

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

Submission date 23/01/2008	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 05/02/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/04/2014	Condition category Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Richard Holland

Contact details

School of Medicine, Health Policy & Practice
University of East Anglia
Norwich
United Kingdom
NR4 7TJ
+44 (0)1603 593574
r.holland@uea.ac.uk

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Substance misuse - opiate dependence

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(s)

Retention in treatment at three months.

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

School of Medicine, Health Policy & Practice

Norwich

United Kingdom

NR4 7TJ

Sponsor information**Organisation**

Hertfordshire Partnership NHS Foundation Trust (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

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?
Results article	results	01/01/2014		Yes	No
Results article	results	01/04/2014		Yes	No