Short title: Family and Social Intervention for Young People

A randomised controlled trial of family and social network intervention for young people who misuse alcohol and drugs: a feasibility study [Y-SBNT]

PROTOCOL

Version 2.0

Authorised by:

Name:	Professor Alex Copello	Role:	Chief Investigator
Signature:		Date:	

Institutions:
University of Birmingham, School of Psychology
Birmingham and Solihull Mental Health Foundation Trust
University of Birmingham, Department of Psychiatry
University of York, Department of Health Sciences
Northumberland Tyne and Wear NHS Foundation Trust
Newcastle University

Sponsor:
Birmingham and Solihull Mental Health Foundation Trust
Dr Paul McDonald PhD AFBPsS
Research Manager, Research & Innovation
BSMHFT, Radclyffe House
66-68 Hagley Road
Birmingham
B16 8PF

TITLE	A randomised controlled trial of family and social network intervention for young people who misuse alcohol and drugs: a feasibility study
SHORT TITLE	Family and Social intervention for Young People
Protocol Version	**Version 2.0**
Date	**19th February 2014**
ISRCTN	ISRCTN93446265
Methodology	Pragmatic, randomised controlled, open feasibility trial delivered in two Young People services.
Study Duration	18 months
Study Centres	Birmingham and Newcastle
Objectives	To demonstrate the feasibility of recruiting young people to a family and network based intervention and the feasibility of training staff from existing young people addiction services to deliver the intervention. To evaluate the level of treatment retention and explore through qualitative interviews the participants' views, acceptability and experiences of the intervention and the study process.
Number of Subjects/Patients	Sixty participants will be recruited to the trial on the basis of 10% sample attrition, expecting data to be successfully collected on 54.
Main Inclusion Criteria	Young people aged 12 to 18 referred for drug and/or alcohol problems to the two services involved in the research.
Statistical Methodology and Analysis	The feasibility and acceptability of YSBNT as an intervention will be measured by recruitment rates, retention in treatment, follow up completion rates and by qualitative interviews. Using the opportunity available to compare the effectiveness of the two treatments, the proportion of days on which the main problem substance was used in the preceding 90 day period covered by each assessment point will be based on the Timeline Follow-Back (TLFB) interview. Analysis will be on an intention to treat basis and the primary analyses will compare the active experimental condition with treatment as usual, and subjects will be analysed using a generalised linear model with identity link and Gaussian error. The therapists will be included as random effects.

Study Summary

Research evidence shows that there is a high prevalence of substance use among young people in the UK. Early onset and high levels of use are associated with a range of negative outcomes, including increased risk of later problematic use and dependence. A growing body of research has identified family interventions to be effective in treating young people's substance use problems. However, despite this evidence, take-up of family based approaches, at least in the UK, has been low. A key factor appears to be the resource-intensive nature of many family interventions, making them difficult to implement and deliver in many service settings, especially in the context of substantial cuts to drug and alcohol services for young people.[1] Another potential barrier may be the cultural adaptation of approaches developed in the USA to a UK setting. There is growing awareness of the need to adapt evidence-based treatments to different cultural groups and settings in order to ensure successful implementation.[2,3,4]

Following on from developmental and adaptation work, this study aims to demonstrate the feasibility of recruiting young people to specifically developed family and network based intervention. In addition the feasibility of training staff from existing young people addiction services to deliver this intervention will be explored and treatment retention will be assessed. Qualitative interviews will elicit the participants' views on the acceptability of the intervention and their experiences of both it and the study process.

Study Identifiers

Full title of trial

A randomised controlled trial of family and social network intervention for young people who misuse alcohol and drugs: a feasibility study

Acronym: Y-SBNT

ISRCTN: ISRCTN93446265

Funder: NIHR HTA Programme grant number 11/60/01

Sponsor: Birmingham and Solihull Mental Health Foundation Trust

List of Common abbreviations

AE	Adverse event
EQ-5D-5L	European Quality of Life -5 Dimensions-5 levels version
FES	Family Environment Scale
IPDA	Important People Drug and Alcohol interview
PIS	Patient Information Sheet
PPI	Patient and Public Involvement
SAE	Serious adverse event
SBNT	Social Behaviour and Network Therapy
SOP	Standard Operating Procedure
SDQ	Strengths and Difficulties Questionnaire
TLFB	Timeline Follow-back
TAU	Treatment as usual
WAI	Working Alliance Inventory
Y-SBNT	Youth -Social Behaviour and Network Therapy

Chief Investigator:

Prof Alex Copello — School of Psychology, University of Birmingham B15 2TT
Email: a.g.copello@bham.ac.uk

Co-applicants:

Mr Charlie Lloyd — Department of Health Sciences, University of York, ARRC Building (Area 4), York YO10 5DD
Email: charlie.lloyd@york.ac.uk

Prof David Torgerson — York Trials Unit, Department of Health Sciences, University of York, ARRC Building (Area 1), York YO10 5DD
Email: david.torgerson@york.ac.uk

Ms Louca-Mai Brady — Independent Research Consultant, Ollerton Road, London N11 2LA.
Email: loucamai.brady@gmail.com

Dr Ed Day — Addictions Department, National Addiction Centre, Addiction Sciences Building, 4 Windsor Walk, Denmark Hill, London SE5 8AF
Email: Edward.day@kcl.ac.uk

Dr Jude Watson — York Trials Unit, Department of Health Sciences, University of York, ARRC Building (Area 1), York YO10 5DD
Email: jude.watson@york.ac.uk

Dr Steve Parrott — Department of Health Sciences, University of York, Seebohm Rowntree Building (Area 4), York YO10 5DD
Email: steve.parrott@york.ac.uk

Dr Paul McArdle — Northgate Hospital, Morpeth, NE61 3BP
Email: Paul.McArdle@ntw.nhs.uk

Dr Paul Toner — Department of Health Sciences, University of York, ARRC Building (Area 4), York YO10 5DD
Email: paul.toner@york.ac.uk

Ms Lorna Templeton — Independent Research Consultant, Devonshire Road, Bristol, BS6 7NQ
Email: ltempleton72@googlemail.com

Dr Kim Cocks — York Trials Unit, Department of Health Sciences, University of York, ARRC Building (Area 2), York YO10 5DD
Email: kim.cocks@york.ac.uk

Research Team Roles

Project lead		
Professor Alex Copello	School of Psychology, University of Birmingham B15 2TT	Email: a.g.copello@bham.ac.uk
Trial Co-ordinator		
Dr Donna Back	School of Psychology, University of Birmingham, Frankland Building Edgbaston, Birmingham B15 8TT	Tel. +44 121 414 2871 Email: d.b.back@bham.ac.uk / donna.back@nhs.net
Clinical expertise		
Dr Ed Day	Addictions Department, National Addiction Centre, Addiction Sciences Building, 4 Windsor Walk, Denmark Hill, London SE5 8AF	Email: Edward.day@kcl.ac.uk
Dr Sangeeta Ambegaokar	Birmingham Children's Hospital, Birmingham	Email: Sangeeta.ambegaokar@bch.nhs.uk
Dr Paul McArdle,	Northgate Hospital NHS Foundation Trust	Email: Paul.mcardle@ntw.nhs.uk
Professor Eilish Gilvarry	Newcastle and North Tyneside Drug and Alcohol Services, Newcastle	Email: Eilish.gilvarry@ntw.nhs.uk
Qualitative Researchers		
Dr Paul Toner	Department of Health Sciences, University of York, ARRC Building (Area 4), York YO10 5DD	Email: paul.toner@york.ac.uk
Dr Donna Back	School of Psychology, University of Birmingham, Frankland Building Edgbaston, Birmingham B15 8TT	Email: d.b.back@bham.ac.uk / donna.back@nhs.net
Implementation of Patient and Public Involvement		
Ms Louca-Mai Brady	Independent Research Consultant, Ollerton Road, London N11 2LA.	Email: loucamai.brady@gmail.com
Ms Lorna Templeton	Independent Research Consultant, Devonshire Road, Bristol, BS6 7NQ	Email: ltempleton72@googlemail.com
Health Economist		
Dr Steve Parrott	Department of Health Sciences, University of York, Seebohm Rowntree Building (Area 4), York YO10 5DD	Email: steve.parrott@york.ac.uk

Statistician		
Dr Kim Cocks	York Trials Unit, Department of Health Sciences, University of York, ARRC Building, York YO10 5DD	Email: kim.cocks@york.ac.uk
Trial methodology		
Professor David Torgerson	York Trials Unit, Department of Health Sciences, University of York, ARRC Building, York YO10 5DD	Email: david.torgerson@york.ac.uk
Charlie Lloyd	Department of Health Sciences, University of York, ARRC Building, York YO10 5DD	Email: charlie.lloyd@york.ac.uk
Dr Jude Watson	York Trials Unit, Department of Health Sciences, University of York, ARRC Building, York YO10 5DD	Email: jude.watson@york.ac.uk
Data Managers		
Val Wadsworth	York Trials Unit, Department of Health Sciences, University of York, ARRC Building, York YO10 5DD	Email: val.wadsworth@york.ac.uk
Ben Cross	York Trials Unit, Department of Health Sciences, University of York, ARRC Building, York YO10 5DD	Email: ben.cross@york.ac.uk
Data Entry		
TBC	York Trials Unit, Department of Health Sciences, University of York, ARRC Building, York YO10 5DD	

