EVALUATION PROTOCOL

Multidimensional Family Therapy to reduce alcohol and drug use in adolescents, an individually randomised controlled trial with embedded internal pilot.

University of Kent; Teesside University

Principal investigator: Professor Simon Coulton

YOUTH ENDOWMENT FUND

Multidimensional Family Therapy to reduce alcohol and drug use in adolescents, an individually randomised controlled trial with embedded internal pilot.

Evaluation protocol

Evaluating institution: University of Kent/ Teesside University

Principal investigator: Professor Simon Coulton

Project title[1]	Multidimensional Family Therapy to reduce alcohol and drug use in adolescents, an individually randomised controlled trial with embedded internal pilot.
Developer (Institution)	MDFT International / Ending Youth Violence Lab / Barnardo's
Evaluator (Institution)	University of Kent / Teesside University
Principal investigator(s)	Professor Simon Coulton
Protocol author(s)	Professor Simon Coulton, Professor Dorothy Newbury-Birch, Dr Andrew Divers, Nadine Hendrie
Trial design	Two-armed individually randomised controlled trial with embedded internal pilot and implementation and process evaluation
Trial type	Internal pilot / efficacy
Evaluation setting	Community
Target group	13-17 years old, who use alcohol and / or drugs and who have offended or are at risk of offending, resident in Newport and Bristol LA
Number of participants	400, 200 in the MDFT group and 200 in the BAU group.
Primary outcome and data source	Percent days abstinent from alcohol and/or substance use at month 6, derived from the time line follow back 28 days.
Secondary outcome and data source	Percent days abstinent from alcohol and/or substance use at month 12, derived from the time line follow back 28 days. Self-reported violent offending behaviour (Self-Report Delinquency Scale) at months 6 and 12),

	Self-report Strengths and Difficulties Questionnaire (SDQ total score, prosocial score, emotional regulation, peer relationships, hyperactivity, conduct, externalising and internalising scores) at months 6 and 12. Self-report Short Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS) at months 6 and 12. Alcohol and substance use problems at months 6 & 12, using the problem scale from the European School survey on Alcohol and Drugs (ESPAD). Self-report Client Service Receipt Inventory (CSRI) to assess police involvement at months 6 and 12 (arrests, cautions, charges, court attendance), educational outcomes (suspensions, exclusions, managed moves) and employment status.

Protocol version history

Version	Date	Reason for revision
1.0 [*original*]	15/01/25	

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Study rationale and background

Most adults with problematic substance use report that their substance use began in adolescence (Simon et al., 2022). Young people are much more vulnerable than adults to the adverse effects of substance use due to a range of physical and psychological factors that often interact and the differential impact of substances on the developing brain (Battistella et al., 2014, Copeland et al., 2013a, Parlar et al., 2021). In addition to an increased risk of accidents and injury (NHS., 2018), substance use in adolescence is also associated with poor educational performance and exclusion from education. Over the academic year 2015-16, almost 9% of permanent school exclusions in state secondary schools were due to alcohol and substance use (DFE., 2019).

While the relationship between offending behaviour and substance use is complex, evidence highlights that the prevalence of substance use is far higher in the youth offending population than the general youth population. Approximately 25% of young people in structured alcohol and drug treatment are referred from criminal justice (OHID., 2022) and data from the Youth Offending Team, ASSETPLUS, indicates that most young people in the CJS, 76%, use substances and 72% have a mental health need.

Evidence from the Youth Endowment Fund Children, Violence and Vulnerability Report (YEF, 2024) highlights the link between substance use and offending with rates of drug use significantly higher among the victims and perpetrators of violent offences, with 19% of victims and 22% of perpetrators reporting cannabis use in the past 12-months compared to 6% who had not experienced violence. Drug use overlaps with poor mental health, disengagement in education, gang membership and involvement in crime (Coulton et al., 2022). Young people themselves view drug use as a major factor associated with youth violence in their area with 66% seeing drug use, 65% addiction and 64% drug supply as major drivers in the committing of violent offences. Since 2012 there has been a reduction in the number of young people accessing substance use services (Black, 2020) in part associated with reduced funding for services (Black, 2020), it is critical that substance use services provide appropriate support for young people who use drugs who often have complex and multiple vulnerabilities.

Ethnic minorities, particularly black children, are disproportionately represented in the offending statistics, both as victims and perpetrators of crime (YEF, 2024). Data from the Youth Justice Board in 2024 highlights that while 6% of those aged 10-17 years are of Black heritage they represent 20% of those stopped and searched, 12% of those arrested, 11% of those cautioned and 26% of those in custody. The reasons for this disproportionality are complex but many ethnic minority groups are more likely to experience discrimination, poverty, neighbourhood deprivation, exclusion from school, have emotional and mental

health needs, use drugs and less likely to have access to early intervention (Bateman et al., 2023). All key risk factors for offending.

While the prevalence of drug use is similar across ethnicity, except for Asian populations who have a lower prevalence (OR 0.39; 95% CI 0.19 to 0.81), the proportion of those receiving treatment is far lower, 5% of ethnic minorities versus 89% White British. Reasons for this disparity include lack of awareness of available services, lack of culturally sensitive services and a lack of trust stemming from previous negative experiences with services (Pinto et al., 2024). Furthermore, the complexities of intersectionality's of marginalised communities also play a role in an individual's openness to engage, and experience of, a range of support and statutory services from healthcare to the justice system (Healy and Colliver, 2022).

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 an integrative, family-based, multiple systems-oriented intervention specifically designed to address adolescent problems including substance use, mental health, aggressive and violent behaviour and delinquency (Liddle, 1991, Liddle et al., 2005). MDFT's aim is to reduce substance use, improve mental health and enhance developmental functioning across several behavioural domains:

1. the adolescent domain helps adolescents to engage in treatment, regulate their emotions, communicate with, and relate effectively to, their parents and other adults, and to develop social competence and alternative behaviours to drug use.

2. the parent domain engages parents in therapy, increases their behavioural and emotional involvement with their children and improves parental practices.

3. the family interactional domain focuses on reducing conflict and improving emotional attachments and patterns of communication and problem-solving using multi-participant family sessions.

4. the extrafamilial domain fosters family competency within all social systems in which the adolescent participates.

The intervention is manualised and delivered by trained therapists through individual and family sessions.

There is established evidence for MDFT in reducing substance use, delinquency and offending, improving adolescent mental health and prosocial behaviour, four systematic reviews (Baldwin et al., 2012, Filges T. et al., 2018, Tanner-Smith et al., 2013, van der Pol et al., 2017b) indicate it has a small to moderate effect size (δ = 0.20 to 0.30) when compared to other psychological therapies, with greater effects for those whose substance use is severe and those actively involved in offending. The established research base has limitations when

compared to the UK context, most studies have been conducted in the US, where business as usual tends to be more intensive than in the UK and studies conducted in Europe have tended to focus on cannabis use (Rigter et al., 2010). But MDFT has been successfully adapted to different contexts including comorbid substance use and mental health problems (Liddle et al., 2018), addiction to internet gaming (Nielsen et al., 2021), use among young adult populations (Liddle et al., 2024a), and different healthcare systems (Rigter et al., 2010).

MDFT has extensive evidence of being effective within diverse communities. For example, the 2008 evaluation by Liddle et al (Liddle et al., 2008) reports 71% of the population were African American and 11% Hispanic, whilst the population for the 2015 study by Dakof et al (Dakof et al., 2015) worked with a population which was 35% African American and 59% Hispanic.

A diverse staff team, who are locally recruited and reflect the diversity within the area and caseload, will deliver the programme. Barnardo's established presence in the research areas mean they are well placed to meet the needs of this diverse community, for example their Children's Services have pre-existing relationships with Black-led and ethnic minority-led community organisations in the Bristol area which they will build on to support the development of this project. Similarly, as a strategic partner in Newport, Barnardo's have close working links with a range of family support services across the city, including black and minority-ethnic-led community organisations where families would rather work with groups more closely aligned to their cultural, religious, and linguistic needs. In addition, Barnardo's SEEN Project works closely with grassroots organisations who offer expertise on providing specialised support for children from African, Asian and Caribbean heritage communities. Barnardo's also has previous experience of recruiting staff from an ethnically diverse background with lived experience to deliver project work supporting young people at risk of criminal exploitation, via their tailored recruitment approach. In both Bristol and Newport, Barnardo's has undertaken targeted recruitment through advertising in places where a diverse workforce exists. The current Bristol Exploitation Service is managed by a Black woman who in turn manages 2 Team Managers, one Black, one White. For this bid, Barnardo's has been sharing possible employment opportunities with a range of partners in Bristol and Newport who will add to a more diverse MDFT staff team and there is active interest in these posts coming out to market. At the point of recruitment, Barnardo's approach to EDI is embedded through interview questions and scoring system that is used. Induction includes a full induction into Barnardo's approach to EDI and the opportunity to join Staff Networks (Race Equality, Disabled staff, Women, LGBTQ) is explained and encouraged. At a service level, take up of support is monitored on a quarterly basis in relation to protected characteristics and services develop action plans to improve access, when and as required. Our internal Race Equality Lead Advisor has supported services in Bristol and Newport to ensure they are better placed to recruit and retain more diverse staff teams.

The proposed research aims to address key questions about the efficacy of MDFT, adapted for use within the UK using a mixed method, two-arm, prospective, individually randomised controlled trial comparing MDFT versus business as usual (BAU). The trial will have an embedded internal pilot to address key questions regarding the parameters for a definitive efficacy study and a concurrent implementation and process evaluation addressing important questions regarding the MDFT intervention in detail.

Intervention

Delivery of MDFT will occur between July 2025 and July 2027. MDFT aims to reduce substance use, improve behavioural issues and reduce young people's involvement in the criminal justice system through multidimensional family therapy. Greater detail on the theoretical framework is available here https://www.mdft.org and a theory of change diagram and narrative provided in figure 2 and appendix I. It is delivered by a qualified MDFT therapist, and it intervenes in four connected areas: (i) the young person, (ii) the parents, (iii) the family, and (iv) the community. The main activities that drive behavioural change are (i) individual therapy sessions between the therapist and young person (typically 8-20 individual sessions), (ii) parent sessions between the therapist and parents (typically 4-10 sessions), (iii) family sessions where the therapist facilitates meaningful conversations among the family members who attend (typically 4-10 sessions), and (iv) sessions between the family and social systems in their community (typically 4-10 community sessions/meetings). Additional activities outside of the session promote individual change, and phone calls to the young person and parents support the development of problem-solving skills for when difficulties in relationships arise.

Families work with the therapist for a period typically lasting 4-6 months, following three stages. While the time in each stage and the time to completion varies significantly depending on the case and the family, we have outlined what the average case roughly looks like. It is important to note that MDFT is not rigid about the time spent in each stage, and transitioning between them can be porous. As such, these timelines are just guidelines based on previous cases and are not a measure of fidelity. This fluid approach ensures that therapists are responsive to the needs of each unique youth and family in traversing treatment stages, ensuring the programme is sensitive and appropriate for all participants, regardless of their demographic background.

