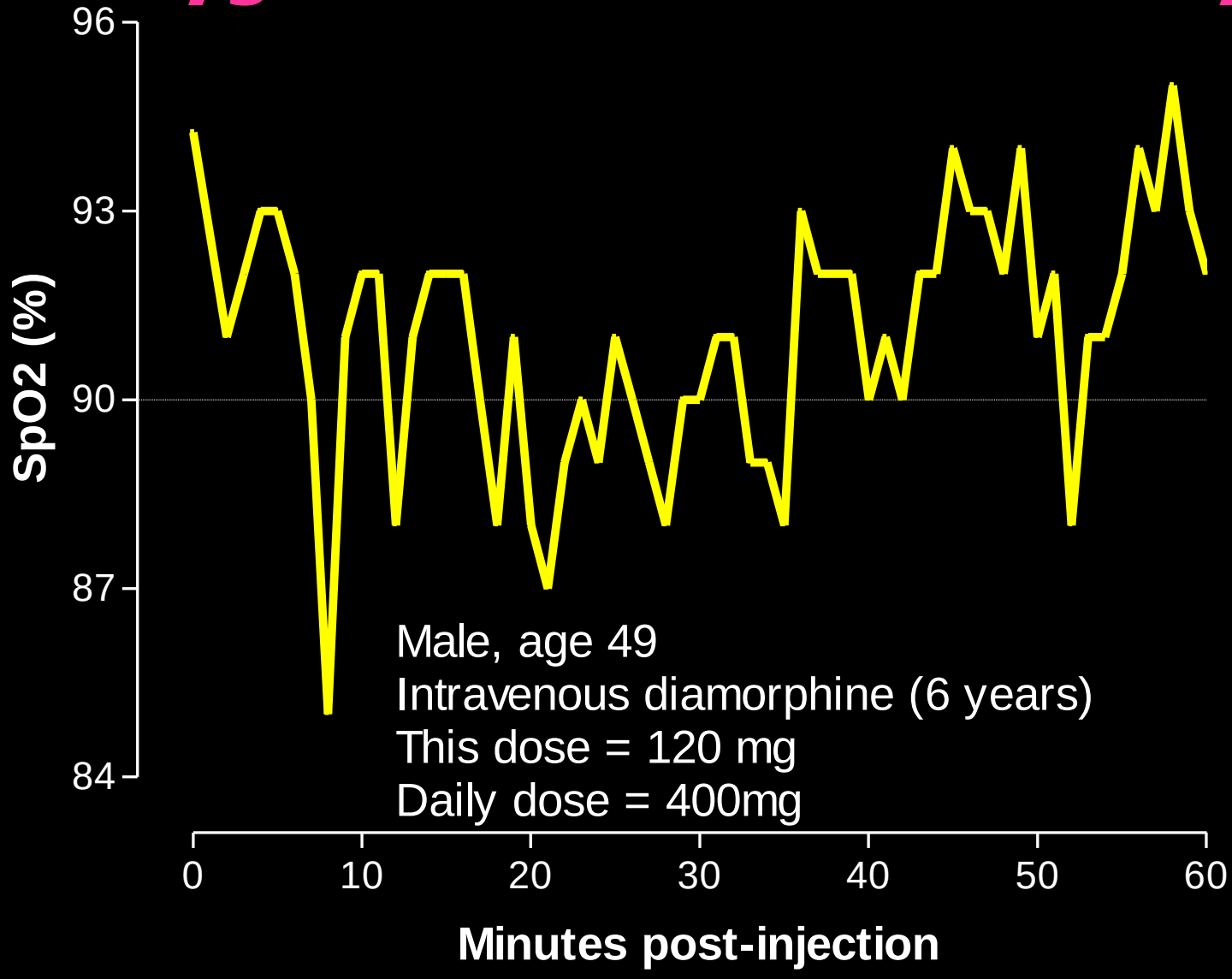
Oxygen saturation: IV versus IM



Oxygen saturation: IV versus IM



Oxygen saturation: case study



Finally (outside RCT) 2 years on

30 of the 43 SIH are at 2 years now:

- 16 still in SIH – 9 still twice-daily, 7 once-daily
- 8 in oral methadone maintenance treatment (6 by choice; 2 ‘disciplinary’)
- 1 successfully detoxed and drug-free
- 2 dead
- 3 missing

Finally (outside RCT) 2 years on

30 of the 43 SIH are at 2 years now:

- 16 still in SIH – 9 still twice-daily, 7 once-daily

  (all now stably abstinent from street heroin, except one transiently)
- 8 in oral methadone maintenance treatment (6 by choice; 2 'disciplinary')

  (the 6 – 2 injecting heroin frequently and one smoking crack; the 2 – both using alcohol and benzos chaotically)
- 1 successfully detoxed and drug-free

  (stably drug-free; returning to work)
- 2 dead

  (one heroin O/D while on oral methadone; one due to pneumonia and longstanding heart disease)
- 3 missing

Conclusions

HM Government

Drugs: protecting families and communities

The 2008 drug strategy

First Edition

"… rolling out the prescription of injectable heroin and methadone to clients who do not respond to other forms of treatment, subject to the findings, due in 2009, of pilots exploring the use of this type of treatment".

(H.M.Government Drug Strategy, 2008)

Research conclusions

Four important conclusions, as I see them

- **SIH (heroin) group strongest achievement**
- **SIM (inj methadone) better than control group**
- **OOM (optimised oral) – notable benefit**
- **Rapid onset of benefit and gain**

Clinical conclusions

And four important clinical conclusions, also

- **Intensive-care – high-dose, high-level care**
- **High-risk – be prepared**
- **The most severe cases (?5-10%)**
- **International critical mass with supervised injectable maintenance treatment modality**

☞ Thank you

Operating costs

- ……..
- Optimised oral methadone maintenance – c 5k pppa
- Supervised injectable methadone maintenance – c 10k pppa
- Supervised injectable heroin maintenance – c 15k pppa
- …..

Operating costs

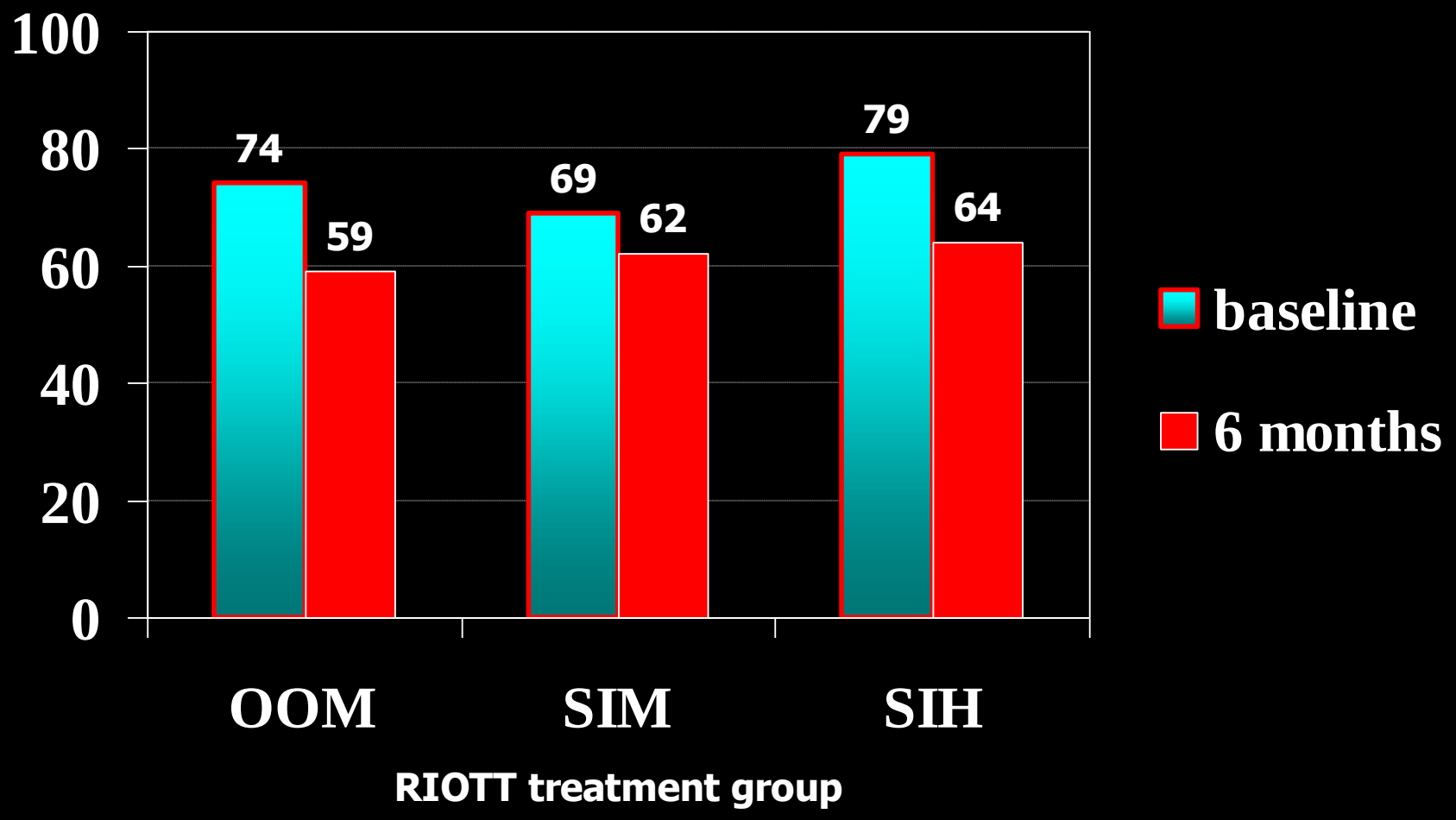
- *'bog-standard' oral methadone maintenance – c 3k pppa*
- *DTTO/DIP methadone treatment + monitoring – c 10k pppa*
- Optimised oral methadone maintenance – c 5k pppa
- Supervised injectable methadone maintenance – c 10k pppa
- Supervised injectable heroin maintenance – c 15k pppa
- *Prison – c 44k pppa*