1. Background and rationale

Early onset of drug use, including alcohol, in children and young people has been associated with later problematic use.[5,6] Early onset and early hazardous use have also been associated with a range of other problems including risky sexual behaviour, injury, antisocial behaviour, violence and changes in brain development.[7,8,9] Furthermore, when investigating the impact of substance use on the family, research has shown that substance use among young people can adversely affect relationships with parents, carers and other family members.[10] In addition, family involvement in interventions has been shown to influence the course of the problem in a positive way.[11]

The two most commonly consumed drugs by young people, accounting for 90 per cent of treatment admissions for young people are cannabis and alcohol.[12] Statistics on drinking and drug use among young people are divided between those drawn from surveys of school age and those drawn from surveys of adult populations, including young adults. Among school-age children, while proportions of those drinking at all have dropped slightly since 1988, the average units consumed increased markedly between 1990 and 2006 and this has since stabilised at this higher level.[13,14] Contrary to popular perceptions, average alcohol consumption among young adults (aged 16 to 24) has fallen since a peak in 2000-2002. Nonetheless, 15 to 16 year olds in the UK have one of the highest rates of underage drinking and drunkenness in Western Europe.[15] Cannabis use among school-age children has also shown a decline since reaching a peak in 2000-2002[14] and a longer decline among young adults since 1998.[16] However, again, the UK is among the ten European countries with the highest proportion of students reporting smoking cannabis within the past 30 days.[15]

Research has highlighted the pivotal role that families play as not only a risk for, but also a protection against, substance-related problems.[11] As a consequence a range of preventive and treatment approaches have focused on the family and in the UK, there has been a strong focus on preventive programmes. A systematic review by Foxcroft and colleagues[17] identified the Strengthening Families Programme (SFP)[18], developed in the USA, as the most promising, with positive outcomes in both the short and the long term. Emerging findings from the application of this model to the UK context have also been promising.[19]

Evaluation evidence in the treatment field predominately relates to family-based interventions, with the four most common being multisystemic therapy, integrated family and cognitive behavioural therapy, multidimensional family therapy and brief strategic family therapy.[20] Reviews of evaluation studies have shown these approaches to be effective in reducing drinking and drug use among young people.[21,20, 22] However, problems remain with regards to engagement of family (however defined), treatment decay and translating research into practice:

Firstly, with regard to family engagement, services frequently have problems engaging individual family members.[23] Furthermore, the definition of 'family' is contested and carries implications for the delivery of family interventions.[24] Young people with substance use problems frequently come from disrupted families and may be looked

after by single parents, grandparents, other relations or the state.[6,25] Traditional, systemic family approaches may be difficult to deliver in such situations.

Secondly, researchers have pointed to the particularly rapid decay in treatment effect for adolescents' drug and alcohol problems.[20,21] Thirdly, in terms of translating research into practice, the intensive training required[22] and the lengthy time required to deliver systemic family interventions can discourage practitioners from implementing them. National Treatment Agency statistics suggest that only two per cent of interventions with the under-18s consisted of 'psychosocial and family work' and six per cent 'psychosocial, family work and harm reduction'.[12] The large majority of young people with substance misuse problems receive psychosocial interventions focused on the individual user that do not engage family members. Likewise, a recent survey conducted in the UK with services for adult family members showed that even those family interventions recommended by NICE[26] such as Behavioural Couples Therapy[27] are rarely implemented in services.[28]

Despite the growing body of research identifying family interventions to be effective in treating young people's substance use problems, take-up of family based approaches, at least in the UK, has been low. A key factor appears to be the resource-intensive nature of many family interventions, making them difficult to implement and deliver in many service settings, especially in the context of substantial cuts to drug and alcohol services for young people.[1] Another potential barrier may be the cultural adaptation of approaches developed in the USA to a UK setting. There is growing awareness of the need to adapt evidence-based treatments to different cultural groups and settings in order to ensure successful implementation.[2,3,4]

Social Behaviour and Network Therapy (SBNT) is an intervention developed in the UK shown to be effective with harmful drinkers[29] and recommended in recent NICE guidance.[22] Utilising cognitive and behavioural strategies SBNT helps clients build family and social networks supportive of change. A key strength of the approach is the primary focus on addressing drug and alcohol problems by engaging with a network of positive support for lifestyle change. SBNT has additional advantages to help sustain engagement with vulnerable young people, who may be disconnected from their families, by broadening the reach of the intervention beyond the traditional family to include supportive peers. Core strategies include motivational techniques, improving communication and coping mechanisms, and crucially given the nature of substance misuse, developing a network-based relapse management plan. The therapeutic approach also has scope to address client-focussed elective areas, for example, educational requirements.[30]

Involving those who are the focus of research can have a positive impact on what is researched, how research is conducted and the impact of research findings.[31] As well as being located within the wider traditions of patient and public involvement in research (PPI), the involvement of children and young people in research is also located within the context of children's participation and rights and in particular the UN Convention on the Rights of the Child.[32] Article 12 of the UNCRC states that all children have a right to have a say in decisions that affect their lives and for their views to be given due weight in

accordance with their age and maturity. In recent years there has been a theoretical and methodological shift amongst social researchers away from traditional approaches which saw children and young people mainly as objects of enquiry, and towards a view that they are social actors, with their own unique views and insight into their own reality.[33,34] There is also increasing acknowledgement of their competence to contribute such insights and the power of the 'child voice' in research.[35,36,37,38,39]

The focus on children's rights has also, been reflected in increasing interest in children and young people's involvement in research (eg Kirby[40]; NCB[41]; Powell and Smith[37]) both as participants and through their active involvement in the planning and process of research.[39,42] Although there is less of an evidence base in relation to children and young people's involvement in research practice compared to adults,[43] the case for their involvement has been explored in a number of publications (e.g. Alderson[35]; Kirby[40]; Kellett[44]; Shaw et al[45]). We therefore feel that young people's collaboration with and involvement in this project will ensure that the research addresses the concerns and issues faced by young people with substance misuse problems, and also be an important addition to the wider evidence bases on PPI and young people's involvement in research.

Driven by the belief that SBNT can be successfully adapted to the youth context and will have great potential as a clinically and cost effective intervention which can be readily and widely implemented in services for young people, in an earlier phase of work this research team has adapted the current SBNT approach to produce a purpose-designed therapy manual. This was achieved by through consultation with young people with experience of services, family members of young people with experience of services and professionals working in young people services as part of Patient and Public Involvement work as well as separate interviews and focus groups.

1.1. The research question

This study aims to demonstrate the feasibility of recruiting young people to a specifically developed family and network based intervention [Adapted youth social network intervention (Y-SBNT)]. In addition, the feasibility of training staff from existing young people addiction services to deliver this intervention will be explored and treatment retention will be assessed. Qualitative interviews will elicit the participants' views on the acceptability of the intervention and their experiences of both it and the study process.

1.2. The treatments under investigation

***Study intervention*:** Adapted youth social network intervention (Y-SBNT). The Y-SBNT will be delivered according to the developed purpose-designed therapy manual. Participants randomised to Y-SBNT will be offered six, 50 minute SBNT sessions for over a maximum period of 12 weeks. Where consent is obtained, sessions will audio-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.[46]

Using the identification of the social network of the young person conducted in the first session as a platform, subsequent core strategies of the adapted Y-SBNT approach include motivational techniques, improving communication and coping mechanisms, and crucially given the nature of substance misuse, developing a network-based relapse management plan. Participants will be given the opportunity to invite members of their network to the treatment sessions. The therapeutic approach also has scope to address client-focussed elective areas, for example, educational requirements.[30] The study manual combines the most effective components of the SBNT intervention used in earlier studies with adults with substance use problems as well as those identified as important through young people, families and staff consultation.

Control intervention: Treatment as usual (TAU). Young people in this arm will continue to receive usual care delivered by the two services. The elements will be monitored and carefully documented as part of the feasibility study. All contacts will be recorded as well as session content. TAU generally focuses on engagement, description of substance use, current issues that the young person brings to sessions and which seem relevant to the substance use and practical matters such as housing or school exclusion. It generally does not involve analysis of co-morbidity, discussion with family or multiagency work.

2. Research Objectives and Design

2.1. Research Objectives

2.1.1. Primary objective

To demonstrate the feasibility of recruiting young people to a family and network based intervention (Y-SBNT) across two service sites.