Stage 1 (month 1): Therapists create an environment where the young person and their parents feel respected and understood. Therapists meet alone with each to begin the change process, establishing a strong therapeutic relationship which enhance motivation, reflection, and self-examination. Family sessions and community work also begin immediately upon starting MDFT to create systemic/relational change. Because these sessions are fundamentally directed at creating an environment of respect, it is here that any factors that

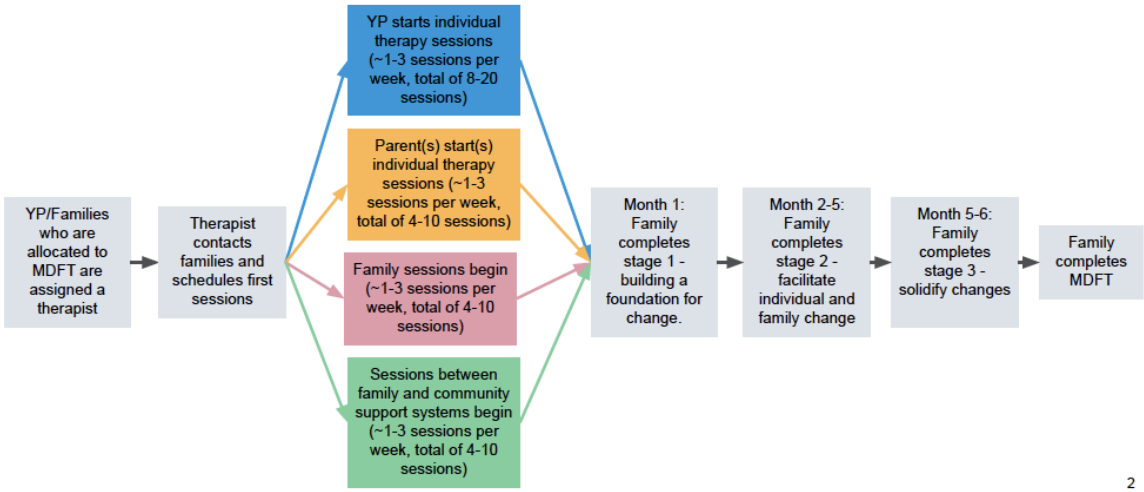
may play an important role within the therapeutic relationship and environment (such as considerations of ethnicity, sex, cultural or religious norms and practices and/or the intersectionality of such) will be addressed. Any such conversations will be led by young people/families, ensuring that individual agency is promoted and respected.

Stage 2 (months 2-5): The focus of stage 2 is on behavioural and interactional change within the young person and their parents in their relationships, as well as their extrafamilial areas. MDFT helps the young person improve self-awareness, self-worth, and confidence, while developing short and long-term goals, improving emotional regulation, coping, problem solving and communication skills. The focus for parents is on strengthening parental teamwork, improving parenting skills and practices, rebuilding parent-child emotional bonds and enhancing parents' individual functioning. In the family domain, MDFT improves family communication, problem solving skills, strengthens emotional attachments between family members and improves everyday family functioning. In the community, the focus is on improving the family's relationships with social systems including, school, the workplace and their wider community while building capacity to access support when needed. If court-involved, the MDFT team is active in helping young people comply with terms of court orders and reducing recidivism.

Stage 3 (month 6): In the last month of the programme therapists highlight the achievements and support families to create action plans for responding to family arguments, substance use relapse or other potential setbacks. Family members engage in self-reflection, acknowledging the efforts made by each other and expressing hope for the future. It is the young person and their family's launch into the next chapter of their lives.

Post-programme support: Stage 3 focuses on reinforcing the positive changes and transitioning to an independent life separate from the program. Moreover, as a short-term intensive intervention, MDFT programmes are working on discharge/transition plans from the beginning of the program. For example, MDFT programmes might engage parents in their own substance use or mental health treatment, and work to get youth and parents engaged in their community (e.g. youth centres, parent and peer support organisations, sports/recreation, clubs, employment). Finally, MDFT programmes always "leave the door open" for youth or parents to reach out to the programme after completion if necessary. MDFT can employ a systematic transition plan with a scheduled set of informal contacts (phone calls, texts) with youth and parents over the first 3 months after programme completion and, if necessary, 1 -3 sessions to avert a crisis. While it is a rare situation where these offers of aftercare are needed, they ensure a solid transition out of the programme. We will monitor the rate of take-up for these services in the pilot to ensure the full-scale trial finds a feasible and financially possible offer for post-programme care.

Figure 1: Delivery of MDFT



Adapting MDFT for delivery within the UK treatment environment

Adaption of the MDFT intervention aims to ensure that the intervention meets the needs of the population it serves. Adaption will include a young person's and stakeholder advisory group who are representative of the ethnic diversity in the delivery areas. MDFT will be adapted to ensure culture sensitivity and the most relevant EDI issues in the local context are reflected in the content.

The membership of the stakeholder advisory group will be fluid, as time progresses it will focus more on those delivering the intervention in the local context. At the outset it is proposed to have representation from those with experience of delivering substance use interventions, those who have previously adapted MDFT for delivery in different environments, those involved in the ICANT trial (Rigter et al., 2010), local authority stakeholders in Bristol and Newport, representatives from Barnardo's, Ending Youth Violence and MDFT international.

The adaption of MDFT will follow the ADAPT guidance (Moore et al., 2021)The initial stage involves a rapid review of the previous adaptions to identify key challenges that need to be overcome and to map similarity and differences in delivery in different contexts. Qualitative work will be undertaken with the young people advisory group to explore issues around feasibility and acceptability of MDFT.

Identifying what elements of MDFT require adaption without undermining the underlying mechanism will be guided using the Modification for Adaption Design and Impact Tool (MADI; (Kirk et al., 2020)). This tool systematically explores what materials require adaption, the potential for unintended consequences and resource requirements. All modified materials

will be reviewed by the stakeholder group and the young persons advisory group to ensure feasibility and acceptability are being maintained.

In the pilot study we will evaluate the adapted version of MDFT with a focus on those who receive it and those who deliver it to explore whether further adaption is needed. This qualitative work will involve qualitative interviews with a population of participants who receive MDFT and therapists who deliver it. The interviews will explore suitability of materials for the intended population, issues around resources required for delivery, unintended consequences, acceptability and feasibility.

Training to deliver the intervention

MDFT training is intensive and individualised, leading to certification of therapists and supervisors. Therapists and supervisors will be recruited that reflect the diversity of the population being served with appropriate backgrounds and experience in providing therapeutic services to young people and families.

Initial therapist training takes about 6 months and supervision training takes an additional 4 – 5 months. MDFT programmes begin serving young people as soon as training begins. Training uses multidimensional training and consultation methods consisting of several integrated components: didactic, demonstration, case consultation, video review, live supervision, and competency assessments. Initially clinicians begin training by completing an Introduction to MDFT on an eLearning platform that is composed of 20 interactive modules. This is followed with weekly case consultations with a certified MDFT trainer who provides a review of the therapists work with young people and carers. These are done in groups of 2- 3 therapists and focus on teaching MDFT theory and practice through application on active cases. Throughout the training therapists participate in several intensive video reviews of their MDFT sessions, focussing on a single training case. Finally, the trainer comes to the programme site for multiday site visits consisting of case consultation, video review, and live supervision.

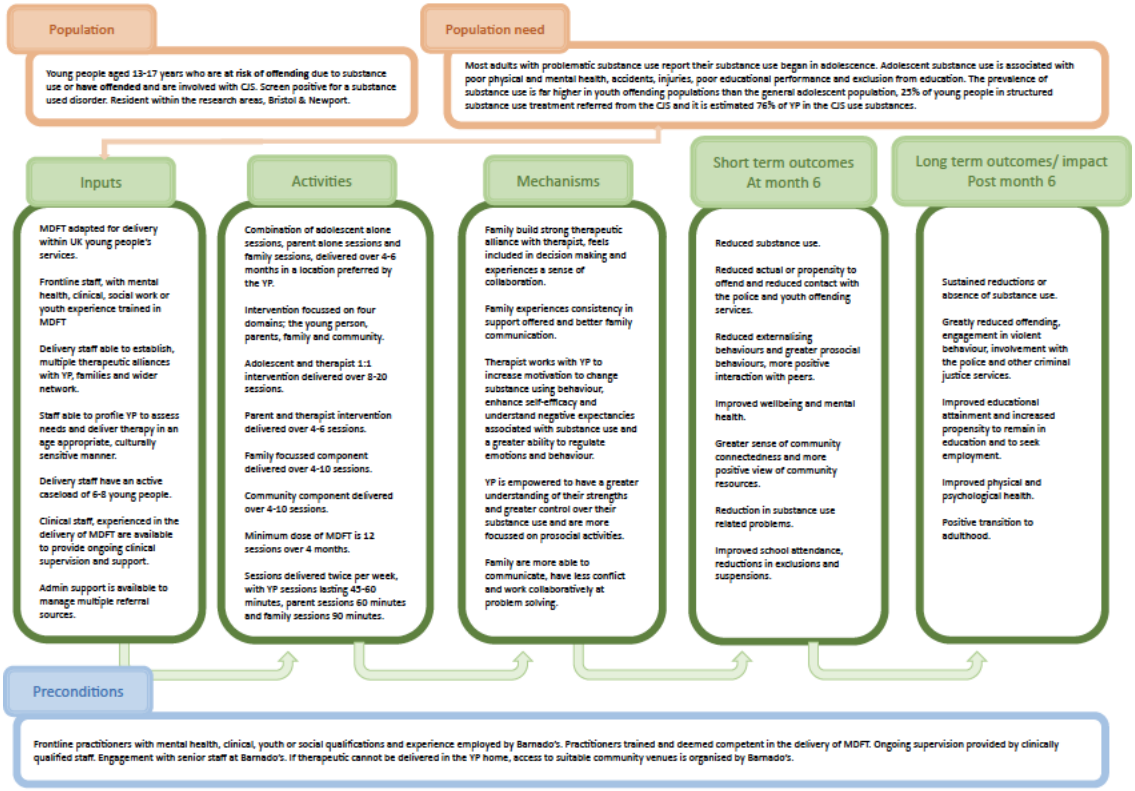
Supervision training involves walking through each aspect of MDFT supervision. It begins with an Introduction to MDFT Supervision. Supervisors then put into practice the methods they have read and written about, submitting recorded samples of their work for the trainer's review. Supervisors also participate in an on-site intensive supervision training focusing on video review and live supervision methods. Therapists and supervisors are recertified annually demonstrating their continuing competency.

Annual quality assurance activities are provided to help programmes maintain fidelity. They include quarterly case consultations, a yearly onsite booster training, and participation in refreshers which are offered monthly to the worldwide MDFT network and consist of 90-

minute sessions focusing on topics of interest. Therapists must attend one refresher per year while supervisors must attend 2 per year to recertify. However, these are continuation of their education, and non-attendance does not impact overall quality of delivery.

The MDFT Clinical Portal is used for tracking treatment fidelity and outcomes without placing undue burden on clinicians. Reports summarising each programme's fidelity and outcomes are provided once per year, or more frequently as required.

Figure 2: MDFT Theory of Change (a detailed narrative is provided in appendix I)



Business as usual

Business as usual will be explored as part of the internal pilot study. There is a paucity of good quality intensive interventions for young people who use drugs. An initial scoping review of services, both statutory and non-statutory, has identified several organisations who provide services for young people who use drugs. Avon and Wiltshire Mental Health Partnership Trust has a specialist young person's substance use service that offers brief interventions such as motivational interviewing and motivational enhancement therapy for those at a high level of severity. Sessions, lasting approximately 45-minutes are offered weekly over a period of 2-4 weeks. Bristol Drugs Project offers 1:1 and group support over a 12-week period. In Newport, Barod offer 1:1 support and peer group sessions over 6-week period addressing alcohol and

drug use, harm reduction and psychoeducation. Gwent Drug and Alcohol Service also offer some support to YP although most of their support is targeted at adults.

Young people who are referred to the Front Door of both Newport and Bristol for reasons that fit with the eligibility criteria of this bid and who are placed in the control group, will not be offered any therapeutic intervention akin to MDFT, BAU is provided by other services rather than Barnardo's so MDFT therapists will not be involved in delivering BAU. They and their family may receive Family Support help which focusses on basic parenting skills and confidence and a "light tough" intervention directly with the young person. This might involve them being referred to a youth work provision which is most likely to be activity based with the aim of diverting them into more positive, pro-social use of their time. For some young people, there may be access to mentoring support, though this is dependent on geography and capacity, not all areas of Newport or Bristol have mentoring support, and it is in demand. It is usually delivered by a youth worker or volunteer and aims to involve young people in more positive activities and, at times, supports them to access education or training opportunities. MDFT differs significantly from BAU.

Impact evaluation

Research questions or 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.