Operating costs

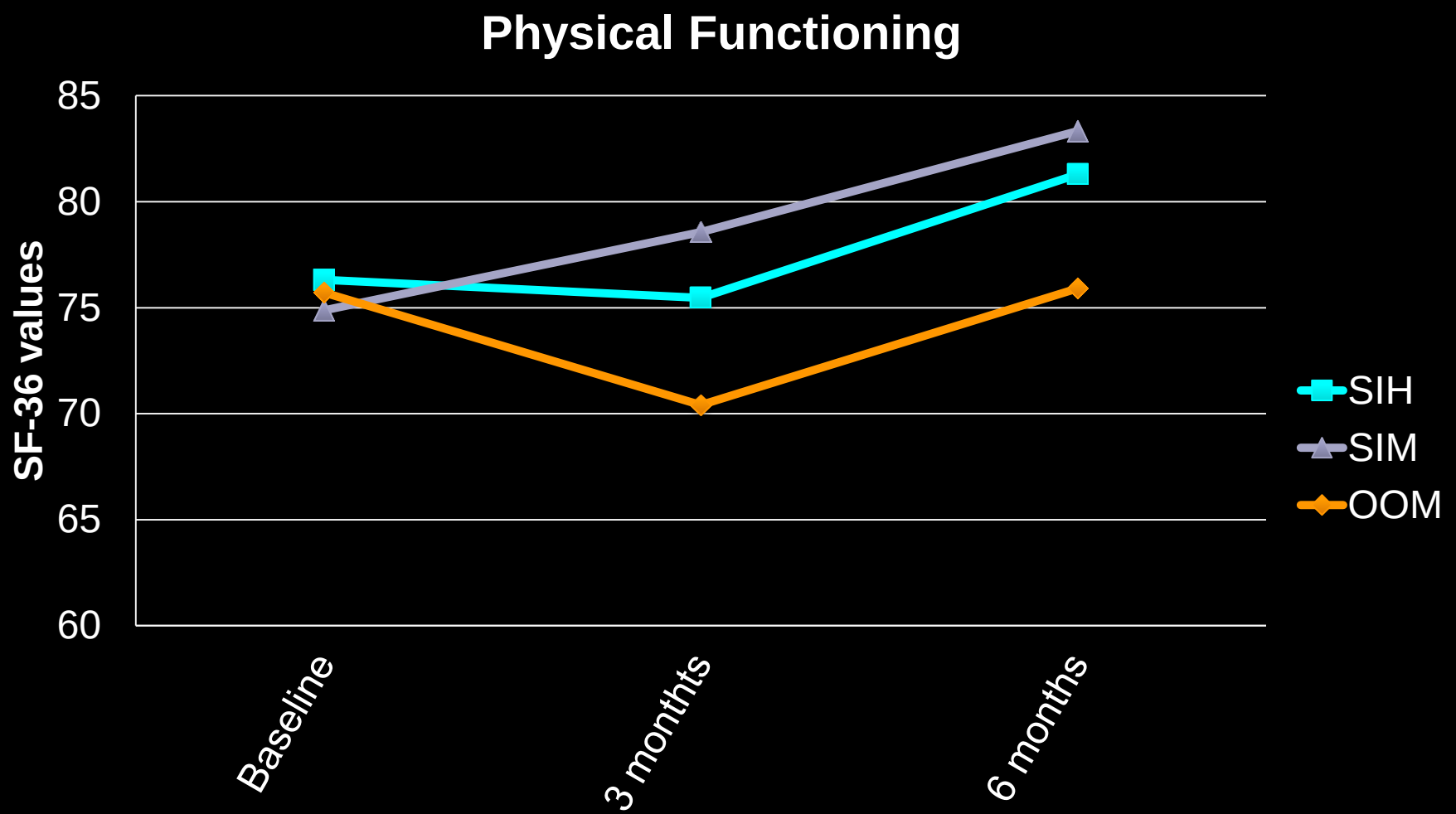
- ‘*An ineffective service is inefficient and cannot be cost-effective, no matter how cheaply it is provided*’

