PARTICIPANT INFORMATION SHEET
28th April 2014

Study Title: Adaptation and Feasibility Study of a Family and Social Network Intervention for Young People Who Misuse Alcohol and Drugs

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We are inviting you to take part in a research study. Before you decide whether to take part or not, we want to tell you why the research is being done and what you can expect if you do take part. Please take time to read the following information carefully and discuss it with your family, friends, or [Site Specific: Name of Research Site] key worker if you wish. Ask us if there is anything that is not clear or if you would like more information, our contact details are given at the end of this information sheet.

The purpose of the study
We want to know if 'Youth Social Behaviour and Network Therapy' or YSBNT works on young people (12 – 18 year olds) with drug and alcohol problems. We also want to test if it is possible to conduct a successful 'trial' on the use of YSBNT in this particular group. A 'trial' or a clinical trial is a type of study that compares one treatment to another. In this study we are comparing the effects of YSBNT and the standard/regular healthcare or treatment that is offered at [Site Specific: Name of Research Site] (also known as treatment as usual).

Why have I been chosen?
We are inviting everyone who uses [Name of service], to take part in this study. This will involve approximately 60 young people from the West Midlands [Site name] and North East [Site name] regions of the country.

Do I have to take part?
No – it is entirely up to you to decide whether or not you want to take part, but if you do it will be of great help to us.

If you are happy to take part, we will ask you to sign a Consent Form (a written confirmation that says you have understood what the study is all about and you happily agreed to take part). After signing the Consent Form, you are still free to change your mind at any time and stop or leave the study if you wish. You do not need to tell us the reason why you want to stop or leave. If you leave the study, we will only use any information already collected unless you tell us not to.

If you are not interested to take part, or if you want to stop/leave the study, your decision will not affect any treatment or care you get, or your relationship with [Site Specific: Name of Research Site].

What should I do if I want to take part?
First of all, think about all the information on this sheet and talk to your [Site Specific: Name of Research Site] key worker whether you want to take part in the study. If you do, we will contact you to arrange an assessment at a time and place that suits you. If the place is not your home, we can also arrange to see you at [Site Specific: Name of Research Site]. Before the assessment, we will go through all the information on this sheet to make sure that you understand it. As mentioned earlier, we will then ask you to sign a Consent Form to agree to the research. Please do not hesitate to ask questions if you are not sure about anything.

What would the assessment be like and how long will it take?

Before the assessment, we will quickly go through the questionnaires/interview guide with you so you will get an idea as to what type of questions we will be asking. The assessment will be a little like a conversation or a chat about yourself, your experiences and your drug/alcohol use.

> The time it takes for an assessment varies, depending on how much you have to say, but most assessments last about an hour. If you would prefer, we can assess you on two different occasions. Remember, if you want to stop the assessment at any time, you can do so without giving any reason at all. If there are questions that you are not happy or comfortable with, you always have a choice not to answer them.

What would happen after the assessment?

After the assessment, your details will be entered onto a computer (excluding your name/address/other personal details) and a computer program will randomly assign you to either of the two groups:

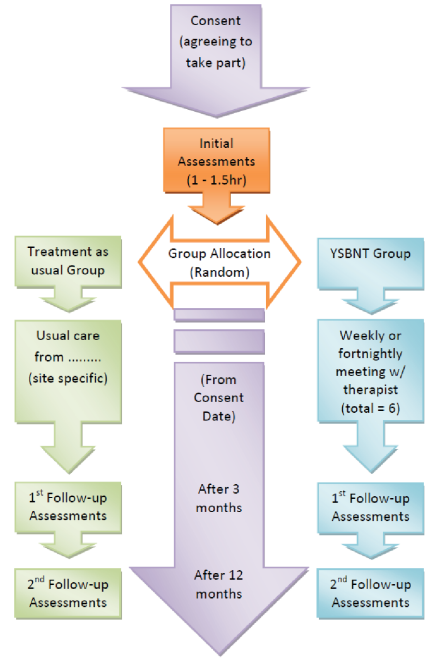
(1) YSBNT Treatment Group – those who will receive the YSBNT

(2) Treatment as Usual (TAU) Group – those who will receive the standard treatment/care from [Site Specific: Name of Research Site]

Overall, you therefore have a 50/50 chance of receiving YSBNT or treatment as usual. This is a randomised trial, which means we do not know which treatment works best. It is only by comparing these two groups that we are able to test which treatment works best.

What do I have to do after this?

If you are randomly allocated to the YSBNT Treatment Group, a therapist will be seeing you on a weekly or fortnightly basis (total of 6 sessions) for up to 12 weeks which will be arranged at a time and place convenient for you. If you are randomly allocated to the Treatment as Usual (TAU) group, a therapist will be seeing you on a weekly or fortnightly basis for as long as you need him/her to. Whether you are allocated to the YSBNT or TAU group, you will receive a Love2shop voucher that can be spent in hundreds of high street shops upon completion of assessments. You will receive a total of £40 worth of vouchers on three different time points:



1) £10 voucher following completion of the first or initial assessment,

2) £10 voucher following completion of 1st follow-up assessment and,

3) £20 voucher following completion of the 2nd follow-up assessment.