Part of this work will be to examine the potential impact of both UK and region-specific issues that may be linked to race, ethnicity, sex, socioeconomic factors and other considerations that may arise which are connected to EDI.

Internal pilot study

Prior to embarking on the efficacy study an internal pilot study will be undertaken. The aim of the internal pilot study is to explore whether it is feasible to deliver MDFT in the UK context and establish key parameters to incorporate into the design of the efficacy study. Progression criteria are detailed in appendix II and the study will be conducted between September 2025 with a transition decision in June 2026.

In the pilot study we will recruit 60 participants, 30 in each arm, across the 2 sites. This will allow for exploration of key parameters needed to confirm sample size calculation for the efficacy study. It is sufficient to allow estimation of two-sided 95% CIs around the proportions of eligible, consenting, adhering and followed up at month 6 in each arm of the study with half-widths less than 0.15. It meets the 30 per group recommended by Lancaster et al (Lancaster et al., 2004) for estimating the SE of a primary outcome with sufficient precision, including accounting for any variation across site, where 12 participants per arm per site is recommended.

Objectives for the internal pilot trial

PRQ1 To conduct a prospective, two-arm, individually randomised RCT to pilot study outcomes and methods and establish the parameters for the conduct of efficacy evaluation.

PRQ2 To assess whether progression criteria have been met and develop an appropriately powered efficacy protocol.

PRQ3 To confirm the pre- post-test correlation on the primary outcome, percent days abstinent from alcohol and/or drugs to incorporate into a sample size calculation.

PRQ4 To estimate an estimate of potential effect for the primary outcome for inclusion in a sample size calculation.

PRQ5 To explore the relationship between the use of alcohol and specific drugs and violent offending. This will be achieved through an analysis of existing datasets; Reframe and RISKIT-CJS, with a confirmatory analysis conducted on the pilot data at the time of transition.

PRQ6 To explore data redundancy at the 6-month end point to provide information on outcome assessments.

PRQ7 To explore what constitutes business as usual across the two sites, Bristol and Newport.

PRQ8 To qualitatively explore the feasibility, acceptability and barriers associated with referral pathways with a particular focus on equity, diversity and inclusion.

PRQ9 To qualitatively explore intervention delivery and outcome assessments from the perspectives of participants, their family, intervention providers and key stakeholders.

PRQ10 To explore the cultural sensitivity of the intervention and trial methods and explore whether further adaption to the intervention is necessary.

PRQ11 To explore whether MDFT has any iatrogenic or unintended consequences.

Design

The study protocol has undergone an independent equality impact assessment (EIA) (appendix III). The EIA explores equity, diversity, and inclusion from a variety of perspectives. The EIA was coproduced with a Young Persons Advisory Group (YPAG). The MDFT intervention will undergo an initial adaption stage, coproduced with an advisory group who are representative of the population where the intervention will be delivered.

Information sheets, privacy notices and consent forms are designed to be understood and completed by young people. All outcome measures are validated for the age of the target population. Experts in the design of research for young people with intellectual disabilities, SEND and neurodiversity will be consulted to ensure the materials align with best practice. Where necessary translated materials will be prepared to meet the needs of a diverse ethnic population and where translated versions are not available, translators, including British Sign Language will be made available. Initial assessment will be conducted in a variety of Barnardo's and community locations that are accessible irrespective of disability status and young people will be encouraged to choose a location they find most comfortable. Follow-up assessments will be conducted using a video link and conducted by a researcher with experience of working with marginalised young people.

The recruitment of MDFT therapists will be conducted through local organisations and aim to reflect the diversity of the population where it will be delivered. Young people will be able to choose a therapist who their own cultural or ethnic background or protected characteristics.

As part of the recruitment process Barnardo's will work with a variety of referral agencies to ensure equity of opportunity to engage in the research. Referral and recruitment data will be carefully monitored in terms of ethnicity, sex and disability status, including an assessment of those eligible but refusing consent, this will provide an early indication of any issues that may arise due to the recruitment practices.

Table 1: Trial design

Trial design, including number of arms		Multidimensional Family Therapy to reduce alcohol and drug use in adolescents, an individually, two-arm randomised controlled trial with embedded internal pilot.
Unit of randomisation		Individual young person
Stratification variables (if applicable)		Geographic area (Bristol, Newport) Severity of substance use (Low/ medium risk, high risk) assessed using the GAIN-SS
Primary outcome	variable	Percent days abstinent from alcohol and drugs
	measure (instrument, scale, source)	Time line follow-back in the 28 days prior to the 6 month follow up.
Secondary outcome(s)	variable(s)	Percent days abstinent from alcohol and drugs in the 28-days prior to the 12-month follow up Self-reported volume of violent offending behaviour at months 6 & 12. Behaviour: internalising behaviour (emotional regulation plus peer relationships subscales), externalising behaviour (hyperactivity plus conduct problems subscales) at months 6 & 12. Mental health and wellbeing at months 6 & 12. Alcohol and substance use problems at months 6 & 12.

		Self-report Client Service Receipt Inventory (CSRI) to assess police involvement at months 6 & 12 (arrests, cautions, charges, court attendance), educational outcomes (suspensions, exclusions, managed moves) and employment status.
	measure(s) (instrument, scale, source)	Offending: Self-report delinquency scale covering the previous 6-month (SRDS), violent offences are classed as carrying a weapon, robbery, assault, racial assault and fire setting. Behaviour: Strengths and difficulties questionnaire (SDQ), externalising behaviour and internalising behaviour. Mental health and wellbeing, Warwick-Edinburgh Wellbeing Scale-short form (WEMWBS-SF). Alcohol and substance use problems, European School Project on Alcohol and Drugs Problem Scale (ESPAD-PS). Self-report Client Service Receipt Inventory (CSRI).
Baseline for primary outcome	variable	Percent days abstinent from alcohol and drugs.
	measure (instrument, scale, source)	Single substance use question assessing the 28 days prior to baseline.
Baseline for secondary outcome	variable	Volume of self-reported offending in the 6 months prior to baseline. Behaviour: internalising behavior and externalising behaviour at baseline. Mental health and wellbeing at baseline. Family cohesion and conflict at baseline. Alcohol and substance use problems at baseline. Self-report Client Service Receipt Inventory (CSRI) in the 6 months prior to baseline to assess police involvement (arrests, cautions, charges, court attendance), educational outcomes (suspensions, exclusions, managed moves) and employment status.
	measure (instrument, scale, source)	Offending: Self-report delinquency questionnaire covering the previous 6-month (SRDS).

		Behaviour: Strengths and difficulties questionnaire (SDQ). internalising behaviour and externalising behaviour. Mental health and wellbeing, Warwick-Edinburgh Wellbeing Scale-short form (WEMWBS-SF). Family: Brief Family Relationship Scale (BFRS). Alcohol and substance use problems, European School Project on Alcohol and Drugs Problem Scale (ESPAD-PS). Self-report Client Service Receipt Inventory (CSRI).

Randomisation

The randomisation of young people to MDFT or BAU will be conducted by research staff after informed consent has been taken and the baseline assessment completed, by intake staff at Barnardo's. The allocation will involve an equal probability of receiving one of the two trial arms, MDFT or BAU, and will employ random permuted blocks of variable size (2, 4 or 6) with a random block seeded throughout. Randomisation will be conducted using a secure, independent randomisation service, Sealed Envelope Ltd. Randomisation will be stratified by geographical site (Bristol, Newport) and severity of substance use (low/ medium, high) ascertained using the GAIN-SS assessed at baseline. A full quality assurance AUDIT trail will be kept of all allocations and research staff will not be able to see future allocations. The allocated group will be relayed back to staff in the sites.

It is not possible, or appropriate, to blind young people or staff to their allocated group although follow-up at months 6 will be conducted by researcher's blind to participant allocation.

Participants

Targeting those at the greatest risk of serious youth violence will be a key priority. The prioritisation of referrals will be decided using a multi-agency approach via intelligence sharing between Barnardo's, Local Authority and education safeguarding teams and Police across Bristol and Newport. It is expected that 70% of referrals will be secondary, not currently involved with CJS and 30% tertiary, currently involved with CJS. Referrals will come from services in Bristol and Newport who are in contact with vulnerable children with known or suspected substance use problems, including schools, Pupil Referral Units, Youth Offending Services, Children's Social Services, CAMHS and specialist drug and alcohol services. It is anticipated that most referrals will come through an agreed referral pathway with both Local Authorities (LA), of their Front Door arrangements, Youth Justice Teams and Violence Reduction / MACE arrangements. Following discussions with both LAs, Barnardo's is

confident that sufficient referrals will come from this pathway to meet the required numbers. In addition, referrals may also be made by other services. This is a similar approach to that adopted by Barnardo's Strategic Child Exploitation Service in Bristol which works directly with young people at the highest risk of harm - gang involvement, serious violence, and exploitation. Initial estimates suggest 35% of participants will be from Black, Asian or other racially minoritised groups, 35% will have special educational needs or disabilities, 15% will be care experienced and 35% female.

Staff at Barnardo's will screen referrals to ensure they are consistent with the study inclusion and exclusion criteria and take informed consent. The principle of Gillick consent will be employed by staff trained in assessing Gillick competence to assess whether participants are mature and intelligent enough to make their own informed decisions. As a rule, young people aged 13 years or more, of average intelligence, are considered Gillick competent. Unless there is a specific reason not to do so, parents/ carers will be informed of the young person's participation in the study. Where consent cannot be taken using the Gillick principle, consent will be sought from a person with parental responsibility, in this scenario if a parent/ carer provides consent the young person will also have to provide assent to ensure there is no parental coercion to participate. Parent/carer consent is not required at the start of delivery. MDFT therapists will work with the young person to build their trust in the process and comfort with seeking parental/carer consent. They will also work to identify a trusted adult that could take the place of a parent/carer where needed. Broadly speaking, we would expect parents to be approached within a month of the young person starting MDFT. Giving young people the time and space to decide whether to approach a trusted adult, who it may be, and how they may approach them is crucial to the rapport building process.

It is anticipated that 60% of the referrals will come from Bristol and 40% from Newport, based on the relative population sizes. This means that 4 therapists will be recruited in Bristol and 3 in Newport. Based on our delivery in Bristol to young people being harmed in their communities through substance use, serious violence, and exploitation, we receive referrals showing a disproportionate percentage of racially minoritised young people. Following discussion with our referring partners in both LAs, we believe this pattern will be reflected in the MDFT pilot.

Consent and baseline assessment will be conducted by staff employed by Barnardo's they will be conducted in a safe, therapeutic and convenient location for the young person, this will include facilities managed by Barnardo's, community facilities accessed as part of community partnerships, children's services, school and the young person's home. Data will be collected on-line, and randomisation will be conducted independent of Barnardo's by research staff after baseline data collection has been conducted.

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 defined as having at least one of the following risk factors, assessed on referral.

   - Previously being in the secure estate.
   - Currently, or previously, persistently absent from school (defined by DfE as 10% or more).
   - Have been the victim of violence.
   - Currently, or have attended alternative education provision.
   - Received multiple suspensions from school or has been permanently excluded.
   - Have a sibling or parent who has been involved in serious violence or identified as facing exploitation harm.
   - Currently, or have been, in the care system.
   - Have been identified as being at risk of criminal exploitation.
   - Currently or have had a social worker.
   - Have previously been in contact with youth justice services.
   - 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.