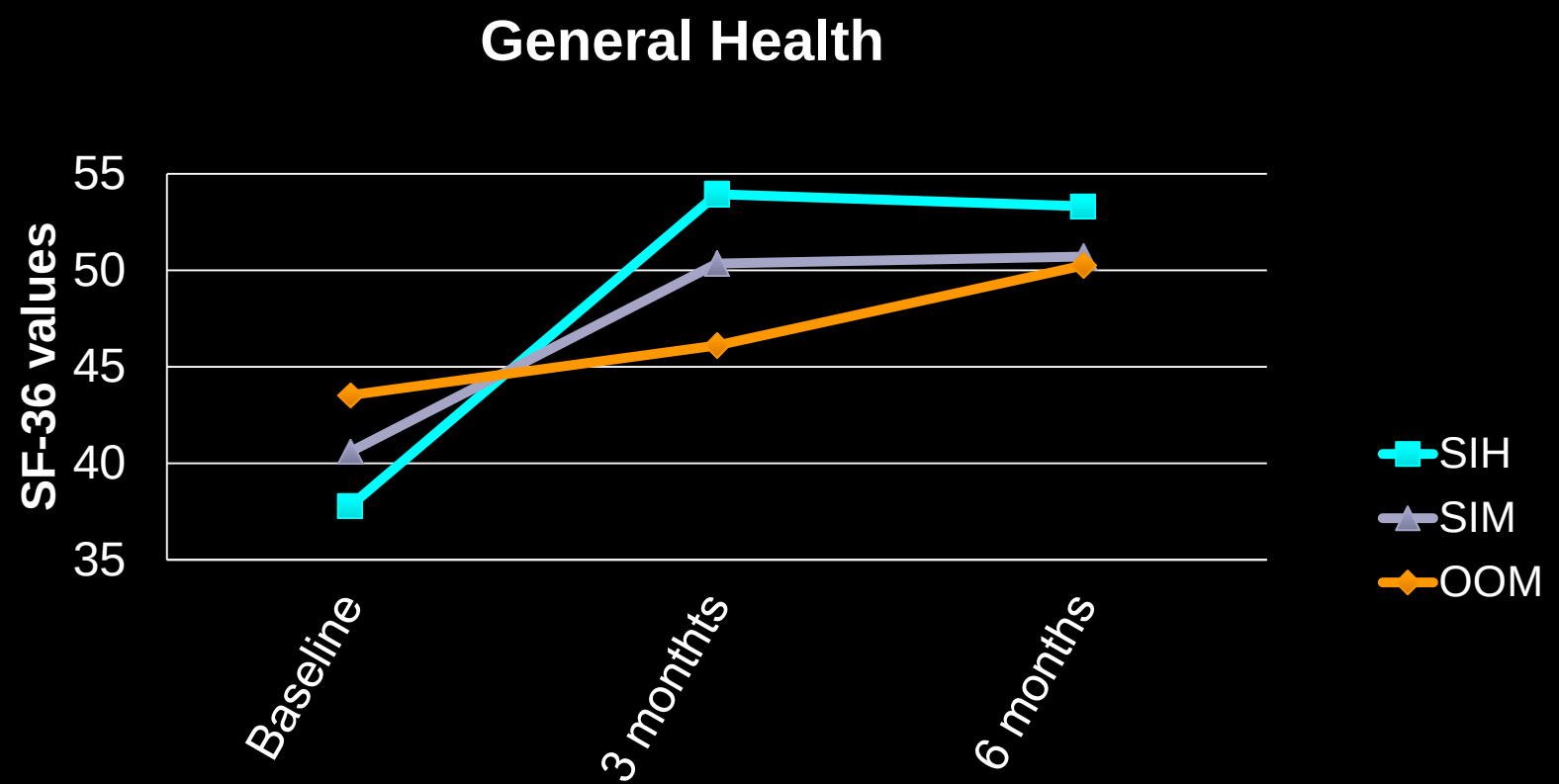
  - Cochrane, 1972

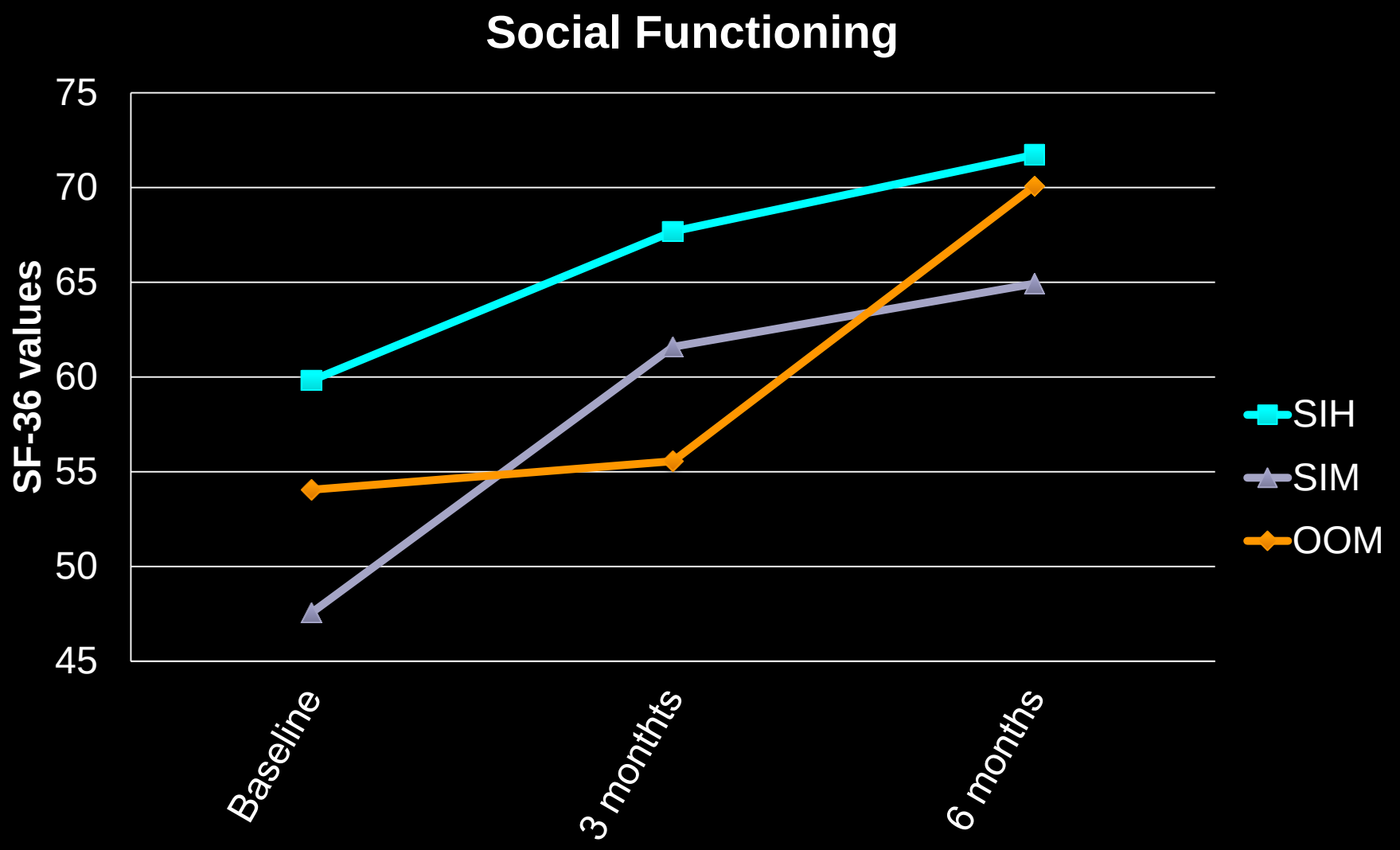
RIOTT- proportion using crack in past 30 days (baseline & 6 months)



