ISRCTN16846554 https://doi.org/10.1186/ISRCTN16846554

SCript In a Day for injecting drug users

Submission date	Recruitment status	[ ] Prospectively registered
25/10/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/10/2012	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/10/2018	Mental and Behavioural Disorders	

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

Who is the main contact?
Dr Angela Beattie
Angela.Beattie@bristol.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Angela Beattie

Contact details
Department of Social Medicine
Canynge Hall
Whiteladies Road
Bristol
United Kingdom
BS8 2PR
-
Angela.Beattie@bristol.ac.uk

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
c/o Dr Birgit Whitman
Department of Social Medicine
Canynge Hall
Whiteladies Road
Bristol
England
United Kingdom
BS8 2PR

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