

# A randomised controlled trial, economic evaluation and qualitative study of supervised consumption in patients managed with opiate maintenance treatment (the Super-C study)

<b>Submission date</b> 23/01/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/02/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/04/2014	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

1

# Study information

## Scientific Title

## Acronym

Super-C

## Study objectives

Null hypothesis: that there is no difference in proportion of patients retained in treatment over three months between those supervised (intervention) and those receiving unsupervised consumption (control) of opiate maintenance therapy.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the Hertfordshire Research Ethics Committee, 11/01/2008, ref: 07/H0311/198

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Substance misuse - opiate dependance

## Interventions

The intervention group will be supervised (i.e. observed by their dispensing pharmacist) consuming whichever opiate replacement drug that they have been prescribed (either methadone or buprenorphine). This intervention will occur daily (6 - 7 days/week) and will continue for three months.

The control group will be dispensed their opiate replacement drug (methadone or buprenorphine) on a daily basis (6 - 7 days per week). Their consumption of this will be supervised for the first week. After that they will be able to consume their medication in private (i.e. unsupervised).

Please note the choice of opiate maintenance therapy (methadone or buprenorphine) and dose of drug used for each participant, is a clinical decision and does not form part of this study (though it will be recorded in each case).

Follow-up will continue for six months.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Buprenorphine, methadone

### **Primary outcome measure**

Retention in treatment at three months.

### **Secondary outcome measures**

1. Retention in treatment at six months (from clinic records)

All others measured at 3 months only, through follow-up interview, data from keyworkers (Christo score) or clinic records/routine data:

2. Evidence of reduction in use of illicit opioids (urine testing and Maudsley addiction profile results [MAP])
3. Use of other illicit drugs and alcohol use (urine testing results from clinic records and MAP results)
4. Addiction severity and social functioning (measured by Christo score - provided by keyworkers)
5. Changes in psychological functioning (measured by the MAP)
6. Changes in quality of life measured by the 12-item short form health survey (SF-12) and the capability index (self-complete questionnaires)
7. Changes in criminal behaviour (MAP)
8. Adverse events (emergency hospital attendance [accidency and emergency department attendance or hospital admission] with symptoms of drug overdose/death)
9. Average dose of drug prescribed over treatment period (clinic records)
10. Self-report satisfaction with pharmacy (3-month follow-up drug use questionnaire)
11. Self-report drug compliance and diversion (3-month follow-up drug use questionnaire)
12. Monthly assessment of injecting sites for those injecting at baseline (clinic records)
13. Treatment outcomes profile (clinic records using National Treatment Agency form which is collected routinely by drug service)

### **Overall study start date**

01/03/2008

### **Completion date**

31/12/2010

# Eligibility

## Key inclusion criteria

1. Confirmed symptoms of opioid dependency (including toxicological investigations)
2. Electing for maintenance treatment (as opposed to other forms of management, e.g., detoxification) with either methadone or buprenorphine
3. Aged 16 years or older, either sex

## Participant type(s)

Patient

## Age group

Adult

## Sex

Both

## Target number of participants

256

## Key exclusion criteria

1. Chronic injectors refusing oral therapy
2. Under 16 years
3. Hypersensitivity to both buprenorphine and methadone
4. Treatment with suboxone (as this is not routinely supervised)
5. Severe medical condition making treatment hazardous in the opinion of the treating physician
6. Incapacity to give informed consent
7. Maintenance treatment during last four weeks
8. Those patients deemed to definitely require supervised consumption at discretion of the treating physician (such as homeless, those with a drug-using partner not in treatment)
9. Those patients where supervised consumption of their agreed treatment can not be provided for reasons of geographical placement (e.g. no provision of supervised consumption in the local pharmacy)

## Date of first enrolment

01/03/2008

## Date of final enrolment

31/12/2010

# Locations

## Countries of recruitment

England

United Kingdom

**Study participating centre**  
**School of Medicine, Health Policy & Practice**  
Norwich  
United Kingdom  
NR4 7TJ

## **Sponsor information**

**Organisation**  
Hertfordshire Partnership NHS Foundation Trust (UK)

**Sponsor details**  
R&D Office  
Department of Psychiatry  
QEII Hospital, Howlands  
Welwyn Garden City  
England  
United Kingdom  
AL7 4HQ

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.hertsparts.nhs.uk/>

**ROR**  
<https://ror.org/0128dmh12>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
National Institute of Health Research (UK) - Research for Patient Benefit Programme

## **Results and Publications**

**Publication and dissemination plan**  
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2014		Yes	No
<a href="#">Results article</a>	results	01/04/2014		Yes	No