All of the questionnaires for the 1st, 3rd, and 12th month assessments are exactly the same. It is only by repeating the assessments that we will be able to measure if there were any changes in your drug or alcohol use. However, there is an additional interview assessment for the 3rd and 12th month follow-ups for those who were allocated to the YSBNT Treatment Group. The purpose of this interview is to talk about your experiences and thoughts about YSBNT (e.g. whether you think it works or not). Again, just like the other assessments, the interview will be more like an informal

chat. You do not have to do all of the assessments in one sitting. You can always ask us to spread the assessments over 2 meetings, whichever is more convenient for you.

Upon completion of the assessments, your data will be entered into a database and analysed together with data from other clients. All data will be anonymised (your name, address, or other personal details will not be written on any of your assessments so your data will be completely non-identifiable).

Why is YSBNT being tested?

The main aim of the YSBNT is to help young people address their alcohol and drug problems by enabling them to access support from the important people in their lives. Unlike other traditional therapies, YSBNT allows your friends or other important people in your life to be a part of this network that will help and support you in your efforts to change. The idea behind YSBNT is to help you:

(1) Develop a genuine motivation to change your drug or alcohol use,
(2) Improve your communication and coping skills, and more importantly,
(3) Create a network of people that will help you change and maintain the changes that you have achieved.

The use of YSBNT in young people has not been tested so far. We still do not know exactly how it helps people to reduce/stop their alcohol and drug use. It is for this reason why we are conducting this study. We also want to improve our understanding so we can help develop YSBNT to be more helpful and effective for young people.

What are the possible disadvantages and risk of taking part?

Apart from the time required to complete the assessment, no known disadvantages or risks are associated in taking part.

What **will happen when the research study stops?**

This study lasts from 1st May 2014 until 15th September 2015. There will be no change to your care or to services when the study stops, but we hope that the final results of the study will help the health professionals involved in running [Site Specific: Name of Research Site] and other young people's drug and alcohol services to make changes in the medium to longer term to further improve services. The results of the study will be written up from about November 2015 onwards, and you will be able to read findings from this project free of charge by the end of November 2015.

Will my taking part in this study be kept confidential?

All anonymised information collected as part of this research including questionnaires, typed up notes of interviews and recording of interviews will be kept in a locked filing cabinet and secure IT systems in the University of York (York Trials Unit). All paper and electronic data will be identified using unique study/trial numbers instead of identifiable information (e.g. name, address, etc.). This means that your anonymity will be preserved at all times during and after the study time period. All of the questionnaires, notes, and audio recordings will be destroyed 5 years after the study has been completed in line with the University of York research policy.

What will happen to the results of the research study?

The results of the study will be written up for publication in health professional journals and will be presented at conferences in the UK and abroad, however your identity will be kept anonymous at all times.

Who is organising and funding the research?

The research is jointly organised by the University of Birmingham and University of York. This project is being funded by the NHS National Institute of Health Research and sponsored by Birmingham & Solihull Mental Health Foundation Trust.

Who has reviewed the study?
This study was given a favourable ethical opinion for conduct by the Coventry and Warwickshire Research Ethics Committee.

Where can I get more information?
We hope that this Information Sheet has told you what you need to know before deciding whether or not to take part. If you have any questions at all about the study or wish to make a complaint please contact:

[CI Photo]

Professor Alex Copello (Chief Investigator)
School of Psychology, University of Birmingham
Frankland Building, Edgbaston B15 2TT
☎
✉

Site Specific [Research Fellow's

[Site Specific]
[Contact details for the Research Fellow in sites]

For an independent advice about getting involved in a research study you can contact:

Patient Advice and Liaison Services (PALS)
☎ [redacted]
✉ [redacted]

Important contact point during the study
Given the nature of this study, it is highly unlikely that you will suffer harm by taking part. However, if you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, please contact:

[Site Specific]
[Contact Details for the local R&D]

If you agree to participate, we will give you a copy of this Information Sheet and a copy the signed consent form to keep.

Thank you for taking the time to read this.

Version 3. 28th April 2018.

[Organisational logos]

Centre No: _____

Participant Identification Number for this study: _____

PARTICIPANT'S CONSENT FORM

Study Title: Adaptation and Feasibility Study of a Family and Social Network Intervention for Young People Who Misuse Alcohol and Drugs

Please initial box

1. I confirm that I have read and understand the information sheet dated 28th April 2013 (Version 3) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. ☐

3. I understand that sections of any of my medical notes may be looked at by responsible individuals from [Site Specific: Name of Research Site], and/or research staff from the [Site Specific] or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the above study. ☐

Optional Consent (You do not have to agree to this to be able to take part in this study)

☐ I do ☐ I do not - consent to the audio-recording of my therapy sessions.

Participant's Name (Please print)	Participant's Signature	Date

Declaration by Researcher: I have explained the project to the participant who has signed above, and believe that they understand the purpose, extent and possible risks of their involvement in this project.

Researcher's Name (Please print)	Researcher's Signature	Date

Name of the person taking consent (If different from Researcher)	Signature	Date

Please note: All parties signing the Consent Form must date their own signature.

Version 3. 28th April 2018.