

An evaluation of multidimensional therapy versus treatment as usual for young people, aged 10-17 years, who use drugs

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| Submission date 14/07/2025 | Recruitment status Not yet recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 17/07/2025 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 14/07/2025 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Most adults with problematic drug use report that their use began in adolescence. Young people are much more vulnerable than adults to the adverse effects of drugs due to a range of physical and psychological factors that often interact and the differential impact of drugs on the developing brain. In addition to an increased risk of accidents and injury, drug use in adolescence is also associated with poor educational performance and exclusion from education. Multidimensional family therapy (MDFT) is widely delivered across the United States, Netherlands, Belgium, Sweden, Finland, Lithuania and Aruba, although there is no current MDFT provision in the UK. MDFT is a family-based, multiple systems-oriented therapy specifically designed to address adolescent problems including drug use, mental health, aggressive and violent behaviour and delinquency. The research aims to test whether MDFT is more effective than existing treatments for adolescent drug use.

Who can participate?

Young people aged 10-17 years who are referred to Barnardo's Children's Services operating in Bristol or Newport, where professionals have concerns about their drug use.

What does the study involve?

Young people will be contacted by Barnardo's, who will explain the study, provide an information sheet and ask the young person if they want to take part. If a young person is willing to take part, staff will conduct an initial assessment and ask a number of questions. Once this is complete, the University of Kent will arrange for the young person's treatment to be selected at random. Those who are selected to receive treatment as usual will be referred to their local substance use service, those who are selected to receive MDFT will have sessions with a trained therapist, some of these sessions will involve the young person's family. The MDFT therapy occurs weekly for 4-6 months. Six and twelve months after the young person gave consent to the study, the young person will be contacted by a researcher who will ask them to complete a number of questions to measure what has changed.

What are the possible benefits and risks of participating?

The research staff and organisations involved in this research have a lot of experience and we do not think that you will experience any harm as a result of taking part in this research study. MDFT has been delivered to many young people across the world and the therapists are highly trained.

Where is the study being run from?

The study involves three organisations. Barnardo's Children's centres in Bristol and Newport and research staff at the University of Kent and Teesside University (UK).

When is the study starting and how long is it expected to run for?

May 2025 to September 2028

Who is funding the study?

Youth Endowment Fund (UK)

Who is the main contact?

Prof. Simon Coulton, s.coulton@kent.ac.uk

Contact information

Type(s)

Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

WP759408)

Study information

Scientific Title

Randomised controlled trial of multidimensional therapy versus treatment as usual for young people aged 10-17 years who use illegal drugs

Study objectives

Primary research question:

ERQ1. What is the effectiveness of MDFT on the frequency of self-reported substance use, measured at 6 months post-randomisation, for young people aged 13-17 years, who are current substance users and involved in criminal activity or considered at risk of becoming involved in criminal activity compared with business as usual?

Secondary research questions

ERQ2. What is the effectiveness of MDFT on the frequency of self-reported substance use, measured at 12 months post-randomisation, for young people aged 13-17 years, who are current substance users and involved in criminal activity or considered at risk of becoming involved in criminal activity compared with business as usual?

ERQ3. What is the effectiveness of MDFT on the frequency of violent offending at 6 and 12 months post-randomisation compared with business as usual?

ERQ4. What is the effectiveness of MDFT on behavioural and emotional difficulties at 6 and 12 months post-randomisation compared to business as usual?

ERQ5. What is the effectiveness of MDFT on mental health and wellbeing at 6 and 12 months post-randomisation compared to business as usual?

ERQ6. What is the effectiveness of MDFT on substance use related problems at 6 and 12 months post-randomisation compared to business as usual?

ERQ7. What is the effectiveness of MDFT on substance use related problems at 6 and 12 months post-randomisation compared to business as usual?

ERQ8. What is the effectiveness of MDFT on the frequency of criminal justice outcomes, arrests, cautions, charges and court attendance, at 6 and 12 months post-randomisation compared to business as usual?

ERQ9. What is the effectiveness of MDFT on the frequency of educational outcomes, suspensions, exclusions and managed moves, at 6 and 12 months post-randomisation compared to business as usual?

ERQ10. What is the cost per participant associated with the delivery of MDFT?

ERQ11. To develop a prognostic model exploring the baseline demographics, psychological and family factors that may impact observed outcomes and using the results to elaborate mechanisms of change and, where appropriate, revise the intervention logic model.