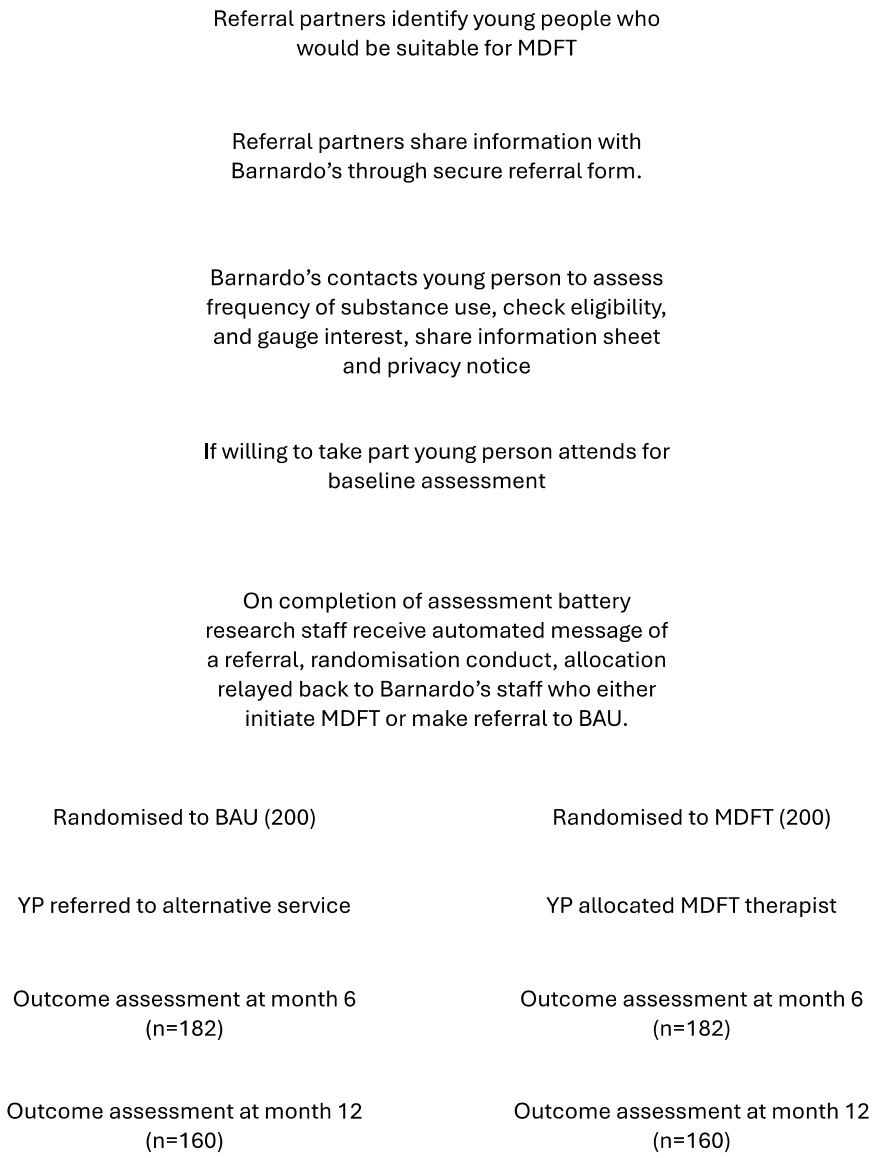
4. Willing and able to provide informed consent or willing to provide assent with a parent/ carer willing to provide consent.

Exclusion criteria:

1. Alcohol or substance severity that requires inpatient residential treatment or immediate detoxification.

2. Severe mental health condition requiring immediate psychiatric assessment.

Figure 3: Flow chart of recruitment processes.



Data is collected at 6- and 12-months using bespoke, secure, on-line data collection system and transferred to secure servers managed by the University of Kent. Six- and 12-month data collection is completed by research staff blind to participant allocation and participants receive a payment of £25 for completing assessments at baseline 6- & 12 months.

Sample size calculations

Sample size estimation was conducted in STATA18. A clinically important effect size for substance use frequency in adolescents is estimated as 0.27, similar to the lower bound

estimates found in systematic reviews of MDFT (Filges T. et al., 2018, van der Pol et al., 2017b). This equates to a number needed to treat of 6, where at least one in six participants receiving MDFT would show clinically important benefits, and a difference in the frequency of substance use of at least 13% in the MDFT group. Detecting an effect size smaller than this provides no additional benefit, the commissioning of services in England and Wales requires the service to achieve a clinically important difference for the target population. To detect this difference, with power at 80% and alpha of 0.05 and a two-tailed test, requires a sample of 480 participants followed-up at the 6-month endpoint. Using data from other studies of substance using adolescents (Coulton S et al., 2023, Deluca et al., 2020) we estimate the pre-post-test correlation of the frequency of substance use to be 0.4, and incorporating this into the sample size calculation reduces the number followed-up to 364, 182 in each group. Assuming a loss to follow-up at the endpoint of 10%, similar to other studies in adolescent substance use populations (Coulton et al., 2024) inflates the number needed to randomise to 400. Assuming 80% of those eligible will be willing to consent an indication of acceptability of the study to participants and a lower figure than other studies in similar populations (Coulton et al., 2024) would mean we would need to approach 480 across both sites. Recruitment will be continuous between September 2025 and January 2027, 28 per month will need to be approached in total across both sites per month with the expectation that 24 will consent to participate in the trial across both sites. We anticipate. Based on relative population size that 40% of referrals will come from Newport and 60% from Bristol.

Table 2: Recruitment/ retention table

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11
Months (e.g. Oct-Dec 23):	**May - Jul 25**	**Aug - Oct 25**	**Nov 25 - Jan 26**	**Feb - Apr 26**	**May - Jul 26**	**Aug - Oct 26**	**Nov 26 - Jan 27**	**Feb - Apr 27**	**May - Jul 27**	**Aug - Oct 27**	**Nov 27 - Jan 28**
Target number of children and young people **referred into the project**	0	50	75	75	75	75	75	75	218	360	500
Target number of children and young people **recruited to the project and evaluation**	0	40	60	60	60	60	60	60	174	288	400
Target number of children and young people who **withdraw/drop out**	0	4	6	6	6	6	6	6	23	35	40

Table 3: Sample size calculations

		PARAMETER
Minimum Detectable Effect Size (MDES)		0.27
Pre-test/ post-test correlations	level 1 (participant)	0.40
	level 2 (cluster)	n/a
Alpha[2]		0.05
Power		0.8
One-sided or two-sided?		2-sided
Number of participants	Intervention	182
	Control	182
	Total	364

Outcome measures

To ensure outcomes are accessible to a wide range of potential participants we will make outcomes available in other languages, where validated and provide translators for other languages. As we anticipate a higher level of intellectual disability than the general population, we will seek the advice from the Tizard centre at the University of Kent who are specialists in the conduct of research with people with intellectual disabilities. We will seek advice on how outcomes can be presented to meet the needs of the target population; this will include using different fonts, colours, and the restriction on the amount of text presented on each page. The completion of outcomes will be supported with research staff available to address any questions. All outcome tools will be agreed with our youth advisory panel prior to use.

[2] Please adjust as necessary for trials with multiple primary outcomes, 3-arm trials, etc., when a Bonferroni correction is used to account for family-wise errors.

Baseline measures

Key demographic variables will be collected at baseline, these include DoB, sex, ethnicity, and index of material deprivation (IMD) derived from the participants postcode and converted to IMD using the IMD lookup tool:

https://geoconvert.ukdataservice.ac.uk/help/faq.html.

The severity of substance use, for stratification, will be determined by Global Assessment of Individual Need short screener for substance use (GAIN-SS; (Dennis et al., 2006)). This 5-item self-completed questionnaire has high sensitivity, 0.86, and specificity, 0.93, with an area under the curve of 0.97, in identifying adolescents who meet DSMIV criteria for low/ moderate or severe substance use disorders. This outcome will be used as a stratification variable in the randomisation to ensure both groups have a similar distribution of low/ moderate and severe cases.

Primary outcome

While the study will collect secondary outcomes on offending behaviour and delinquency, it is important to note the heterogeneity of the population is such that some participants will not be engaging in offending while all will have used substances. The proposed primary outcome for the study is frequency of substance use over a given period.

The YEF outcomes database for substance use contains five outcome measures: Alcohol Use Disorders Identification Test (AUDIT), Substance and Choices Scale (SACS), CRAFFT Substance Abuse Screening Test (CRAFFT), GAIN-I Substance Problems Scale, Adolescent Alcohol Involvement Scale (AAIS). AUDIT and AAIS are specific to alcohol only. All the measures in the YEF database are screening tools, the outcome is dichotomous, none measure frequency of use beyond simple ordinal values with broad categories and none have adequate psychometric evidence of sensitivity to change over time. The only suitable measure in the database that measures frequency of alcohol and/ or substance use is the substance use domain of the Global Assessment of Individual Need (GAIN). This instrument is delivered as a structured interview. It collects data over a 90-day retrospective period on the frequency of use of different substances. It is long, 100+ items, and repetitive. Only frequency of use of individual substances can be derived using GAIN, rather than overall substance use because a young person may use multiple substances in a day. This makes it difficult to operationalise as a primary outcome measure.

We propose assessing alcohol and/ or substance use with the Time Line Follow Back method (TLFB; (Sobell and Sobell, 1995)). The TLFB is conducted as a structured interview using a calendar to aid recall. TLFB has established validity and reliability for multiple substances (Martin-Willett R et al., 2020) over time periods ranging from one to 365 days. It has been specifically validated for use with adolescents (Levy et al., 2004) and college students

(Fishburne and Brown, 2006, Sobell et al., 1986). The TLFB has been used to collect data on cannabis use (Donohue et al., 2004), cigarette smoking (Gariti et al., 1998) risky sexual behaviour (Carey et al., 2001) and use of illicit substances (Hersh et al., 1999). The research team have experience of using the TLFB in adolescent populations (Coulton et al., 2023, Coulton et al., 2024), and it has been widely used in evaluations of MDFT (Dakof et al., 2015). The research team have used the TLFB in several RCT's to assess alcohol and substance use among school pupils (SIPS Jnr High, RISKIT), adolescents attending emergency departments (SIPS Jnr), adolescents involved in the criminal justice system (RISKIT-CJS) and adolescents in police custody (Reframe).

In adolescent populations a standard TLFB with a recall period of 28 days. Frequency of use is calculated as percent days abstinent from alcohol and/ or other substances in the previous 28-days. It provides a fractional outcome and is far more detailed than standard measures of alcohol and substance use and can yield information on the overall frequency of alcohol and substance use, frequency of individual substances, quantity of use and periods of heavy episodic use. With a trained researcher the TLFB28 takes on average 10 minutes to complete.

The covariate for the primary outcome is assessed at eligibility and baseline using a Single Substance Use Question (SSUQ; (Levy et al., 2021)) over the past 28-days. This single frequency question reduces the burden on participants at baseline and addresses the issue of potential assessment reactivity, where the assessment of substance use in detail acts as a brief intervention. The SSUQ meets the criterion as a covariate for adolescent populations in that it is highly correlated with frequency of substance use derived from the primary outcome time line follow-back 28 (rho = 0.903 for alcohol and 0.830 for drugs).

Secondary outcomes

Self-reported violent offending will be assessed using the volume score of the Self-Report Delinquency Scale (SRDS; (Smith and McVie, 2003)) over the previous six months. This 19-item questionnaire has established psychometric properties (Fonagy et al., 2018) in this population and has a strong correlation (R=0.95) with police charges (McAra and McVie, 2007). Violent offences are classified as carrying a weapon, robbery, assault, racial assault and fire setting.

Emotional symptoms and behavioural difficulties will be assessed using the self-completed Strength and Difficulties questionnaire (SDQ; (Goodman, 1997)). This assesses behaviour across several domains including, conduct, hyperactivity, emotional regulation, peer relationships and prosocial behaviour and allows for the generation of two multi-component outcomes: internalising and externalising behaviours with the latter highly associated with current or future offending behaviour. We will assess total score, externalising behaviour, internalising behaviour. The outcome is widely used and has demonstrated excellent validity and moderate reliability in adolescent populations (Goodman, 2001). The SDQ is suitable for

completion by those aged 10-17 years and those with mild learning disabilities (Law and Wolpert, 2014).

Wellbeing will be assessed using the Short Warwick-Edinburgh Mental Well-being scale (SWEMWBS; (Clarke et al., 2011)). SWEMWBS is a 7-item, self-completed scale addressing different aspects of eudemonic and hedonic mental health wellbeing. The scale is validated for adolescents and demonstrates good internal consistency (Ng Fat et al., 2017), and discriminant, construct and convergent validity (McKay and Andretta, 2017, Ng Fat et al., 2017).