What about health & social functioning ?


Physical Functioning
SF-36 values
85
80
75
70
65
60
Baseline
3 months
6 months
SIH
SIM
OOM


General Health
SF-36 values
55
50
45
40
35
Baseline
3 monthts
6 months
SIH
SIM
OOM


Social Functioning
SF-36 values
75
70
65
60
55
50
45
Baseline
3 monthts
6 months
SIH
SIM
OOM

Research Report

European Addiction Research

Eur Addict Res 2008;14:213–218
DOI: 10.1159/000141646

Published onl

The Fine Line between Harm Reduction and Harm Production – Development of a Clinical Policy on Femoral (Groin) Injecting

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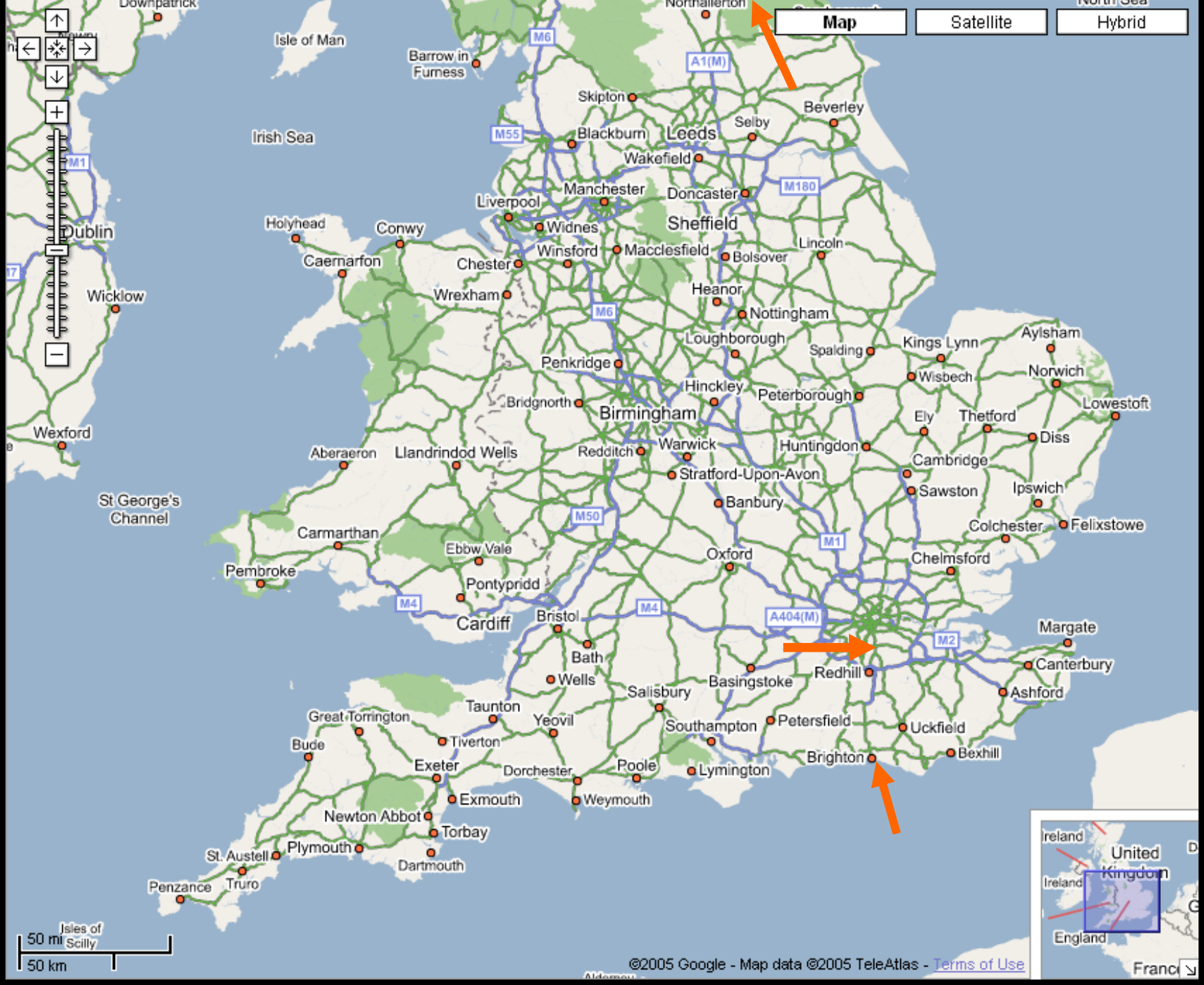
Nicola Metrebian[a] John Strang[a]