2.1.1. Secondary objectives

- To test the feasibility of training staff from existing young people addiction services to deliver the family and social network intervention.
- To evaluate the level of treatment retention amongst participants randomised to the family and social intervention.
- To explore through qualitative interviews the participants' views, acceptability and experiences of the intervention and the study process.
- To explore through qualitative interviews the views, acceptability and experiences of those attending treatment sessions as members of the young person's network.
- To establish treatment effectiveness through 3 and 12 month outcome quantitative data
- To explore cost effectiveness in preparation for a large definitive randomised controlled trial
- To explore and develop models of patient and public involvement which support the involvement of young people in a study of this nature.

3. Study design

Pragmatic, randomised controlled, open feasibility trial delivered in two Young People services.

3.1. Outcomes

The main objective of this feasibility study are to evaluate the feasibility of recruiting young people to a family and network based intervention (Y-SBNT) across two service sites, the acceptability of the intervention to the participants, and elements and processes of the design. Using the opportunity available to compare the effectiveness of the two treatments and advising whether this could be taken forward into a large-scale study, the stated measures cover all aspects.

All data for the patient outcome measures will be collected by research fellows during face-to-face meetings.

3.1.1. Primary outcome

In conjunction with the qualitative aspect of the study, the feasibility of this current study and the potential of a future large-scale study designs will be measured by:

- Recruitment rates: Quantitative assessment of the acceptability of the research will be assessed by numbers referred, number eligible and those agreeing to participate.
- Retention in treatment: Retention in treatment will be evaluated by number of sessions attended as a measure of acceptability of the interventions to participants.
- Follow up completion rates: Quantitative assessment of the number of follow-up interviews completed.

3.1.2. Secondary outcomes

3.1.2.1. Qualitative interviews

The acceptability of the Y-SBNT intervention to the young people and the wider context of the impact of the intervention will be explored by undertaking semi-structured qualitative interviews conducted at three and 12 months post-randomisation. In addition, the acceptability of the intervention to those attending as network members will be explored through similarly semi-structured interviews at three months post-randomisation.

3.1.2.2. Emotional well-being

Emotional well-being will be measured at baseline, three and 12 months post-randomisation using the Strengths and Difficulties Questionnaire (SDQ)[47] has five separate sub-scales for different aspects of problems or behaviours: emotional problems, conduct/behaviour problems, inattention/hyperactivity, relationships with peers, and pro-social behaviour. The first four scales can be added together to produce a score for total difficulties. The SDQ has been used extensively and has demonstrated high levels of reliability and validity.[48,49]

3.1.2.3. Social Network Support:

Given the emphasis on family and peer support of the intervention, social network support will be measured at baseline, three and 12 months post-randomisation using the Important People Drug and Alcohol interview (IPDA) in order to understand the influence of social support on treatment for substance misuse. Researchers have described 4 sub-types of support: General structural support refers to embeddedness in a social network. e.g. number of close friends; Abstinence-specific structural support is the prevalence of nondrug or alcohol users relative to drug or alcohol users in the social network; General functional support refers to assistance from others that does not specifically address drug or alcohol use (e.g. giving advice); Abstinence-specific functional support consists of behaviours that focus on abstinence or substance use more directly, such as encouraging someone to remain in treatment or (as a negative example) offering alcohol or drugs. These four areas will be covered using the IPDA.

3.1.2.4. Family Environment:

Family environment will be measured at baseline, three and 12 months post-randomisation using the 27-item Relationship dimension of the Family Environment Scale[50] consisting of Cohesion, Expressiveness, and Conflict subscales (9 items each). It is designed to measure the atmosphere in the family household and will be used where appropriate to the circumstances of the participant. These subscales measure support, expression of opinions, and angry conflict within a family. This 27-item measure has been used by some of the applicants in previous studies and yields scores for family cohesion, free expression of emotion in the family and absence of open conflict.

3.1.2.5. Working Alliance Inventory:

Working Alliance Inventory[51] will be administered at end of treatment sessions one and three 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. The young people will be provided with envelopes to seal their completed WAI in.

3.1.2.6. Health Related Quality of Life (HRQoL):

HRQoL will be assessed at baseline, three and 12 months post-randomisation using the European Quality of Life - 5 Dimensions-5 levels (EQ-5D-5L). EQ-5D is a standardised measure of health status developed by the EuroQol Group in order to provide a simple, generic measure of health for clinical and economic appraisal, where health is characterised on five dimensions (mobility, self-care, ability to undertake usual activities, pain, anxiety / depression).[52]

3.1.2.7. Other:

School attendance and engagement; self-reported crime and health care and social services contact will be measured at baseline and 12 months post-randomisation.

3.1.2.8. Intervention effectiveness

This outcome measure 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 (baseline, 3 and twelve months post-randomisation).

3.1.2.9. Young peoples' involvement

This study will allow us to explore ways in which young people with experience of using services can be involved in a study of this nature, informing patient and public involvement (PPI) in a larger trial that may take place. Learning from the study will also contribute to the wider emerging evidence base on PPI, and hopefully inform other studies and involvement activity with young people whose voices are less frequently heard, or who may be excluded by traditional models of patient and public involvement.

3.2. Summary of treatments

Participants will be randomised to either Y-SBNT or TAU.

Y-SBNT: Y-SBNT is an adaptation of SBNT developed during an earlier phase of work, which comprised of a systematic review of the current evidence-based literature, PPI involving service users and parents, and consultation with therapists and service managers. The intervention will be delivered by a therapist trained to do so. The developed therapy comprises of social network identification, motivational techniques, improving communication and coping mechanisms, and crucially given the nature of substance misuse, developing a network-based relapse management plan. The therapeutic approach also has scope to address client-focussed elective areas, for example, educational requirements. An initial appointment will be followed by five further sessions in a maximum of 12 weeks (aiming for one per week where possible).

TAU: Those participants randomised to receive TAU will continue to receive their usual care delivered by the two services. Treatment as usual generally focuses on engagement, description of substance use, current issues that the young person brings to sessions and which seem relevant to the substance use and practical matters such as housing or school exclusion. It generally does not involve analysis of co-morbidity, discussion with family or multiagency work. Participants allocated to TAU will be seen by a therapist not trained in Y-SBNT.

3.3. Study Scheme Diagram

A flow diagram is detailed in Appendix 1

3.4. Frequency and duration of follow-up

Data will be collected face-to-face at baseline, at each treatment session and three and 12 months post randomisation. For those participants randomised in the last two months of the recruitment period, final follow-up may take place within a 10 to 12 month period.

4. Participant selection

4.1. Source

New referrals to Young People services in two UK regions (the West Midlands – Birmingham; and North East - Newcastle) will be approached to take part.

4.2. Number of centres

This feasibility study will be conducted in two centres:

Birmingham: the project will work with a tier 3 service in Birmingham providing information, advice, treatment and support for issues related to the use of drugs, alcohol and other substances for people less than 18 years of age. The service consists of a multidisciplinary team offering individual and group services to young people with substance misuse problems and complex needs and delivers both assessment and treatment.

Newcastle: The Young People's Drug & Alcohol Service in Newcastle upon Tyne is a specialist service that links with a number of Tier 2 generic youth services and with other primary care services such as GPs and school nurses. There are workers from various backgrounds such as social worker, third sector, primary care and offender management, who have much experience in addictions and youth development. This service is for under 18s, with a mean age of 15/16.

4.3. Eligibility criteria

4.3.1. Inclusion criteria

Patients will be considered eligible if all the following apply:

- Young people aged 12 to 18: The older age range cut-off is the age range included within young people's services.
- Young people with drug and/or alcohol problems newly referred and accepted for treatment by the two agencies during the period of recruitment.
- Willing to provide written informed consent.
- Able to provide written informed consent.

4.3.2. Exclusion criteria

Patients will be considered ineligible if one or more of the following apply:

- Concurrent severe mental illness that precludes them from active participation.
- Severe physical illness that precludes them from active participation.
- Unable or unwilling to give written informed consent.

4.4. Expected number of eligible participants

Recent figures showed that the Birmingham service currently receives approximately 45 new referrals per month, and carries a caseload of over 200 clients. In the last year approximately 280 young people accessed the Newcastle service. Drawing on National Treatment Agency statistics, it is expected that 90 per cent of the sample will fall into the target age range.[12]

5. Participant recruitment

5.1. Method

All young people newly referred to the two treatment services during the recruitment period will be considered potential participants.

5.2. Eligibility assessment

As part of the normal course of the referral process within routine services, all referred young people will initially take part in an assessment session either at one of the two treatment agencies, their own home or at their usual place of treatment. Those found to be appropriately referred and meeting the inclusion criteria will be deemed potentially eligible for the trial.

Eligible patients who do not wish to take part (i.e. unwilling to give consent) and those found to be ineligible will go on to receive usual care from the service.

Where offered, reasons for non-participation will be collected to inform future studies.

5.3. Information regarding study

Eligible young people and their parents/person with parental responsibility will be given a leaflet and PIS at assessment by the assessment staff. If after reading the materials they are interested, a meeting will be arranged with the researcher who will fully explain the study and give the young person the opportunity to ask questions. If interested, the researcher will invite the young person to participate. Written informed consent to inclusion in the trial will then be sought. Potential participants will be assured of confidentiality, what to expect after the study ceases and given contact details in case of complaint or need for further information. They will be informed that participation is not compulsory and that they can withdraw at any time without affecting their care. The PIS will meet the requirements of the local ethics committees and will clearly present the possible positives and negatives associated with taking part in the trial.

