ISRCTN93446265 https://doi.org/10.1186/ISRCTN93446265

Youth-Social Behaviour and Network Therapy: a study of a family and social network intervention for young people who misuse alcohol and drugs

Submission date
28/05/2013

Recruitment status
No longer recruiting

Registration date
31/05/2013

Overall study status
Completed

Last Edited
13/04/2017

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
We are conducting an adaptation of a family and social network intervention shown to be effective in helping adults experiencing alcohol and drug problems to be implemented with young people with alcohol and drug problems and tested in a small pilot study. Previous research has shown that the family has a considerable impact on young peoples drinking and drug use. Interventions involving the family and wider social networks have shown promise in helping young people to deal with substance abuse problems. At present there is limited delivery of family interventions for young people with alcohol and drug problems in routine practice in the UK. The study will adapt and further develop the Social Behaviour and Network Therapy (SBNT) approach that has been shown to be effective and cost-effective with adults with alcohol problems. This study will test feasibility of delivery and preliminary outcomes.

Who can participate?
Young people (aged between 12 and 18) with drug and/or alcohol problems

What does the study involve?
Participants will be randomly allocated to receive the adapted SBNT approach or existing treatment as usual that is not family-focused. Half of those participating (N=30) will receive the adapted intervention and the remaining half treatment as usual. The family-based intervention will be adapted to support young people aged 12-18. Following consultation with young people who had experience of alcohol and drug problem services and their carers, we will adapt the family and social approach. The intervention will then be tested in a small pilot study in routine young people services in Birmingham and Newcastle. Once this intervention is adapted and produced in manual form, a selection of therapists delivering treatment for young people in those services will be trained and supervised to deliver this adapted treatment. The family and social intervention (SBNT) will consist of 6 meetings with the young person with the alcohol or drug problem and their close family members or friends that they wish to involve. Treatment as usual will consist of what is normally delivered in those services. Those receiving the

intervention or the control treatment as usual will be assessed at the beginning of the study and 3 and 12 months later. The study will also measure other aspects that affect the young people, such as mental health, family factors, crime and the use of other services. The research team will assess whether the intervention reduces the use of these other services, and is therefore more cost-effective. The study will also help to inform a decision on whether to prepare for a larger study with more participants in the future.

What are the possible benefits and risks of participating?
If the intervention was shown to be successful, those receiving the adapted intervention will show some benefit. Those participants randomised to the treatment as usual will have an opportunity to receive the family intervention once the study is completed if they wish to do so. There should also be benefit for those young people receiving help for alcohol and drug problems in the future through the results informing practice. There are no anticipated risks of participating in this study.

Where is the study run from?
School of Psychology, University of Birmingham and the Birmingham and Solihull Mental Health Trust (UK)

When is the study starting and how long is it expected to run for?
February 2014 to November 2015

Who is funding the study?
Health Technology Assessment (HTA)- National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Alex Copello
a.g.copello@bham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Alex Copello

Contact details
School of Psychology
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 (0)121 414 7414
a.g.copello@bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 11/60/01

Study information

Scientific Title
Adaptation and feasibility study of a family and social network intervention for young people who misuse alcohol and drugs

Acronym
Youth-SBNT

Study objectives
Expressed in null form, the study hypothesis is that the Social and Family Intervention (Youth-Social Behaviour and Network Therapy) will be as effective and cost-effective as treatment as usual (TAU).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Coventry & Warwickshire, 24/02/2014, ref: 14/WM/0021

Study design
Pragmatic pilot feasibility randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Alcohol and drug addiction

Interventions

Each group will have 30 participants (N=30 allocated to Youth-Social Behaviour and Network Therapy and N=30 allocated to Treatment as Usual).

Young people randomised to SBNT will be offered 6, weekly, 50-minute SBNT sessions for a period of a maximum of 12 weeks. Treatment as usual in the clinical centres (Newcastle and Birmingham) which will provide the comparison to the trial intervention is broadly similar. The fundamental contrast between the two treatments under study is that the trial intervention will have a family and social network focus and the treatment as usual will be individually focused. Young people randomised to receive treatment as usual will receive a similar number of individual sessions i.e.6 over a period of 12 weeks. Participants will then be followed up 3 and 12 months after baseline assessment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary outcome measure for the pilot trial will be based on the Timeline Follow-Back (TLFB) interview and will be the proportion of days on which the main problem substance was used in the preceding 90 day period covered by each assessment point. The main problem substance will be that for which the referral to the services was made and this will be corroborated at the research assessment interview prior to completion of the TLFB.

Secondary outcome measures
Family-based approaches have the potential to impact on other facets of young people's lives and may lead to changes in a number of secondary areas including, family, psychological and social outcome variables that will be measured with validated questionnaires that have been widely used in trials of young people: The following measures will be used.
1. Emotional well-being: The Strengths and Difficulties Questionnaire (SDQ) (Goodman, 1997) has five separate sub-scales for different aspects of problems or behaviours: emotional problems, conduct/behaviour problems, inattention/hyperactivity, relationships with peers, and pro-socialbehaviour. The first four scales can be added together to produce a score for total difficulties.
2. Social Network Support: Given the emphasis on family and peer support of the intervention, the Important People Drug and Alcohol interview (IPDA) will be used in order to understand the influence of social support on treatment for substance misuse.
3. Family Environment: The Family Environment Scale (Moos and Moos, 1986) is designed to measure the atmosphere in the family household and will be used where appropriate to the circumstances of the participant. It is a 27-item measure and yields scores for family cohesion, free expression of emotion in the family and absence of open conflict.
4. Working Alliance Inventory (Horvath & Greenberg, 1989) will be administered at 3-month follow-up to the young people and also to the therapists delivering the intervention and treatment as usual. The questionnaire measures the perceived strength of the working alliance between therapists and their clients during therapy sessions.
5. School attendance and engagement, self-reported crime and health care and social services contact will be measured based on questionnaires used by the applicants in previous alcohol trials (UKATT Research Team, 2005; Coulton, 2009).
6. EQ-5DY (version of the EQ-5D validated with youth populations.

Overall study start date
01/02/2014

Completion date
01/11/2015

Eligibility

Key inclusion criteria
1. Young people aged 12-18, either sex
2. Young people with drug and/or alcohol problems accepted for treatment by the two agencies and willing and able to provide written informed consent

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. With concurrent severe mental illness
2. Pending imprisonment. (i.e. will not be available for follow-up)
3. With severe physical illness
4. Unable or unwilling to give written informed consent

Date of first enrolment
01/02/2014

Date of final enrolment
01/11/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

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

Sponsor details
c/o Dr Paul McDonald
Research Manager
Research & Innovation
Radclyffe House
66-68 Hagley Road
Birmingham
England
United Kingdom
B16 8PF
+44 (0)121 301 4330
paul.mcdonald@bsmhft.nhs.uk

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/00cjeg736

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

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	01/12/2015		Yes	No
Results article	results	01/03/2017		Yes	No
HRA research summary			28/06/2023	No	No