[a]National Addiction Centre, Institute of Psychiatry, King's College London, and [b]South London and Maudsley NHS Foundation Trust, London, UK; [c]Drug Health Services, Sydney South West Area Health Service, Royal Prince Alfred Hospital, Camperdown, NSW, Australia


Map
Satellite
Hybrid
Isle of Man
Irish Sea
Barrow in Furness
Skipton
Blackburn
Leeds
Selby
Beverley
Wakefield
Manchester
Doncaster
Liverpool
Widnes
Sheffield
Holyhead
Conwy
Caernarfon
Chester
Winsford
Macclesfield
Bolsover
Lincoln
Dublin
Wicklow
Wrexham
Heanor
Nottingham
Loughborough
Spalding
Kings Lynn
Aylsham
Norwich
Wisbech
Penkridge
Hinckley
Peterborough
Lowestoft
Bridgnorth
Birmingham
Ely
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Wexford
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Redditch
Warwick
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Injecting Room


David was clean when he got out of prison. He had done detox and was really turning his life around.
I remember this one time. I did a bit with two other people. Next thing I know I was coming round.
I REALISED I HAD GONE OVER.
It was my responsibility. I WAS TAKING STUPID RISKS. Why should he give a shit about my life if I don't?
OVERDOSE
WHAT RISKS ARE YOU TAKING?
STAYING ALIVE
He overdosed on it. I COULDN'T BELEVE IT.
I KNEW MOUTH TO MOUTH.
He just suddenly came round. I don't know why, but I burst into tears.
OVERDOSE
COULD YOU SAVE SOMEONE'S LIFE?
STAYING ALIVE
DANGER


DANGER


Diamorphine
Hydrochloride BP
Lyophilisate for Solution for Injection
500 mg
Caution: High Dose
Route of administration: SC/IM/IV
Reconstitute before use
Please read ampoule label and leaflet carefully
5 ampoules
500 mg
500 mg
500 mg
500 mg
Hydrochloride BP
500 mg


TO ALL STAFF & CLIENTS
SE MAKE SURE & DISPOSE OF ALL
ARPS MATERIALS IN SHARPS BIN
PROVIDED
BE CAREFUL NOT TO DISPOSE OF
SHARPS IN CLINICAL WASTE BAG
NERATION ONLY