We will use questions derived from a Client Service Receipt Inventory (CSRI; (Coulton S et al., 2023) to assess school, work and criminal justice involvement over the previous 6-months. All these outcomes will be assessed at baseline and again at month 6.

To explore the mechanism of change we aim to assess changes in domains that are key targets of MDFT. The Brief Family relationship Scale (BFRS; (Fok et al., 2014)) will be used to assess family conflict and cohesion. Motivation to change will be assessed using the readiness to change ruler (RR; (Maisto et al., 2011)). Self-efficacy will be assessed using the short Situational Confidence Questionnaire (SCQ-8;(Breslin et al., 1998)). Positive and negative Expectancy will be assessed using a four-item expectancy measure (SUE; (Montes et al., 2019)).

Secondary outcomes will be assessed at baseline and at the 6-and 12-month follow-up points and have established psychometric properties in adolescent population. Therapeutic alliance will be assessed using the revised Therapeutic Alliance Scale for Children (TASC-r; (Shirk and Saiz, 1992)) at the 6-month follow-up only.

All outcome measures have been used previously in adolescent populations, and we estimate the outcome data set takes on between 10 and 20 minutes to complete.

Table 4: Core outcomes and the time of data collection.

Outcome	No of items	Baseline	Six months
Stratification			
Global Assessment of Individual Need – short screen (GAIN-SS)	5	✓	
Covariate			
Single Substance Use Question – 28 day (SUSQ28)	1	✓	
Primary			
Time Line Follow-Back – 28 (interview)			✓
Secondary			
Self-reported delinquency (SRDS)[1]	36	✓	✓
Strength and Difficulties (SDQ)[1]	25	✓	✓
Wellbeing (SWEBWMS)	7	✓	✓
Family cohesion and conflict (BFRS)	15	✓	✓
Alcohol and substance use problems (ESPAD)	8	✓	✓
Client Service Utilisation (CSRI)	8	✓	✓
Exploratory			
Motivation to change (RR)	1	✓	✓
Substance use expectancy (SUE)	4	✓	✓
Substance use efficacy (SCQ8)	8	✓	✓
Therapeutic Alliance (TASC-r)	12		✓

[1] SRDS and SDQ are YEF core outcomes.

Compliance

We will assess adherence using the MDFT clinical portal, this assesses the dose and duration of interventions planned and delivered including the specific domains targeted at each session. A minimum dose of MDFT is defined as completion of the following metrics over a 6-month period. :

- Adolescent-only Sessions: 55% of total sessions being completed.
- Family Sessions: 30% of total sessions (includes the time within family sessions when therapist might have a little one on one time with youth or parent if needed).
- Parent/ carer-only sessions: 15% of total sessions (maybe with a single parent/ carer alone, and/ or time with the parenting team/ system together.

We plan on conducting a secondary analysis using a Complier Average Causal Effects (CACE) model using an instrumental variable framework. CACE analysis allows us to avoid bias by weighting the ITT treatment effect by compliance with the intervention or control treatment received, this provides an unbiased estimate of the role of compliance in the outcomes observed. By using different thresholds of compliance, a minimum threshold of 12 sessions over 4 months versus complete compliance, we can explore the nature of the relationship between compliance with the intervention and outcomes observed.

Analysis

Pilot study analysis

In the pilot study we will explore the distributional assumptions for each outcome measure and present descriptive statistics, either parametric or non-parametric overall, by allocated group and by stratification variables. We will estimate likely proportions of participants who are eligible, consent and followed up at 6 months. Each of these will be assessed against progression criteria detailed in appendix I (**PRQ1, PRQ2**).

We will conduct a descriptive analysis of outcomes including measures of central tendency and estimates of precision for continuous outcomes and proportions for categorical outcomes. Inferential analysis at the pilot stage will focus on the primary outcome and will involve a futility analysis using a fractional regression adjusted for stratification variables. This will allow us to confirm or revise our sample size calculation (**PRQ3, PRQ4**).

We will explore the relationship between alcohol and substance use and violent offending (**PRQ5**) by comparison of data derived from the TLFB for specific substances and the SRDS. This will enable decisions to be taken about whether specific substances should be the target of the efficacy trial. Data redundancy (**PRQ6**) will be explored by examining the pattern of missing data for each outcome.

We will explore business as usual (**PRQ7**) through interviews with key stakeholders across both sites, those that deliver business as usual and those that refer to their services. We will explore key questions around acceptability of the intervention, factors that facilitate or hinder participation, intervention delivery and outcome assessment (**PRQ8**, **PRQ9**) by conducting interviews with young people and parents/ carers, purposively sampling those who did not consent and those who consented but dropped out of the intervention or follow up. To explore how the intervention is sensitive to the sociocultural needs of the target population and determine potential culturally influenced barriers towards the acceptability of the intervention in relation to ethnicity and equity, as well as the presence of structural barriers, we will conduct in-depth qualitative interviews with young people from minority ethnic communities and other marginalised groups including those with SEND and LAC, as well as with staff, and providers. Thematic analysis (Braun and Clarke, 2006) will be used to elicit young people's experiences of the programme, in addition to staff, and service providers' perspectives, and how these experiences impact on the acceptability of the intervention. The findings will inform future adaptations of the intervention to various socio-cultural contexts.

Efficacy study analysis

The primary analysis will take the form of a fractional regression model, adjusted for baseline stratification variables and the baseline covariate.

Data from the internal pilot and efficacy study will be combined and analysed blind to group allocation. The efficacy analysis will follow CONSORT guidelines. The primary outcome is fractional, a proportion constrained by 0 or 1. The analysis will be conducted using an analysis by intention to treat and will include all available data to maintain participants as members of their allocated group, irrespective of what intervention was received, this provides an unbiased estimate of effect. To adjust for potential bias from recruiting participants to the pilot or efficacy stage, we will use an individual patient data meta-analysis, entering a dichotomous pilot/efficacy variable into the model as a fixed effect. Differences between the groups will be presented as marginal means and their associated 95% confidence intervals. If the missing primary outcome data exceeds 10% sensitivity analyses will be performed using a pattern mixture approach and multiple imputation to compare the sensitivity of conclusions to varying assumptions about the missing data, particularly whether data is missing at random (MAR) or missing not at random (MNAR) this allows for an assessment of both random and systemic bias.

Secondary outcomes will be assessed in a similar way by establishing diagnostic plots to identify the most appropriate regression approach, including stratification factors and baseline covariates within a multi-level model.

The primary end point is 6 months post-randomisation. This will allow an assessment of impact for short term outcomes. In order to explore whether effects are sustained over time and assess impact on longer term outcomes a secondary analysis will be conducted at 12-months post randomisation.

Exploratory analysis

Fractional regression analysis will be performed to model the relationship between pre-randomisation factors, and demographics on observed outcomes at 6 months, for the primary outcome. Interaction terms with allocation arm will be included in the analysis, and a significance level of 0.1 will be used to determine which factors are to be included in the model. Pre-randomisation factors will include ethnicity, sex, age, IMD decile, severity of substance use, and baseline family cohesion, motivation, self-efficacy and expectancy. This analysis will be augmented by an additional analysis including participants in the intervention arm only using the same pre-randomisation factors but also including process measures of adherence, intervention fidelity, and therapeutic alliance.

Latent class approaches will be used to explore the hypothesised mechanism of change exploring changes over time in family cohesion, motivation to change, self-efficacy and substance use expectancy.

Qualitative analysis

The aim of the qualitative analysis in the efficacy study will be to link samples by grouping, comparing, and contrasting responses from all data sources to address the research questions. This linking of data allows for a concentrated and more meaningful analysis of the influence of the programme through its contexts and mechanisms, and of its perceived impact through a thematic blending of data elements. The key questions that we will seek to answer at this stage will include:

- Are there any residual or new external or logistical issues impacting referral, intervention delivery, or attrition?
- What are young peoples' positive and negative experiences of the intervention and how do these fit with providers' perceptions?
- At what points in the intervention have these experiences occurred?
- Are there practices associated with the intervention that can be amended to further increase its acceptability and impact?
- Do stakeholders see the intervention as impacting participant's behaviour?
- In what ways has substance use and offending been impacted?

This provides an opportunity to explore the perceptions of the intervention from the point of view of a variety of stakeholders using Normalisation Process theory (NPT; (Finch et al., 2012). Bracketing, reflexivity, and member checking will be employed to ensure trustworthiness and rigour.

Using NPT, the objectives of the qualitative analysis will be to identify useful and unnecessary elements of the intervention, explore planning and implementation issues, understand issues around ethnicity and equity, and identify perceived barriers or facilitators of implementation in usual practice. Taking an inductive and deductive approach, no existing theory will be used to facilitate the coding, which will allow for findings to emerge naturally from the data. Findings will be mapped onto NPT to elucidate coherence (the extent to which the intervention makes sense to those involved in its implementation), cognitive participation (the extent to which individuals involved in implementing the intervention are motivated to engage with it), collective action (the extent to which the intervention is incorporated into everyday practice and is implemented consistently and reliably), and reflexive monitoring (the extent to which the intervention is evaluated and reviewed over time to ensure it remains relevant and effective).

Sub-group analyses

Sub-group analyses by their nature tend to be under-powered. To maintain power in the analysis we will use latent-class cluster analysis to explore the emergence of different clusters

who might experience differential effects. Latent class analysis will explore the potential effect of ethnicity, age, sex, socio-economic status, criminal involvement and severity of substance use on the effects observed for the primary outcome.

Longitudinal follow-ups

Participant data will be collected at baseline, prior to randomisation and again at 6- and 12-months post randomisation. Our primary endpoint will be the 6-month post-randomisation date. Core outcomes and the time of data collection are presented in table 4.

Implementation and process evaluation

The implementation and process evaluation will use purposive sampling for interviews with participants, parents or carers, intervention staff, and key stakeholders, including community leaders working with diverse populations. Participants will be selected purposively to ensure diversity by site, age, sex, social class, and ethnicity. Sample size will be based on achieving data saturation, judged in practice rather than stated upfront but is expected to be about 30 interviews in total. The pilot stage will address key qualitative questions: whether the intervention reaches all potentially eligible participants, especially across cultures; identifying barriers and facilitators to implementing MDFT; and exploring the business-as-usual pathway.

Research questions

Fidelity, Exploring Fidelity/ Adherence, Differentiation, and Quality

1. What impact does compliance with the intervention and fidelity of the intervention have on the outcomes observed.
2. What impact does therapist communication style have on the outcomes observed.

Exploring non-compliance

3. What factors are associated with non-compliance with the intervention.
4. Is non-compliance associated with specific characteristics of the target population, such as ethnicity, SEN or neurodiversity.

Exploring Reach

5. Are their specific reasons CYP decide not to engage with the intervention.
6. Is the generalisability of the intervention appropriate to ensure all potential participants can access the intervention.

Exploring responsiveness

7. What are participants' positive and negative intervention experiences and how do these fit with providers' perceptions? At what points in the intervention are these most likely.

8. Can practices associated with the intervention be amended to increase its acceptability and impact?

Exploring adaptation

9. Are there causal pathways that influence the outcomes observed and are they to those proposed in the theory of change.
10. What factors associated with these causal pathways mediate the outcomes observed.

Exploring factors associated with wider implementation

11. How sustainable do delivery partners and key stakeholders believe the intervention is.

Research methods

Exploring Fidelity/ Adherence, Differentiation, and Quality

We propose to conduct an analysis to explore the role compliance, therapeutic alliance, fidelity and interventionist impact on the outcomes observed. A regression model, with the primary outcome as dependent variable and adjusting for key covariates identified will be conducted. This will allow for a quantification of what dimensions of the intervention are associated with outcomes and will enable an exploration of whether certain domains are more important than others and should be emphasised in the intervention delivery and, by extension, the training. Allied to this, the perception of therapeutic alliance will provide an insight into whether therapist communication style influences outcomes.

