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A social network intervention for opiate users

Submission date	Recruitment status	[X] Prospectively registered
27/04/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/04/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/01/2018	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11845

Study information

Scientific Title
A pilot study of a social network intervention for heroin users in routine NHS opiate substitution treatment

Study objectives
Hypotheses:
1. Social behaviour and network therapy (SBNT) is more effective than a case management intervention of similar intensity or treatment as usual in reducing illicit heroin use 3 and 12 months after treatment in clients receiving opiate substitution treatment for more than a year.
2. The formal null hypothesis is that there will be no difference in heroin use 3 and 12 months after treatment in opiate substitution clients receiving social behaviour and network therapy when compared with a case management intervention or treatment as usual.

Social Behaviour and Network Therapy (SBNT) is an intervention developed in the UK by members of our research group. It integrates effective strategies from other treatment approaches and is built upon the premise that social network support for change is central to the resolution of addictive behaviour. As an intervention, SBNT has much potential but more research is needed to establish whether it is feasible to deliver SBNT in routine service provision and establish efficacy through a randomised controlled trial design. This is the overall long term aim for which this initial feasibility study will be conducted. Clients still using heroin in two NHS community drug treatment teams (Solihull & Leicester) will take part. Two clinicians per team will be trained in a 4-session manual-driven intervention (SBNT), and a further 2 in a 4-session case management intervention. Participants will be randomised to one of the two interventions or treatment as usual. Forty clients will be recruited to each of three arms, and interviewed at baseline and 3 and 12 months after the start of the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - The Black Country, 08/03/2012, ref: 12/WM/0046

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Addiction to illegal substance

Interventions
(i) Social Behaviour and Network Therapy (SBNT)
Therapy will be delivered according to a purpose designed therapy manual. Clients randomised to SBNT will be offered 4 x weekly 50-minute SBNT sessions over a maximum of 6 weeks. All sessions will be video-recorded and reviewed by the research team to ensure fidelity with the SBNT manual and principles of practice. These procedures were developed and tested in UKATT, and further refined by our research group with drug treatment staff. The study manual will combine the most effective components of the SBNT intervention used in these earlier studies with elements of node-link mapping to facilitate the training and delivery of the intervention. The treatment will involve working with the client to draw a network diagram during the first session in order to identify potential social support for change that could be drawn upon during the treatment. Following this, potential supportive network members identified by the patient will be approached and invited to participate in treatment sessions in order to enhance the social support for change in drug use. The therapist will use elements of communication skill development, coping behaviours and the development of joint activities in order to support the process, with the ultimate aim of building a network-supported relapse management plan.

(ii) Case Management
This arm has been included in order to control for the intensity of treatment as well as the process and experience of receiving an intervention from a different therapist to the one delivering the routine care. This intervention will be close to usual key-working and will include a supportive interaction, reviewing current situation and goals, progress during the weeks between sessions and a discussion of any issues identified by the client. It will be manual-guided for standardisation. In common with the brief SBNT arm, clients will be expected to attend 4 weekly sessions over a maximum of 6 weeks

(iii) Treatment as usual
Clients in this arm will continue to receive usual care. Our research group conducted one of the few published studies describing treatment as usual in OST services in Birmingham. Meetings with clients occurred between weekly and fortnightly, and lasted an average of 45 minutes. Session activities fell into 4 broad categories, each delivered in similar amounts: case management, signposting of other services, structured psychosocial interventions, and other activities (e.g. medication issues).

All clients will be assessed at baseline, as well as 3 and 12 months after the start of treatment. Family members of clients involved in the trial will also be assessed at baseline, 3 and 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Heroin use measured at 3 and 12 months, measured using urinary drug analysis and self-report

Secondary outcome measures
1. Drug related problems measured at 3 and 12 months using the Maudsley Addiction Profile
2. Motivation to change measured at 3 and 12 months using the Readiness to Change Questionnaire - Treatment Version
3. Psychological symptoms measured at 3 and 12 months using the CORE-OM
4. Severity of dependence measured at 3 and 12 months using the Leeds Dependence Questionnaire
5. Social satisfaction measured at 3 and 12 months using the Social Satisfaction Questionnaire
6. Therapeutic engagement measured at 3 and 12 months using the Client Evaluation of Self and Treatment

Overall study start date
01/06/2012

Completion date
01/01/2014

Eligibility

Key inclusion criteria
1. Clients who have been receiving opioid substitution treatment (with either methadone or buprenorphine) continuously for more than a year but who still report heroin or other illicit opiate use in the preceding 28 days.
2. Adults (greater than 18 years old) with opioid dependence
3. Male and female participants
4. Aged 18 - 65 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 120

Key exclusion criteria
1. Patients with concurrent severe mental illness (e.g. schizophrenia, bipolar affective disorder, severe cognitive impairment)
2. Severe physical illness
3. Pending imprisonment

Date of first enrolment
01/06/2012

Date of final enrolment
01/01/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham and Solihull Mental Health NHS Foundation Trust
Birmingham
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Sponsor information

Organisation
Birmingham and Solihull Mental Health NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.bsmhft.nhs.uk/

ROR
https://ror.org/00cjeg736

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme ref: PB-PG-0610-22392

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?
Protocol article	protocol	19/08/2013		Yes	No
Results article	results	15/01/2018		Yes	No