5.4. Consent procedure

For those that agree to participate, the researcher will:

(a) Obtain written consent from them to participate in the trial;

(b) Conduct a baseline assessment;

(c) Telephone the York Trials Unit Freephone randomisation service or use the online system to randomise the patient (hereafter referred to as the participant);

(d) Provide the participant with an appointment to see the therapist or clinician appropriate to their allocation.

The research process must ensure that informed decisions are made by young people and their parents/person with parental responsibility whether or not to take part in the trial and draws on the recent experience York Trials Unit has of seeking consent with young people.[53] In addition, the research team consists of people with vast experience of obtaining consent in such circumstances and age groups. However, competence is not related to age in a simple way but depends on a child's ability to understand, weigh the options and reach an informed decision.[54] Nonetheless, young people aged between 16 and 18 are presumed to be competent to give consent.

Since the research in question is integral to a service that the child is already involved in, and the parents or person with parental responsibility will have already given consent for the young person to attend the service, then in line with the National Children's Bureau (NCB) guidelines[55] it is not felt necessary to additionally obtain consent from the parents/person with parental responsibility for the child to participate in the research. Conversely, there may be situations where, given the nature of the service, seeking parental consent would potentially breach a child's right to confidentiality if they are attending the service without their parent's knowledge. NCB guidelines state that in such situations parental/person with parental responsibility consent may be waived.[55]

For the purpose of this study, the following will apply:

- If consent is not forthcoming from a parent/person with parental responsibility, but the young person (aged 12 to 15) does consent they will still enter the trial.
- For those aged 16 and above, consent will be only be sought from the young person.
- If consent is given by a parent/person with parental responsibility but the young person does not consent, the young person will not enter the trial.

However, bearing in mind the possibly 'chaotic' and complex lives many of these young people can be experiencing, discussion about consent in all cases will be handled in a sensitive manner. It is expected, on the basis of previous experience, that young people and their parents/ person with parental responsibility decisions will usually be concordant.

5.5. Definition for the End of Trial

End of study will be defined as the date at which the last participant has completed the study processes.

6. Trial Interventions

Participants will be randomised to receive treatment from a therapist trained in either:

1) **Y-SBNT:** an initial appointment with one of the clinicians trained in the intervention, followed by five further sessions in a maximum of 12 weeks.

   Y-SBNT is an adaptation of SBNT developed during an earlier phase of work, which comprised of a systematic review of the current evidence-based literature, PPI involving service users and parents, and consultation with therapists and service managers. The intervention will be delivered by a therapist trained to do so. The developed therapy comprises of social network identification, motivational techniques, improving communication and coping mechanisms, and crucially given the nature of substance misuse, developing a network-based relapse management plan. The therapeutic approach also has scope to address client-focussed elective areas, for example, educational requirements. An initial appointment will be followed by five further sessions in a maximum of 12 weeks (aiming for one per week where possible).

2) **TAU:** an initial appointment with one of the therapists in the team not trained in the experimental intervention in order to receive treatment as usual with further appointments as required.

   Those participants randomised to receive TAU will continue to receive their usual care delivered by the two services. Treatment as usual generally focuses on engagement, description of substance use, current issues that the young person brings to sessions and which seem relevant to the substance use and practical matters such as housing or school exclusion. It generally does not involve analysis of co-morbidity, discussion with family or multiagency work. Participants allocated to TAU will be seen by a therapist not trained in Y-SBNT.

6.1. Concurrent treatments

Additional treatments identified as required will be available to both groups as and when necessary (e.g. treatment for Attention deficit hyperactivity disorder).

6.2. Arrangements for continuation of treatment after study treatment

Treatment will be provided as required and according to need after the study is completed.

7. Randomisation

7.1. Treatment allocation

Patients who fulfil the eligibility criteria and who have provided written consent to take part in the study will be eligible for randomisation. Randomisation, stratified by centre will follow the baseline assessment in order to avoid any possible bias that may emerge from the assessor's knowledge of treatment allocation prior to completing the measurement. Patients will be randomised by remote computer to either Y-SBNT or TAU. This will be conducted using the secure remote randomisation service at York Trials Unit. This will be available as a web-based system (24 hours)

and a telephone system (09:00 to 17:00, Monday to Friday, excluding Bank Holidays).

The following information will be collected at randomisation from the researcher:

1) Centre
2) Patient details including full name, gender, date of birth, full postal address, contact telephone number(s) and email address.
3) Details of up to 3 tracing contacts.
4) Confirmation that patient meets all the eligibility criteria.
5) Confirmation that written informed consent has been obtained.
6) Confirmation that all baseline data has been collected.

8. Blinding

8.1. Level of blinding

By the nature of the interventions used within this study, blinding of the participants, therapists and the researchers is not possible. However, those involved in the analysis of the data will be blind to treatment allocation.

8.2. Measures to avoid/ minimising bias

Potential sources of bias will be minimised by having minimal exclusion criteria, randomisation, standard training of clinicians guided by a treatment manual, measures of treatment fidelity and adherence to the manual, validated outcome measures and an intention to treat analysis.

9. Data collection

All information collected during the course of the trial will be kept strictly confidential. Information will be held securely on paper and electronically at York Trials Unit. All trial data will be identified using a unique trial identification number. Analytical datasets will not contain any identifiable information. Data will be archived for a period of 5 years following the end of the study.

9.1. Baseline data

At baseline, information will be collected from the patient regarding TLFB; SDQ; IPDA; FES (relationship dimension); EQ-5D-5L; school attendance; self-reported crime; health care use; social services contact and demographics.

9.2. Follow up interviews

These will be conducted at 3 months and 12 months post-randomisation for both treatment groups. For those participants randomised in the last two months of the recruitment period, final follow-up may take place within a 10 to 12 month period. Interviews will be undertaken by the research fellows, covering the main and secondary outcome measures using TLFB; SDQ; IPDA; FES (relationship dimension); EQ-5D-5L. Data on school attendance, self-reported crime, health care use and social services contact will be collected at 12 months. In addition, interviews with those allocated to Y-SBNT will be used to explore the acceptability of the intervention to the young people and the wider context of the impact of the intervention. We will use semi-structured interviews building on the work conducted as part of

UKATT[56,57,58,59] and previous studies of SBNT with drug users (e.g. Copello et al.[46]) in order to explore perceptions of the effectiveness and utility of the new intervention. The interviewer will seek to establish satisfaction with the treatment received and perceived processes of change, including helpful aspects of the therapeutic process. We will aim to understand which elements of SBNT were beneficial and acceptable in the care of young people. This will complement the analysis of the quantitative data and identify ways in which SBNT may need to be modified in preparation for a definitive trial.

In addition, interviews will be conducted with members of the young person's network who attended treatment sessions. Therapists will be requested to ask attending network members as to whether they would be interested in being interviewed. The researchers will subsequently follow up those willing to arrange an interview appointment. These interviews will be conducted either face-to-face or by telephone. Ideally, we would look to interview five network members (one per young person) from each participating service, giving us a total of 10 interviews.

9.3. Treatment sessions

For each therapy session, a short form will be completed by therapists delivering both experimental and control interventions. They will record the time of the event, the length of the event, who attended the session as network members, the therapist involved, the location and any materials used. These data will be used to compare delivery costs.

At the end of treatment sessions one and three, both participant and therapist will be asked to complete the 12-item (Short version) Working Alliance Inventory (WAI)[51] in order to assess the participant-therapist relationship.

Each treatment session will be audio recorded. For those allocated to Y-SBNT, these data will be used by the research team to assess staff fidelity and adherence to the intervention protocol. For those allocated to TAU, these data will be used to provide a clearer picture of what TAU consists of. All recordings will be identified by an identification number rather than personal information. Research findings addressing the process of therapy may contain anonymised participant quotations. Should a participant not be willing to have their sessions audio recorded (which can be indicated on the consent form), this will not affect their treatment nor preclude them from participating. These audio recordings will be stored and archived securely at the University of Birmingham.

9.4. Table of data collection schedule

Event	Time period	Data collected
Pre	Day 0	Consent for study; Baseline assessment of; TLFB; SDQ; IPDA; FES (relationship dimension); EQ-5D-5L; school attendance; self-reported crime; health care use; social services contact and demographics. Randomisation: including confirmation of consent; contact details; confirmation of Baseline questionnaire completion

1	1-2 weeks	First appointment: time of event; the length of event; participant attendance; network member attendance (Y-SBNT group only); therapist involved; location; and any materials used, network member willingness to be interviewed (Y-SBNT group only). Audio recording of session. WAI completion at end of session one.
2-6	2-12 weeks	Subsequent appointments: time of event; the length of event; participant attendance; network member attendance (Y-SBNT group only); therapist involved; location; any materials used, network member willingness to be interviewed (Y-SBNT group only). Audio recording of sessions. WAI completion at end of sessions three.
3	Month 3	Three month follow-up assessment; TLFB; SDQ; IPDA; FES (relationship dimension); EQ-5D-5L. Semi-structured qualitative interviews.
4	Months 10 -12	Twelve (final) month follow-up assessment; TLFB; SDQ; IPDA; FES (relationship dimension); EQ-5D-5L; school attendance; self-reported crime; health care use; and social services contact. Semi-structured qualitative interviews.