Exploring Non-compliance

In addition to this we would want to explore whether certain factors are associated with non-compliance to identify potential clusters of participants who do not comply. We will conduct a latent class analysis to identify clusters associated with non-compliance, this will enable an exploration of whether there are groups of participants who are harder to reach than others and by augmenting this quantitative approach with targeted qualitative interviews with young people and interventionists, enable the wider research group to explore what adaptations may be necessary to increase accessibility and compliance.

Exploring Reach

A key area to explore in terms of reach is whether all potential participants are being identified and referred to participate in the study. We will conduct specific research to explore for differences in potentially eligible and referred participants in each site with a key focus on ethnic and culturally appropriateness of both the referral mechanism and intervention delivery. Through the qualitative work we will also focus on reasons why some may not want to engage with the intervention. This information will allow us to quantify any inherent biases associated with referral in terms of key demographics, such as age, sex or ethnicity and to further explore these with our stakeholder interviews. This approach will enable us to understand how generalisable the study results are and whether changes need to be made to referral pathways or intervention delivery to make the population more inclusive.

Exploring Responsiveness

An aspect of our qualitative work with key stakeholders involves examining participants' positive and negative experiences of the referral process and intervention, exploring how these perspectives concur with those who deliver the intervention, explore at what points negative and positive experiences are at their greatest and what steps could be taken to ameliorate these experiences to improve the delivery and acceptability of the intervention.

Exploring Adaptation

The mechanism of change will be explored using a latent class mediation model. Exploring factors that impact on the mechanism of change will be assess the relationship between pre-randomisation factors and observed outcomes at 6 months. Pre-randomisation factors include sex, age, ethnicity, IMD decile, family cohesion, motivation to change, self-efficacy and substance use expectancy.

In addition to quantitatively understanding the mechanism of action, the qualitative analysis will provide an opportunity to explore the perceptions of the intervention from the point of view of a variety of stakeholders. The analysis will allow us to explore what elements of the interventions are useful and what elements are unnecessary, issues around how the interventions are planned and implemented and the perceived barriers or facilitators of implementation in usual practice.

Through a detailed exploration of the key dimensions, we plan on stating our logic model at the start of the project, and revise this again at the end of the internal pilot stage. The logic model will incorporate the qualitative research exploring stakeholder perceptions of acceptability and usefulness, hindrances and facilitators associated with the process and intervention but will also combine quantitative analysis exploring adherence, dosage, fidelity, and mediators associated with behaviour change. This mixed methods synthesis will enable

us to understand what works, how it works, when it works and for whom it works and provide a detailed elaboration of the mechanisms and processes through which it works.

Exploring Factors Affecting Implementation

Interviews with intervention delivery partners and key stakeholders, including those delivering similar substance use services to CYP, will explore how sustainable the intervention is in its current format. What key challenges were experienced and what changes might be necessary to roll out the intervention more widely.

The qualitative aspect of the work will involve the collection of narrative accounts from a range of individuals using semi-structured interviews. These will be collected from young people participating, carers and staff involved in the programme delivery and professionally associated with the young people. Professionals will be sampled purposefully from the different staff groups, and young people will also be purposefully sampled. Synthesis of these data sources will allow a detailed overview of the implementation and processes associated with successful delivery of the intervention.

Table 5: IPE methods overview

IPE Question	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed	Implementation/ logic model relevance
Fidelity/ adherence/ differentiation/ quality	Participant survey, therapeutic alliance, session data	400 participant surveys and TASC-r	Regression analysis	Quantification of the role fidelity, and quality plays in the outcomes observed	Better quality interventions that involve better alliance and communication between young people and practitioners are associated with better outcomes.
Compliance	Session planned and attended, outcome data	400 participant surveys, process database	Complier Average Causal Effect analysis	Estimation of the role compliance plays on observed outcomes at variable thresholds	Greater frequency of intervention is associated with better outcomes

	Factors associated with non-compliance	400 participant surveys, process database	Latent Class Analysis	Explore factors associated with non-compliance	Create targeted opportunities to reduce non-compliance and maximise acceptability.
Reach	Cohort Approach	Data on all young people referred to the service compared with data for those who consented	Logistic regression model with consent as the dependent outcome	Explore whether the intervention was accessible to all those referred to the services	Identify any potential issues with accessibility.
	Qualitative interviews with service leads and key stakeholders	10 semi-structured interviews	Transcribing and inductive analysis to allow themes to emerge naturally	Identify any populations that experienced limited accessibility and the potential reasons for this.	Identify issues with accessibility and how these may be addressed
Responsiveness	Qualitative interviews with MDFT participants	15 semi-structured interviews with participants, 10 interviews with parents/ carers and 10 semi-structured interviews with key stakeholders, purposive sampling to get variety by site, age and ethnicity	Inductive analysis	To explore acceptability of the referral and intervention process. To explore positive and negative experiences and when these occur. To triangulate child-parent-practitioner experiences.	To understand how the referral and delivery processes can be maximised.

Adaption	Quantitative analysis	400 participant surveys	Latent class mediation analysis.	To explore factors at baseline and follow-up that mediate the outcomes observed	To understand the mechanisms of change and provide information for refinement of the Theory of Change Model.
	Qualitative analysis	15 semi-structured interviews with participants and 10 semi-structured interviews with key stakeholders, purposive sampling to get variety by site, age and ethnicity	Inductive analysis	To explore participant and practitioner perspectives on how the intervention works and perceived barriers or facilitators to the intervention	To understand who the how the intervention works and who it works for to refine the theory of change.
Implementation	Qualitative analysis	15 semi-structured interviews with participants and 10 semi-structured interviews with key stakeholders, purposive sampling to get variety by site, age and ethnicity	Inductive synthesis	Synthesis of qualitative findings to explore positive and negative experiences and how changes can be made to maximise the impact of the intervention.	Identify potential modifications that can be made to maximise the impact of the intervention.

Cost data reporting and collecting

Costs associated with delivering the intervention will be derived using a micro-costing approach accounting for the actual local costs and resources used in delivering the

intervention and associated training. This will include salaries, resources, facilities, overheads, and management costs. The cost perspective will be that of the intervention provider, Barnardo's. We will include any costs associated with supervision and additional training and use the time horizon of the trial to estimate staff turnover. We aim to estimate the cost of delivering the intervention in real practice rather than the cost of delivering the intervention in the trial. The cost data will be provided as a mean cost per participant with 95% confidence intervals and be adjusted to occur each year. Data will be collected using activity logs completed by interventionists highlighting all activity associated with a single participating case.

Diversity, equity and inclusion

Participants in research should reflect the diversity of the society where any intervention will be delivered. All the research team will engage in unconscious bias training, training in delivering research to diverse populations. A further part of this work will be to consult both our YPAG and local agencies working directly with the target population to develop not only recruitment and dissemination materials and protocols that promote equitable participation, but to ensure that interventions are themselves suitable for the target populations to be included. This will involve ensuring scenarios and examples used in sessions are culturally inclusive and appropriate. The study has been reviewed by a race equity associate. The study will also undergo an Equality, Diversity and Inclusion Audit (EDIA). A copy of our equality impact assessment is attached as an appendix to this protocol.

Based on our delivery in Bristol to young people being harmed in their communities through substance use, serious violence, and exploitation, we receive referrals showing a disproportionate percentage of racially minoritised young people, we would expect a similar percentage being referred and recruited to the trial.

As was the case during the co-design phase, a group of young people (13-17 to reflect the age groups involved in the study) will be convened monthly. This group (YPAG) will advise on matters pertaining to recruitment (and materials) and the cultural appropriateness of both the intervention and evaluation activities. Involvement will take the form of a monthly group meeting in which specified questions from the wider project team and Equity Team will be brought to the group for discussion. In addition, each session will allow dedicated space for young people to raise any issues identified that may not have been considered already to ensure the avoidance of 'unknown unknowns' (Wynne, 2015) and ground the study within real rather than '*imagined* publics'. (Wynne, 2015) Young people that choose to take part in the YPAG will be remunerated £25 (via voucher) for their time, in line with the National Institute of Health and Care Research (NIHR) guidance on public participation in research (NIHR, 2022). The YPAG will be representative of the communities where the research takes place in terms of ethnicity and will purposively sample to ensure diversity for YP with SEN,

LAC and neurodiverse YP. The YPAG will include young people of the target age who have experience of substance use. The YPAG will be managed by a specific member of the research team who has extensive experience in working with YPAG and associated safeguarding issues. Meetings will take place on-line to avoid any potential for iatrogenic effects.

The study has been designed to minimise sources of bias. This includes having enough participants to encompass a diverse population that is representative of the target population, minimising inclusion, and exclusion criteria to reduce barriers to participation, ensuring randomisation is conducted independent of the research team, flexibility in conducting baseline and follow-up assessments to allow those with literacy difficulties to complete assessments verbally if required.

We will actively monitor recruitment on key ethnic, socio-cultural and inclusion parameters and where differences occur in the numbers eligible and the numbers consenting, we will explore the reasons why using qualitative interviews to provide an insight into the cultural and ethnic acceptability of the intervention.

We will conduct qualitative and quantitative analysis to explore the role inequality, ethnicity, and socio-economic disadvantage plays in the outcomes observed.

All materials will be available in both English and Welsh and for those who have difficulties in spoken English or Welsh we will provide a translation service, the need for translations will be assessed at the referral stage. During our co-production phase we identified a high prevalence of potential participants with intellectual disabilities. We will link with existing services to modify the presentation of outcomes to address the needs of the population. This will include using larger fonts, coloured transitions between outcomes, simplification in language used and presenting less text on each page of the outcome assessment. All materials will be considered by our young people advisory panel and should the need for further adaptation be identified during this study, this will be considered by the Equity Team and discussed with the wider project team.

Throughout MDFT's development and testing, racial and cultural issues have been core factors in tailoring interventions to each individual youth and family. Racial and cultural diversity has been one of the hallmarks of MDFT development and in the research supporting the model. In clinical trials of MDFT, 83% of young people and their families were from minority groups. The model has thus developed to address the needs of racial and cultural minority groups, primarily African American and Hispanic families in the Unites States. We recognize that the U.K. 's minority groups will have their own unique historic and cultural issues and themes to address, MDFT has been deemed one of the only empirically established interventions for diverse youth populations in the Unites States. In a review of the research on evidence-based psychosocial treatments, MDFT was ranked the most effective treatment for substance use among African American and Hispanic youth.

Additionally, a meta-analysis examining culturally sensitive substance use treatments indicated that participation in MDFT was associated with significantly greater reductions in substance use. In one MDFT study with youth who were 42% Hispanic, 38% African American, and 11% Haitian or Jamaican, MDFT led to more rapid decreases in drug use than peer group-based cognitive behavioural therapy. In an analysis of data from 5 MDFT clinical trials with a total of 646 adolescents who were 51% African American, 35% Hispanic, and 14% European American, MDFT was more effective than the comparison treatment for every group. The only effective treatment for young African American men in these 5 trials was MDFT.

MDFT research has also identified key processes in successful therapy with minority youth. In MDFT therapy sessions, talking about issues like anger from prejudice, feeling alienated, and the challenges and rites of passage of growing up helped African American youth stay more engaged. Clinically, MDFT delivers culturally sensitive treatment by probing into the multiple systems of the young person's life. We seek the youth's and parents' perspectives on their lives and their interests in popular culture, music, film, social media, and art. Therapists must be aware of how society affects marginalized young people. Positive development is challenging when faced with a clash of cultures, racism, discrimination, prejudice, and with little prospect of meaningful work. MDFT therapists must recognize that adolescents create subcultures with distinct values and norms. In turn, breaking through the strong social control within these groups can be challenging. The shared culture manifests in street language, attire, music tastes, and pastimes. We strive to understand and connect with these young people in their natural environments and during our therapy sessions.

s and registration

The study will be conducted in accordance with the principles of Good Clinical Practice, the Declaration of Helsinki and Caldicott principles. The trial will be registered in an appropriate trial registry. Participants will only be recruited to the study once independent full ethical approval has been granted by the University of Kent Social Research Ethics Committee and Barnardo's. Trial methods and data collection instruments will be assessed by a young person advisory group and their recommendations for changes will be incorporated.

