## Youth social behaviour and network therapy (Y-SBNT): adaptation of a family and social network intervention for young people who misuse alcohol and drugs – a randomised controlled feasibility trial

Judith Watson,<sup>1</sup> Paul Toner,<sup>2</sup> Ed Day,<sup>3,4</sup> Donna Back,<sup>4,5</sup> Louca-Mai Brady,<sup>6</sup> Caroline Fairhurst,<sup>1</sup> Charlotte Renwick,<sup>2</sup> Lorna Templeton,<sup>7</sup> Shabana Akhtar,<sup>4,5</sup> Charlie Lloyd,<sup>2</sup> Jinshuo Li,<sup>2</sup> Kim Cocks,<sup>1</sup> Sangeeta Ambegaokar,<sup>8</sup> Steve Parrott,<sup>2</sup> Paul McArdle,<sup>9</sup> Eilish Gilvarry<sup>10</sup> and Alex Copello<sup>4,5</sup>\*

<sup>1</sup>York Trials Unit, Department of Health Sciences, University of York, York, UK <sup>2</sup>Department of Health Sciences, University of York, York, UK <sup>3</sup>Addictions Department, Institute of Psychiatry, London, UK <sup>4</sup>Birmingham and Solihull Mental Health NHS Foundation Trust, Birmingham, UK <sup>5</sup>School of Psychology, University of Birmingham, Birmingham, UK <sup>6</sup>Independent Research Consultant, London, UK <sup>7</sup>Independent Research Consultant, Bristol, UK <sup>8</sup>Birmingham Children's Hospital, Birmingham, UK <sup>9</sup>Northumberland, Tyne and Wear NHS Foundation Trust, Newcastle upon Tyne, UK <sup>10</sup>North of Tyne Community Children and Young People's Services, Northgate Hospital, Morpeth, UK

\*Corresponding author

Declared competing interests of authors: Judith Watson reports grants from the National Institute for Health Research (NIHR) Health Technology Assessment programme during the conduct of the study. Ed Day reports grants from the NIHR Health Technology Assessment programme, personal fees from PCM Scientific and personal fees from Public Health England outside the submitted work and he is the author of the treatment manuals Routes to Recovery via Criminal Justice and Routes to Recovery via the Community. Materials from these manuals influenced the final treatment manual in this study. He produced these manuals with the aid of a small grant from Public Health England and they are now freely available in the public domain [see www.nta.nhs.uk/ routes-to-recovery.aspx (accessed 29 November 2016)]. Louca-Mai Brady reports that public involvement of young people in this study has also formed a case study for her PhD thesis, for which she received a bursary from the University of the West of England. This does not constitute a conflict of interest and any claims to intellectual property have been waived. Caroline Fairhurst reports grants from the NIHR Health Technology Assessment programme during the conduct of the study. Kim Cocks reports grants from the NIHR Health Technology Assessment programme during the conduct of the study. Eilish Gilvarry reports grants from the NIHR Health Technology Assessment programme during the conduct of the study. Alex Copello reports having a patent relating to Social Behaviour and Network Therapy for Alcohol Problems (Adult), broadly relevant to this work, with royalties paid.

**Disclaimer:** This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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# **Scientific summary**

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## **Scientific summary**

### Background

Research has identified family interventions to be effective at treating young people's substance use problems. However, despite this evidence, the implementation of family approaches in UK services remains low. The potential reasons for this appear to include the resource-intensive nature of most family interventions, thereby challenging implementation and delivery in many service settings. In addition, approaches developed in the USA require adaptation to a UK setting. This study aimed to demonstrate the feasibility of recruiting young people to a specifically developed family- and wider social network-based intervention by testing an adapted version of adult social behaviour and network therapy (SBNT).

## **Objectives**

- To adapt an evidence-based family and social network intervention developed and tested with adult substance misusers to the youth context.
- To involve young people, parents and therapists in the adaptation process to improve acceptability to these groups and ensure ready implementation in routine services.
- To develop a manual, resource kit and training programme for the delivery of the adapted intervention in a feasibility trial.
- To demonstrate the feasibility of recruiting young people to a family- and network-based intervention (youth SBNT or Y-SBNT) across two service sites.
- To test the feasibility of training staff from existing young people's addiction services to deliver the family and social network intervention.
- To evaluate the level of treatment retention among participants randomised to the family and social network intervention.
- To explore, through qualitative interviews, participants' views, acceptability and experiences of the intervention and the study process.
- To explore, through qualitative interviews, the views and experiences of those attending treatment sessions as members of the young person's network and the acceptability of the intervention.
- To examine treatment effectiveness through 3- and 12-month quantitative outcome data.
- To explore the cost-effectiveness of the intervention and the acceptability of service use questions in preparation for a large definitive randomised controlled trial.
- To explore and develop models of patient and public involvement that support the involvement of young people in a study of this nature.

### **Methods**

#### Design

This study involved adaptation of the current SBNT to produce a purpose-designed therapy manual and associated resources suitable for use with young people, which was achieved by extensive and ongoing public involvement with young people with experience of services, as well as consultation with treatment professionals working with young people. A pragmatic, two-armed randomised controlled open feasibility trial followed. Randomisation was performed by a remote service. Treating therapists and participants were aware of the allocation result and the clinical outcome assessment was substance use based on the Timeline Follow-Back (TLFB) interview and in particular the proportion of days on which the main problem substance was used in the preceding 90-day period at each assessment point (3 and 12 months post randomisation).