9.5. Completeness of data

As data collection is being conducted by the therapists proving the treatment and by researchers conducting the baseline and follow up assessments, it is anticipated that missing data will be minimal with the exception of those participants who do not attend appointments or follow up and researchers are not able to locate.

9.6. Data handling and storage

Information with regards to the study participants will be kept confidential and managed in accordance with the Data Protection Act, NHS Caldicott Guardian, Research Governance Framework for Health and Social Care and the Research Ethics Committee (REC) approval.

Personal addresses, postcodes and other contact details of consenting participants will be stored on a secure password protected server located at the University of York, for the purposes of assisting in follow-ups during the study. All paper data collected from participants will be maintained in a safe secure environment at York Trials Unit. Paper records will be identified using identifiers rather than personally identifiable information.

Randomised participants will have their treatment session(s) audio recorded. These data will be used by the research team to assess therapist compliance with the intervention protocol and obtain a clearer picture of the components that are contained within TAU. All recordings will be identified by an identification number rather than personal information. Research findings addressing the process of

therapy may contain anonymised participant quotations. These recordings will be archived in a secure location for a minimum period of 5 years.

Data will be collected through questionnaires designed on paper. Scanned data from the paper forms are stored in a download database where they are checked against the hard copy of the questionnaire. Data is error checked and then validation checks are run against the validate database. Discrepancies identified during validation which require resolution are communicated to the relevant person who is in a position to be able to obtain the information required to rectify the discrepancy.

Qualitative interview participants' confidentiality will be ensured by assigning a unique identification code to electronic sound files and transcripts of individual interviews, known only to the qualitative researcher and appropriate members of the research team. Any personal information required will also be coded with this identification number and kept in a password protected electronic file or separate filing cabinet which will be locked at all times. Any quotes published will be anonymous further protecting participant confidentiality.

All information collected during the course of the trial will be kept strictly confidential. Information will be held securely on paper and electronically at York Trials Unit. All trial data will be identified using a unique trial identification number. Analytical datasets will not contain any identifiable information. Data will be archived for a minimum period of 5 years following the end of the study.

10. Treatment fidelity

All treatment sessions will be audio-recorded for the purpose of supervision, assess staff fidelity and adherence to the intervention protocol. This will be done by rating frequency and quality of behaviour change techniques. We will adapt the fidelity assessment scale developed as part of the UKATT trial[60] for the delivery of SBNT in order to assess a sample of the Y-SBNT recordings. In addition, a sample of the TAU recordings will be assessed to try and identify the components of TAU. It is envisaged that a sample of 10-20% of the recordings across all therapists and both centres from the middle and end of the therapy will be assessed.

11. Therapist and Service Manager interviews

The therapists delivering the experimental intervention in each site will be interviewed during the trial, along with therapists delivering treatment as usual. Interviews with therapists delivering the adapted Y-SBNT will also be used to explore a number of themes, including the training and implementation process, how the intervention differs from usual treatment and how easy it has been to engage young people and their social networks. These interviews will seek to identify potential problems with the delivery of the intervention and the trial process, with a view to ironing out any difficulties in a full trial. Interviews with service managers will cover similar ground, exploring issues of implementation but also broader questions about the popularity of the intervention among service staff. written informed consent will be gained from therapists and service managers prior to their qualitative interview.

12. Statistical considerations

12.1. Sample size

As this is feasibility study, the main purpose is to assess the acceptability and feasibility and to obtain information that would inform the design of a larger full scale trial. In addition, there is debate as to the desirability of undertaking a formal sample size calculation for a feasibility or pilot study. However, for this study we have undertaken a sample size calculation based upon the proposed sample size of the main study and we propose to recruit at least 60 participants to our study.

For the main trial we would want to detect about 0.3 of a standard deviation between the two groups. If such a difference did exist, then should this feasibility study include data on 54 participants then we could generate a 1-sided 80% confidence interval (for the 3 month follow-up data), which would exclude a 0.3 effect size difference. Consequently, if we find a non-negative effect size we would consider that this gives us a priori support for developing the main trial. In contrast, should we observe a negative effect size then we would consider, unless there was a clear explanation, that there was poor justification for moving towards a fully powered main trial as it would be unlikely that an effect size of 0.3 or greater would be found in a main trial.

Allowing for 10 % attrition, we will need to recruit 60 participants to the trial, expecting data to be successfully collected on 54.

12.2. Planned recruitment rate

It is expected that recruitment will be at the rate of 10 patients per month. Should recruitment fall below the expected rate, we will address this by meeting with the sites to review progress and discuss any problems and take any necessary action in order to address any issues affecting recruitment.

13. Qualitative research

As well obtaining data relating to the stated outcome measures, the follow-up interviews conducted at three and 12 months post-randomisation will be undertaken by the research fellows to explore the acceptability of the intervention to the young people and the wider context of the impact of the intervention. The interviews will be semi-structured in nature and build on the work conducted as part of UKATT[56,57,58,59] and previous studies of SBNT with drug users (e.g. Copello et al.[46]) in order to explore perceptions of the effectiveness and utility of the new intervention. The research fellows will be trained in qualitative interview techniques and will use interview topic guides in order to standardise procedure across the two sites. The interviewer will seek to establish satisfaction with the treatment received and perceived processes of change, including helpful aspects of the therapeutic process. We will aim to understand which elements of SBNT were beneficial and acceptable in the care of young people. This will complement the analysis of the quantitative data and identify ways in which SBNT may need to be modified in preparation for a definitive trial. Interviewing network members at three months post-randomisation will provide essential information around their thoughts on being involved in such a process including any impact it had on them and their relationship with the young person. In addition, this will provide an opportunity to

explore whether taking part in the treatment was acceptable to them and their perceived influence of their involvement on the young person's substance use.

13.1. Interview format

The interviews will be semi-structured in nature and based around a topic guide. The topic guide will cover areas including satisfaction and acceptability of the intervention, aspects that were helpful or unhelpful from the participant's perspective, the overall experience of the treatment and suggestions for improvement.

13.2. Transcription and analysis of data

In line with our previous work involving qualitative evaluation of SBNT[61], analysis will be based on Grounded theory methods.[62] Interviews will be recorded and transcribed in full. Initial ideas will be identified and organised into higher order themes following group discussions and research group seminars. Some of the emerging findings will be presented to a selection of the original participants in order to check validity of the resulting interpretation.

14. Statistical analysis

14.1. Data management

All data from the trial will be collected using paper-based forms (Baseline booklet, Treatment session forms; WAI forms; Follow-up booklets). Researchers and therapists will be responsible for ensuring the completeness and reliability of the data from their site, and then for conveying records to the York Trials Unit. Data from paper forms will then be entered into a master database for the trial using either optical scanning techniques or entered manually.

14.2. Analysis of clinical data

14.2.1. Primary analysis

The primary clinical outcome measure for the study is based on the TLFB score measured 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. Analysis will be on an intention to treat basis using two sided, 5% significance. Missing data will be treated as failing to achieve reduction. The primary analyses will compare the active experimental condition with treatment as usual, and subjects will be analysed using a generalised linear model with identity link and Gaussian error. The therapists will be included as random effects.

14.2.2. Secondary Analyses

Secondary analyses will be conducted using analogous statistical models.

14.2.3. Analysis of economic and quality of life data

The economic component of the study is designed to assess the feasibility of conducting a cost-effectiveness analysis of a full trial. This will involve piloting a

short questionnaire, analysing responses and calculating QALY changes using EQ-5D-5L. We would not expect to see significant changes between groups due to the small sample size in this pilot.

A simple questionnaire will measure participants' use of health care will be identified retrospectively by means of service use questions. The economic analysis will assess the feasibility of using such a questionnaire in the 12 to 18 population. The questionnaire will ask about primary care, hospital visits and hospital stays. In a full trial resource use data will be multiplied by national average unit costs to calculate per participant costs in the 3 month period before the intervention and the 3 month period after receiving Y-SBNT or TAU.

Quality of life will be measured by EQ-5D-5L at baseline and each follow up time point. The use of EQ-5D-5L enables the estimation of Quality Adjusted Life Years. Measuring health status using QALYs follows the recommendations of NICE[63] and enables the value for money afforded by treatment to be compared to a range of other health care interventions.

A full cost-effectiveness analysis will not be conducted as this is a pilot trial and is not powered to detect significant differences. The economic component of this trial will examine the feasibility of conducting a full incremental cost-effectiveness analysis of Y-SBNT compared to TAU.