We will ensure participants do not feel coerced to consent. Once a participant is referred to the service any consent to participate in the trial is theirs solely to make. Not consenting to the research will not impact on the BAU they receive, and this will be explained verbally and in writing. If a participant does consent it will be made clear that they can withdraw consent at any time.

We will minimise the potential for participants and staff to experience any adverse or iatrogenic events. In our experience of conducting similar studies in similar populations the risk of adverse events is low, as is the risk of iatrogenic events. We will implement a standard operating procedure for the reporting of adverse events that involves an independent

experienced third-party making recommendations on the severity of any event and whether they are associated with the trial. All staff involved in the study will have enhanced DBS accreditation and will be familiarised with safeguarding practice and procedures.

University of Kent Social Research Ethics Identifier: SRE 1200

Barnardo's Research Ethics Committee Identifier: BREC (23)

Trial Registration: ISRCTN10024151

Data protection

All systems and personnel are approved for the management of clinical and sensitive data and are ISO certified to ISO27001 standard. This includes all physical systems, systems to detect intrusion, encryption of data from point of collection to storage, quality assurance and audit trails associated with any data collected. All identifiable data collected will be done with explicit consent and limited to data to allow participants to be contacted for follow-up. Data linkage will employ a unique identifier where the link to identifiable information will be stored on an encrypted secure database. Researchers will be trained to GCP standard and will comply with all relevant data protection legislation. Once final follow-up is completed, personally identifiable information will be deleted from the dataset held by the university and where consent to the trial has been granted encrypted data will be transferred to the Youth Endowment Fund data archive. Consent for transfer of data will be taken from those resident in England, and data used by DfE, name, DoB and postcode will be transferred. Data collection and management will be governed by a trial specific Standard Operating Procedure agreed and approved by ethics.

The basis of processing data was the public task basis to use their personal information. We only use special category information (such as information about health, religion, race, or ethnic origin) if it is necessary for research purposes or statistical purposes which are in the public interest. Potential participants and their carers, if applicable, will be provided with a trial specific privacy notice prior to providing consent. This privacy notice outlined what data was being collected, for what purposes and for how long. In addition to the trial specific privacy notice the evaluation team at the University of Kent and the intervention delivery team at Barnardo's will agree and sign an information sharing agreement highlighting what information will be shared, the reasons for sharing information and the means of sharing information. All communication between the intervention and evaluation team will use encrypted channels secured using a virtual private network.

Stakeholders and interests

Development and delivery team

Gayle Dakoff, MDFT International, MDFT training, supervision and fidelity.

Mohamed Adhar, MDFT International, MDFT training, supervision and fidelity.

Duncan Stanway, Barnardo's, delivery of MDFT and management of the Bristol site.

Mark Carter, Barnardo's, delivery of MDFT and management of the Newport site.

Lilli Wagstaff, Ending Youth Violence Lab, supporting MDFT delivery and adaption.

Tom McBride, Ending Youth Violence Lab, supporting MDFT delivery and adaption.

Evaluation Team

Simon Coulton, University of Kent, overall evaluation lead.

Nadine Hendrie, University of Kent, trial manager.

Dorothy Newbury-Birch, Teesside University, implementation and process evaluation research lead.

Andy Divers, Teesside University, qualitative research, equity and diversity and young person's advisory group.

Risks

Risk	Mitigation
Failure to adapt intervention for delivery in UK setting	Evaluation and implementation teams have clear plans for the adaptation of the intervention involving those who have developed and modified the original MDFT for delivery in different settings, intervention who have previously adapted the intervention for delivery in settings outside the US, key stakeholders including those with experience of delivering substance use interventions in the UK and those in receipt of substance use interventions, either directly (young people) or indirectly (parents/ carers). We are confident an appropriately, culturally sensitive adapted version will be available.

Failure to create an intervention that is culturally sensitive to the community	In adapting the intervention, a key objective will be to ensure MDFT considers cultural sensitivity. The adaption group involves young people, carers and stakeholders that represent the community within the sites. Barnardo's has a clear commitment to EDI and ensuring intervention delivery takes account of the diversity of potential participants, they have a great deal of experiencing in producing culturally sensitive interventions.
Failure to engage stakeholders in project set-up and delivery	Evaluation and implementation stakeholders have positive, constructive relationships and communication is ongoing. As the project progresses the evaluation team will make site visits to discuss processes with the intervention team.
Families in the control group might receive a range of interventions from different providers. This may overlap with interventions delivered as part of MDFT	Data will be collected to monitor what interventions are being delivered and by whom in the BAU group as part of the pilot study. Data from the sites to date suggests that while several providers deliver substance misuse services, both NHS and non-statutory, this tends to be based on 1:1 and group approaches involving motivational interventions and psychoeducation. The use of intensive, family-based interventions is rare in young people's substance use services in the UK. We do not anticipate any contamination within the study.
Trial does not recruit to target	The process of recruitment is an outcome of interest in a pilot study rather than a threat to validity. We will monitor key recruitment criteria and explore, through qualitative interviews key barriers and facilitators associated with recruitment, ensuring that lessons learnt are incorporated within the efficacy study. The evaluation team have extensive experience of recruiting participants in RCT's involving substance using adolescents and have consistently achieved recruitment targets.

Not recruiting sufficient therapists to deliver MDFT may impact on recruitment in the trial.	We have allowed for a three-month lead in to recruit therapists for the trial. Barnardo's has demonstrated experience in recruiting specialist staff to deliver specialist interventions in the target sites and have key contacts with organisations within the community to identify staff.
Trial does not retain sufficient participants at the final end point	We estimate 90% of eligible and consenting participants will be available at the 6-month endpoint, a figure to be reviewed at the end of the pilot study. Evaluation staff have multiple strategies for retaining young people in research studies including payments for outcome completion, collection of multiple contact methods and the use of co-locators. In other studies, involving similar populations the target retention rate has been achieved and, in some cases, exceeded.
Therapists not retained.	Therapist retention will be monitored in the MDFT group at both sites. Barnardo's have specific strategies to retain staff and as MDFT is not delivered currently within the UK opportunities for staff to move to new services are limited.
The random nature of selecting young people could be seen by some as unethical.	we are in a state of equipoise regarding the effects of the intervention. Control group participants will receive established BAU that is current practice in accordance with the Declaration of Helsinki. No participant will be disadvantaged by being allocated to BAU.
Young people may not want to consent to being part of study resulting in lack of numbers for the evaluation	Young people will have access to a clear information sheet highlighting the need to evaluate a new service. Information will be reviewed by a young person's advisory group who will provide input on how best to engage young people in the research. Our experience of other studies with similar populations is that many young people are motivated by altruism, the opportunity to contribute to services that will help others in a similar position in the future.

The potential that young people, therapists and researchers experience negative impacts of participating in the study.	All staff and researchers have access to supervision to raise issues relating to the trial. We will implement a reporting system to allow all staff, young people and their carers and researchers to highlight any potential adverse events and, if needed, seek support. We will implement an independent DMEC to review adverse and iatrogenic effects as they arise and if they believe these are directly attributable to the trial and severe in nature, they will raise the potential of stopping the trial with the research team and funder.
Families may be resistant to participating in the trial.	We have extensive experience of including marginalised populations in evaluations. The pilot study will explore qualitatively barriers to participation. All information about the trial will be available in advance of consent and potential participants provided an opportunity to discuss participation. Consent will be based on the consent of the young person rather than the family and early work in delivering MDFT identifies the most appropriate family members to be involved in the delivery of MDFT.
Young people may exhibit demoralisation if randomised to BAU rather than the MDFT intervention.	Clear information to participants that the study involves a state of equipoise, that at this stage we have no evidence that MDFT is better than BAU and this is what is being tested. Disengagement and 'faking bad' are key signs of resentful demoralisation and both concepts will be explored qualitatively with young people.
Sites may drop out of the study due to changes locally related to financial issues or leadership.	All sites have a track record of commitment to the delivery of services and an understanding of research. Senior sign off has been secured at all sites and commitment made to deliver the research as planned.
Imposition of COVID, or similar, restrictions	Both the delivery team and research team have contingency plans for remote working.
Poor quality delivery of MDFT	Fidelity and quality assurance are monitored throughout the study through the MDFT portal. Therapists are supervised both on-site and by staff from MDFT international. Regular

	reports relating to fidelity on the part of the therapist, adherence on the part of participants and quality assurance are made available and reviewed. Issues can be identified quickly and remedial action taken.
Participants do not complete questionnaires because they are too long	The outcome battery has been used in similar populations and takes on average 15 minutes to complete at baseline and 25 minutes at follow up. Response from other studies suggest burden will not be an issue.

Timeline

05/25 – 09/25: Adapt MDFT for delivery in UK, trial set-up, ethics, registration, recruitment of supervisors and therapists.

09/25 – 12/25: Conduct internal pilot with 60 participants recruited.

06/26 : Evaluate transition criteria and submit transition report form.

07/26 - 05/27: Recruit 340 to efficacy study.

01/27 – 11/27: Conduct efficacy 6-month follow-up.

07/27 – 05/28: Conduct efficacy 12-month follow-up.

06/28: Analyse results.

09/28: Submit final report

Bibliography

BALDWIN, S. A., CHRISTIAN, S., BERKELJON, A. & SHADISH, W. R. 2012. The effects of family therapies for adolescent delinquency and substance abuse: a meta-analysis. *J Marital Fam Ther,* 38**,** 281-304.

BATEMAN, T., BRODIE, I., DAY, A.-M., PITTS, J. & OSIDIPE, T. 2023. 'Race', disproportionality and diversion from the youth justice system: a review of the literature. . London: Nuffield Foundation.

BATTISTELLA, G., FORNARI, E., ANNONI, J. M., CHTIOUI, H., DAO, K., FABRITIUS, M., FAVRAT, B., MALL, J. F., MAEDER, P. & GIROUD, C. 2014. Long-term effects of cannabis on brain structure. *Neuropsychopharmacology,* 39**,** 2041-8.

BLACK, C. 2020. review of Drugs - evidence relating to drug use, supply and effects, including current trends and future risks. London: HMSO.

BRAUN, V. & CLARKE, V. 2006. Using thematic analysis in psychology. *Qual Res Psychol,* 3**,** 77-101.

BRESLIN, F., SOBELL, L., SOBELL, M. & AGRAWAL, S. 1998. A comparison of brief and long versions of the Situational Confidence Questionnaire. *Beh Res & Ther,* 38**,** 1211-1220.

CAREY, M. P., CAREY, K. B., MAISTO, S. A., GORDON, C. M. & WEINHARDT, L. S. 2001. Assessing sexual risk behaviour with the Timeline Followback (TLFB) approach: continued development and psychometric evaluation with psychiatric outpatients. *Int J STD AIDS,* 12**,** 365-75.

CLARKE, A., FRIEDE, T., PUTZ, R., ASHDOWN, J., MARTIN, S. & BLAKE, A. 2011. Warwick-Edinburgh Mental Well-being Scale (WEMWBS): validated for teenage school students in England and Scotland. A mixed methods assessment. 11**,** 487.

COPELAND, W., ADAIR, C., SMETANIN, P., STIFF, D., BRIANTE, C., COLMAN, I., FERGUSSON, D., HORWOOD, J., POULTON, R., COSTELLO, E. & ANGOLD, A. 2013a. Diagnostic transitions from childhood to adolescence to early adulthood. *J Child Psychol Psychiatry,* 54**,** 791-9.

COPELAND, W. E., ADAIR, C. E., SMETANIN, P., STIFF, D., BRIANTE, C., COLMAN, I., FERGUSSON, D., HORWOOD, J., POULTON, R., COSTELLO, E. J. & ANGOLD, A. 2013b. Diagnostic transitions from childhood to adolescence to early adulthood. *J Child Psychol Psychiatry,* 54**,** 791-9.