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#### Setting

Two UK-based treatment services for young people with substance use problems.

#### **Participants**

Young people aged 12–18 years, newly referred and accepted for structured interventions for drug and/or alcohol problems.

#### Sample size

As this was a feasibility study, the main purpose was to assess acceptability and feasibility and to obtain information that would inform the design of a larger full-scale trial. Although a formal sample size calculation for a feasibility or pilot study is not required, for this study we calculated the number of participants required so that an effect smaller than that desired in the main trial could be ruled out. This number was used to inform whether the main trial would be worthwhile with respect to likely effectiveness.

Assuming a continuous primary outcome measure, for the main trial we would want to detect about 0.3 of a standard deviation between the two groups. This would require a sample size of approximately 350 patients. A pilot study of 32 patients is sufficient to exclude this difference in the event of a zero or negative intervention effect using a one-sided 80% confidence interval (CI).

Given the patient population, a reasonably high level of attrition may be expected; therefore, we aimed to recruit 60 participants.

#### Interventions

Participants were randomised 1 : 1 to either adapted youth SBNT (Y-SBNT) or treatment as usual (TAU). Those allocated to Y-SBNT received up to six 50-minute sessions over a maximum of 12 weeks, delivered by a trained therapist at a location preferred by the participant. Those allocated to TAU continued to receive the usual care delivered by their service, with appointments offered as required in the first 12 weeks. When consent was obtained, sessions were recorded and rated to ensure treatment fidelity.

#### Main outcome measures

The feasibility and acceptability of this intervention was measured by recruitment rates, retention in treatment and follow-up completion rates as well as in patient and staff qualitative interviews. The main clinical outcome was the proportion of days on which the main problem substance was used in the preceding 90-day period as captured by the TLFB interview at each assessment point (3 and 12 months post randomisation).

#### Public involvement

Seventeen young people with a history of treatment for substance misuse were actively involved throughout the study and their input informed key elements of the intervention and the research process. They also contributed ideas for a new model of public involvement. In phase 1, young people were supported to work alongside the research team to ensure that the intervention was acceptable and relevant to our target groups. During phases 2 and 3, young people were involved in the design of key trial documents such as the recruitment leaflet and information sheet, the production of training materials, advising on data collection tools, data analysis and interpretation, reporting and dissemination. There were some challenges in recruiting and working with this group of young people, which have informed wider learning on how best to involve a group of young people who do not often get involved in research.

#### Results

In total, 53 young people were randomised in the study (Y-SBNT, n = 26; TAU, n = 27) against a target of 60 (88.3%). Although recruitment was marginally below target, loss to follow-up was lower than anticipated and so the required sample size of 32 patients (16 per group) with outcome data was achieved

at all time points. Participants were recruited between 30 May and 14 November 2014 at an average recruitment rate of nine young people every 4 weeks of active recruitment. Follow-up rates were > 73% at all time points and the majority of young people attended at least one treatment session, with uptake higher in the Y-SBNT group [Y-SBNT 22/26 (84.6%); TAU 20/27 (74.1%)]. At month 12, the average proportion of days that the primary problem substance was used in the previous 90 days was lower in the TAU group than in the Y-SBNT group (0.41 vs. 0.54; adjusted mean difference 0.13, 95% CI –0.12 to 0.39; p = 0.30). This equates to a negative effect size of –0.32 with an upper 80% confidence limit of –0.05, which excludes an effect size of 0.3 and indicates that an effect size of this magnitude is unlikely to be achieved in a definitive, powered trial. The intervention cost was greater in the Y-SBNT group than in the TAU group (£595 vs. £75). The Y-SBNT group saw a 45% increase in health-care costs from baseline to 12 months, whereas the TAU group saw a decrease of 19%. There was an increase in criminal justice service costs between baseline and 12 months for both groups; however, the TAU group began with a much greater baseline cost than the Y-SBNT group. Qualitative interviews found that Y-SBNT was acceptable to young people, family members and staff.

## Conclusions

The adapted intervention could be delivered in young people's services, and qualitative interviews found that Y-SBNT was acceptable to young people, family members and staff. Although the findings of this feasibility trial do not support a recommendation for a full trial of the Y-SBNT intervention compared with TAU, they can inform future UK research within routine addiction services.

### Implications for public involvement

As well as being a pilot of the Y-SBNT intervention, the study was a pilot for exploring how best to involve a group of young people who do not often get involved in research. The standard public involvement model of a fairly static advisory group of 10–12 young people was not particularly successful with the young people whom we wished to engage. We therefore developed a more flexible and young people-centred way of working, which we hope will be useful for future studies and also contribute to the debates about inclusive practice and diversity in public involvement.

#### **Recommendations for future research**

The experience of conducting this study alongside the results obtained does not support a recommendation for a future definitive trial but prompts a number of suggestions for future research:

- 1. Future research on interventions should take into account the broader, longer-acting social and environmental systems within which treatment is delivered.
- 2. The impact of referral source is important and should be considered when determining samples for future studies.
- 3. Validation of the EuroQol-5 Dimensions (EQ-5D) in the age group 12–18 years needs to be considered.
- 4. Models for involvement of young people in research need to be flexible to achieve inclusive representation throughout all aspects of the research process.

## **Trial registration**

This trial is registered as ISRCTN93446265.

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