14.2.4. Treatment Fidelity Analyses

The experimental Y-SBNT treatment is specified and described in a treatment manual. Therapists are trained in trial procedures and in treatment delivery by attendance at initial workshops followed by regular supervision based on recordings of practice. Once deemed competent to deliver treatment in line with protocols, therapists record all treatment sessions in the study where consent has been obtained and these recordings form the basis of continuing supervision to avoid therapist drift.

Recorded sessions are used separately for the purpose of rating the quantity and quality of the treatments delivered. This rating is based upon an instrument adapted from the UKATT Process Rating Scale and performed by a researcher trained in the method of process rating and blind to the practitioner identity. Correlational analysis of the data derived from rating is performed to detect protocol adherence and discriminability between the treatments.

15. Compliance and withdrawal

15.1. Subject compliance

The issue of compliance has been explored with young people and also through a review of academic reviews of family interventions with young people conducted as part of an earlier phase of work and important strategies were identified to minimise drop out. These strategies included factors related to the therapist style and

orientation, structural factors, the actual therapy orientation and additional factors for example the provision of a quick service response and the use of mobile systems for appointment reminders and communication with young people. The intervention has in addition, been built to be flexible and delivered through outreach in a range of settings e.g. schools, other services, participants homes.

15.2. Loss to follow up

Attrition from follow-up is a major threat to internal validity and longitudinal studies of substance users frequently suffer from low follow-up rates, reflecting the 'chaotic' nature of this group (e.g. Ziek *et al.*[64]). An American study found assessment completion rates of 77 per cent for the experimental condition and 56 per cent for the controls in a study of Multisystemic Treatment for young offenders.[65] The authors state that their participation rates were attenuated by a lack of financial incentive for the families involved and the mobility of the young offenders' families.

This study will draw on aspects of Scott's Engagement, Verification, Maintenance and Confirmation (EVMC) model[66] to track and follow-up participants, including techniques for building rapport with respondents, detailed locator information (including at least three collateral contacts), periodic reminders and (wherever possible) use of the same researcher to carry out interviews at baseline, three months and 12 months (final). It is anticipated that contact problems in this sample of young people will be less severe than those experienced among adult users (many of whom may be homeless). Family members and other contacts are likely to know how the young people can be reached. Problems are more likely to revolve around families moving address and refusal to take part in the study post-treatment. Good rapport at baseline, periodic reminders over the course of the study that involve direct contact with participants (or collaterals) and Love2Shop vouchers to compensate for their time involved in interview completion (at baseline, month 3 and month 12/final) should minimise such problems. All of these approaches could be replicated in a larger trial. Even though it is a younger group of participants in this study, we will also draw from our experience in the UKATT trial where good follow up rates of 93 per cent at 3 months and 83 per cent at 12 months were achieved.[29] We expect to be able to follow-up 90 per cent of the sample at 12 months with the intensive approach outlined here.

15.3. Withdrawal/ dropout of subjects

Participants may withdraw from the study at any time without influencing their future care or treatment. Withdrawal may refer to the following situations:

1) Where a participant wishes to withdraw from the study treatment, but is prepared to continue completing follow-up questionnaires (i.e. no treatment sessions are attended but the TLFB; SDQ; IPDA; FES (relationship dimension); EQ-5D-5L; school attendance; self-reported crime; health care use; social services contact data is still collected). This is classed as 'Withdrawal from treatment'.

2) Where a participant wishes to withdraw from completing any further follow-up interviews after completing their treatment sessions. This is classed as 'Withdrawal from follow-up'.
3) Where a participant wishes to withdraw from both the study treatment AND from completing any further follow-up interviews. This is classed as 'Full withdrawal'.

We will ensure that the researchers are aware of the difference in these situations, and that they are explicit about whether participants wish to withdraw from treatment, follow up, or both.

In either event, York Trials Unit will be informed.

16. Interim analyses
No interim analyses will be conducted.

17. Data Monitoring
The Chief Investigator will ensure that the study is appropriately monitored by ensuring that: all rights of the trial participants are adequately protected; that written informed consent was obtained; the trial data are accurate and complete; and that the conduct of the trial is in compliance with the protocol and its subsequent amendments, with GCP and applicable regulatory requirements.

The study may be monitored and/or audited by the Trust at any time as part of the organisation's commitment to maintaining the highest standards of GCP.

18. Training
One of the main aims of this study is to test the feasibility of training staff from existing young people drug services to deliver the family and social network intervention. Participating staff will be asked to volunteer to take part in delivering the experimental condition. A minimum of two clinicians for the experimental condition is required at each project service site.

Training in the adapted SBNT will follow the format adopted in previous pilot work in this area.[46] The intervention will be manual based, and the treatment manual will be adapted in accordance with the current trial. There will be an initial one day training session to introduce staff to the key-concepts and procedures involved in the intervention, and all staff will be required to pilot the methods with a minimum of one clinical case prior to the commencement of the trial. The trial will only commence once it has been established that the adapted SBNT is being delivered with sufficient fidelity. Once the trial commences, supervision will be provided on a regular on-going basis. In the Newcastle service, the nurse responsible for the management of the team will attend the training and supervise the delivery of the new intervention.

19. Ethical considerations

19.1. Regulatory approvals

The proposed study will be conducted in accordance with the MRC Guidelines on Good Clinical Practice in Clinical Trials. Prior to undertaking the study, approval will be sought from the Local REC and Research and Development department.

19.2. Informed consent

All eligible young people will be provided with a PIS prior to giving consent. The information sheet will outline fully the potential benefits and risks of being involved in the trial. This information sheet will meet all the requirements of the local ethics committees. Maintenance of confidentiality and compliance with the UK Data Protection Acts will be emphasised to all study participants. Participation in the study will be entirely voluntary and written consent will be sought. All data will be treated with the strictest confidence.

Competence is not related to age in a simple way but depends on a child's ability to understand, weigh the options and reach an informed decision.[54] Nonetheless, young people aged between 16 and 18 are presumed to be competent to give consent. Below this age, since the research in question is integral to a service that the child is already involved in, and the parents or person with parental responsibility may already given consent for the young person to attend the service, then in line with the National Children's Bureau (NCB) guidelines[67] it is not felt necessary to additionally obtain consent from the parents/person with parental responsibility for the child to participate in the research. Equally, there may be situations where seeking parental consent would potentially breach a child's right to confidentiality if they are attending a drug and alcohol treatment service without their parent's knowledge. NCB guidelines state that in such situations parental/person with parental responsibility consent may be waived.[55]

19.3. Risks and anticipated benefits for trial participants and society

Risks are considered to be minimal. The research will be undertaken in a sensitive way, maintaining awareness of the vulnerability of many of the young people. Given the available evidence supporting family and social network approaches, it seems highly unlikely that the experimental group will suffer any adverse consequences as a result of not receiving usual treatment. In our experience, young people usually enjoy taking part in research and, if explained properly, this can be a useful experience for them.

In terms of benefits to society, should this new intervention prove clinically and cost effective in a larger, multi-site trial and should it be widely implemented, it would have a significant impact on the effectiveness of young people's drug and alcohol treatment and associated health and social problems, thus reducing the costs to society. The aim is to design and trial a realistic intervention that can be readily delivered even in a climate of cuts for treatment services. The scope for implementation and impact is therefore great.

19.4. Adverse events

There are no anticipated risks in relation to either treatment arm. However, if in the course of the delivery of either treatment, risks of harm to the young person or others are identified, these will be reported to an Independent Data Monitor and also the Trial Steering Committee (TSC). All adverse events (AE) [serious and non-serious] will be reported to the Chief Investigator according to a Standard Operating Procedure (SOP) specific to this study. We are aware that judgements regarding relatedness can be difficult in this type of study, and therefore all serious adverse events (SAE) will be forwarded to the Independent Data Monitor within 48 hours of the CI becoming aware of the event. Any deemed by the team and the Independent Data Monitor as 'related' to study treatment will be reported to the sponsor, ethics committee and TSC. Any non-serious AEs considered as 'related' to study treatment will also be forwarded to the Data Monitor.

19.5. Independent Steering Committee

Due to the low risk nature of this trial, approval has been obtained to set up one independent steering and monitoring committee to undertake the roles traditionally undertaken by the Trial Steering Committee (TSC) and Data Monitoring and Ethics Committee (DMEC). However, as we have done in previous pilot trials, we have also approached and set up an independent person in the field not associated with the project to act as Independent Data Monitor and provide regular independent review of interim safety and efficacy of the data. The TSC comprises of independent members including a Chair who is an expert in the area, a statistician, one other independent person from a relevant discipline/ profession, and input from the user and carer groups. The research team also attend these meetings. The committee will meet at least annually or more often as appropriate.

19.6. Trial Management Group

Regular meetings of a Trial Management Group will take place to oversee the progress of the study and review recruitment. This group will include all co-applicants, collaborators and the research staff. The study will be managed on a day-to-day basis by the Birmingham team. The group will meet bi-monthly early in the project and less often (once every 3 months) as the project develops. The group will provide timely reports on the progress, or completion, termination or discontinuation of the study to the local ethics committees.