ERQ12. To conduct a latent class analysis to explore potential interactions between population subgroups, intervention received, and outcomes observed. Specific sub-groups include ethnicity, sex, age, offending behaviour and substance use severity.

ERQ13. To conduct a latent class mediation analysis to explore how the volume of violent offences is mediated by the frequency and type of substance used at 6 and 12 months.

Ethics approval required

Ethics approval required

Ethics approval(s)

Submitted 19/05/2025, University of Kent Social Research Ethics Committee (University of Kent, Canterbury, CT2 7NZ, United Kingdom; +44 (0)1227 824535; lssjethics@kent.ac.uk), ref: SRC1200

Study design

Multicenter individually randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Charity/Voluntary sector

Study type(s)

Screening, Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Substance use treatment for young people who offend or at risk of offending

Interventions

Multidimensional Family Therapy delivered face-to-face by a trained therapist weekly over a 4-6 month period versus existing treatment as usual control. Participants have an equal probability of being randomised to MDFT or control. Randomisation is conducted by a secure, independent service and employs random permuted blocks of size 4, 6 or 8.

Intervention Type

Behavioural

Primary outcome measure

Percent days abstinent from substance use in the past 28 days assessed using the Time Line Follow-Back method at 6 months post-randomisation

Secondary outcome measures

1. Percent days abstinent from substance use in the past 28 days assessed using the Time Line Follow-Back method at 12 months post-randomisation
2. Self-reported volume of violent offending behaviour assessed using the Self-Report Delinquency Scale at 6 and 12 months post-randomisation
3. Behaviour: internalising behaviour (emotional regulation plus peer relationships subscales) assessed using the Strengths and Difficulties Questionnaire at 6 and 12 months post-randomisation
4. Externalising behaviour (hyperactivity plus conduct problems subscales) assessed using the Strengths and Difficulties Questionnaire at 6 and 12 months post-randomisation
5. Mental health and wellbeing assessed using the short Warwick Edinburgh Mental Wellbeing Scale at 6 and 12 months post-randomisation
6. Alcohol and substance use problems assessed using the European School Survey on Alcohol and Drugs - Problems Scale at 6 and 12 months post-randomisation

Overall study start date

19/05/2025

Completion date

30/09/2028

Eligibility

Key inclusion criteria

1. Young people aged 13-17 years inclusive who are resident in the Bristol or Newport LA
2. Currently involved with the police or youth justice service or at risk of offending. At risk of offending is defined as having at least one of the following risk factors, assessed on referral:
 - 2.1. Previously being in the secure estate.
 - 2.2. Currently, or previously, persistently absent from school (defined by DfE as 10% or more)
 - 2.3. Have been the victim of violence
 - 2.4. Currently, or have attended alternative education provision
 - 2.5. Received multiple suspensions from school or has been permanently excluded
 - 2.6. Have a sibling or parent who has been involved in serious violence or identified as facing exploitation harm
 - 2.7. Currently, or have been, in the care system
 - 2.8. Have been identified as being at risk of criminal exploitation
 - 2.9. Currently or have had a social worker
 - 2.10. Have previously been in contact with youth justice services
 - 2.11. Have been arrested, admitted an offence and released by the police with no further action
3. Evidence of alcohol or substance use on at least 4 occasions in the past 28 days, assessed using a single substance use frequency question on referral to Barnardo's
4. Willing and able to provide informed consent or willing to provide assent with a parent/carer willing to provide consent

Participant type(s)

Population, Other

Age group

Child

Lower age limit

13 Years

Upper age limit

17 Years

Sex

Both

Target number of participants

400

Key exclusion criteria

1. Alcohol or substance severity that requires inpatient residential treatment or immediate detoxification
2. Severe mental health condition requiring immediate psychiatric assessment

Date of first enrolment

01/11/2025

Date of final enrolment

31/05/2027

Locations**Countries of recruitment**

England

United Kingdom

Wales

Study participating centre**Barnardos Childrens Service**

Barnardos

Junction 3 Library

Baptist Mills Court

Bristol

United Kingdom

BS5 0FJ

Study participating centre**Barnardos Childrens Service**

Civic Centre

Godfrey Road

Newport
United Kingdom
NP20 4UR

Sponsor information

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Sponsor type

University/education

Website

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ROR

<https://ror.org/00xkeyj56>

Funder(s)

Funder type

Charity

Funder Name

Youth Endowment Fund

Alternative Name(s)

YouthEndowFund, YEF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Publication of a final report for the funder and publications in peer reviewed journals

Intention to publish date

01/01/2029

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date