

S-Script In a Day for injecting drug users

Submission date 25/10/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/10/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/10/2018	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

We are conducting a feasibility study to see if offering people who inject heroin same day access to a GP and a methadone script (called opium substitution treatment (OST)) can help these individuals get into and stay on OST. We are focusing upon individuals who find it particularly hard to engage in OST or those who have recently dropped out of treatment. The reason why we are conducting this study is because we know that accessing OST reduces the risk of drug related deaths and blood borne virus transmission.

Who can participate?

Individuals (male and female) accessing the Bristol Drugs Project (BDP) needle exchange are asked if they are interested in participating in this study. Participants are eligible if they are injecting opiates (heroin), live in Bristol and are not currently receiving a script of OST.

What does the study involve?

Participants who consent and complete questionnaires at baseline are randomised into two groups either to receive the intervention i.e., receive a script of methadone on the same day, or, 'care as usual' (offer to make an appointment with GP to start OST). All participants are followed up at three months, complete further questionnaires and asked if they are still on a script of OST at this time point.

What are the possible benefits and risks of participating?

Participants may benefit from having same day access to a script of methadone rather than waiting up to one to two weeks (longer in some areas) for a script. Participants will need to spend about 30 minutes filling in questionnaires and be available to go to an appointment at the recruiting GP practice on the same day. They will also need to return at one and then two weeks later to renew their script. No other risks associated with this study.

Where is the study run from?

The study is run from the University of Bristol in collaboration with the Bristol Drugs Project (BDP), Bristol.

When is the study starting and how long will it run for?

The study started participant recruitment in October 2011. The aim was to recruit for one year or when the target sample (100) was achieved. This was completed in September 2012.

Who is funding the study?

This study is funded by the NHS via the National Institute for Health Research (NIHR), Research for Patient Benefit (RfPB).

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

10169

Study information

Scientific Title

SCript In a Day for injecting drug users: feasibility trial

Acronym

SCID

Study objectives

Script in a day (SCID) is an exploratory randomised controlled trial.

Key aims include:

1. To explore whether providing access to a GP and same day scripting of methadone opiate

substitution treatment (OST) helps people who are injecting heroin to get into and stay on treatment.

2. To estimate some degree of benefit of receiving immediate access to a script in a day.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NHS National Research Ethics Service, South West Rec 4, First MREC approval date 28/01/2011, ref: 11/H0102/1

Study design

Two-arm non-blinded randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Drug misuse, individuals injecting opiates, opiate substitution treatment (OST)

Interventions

Participants are randomised into two groups. All participants complete baseline questionnaires and at the 3 month follow-up.

The control group receive 'care as usual' (offer to make an appointment with GP to initiate OST).

The intervention group receive a script of methadone on the same day they are randomised. Participants are offered an appointment with the study GP and a BDP peer support worker is available if requested, to accompany participants to their first and subsequent appointments. Following a urine test confirming the presence of opiates, and, confirmation from participant's medical and drug treatment agency records they are not currently prescribed OST, methadone treatment is initiated. Participants return to see the study GP one week and two weeks later. At the end of this period participants are transferred to their own Shared Care Worker. If there are no spaces available participants are supported by the study shared care workers until a space becomes available.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Participants on a script of OST at three month follow-up

Secondary outcome measures

1. Number of participants eligible for the trial, recruitment and retention rates
2. The TOP scale is a widely used treatment outcomes profile measure in drug services which collects information about frequency and cost of substance use, injecting risk behaviour, health and social functioning and crime
3. EQ-5D is a generic measure, with 5 domains (mobility, self-care, usual activities, pain /discomfort, anxiety/depression) and can be used to calculate quality-adjusted life years (QALY) for formal cost-effectiveness analyses
4. A health questionnaire (adapted from Medical Outcomes Study: 36-item short form survey by Rand) will also be used. This questionnaire measures quality of life and is based on 6 domains including physical function and well-being. Higher scores indicate better QOL

Overall study start date

01/04/2011

Completion date

30/09/2013

Eligibility

Key inclusion criteria

1. Participants are living in Bristol
2. Injecting opiates
3. Not currently prescribed OST

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 100; UK Sample Size: 100

Key exclusion criteria

Participants already prescribed OST

Date of first enrolment

01/10/2011

Date of final enrolment

01/09/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Bristol

Bristol

United Kingdom

BS8 2PR

Sponsor information

Organisation

University of Bristol (UK)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/0524sp257>

Funder(s)

Funder type

Government

Funder Name

Research for Patient Benefit Programme: PB-PG-0909-20007

Alternative Name(s)

NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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?
Results article	results	18/11/2014		Yes	No
Results article	results	02/12/2016		Yes	No