19.7. Input from Young People

As part of the significant PPI component of this study, the project team will actively involve a sample of young people with a history of treatment for substance abuse and a sample of parents of young people with substance abuse problems throughout the research process. In phase one young people are being supported to work alongside the research team in order to ensure that the intervention is acceptable and relevant to our target groups, and reflects the views of service users and their families. Later on, in phases two and three they would be involved in the project as it develops, including for example in the delivery of training and/or production of training materials, design of data collection tools, data analysis and

interpretation, reporting and dissemination. Both young people and parents will also be supported to contribute to the trial steering committee.

This study is also piloting PPI with a cohort of young people whose voices are seldom heard in research. The project team had originally planned to recruit a group of young people who would be actively engaged throughout the project on an on-going basis through a London-based 'young advisors' group. However, while we are continuing to pursue this option, we are also exploring more flexible and accessible options to enable more young people to be involved.

20. Financing and insurance

This study is being co-ordinated and conducted by the University of Birmingham and Birmingham and Solihull Mental Health Foundation Trust. The research has been funded by the National Institute of Health Research Health Technology Research Programme.

NHS Indemnity will apply for patients treated within NHS sites. The University of Birmingham and the University of York will provide legal liability cover for their employed staff. Non-negligent harm will not be covered.

21. Reporting and dissemination

The results from this study will be submitted to the funders, peer-reviewed journals and presented at relevant meetings/conferences.

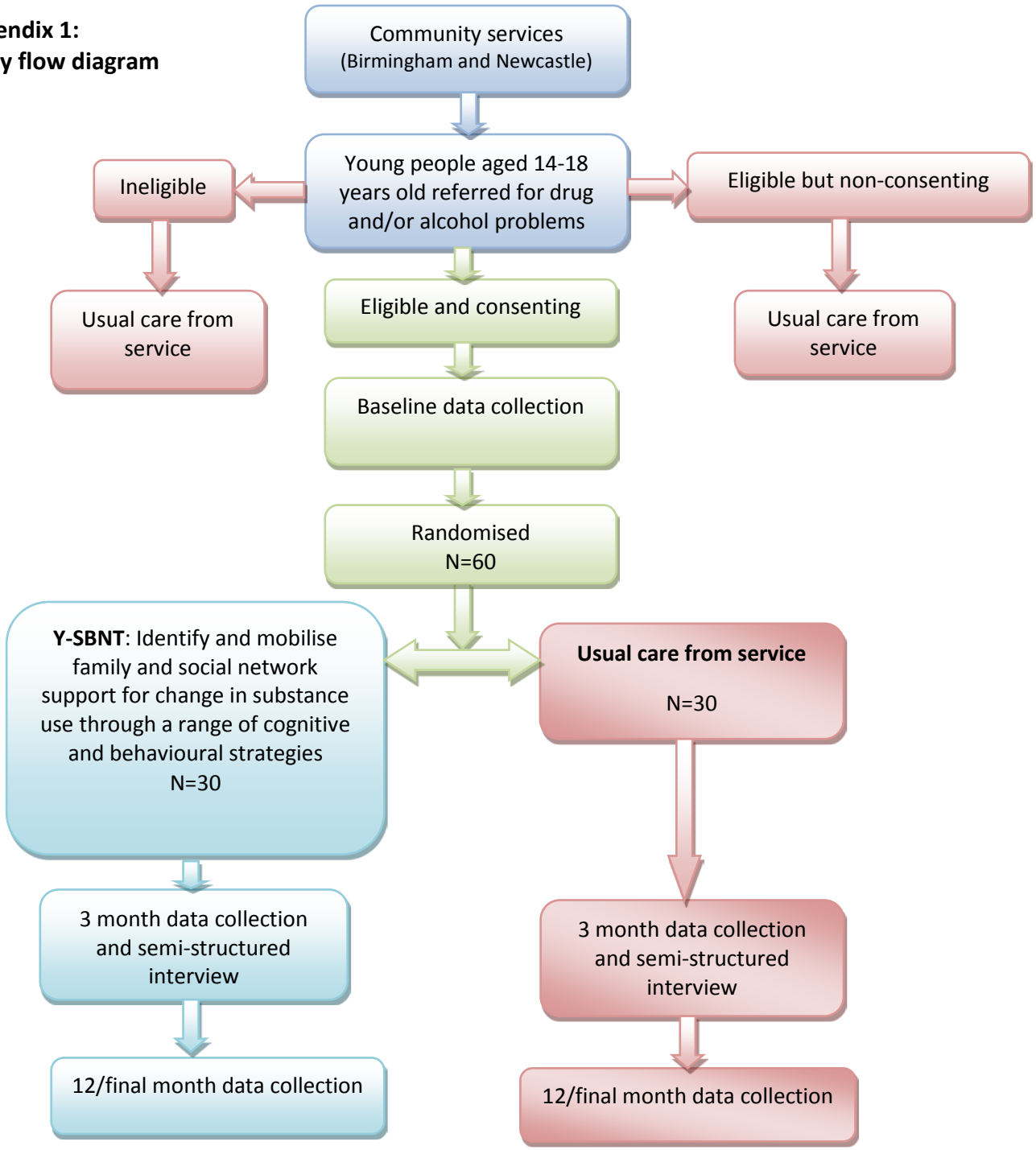
22. Project timetable

Proposed timeline

End Dec 2013	Ethics submission
January 2014	Therapist training completed
01st May 2014	Start recruitment
31st October 2014	End recruitment
15th December 2014	Therapists/ service managers interviews completed
15th February 2015	End 3 month data collection (incl. time to complete)
31st October 2015	End final data collection (incl. time to complete)
December 2014 to November 2015	Data scanning, entry, cleaning and validation checks
Sept 2015 to November 2015	Data analysis and report writing
30th November 2015	Report to NIHR HTA submitted

23. Appendices

Appendix 1:
Study flow diagram



24. References

1. Drugscope. *Charities warn of 'devastating impact' of cuts to young people's drug and alcohol services*. 2011; 20 July.
2. Bernal G, Jimenez-Chafey M, Domenech Rodriquez MM. Cultural adaptation of treatments: a resource for considering culture in evidence-based practice. Professional Psychology; Research and Practice. 2009: 40 (4); 361-368.
3. Cortese CA (1999). Drug services and cultural adaptation. Drugs: education, prevention and policy. 1999: 6 (3); 361-366
4. Lau, A.S. Making the case for selective and directed cultural adaptations of evidence-based treatments: examples from parent training. Clin Psychol Sci Prac. 2006: 13; 295-310.
5. Hingson R, Heeren T, Winter M. Age of alcohol-dependence onset: associations with severity of dependence and seeking treatment. Pediatrics. 2006: 118; e755-e763.
6. Lloyd C. Risk Factors for Problem Drug Use: identifying vulnerable groups. Drugs: education, prevention and policy. 1998: 5; 217-232.
7. Jones L, James M, Jefferson T et al. A Review of the Effectiveness and Cost-Effectiveness of Interventions Delivery in Primary and Secondary Schools to Prevent and/or Reduce Alcohol Use by Young People under 18 Years Old: Final Report. London: National Institute for Health and Clinical Excellence; 2007
8. Mistral W, and Templeton L. The role of schools in reducing alcohol-related harm among young people. In Aggleton, P., Dennison, C. and Warwick, I., (eds) Promoting Health and Wellbeing through Schools. Abingdon: Routledge; 2010. pp. 69-83.
9. Brown S, McGue M, Maggs J, et al. A developmental perspective on alcohol and youths 16 to 20 years of age. Pediatrics. 2008: 121 (Suppl. 4); S290–S310.
10. Copello AG, Velleman RD and Templeton LJ. Family interventions in the treatment of alcohol and drug problems. Drug and Alcohol Review. 2005: 24; 369–385.
11. Velleman R, Templeton L and Copello A. The role of the family in preventing and intervening with substance use and misuse: a comprehensive review of family interventions with a focus on young people. Drug and Alcohol Review. 2005: 24(2); 93-109.
12. National Treatment Agency. Substance Misuse Among Young People 2010-2011. London: National Treatment Agency; 2011.
13. Smith L and Foxcroft D. Drinking in the UK. An exploration of trends. York: Joseph Rowntree Foundation; 2009
14. Fuller E. Smoking, drinking and drug use among young people in England in 2010. London: National Statistics; 2011
15. Hibell B, Guttormsson U, Ahlström S, et al. The 2007 ESPAD Report: Substance Use Among Students in 35 European Countries. Stockholm: The Swedish Council for Information on Alcohol and Other Drugs; 2009
16. Smith K. and Flatley J. Drug Misuse Declared: Findings from the 2010/11 British Crime Survey. London: Home Office; 2011.

17. Foxcroft D, Ireland D, Lister-Sharp D, Lowe G and Breen R. Longer-term primary prevention for alcohol misuse in young people: A systematic review. Addiction. 2003: 98(4); 397–411.
18. Spoth RL, Redmond C, Trudeau L and Shin C. Longitudinal substance initiation outcomes for a universal preventive intervention combining family and school programs. Psychology of Addictive Behaviours. 2001: 16; 129–134.
19. Coombes L, Allen D, Marsh M and Foxcroft D. The Strengthening Families Programme (SFP) 10–14 and substance misuse in Barnsley: The perspectives of facilitators and families. Child Abuse Review. 2009: 18; 41–59
20. Tripodi SJ, Bender K, Litschge C and Vaughn, MG. Interventions for reducing adolescent alcohol abuse. A meta-analytic review. Arch. Pediatr. Adolesc. Med. 2010: 164 (1); 85-91.
21. Perepletchikova F, Krystal JH and Kaufman J. Practitioner review: adolescent alcohol use disorders: assessment and treatment issues. Child Psychology and Psychiatry. 2008: 49 (11); 1131-1154.
22. National Institute for Health and Care Excellence. Alcohol-use disorders. Diagnosis, assessment and management of harmful drinking and alcohol dependence. National Clinical Practice Guideline 115. London: The British Psychological Society and The Royal College of Psychiatrists. 2011
23. Hogue A and Liddle HA. Family-based treatment for adolescent substance abuse: controlled trials and new horizons in services research. Journal of Family Therapy. 2009: 31; 126-154.
24. Asen E. Outcome research in family therapy. Advances in Psychiatric Treatment. 2002: 8; 230-238.
25. Boys A, Farrell M, Taylor C, et al. Psychiatric morbidity and substance use in young people aged 13–15 years: results from the Child and Adolescent Survey of Mental Health. British Journal Psychiatry. 2003: 182; 509-517.
26. National Institute for Health and Care Excellence. Drug Misuse: Psychosocial Interventions. London: National Institute for Health and Clinical Excellence. 2007
27. Fals-Stewart W, Kashdan TB, O'Farrell TJ, Birchler GR. Behavioral couples therapy for drug-abusing patients: effects on partner violence. Journal of Substance Abuse Treatment. 2002: 22; 87-96
28. Copello A. and Templeton L. The forgotten carers: support for adult family members affected by a relative's drug problems. UK Drug Policy Commission. 2012
29. UKATT research team. Cost effectiveness of treatment for alcohol problems: findings of the randomised UK alcohol treatment trial (UKATT). British Medical Journal. 2005: 331; 541-544.
30. Copello A, Orford J, Hodgson R. and Tober G. Social Behaviour and Network Therapy for Alcohol Problems. Brunner Routledge. 2009
31. Staley K. Exploring impact: public involvement in NHS, public health and social care research. Eastleigh, Hampshire: INVOLVE. 2009
32. United Nations. Convention on the Rights of the Child. Geneva: The Office of the United Nations High Commissioner for Human Right. 1989

33. Greig , A Taylor J and MacKay T. *Doing Research with Children*. London: Sage. 2007
34. Prout A. Researching children as social actors: an introduction to the Children 5-16 programme. Children and Society. 2002: 16 (2); 67-76.
35. Alderson P. Research by Children. International Journal of Social Research Methodology. 2001: 4, 2; 139-153.
36. Hill M. Participatory Research with Children. Child and Family Social Work. 1997: 2 (3); 71-183.
37. Powell MA and Smith AB. Children's Participation Rights in Research. Childhood. 2009: 16; 124-142.
38. Sinclair R. Participation in practice: making it meaningful, effective and sustainable. Children & Society. 2004: 18(2); 106-118.
39. Brady LM, Davis E, Ghosh A, Surti B and Wilson L. Involving young people in research: making an impact in public health. In Barnes, M and Phil Cotterell, P (eds): Critical Perspectives on User Involvement. Bristol: Policy Press. 2011
40. Kirby P. A Guide to Actively Involving Young People in Research, for researchers, research commissioners and managers. Eastleigh: INVOLVE. 2004
41. National Children's Bureau. Including Children in Social Research. Highlight no.193. London: National Children's Bureau. 2002
42. Brady L.M., Davey C, Shaw C and Blades R. Involving children and young people in research – principles into practice. In Beresford P and Carr S (eds): Social Care, Service Users and User Involvement: building on research. London: Jessica Kingsley. (in press)
43. Brownlie J. Anderson S. and Ormston R. Children as researchers. Edinburgh: Scottish Executive Education Department. 2006
44. Kellett M. How to Develop Children as Researchers. London: Paul Chapman. 2005
45. Shaw C. Brady LM, and Davey C. NCB Research Centre Guidelines for Research with Children and Young People. London, National Children's Bureau. 2011
46. Copello A, Williamson E, Orford J. and Day E. Implementing and evaluating Social Behaviour and Network Therapy in drug treatment practice in the UK: a feasibility study, Addictive Behaviors. 2006: 31; 802-810.
47. Goodman R. The Strengths and Difficulties Questionnaire: A Research Note. Journal of Child Psychology and Psychiatry. 1997: 38; 581–586.
48. Achenbach T M, and Rescorla L. Manual for the ASEBA School-Age Forms and Profiles: An Integrated System of Multiinformant Assessment. Burlington, VT: University of Vermont, Research Center for Children, Youth and Families. 2001
49. Goodman R. Psychometric properties of the Strengths and Difficulties Questionnaire (SDQ). Journal of the American Academy of Child and Adolescent Psychiatry. 2001: 40; 1337–1345.
50. Moos RH and Moos R. Family Environment Scale Manual (2nd ed.). Palto Alto, CA: Consulting Psychologists Press. 1986
51. Horvath AO and Greenberg LS Development and validation of the Working Alliance Inventory. Journal of Counseling Psychology. 1989: 36 (2); 223-233.
52. EuroQol Group. EuroQol-a new facility for the measurement of health-related quality of life. Health Policy. 1990: 16; 199-208

53. Cockayne S, Hewitt C, Hicks K, Jayakody S, Kang'ombe AR, Stamuli E, Turner G, Thomas K, Curran M, Denby G, Hashmi F, McIntosh C, McLaron N, Torgerson, D. and Watt, I. Cryotherapy versus salicylic acid for the treatment of plantar warts (verrucae): a randomised controlled trial. British Medical Journal. 2011: 342:d3271 doi:10.1136/bmjd3271.
54. Medical Research Council. MRC Ethics Guide. Medical research involving children. London: Medical Research Council. 2004
55. Shaw C, Brady L-M and Davey C. Guidelines for Research with Children and Young People. London. National Children's Bureau Research Centre. 2011
56. Orford J, Hodgson R, Copello A, et al. The clients' perspective on change during treatment for an alcohol problem: qualitative analysis on follow-up interviews in the UK Alcohol Treatment Trial. Addiction. 2006a: 101; 60-68.
57. Orford J, Kerr C, Copello A, Hodgson R et al. Why people enter treatment for alcohol problems: findings from UKATT pre-treatment interviews. Journal of Substance Use. 2006b: 11; 161-176.
58. Orford J, Hodgson R, Copello A, et al. What was useful about that session? Clients' and therapists' comments after sessions in the UK Alcohol Treatment Trial (UKATT). Alcohol and Alcoholism (2009a): 44; 306-313.
59. Orford J, Hodgson R, Copello A, et al. To what factors do clients attribute change? Content analysis of follow-up interviews with clients of the UK Alcohol treatment trial. Journal of Substance Abuse Treatment. 2009b: 36; 49-58.
60. Tober G, Clyne W, Finnegan O et al. Validation of a scale for rating the delivery of psycho-social treatments for alcohol dependence and misuse: the UKATT Process Rating Scale (PRS), Alcohol and Alcoholism. 2008: 43; 675-682.
61. Williamson E, Smith M, Orford J, Copello A. and Day E. Social behaviour and network therapy for drug problems: evidence of benefits and challenges, Addictive Disorders & their Treatment. 2007: 6(4); 167-179.
62. Strauss A. and Corbin J. Basics of qualitative research: Grounded theory procedures and techniques. London: Sage Publications. 1990
63. Briggs AH and Gray AM. Handling uncertainty when performing economic evaluation of healthcare interventions. Health Technology Assessment. 1999: 3(2)
64. Ziek, K., Beardsley, M., Deren, S., Tortu, S. Predictors of follow-up in a sample of urban crack users. Eval. Program. Plan. 1996: 19(3); 219–224.
65. Henggeler SW, Melton GB, Smith LA. Family preservation using multisystemic therapy: an effective alternative to incarcerating serious juvenile offenders. Journal of Consulting and Clinical Psychology. 1992: 60 (6); 953-961.
66. Scott CK. A replicable model for achieving aover 90% follow-up rates in longitudinal studies of substance abusers. Drug and Alcohol Dependence. 2004: 74; 21-36.
67. Shaw C, Brady L-M and Davey C. Guidelines for Research with Children and Young People. London. National Children's Bureau Research Centre. 2011