COULTON S, NIZALOVA O, PELLATT-HIGGINS T, STEVENS A, HENDRIE N, MARCHAND C, VASS R, DELUCA P, DRUMMOND C, FERGUSON J, WALLER G & D., N.-B. 2023. *A multicomponent psychosocial intervention to reduce substance use by adolescents involved in the criminal justice system: the RISKIT-CJS RCT. ,* Southampton, UK, NIHR.

COULTON, S., HENDRIE, N., VASS, R., GANNON, T., WOOTON, A., RUSHWORH-CLAEYS, J. & SINETOS, J. 2024. Randomized controlled internal pilot trial of a diversion programme

for adolescents in police custody who possess illicit substances. *J Public Health (Oxf),* 46**,** e269-e278.

COULTON, S., NIZALOVA, O., PELLATT-HIGGINS, T., STEVENS, A., HENDRIE, N., MARCHAND, C., VASS, R., DELUCA, P., DRUMMOND, C., FERGUSON, J., WALLER, G. & NEWBURY-BIRCH, D. 2022. *RISKIT-CJS: Pragmatic randomized controlled trial to evaluate the effectiveness and cost-effectiveness of a multi-component intervention to reduce substance use in adolescents involved in the criminal justice system* Southampton (UK), NIHR Journals Series.

DAKOF, G. A., HENDERSON, C. E., ROWE, C. L., BOUSTANI, M., GREENBAUM, P. E., WANG, W., HAWES, S., LINARES, C. & LIDDLE, H. A. 2015. A randomized clinical trial of family therapy in juvenile drug court. *J Fam Psychol,* 29**,** 232-41.

DELUCA, P., COULTON, S., ALAM, M. F., BONIFACE, S., DONOGHUE, K., GILVARRY, E., KANER, E., LYNCH, E., MACONOCHIE, I., MCARDLE, P., MCGOVERN, R., NEWBURY-BIRCH, D., PATTON, R., PELLATT-HIGGINS, T., PHILLIPS, C., PHILLIPS, T., POCKETT, R., RUSSELL, I. T., STRANG, J. & DRUMMOND, C. 2020. *Screening and brief interventions for adolescent alcohol use disorders presenting through emergency departments: a research programme including two RCTs.* Southampton (UK).

DENNIS, M. L., CHAN, Y. F. & FUNK, R. R. 2006. Development and validation of the GAIN Short Screener (GSS) for internalizing, externalizing and substance use disorders and crime/violence problems among adolescents and adults. *Am J Addict,* 15 Suppl 1**,** 80-91.

DFE. 2019. Permanent and Fixed-period Exclusions in England: 2018 to 2019. London: Department for Education.

DONOHUE, B., AZRIN, N. H., STRADA, M. J., SILVER, N. C., TEICHNER, G. & MURPHY, H. 2004. Psychometric evaluation of self- and collateral timeline follow-back reports of drug and alcohol use in a sample of drug-abusing and conduct-disordered adolescents and their parents. *Psychol Addict Behav,* 18**,** 184-9.

FILGES T., DITTE A. & A, K. J. 2018. Multidimensional Family Therapy (MDFT) on Nonopioid Drug Abuse: A Systematic Review. *Campbell Sys Rev,* 11**,** 1-124.

FINCH, T. L., MAIR, F. S., O'DONNELL, C. & MAY, C. 2012. From theory to 'measurement' in complex interventions: Methodological lessons from the development of an e-health normalisation instrument. . *BMC Med Res Methodol,* 12**,** 69.

FISHBURNE, J. W. & BROWN, J. M. 2006. How do college students estimate their drinking? comparing consumption patterns among quantity-frequency, graduated frequency, and timeline follow-back methods. *Journal of Alcohol and Drug Education,* 50**,** 15-33.

FISHER-BORNE, M., CAIN, J. M. & MARTIN, S. L. 2015. From mastery to accountability: Cultural humility as an alternative to cultural competence. *Social Work Education,* 34**,** 165-181.

FOK, C. C., ALLEN, J., HENRY, D. & PEOPLE AWAKENING, T. 2014. The brief family relationship scale: a brief measure of the relationship dimension in family functioning. *Assessment,* 21**,** 67-72.

FONAGY, P., BUTLER, S., COTTRELL, D., SCOTT, S., PILLING, S., EISLER, I., FUGGLE, P., KRAAM, A., BYFORD, S., WASON, J., ELLISON, R., SIMES, E., GANGULI, P., ALLISON, E. & GOODYER, I. M. 2018. Multisystemic therapy versus management as usual in the treatment of adolescent antisocial behaviour (START): a pragmatic, randomised controlled, superiority trial. *Lancet Psychiatry,* 5**,** 119-133.

GALANTER, M., WHITE, W. L., KHALSA, J. & HANSEN, H. 2024. A scoping review of spirituality in relation to substance use disorders: Psychological, biological, and cultural issues. *Journal of addictive diseases,* 42**,** 210-218.

GARITI, P. W., ALTERMAN, A. I., EHRMAN, R. N. & PETTINATI, H. M. 1998. Reliability and validity of the aggregate method of determining number of cigarettes smoked per day. *Am J Addict,* 7**,** 283-7.

GOODMAN, R. 1997. The Strengths and Difficulties Questionnaire: a research note. *J Child Psychol Psychiatry,* 38**,** 581-6.

GOODMAN, R. 2001. Psychometric properties of the strengths and difficulties questionnaire. *J Am Acad Child Adolesc Psychiatry,* 40**,** 1337-45.

GREENBAUM, P. E., WANG, W., HENDERSON, C. E., KAN, L., HALL, K., DAKOF, G. A. & LIDDLE, H. A. 2015. Gender and ethnicity as moderators: Integrative data analysis of multidimensional family therapy randomized clinical trials. *Journal of Family Psychology,* 29**,** 919.

GROUP, E. 2021. ESPAD 2019 Methodology: Methodology of the 2019 European School Survey

Project on Alcohol and other Drugs. *EMCDDA.* Luxembourg.

HEALY, J. & COLLIVER, B. 2022. *Contemporary Intersectional Criminology in the UK: Examining the Boundaries of Intersectionality and Crime*, Policy Press.

HERSH, D., MULGREW, C. L., VAN KIRK, J. & KRANZLER, H. R. 1999. The validity of self-reported cocaine use in two groups of cocaine abusers. *J Consult Clin Psychol,* 67**,** 37-42.

HORTON, C. 2022. " Of Course, I'm Intimidated by Them. They Could Take My Human Rights Away": Trans Children's Experiences with UK Gender Clinics. *Bulletin of Applied Transgender Studies,* 1**,** 47-70.

KIRK, M. A., MOORE, J. E., WILTSEY STIRMAN, S. & BIRKEN, S. A. 2020. Towards a comprehensive model for understanding adaptations' impact: the model for adaptation design and impact (MADI). *Implement Sci,* 15**,** 56.

LANCASTER, G. A., DODD, S. & WILLIAMSON, P. R. 2004. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract,* 10**,** 307-12.

LAW, D. & WOLPERT, M. 2014. Guide to using outcomes and feedback tools with children, young people and families. London: CAMHS.

LEVY, S., SHERRITT, L., HARRIS, S. K., GATES, E. C., HOLDER, D. W., KULIG, J. W. & KNIGHT, J. R. 2004. Test-retest reliability of adolescents' self-report of substance use. *Alcohol Clin Exp Res,* 28**,** 1236-41.

LEVY, S., WISK, L. E., CHADI, N., LUNSTEAD, J., SHRIER, L. A. & WEITZMAN, E. R. 2021. Validation of a single question for the assessment of past three-month alcohol consumption among adolescents. *Drug Alcohol Depend,* 228**,** 109026.

LIDDLE, H. A. 1991. A multidimensional model for treating the adolescent who is abusing alcohol and other drugs. . *In:* SNYDER, W. (ed.) *Empowering families, helping adolescents: Family-centered treatment of adolescents with alcohol, drug abuse and other mental health problems* Washington: United States Public Health Service.

LIDDLE, H. A. 2016. Multidimensional family therapy: Evidence base for transdiagnostic treatment outcomes, change mechanisms, and implementation in community settings. *Family process,* 55**,** 558-576.

LIDDLE, H. A., DAKOF, G., ROWE, C., MOHAMED, A. B., HENDERSON, C., FOULKROD, T., LUCAS, M. & DIFRANCESCO, M. 2024a. Multidimensional Family Therapy for Justice-Involved Young Adults with Substance Use Disorders. *J Behav Health Serv Res,* 51**,** 250-263.

LIDDLE, H. A., DAKOF, G., ROWE, C., MOHAMED, A. B., HENDERSON, C., FOULKROD, T., LUCAS, M. & DIFRANCESCO, M. 2024b. Multidimensional family therapy for justice-involved young adults with substance use disorders. *The journal of behavioral health services & research,* 51**,** 250-263.

LIDDLE, H. A., DAKOF, G. A., ROWE, C. L., HENDERSON, C., GREENBAUM, P., WANG, W. & ALBERGA, L. 2018. Multidimensional Family Therapy as a community-based alternative to residential treatment for adolescents with substance use and co-occurring mental health disorders. *J Subst Abuse Treat,* 90**,** 47-56.

LIDDLE, H. A., DAKOF, G. A., TURNER, R. M., HENDERSON, C. E. & GREENBAUM, P. E. 2008. Treating adolescent drug abuse: a randomized trial comparing multidimensional family therapy and cognitive behavior therapy. *Addiction,* 103**,** 1660-70.

LIDDLE, H. A., RODRIGUEZ, R. A., DAKOF, G. A., KANZKI, E. & MARVEL, F. A. 2005. Multidimensional Family Therapy: A science-based treatment for adolescent drug abuse. *In:* LEBOW, J. (ed.) *Handbook of clinical family therapy* New York: John Wiley & Sons.

LIDDLE, H. A. & SCHWARTZ, S. J. 2002. Attachment and family therapy: clinical utility of adolescent-family attachment research. *Fam Process,* 41**,** 455-76.

LOCAL GOVERNMENT ASSOCIATION 2024. Girls Involved in Youth Violence: Key Findings and Recommendations. Local Government Association.

MAISTO, S. A., KRENEK, M., CHUNG, T., MARTIN, C. S., CLARK, D. & CORNELIUS, J. 2011. Comparison of the concurrent and predictive validity of three measures of readiness to change marijuana use in a clinical sample of adolescents. *J Stud Alcohol Drugs,* 72**,** 592-601.

MARTIN-WILLETT R, HELMUTH T, ABRAHA M, BRYAN AD, HITCHCOCK L, LEE K & LC., B. 2020. Validation of a multisubstance online Timeline Followback assessment. . *Brain Behav,* 10.

MCARA, L. & MCVIE, S. 2007. Youth justice? The impact of system contact on patterns of desistance from offending. *European Journal of Criminology,* 4**,** 315–345.

MCKAY, M. T. & ANDRETTA, J. R. 2017. Evidence for the Psychometric Validity, Internal Consistency and Measurement Invariance of Warwick Edinburgh Mental Well-being Scale Scores in Scottish and Irish Adolescents. *Psychiatry Res,* 255**,** 382-386.

MEADS, C., ZEEMAN, L., SHERRIFF, N. & ARANDA, K. 2023. Prevalence of alcohol use amongst sexual and gender minority (LGBTQ+) communities in the UK: a systematic scoping review. *Alcohol and Alcoholism,* 58**,** 346-356.

MONTES, K. S., WITKIEWITZ, K., PEARSON, M. R. & LEVENTHAL, A. M. 2019. Alcohol, tobacco, and marijuana expectancies as predictors of substance use initiation in adolescence: A longitudinal examination. *Psychol Addict Behav,* 33**,** 26-34.

MOORE, G., CAMPBELL, M., COPELAND, L., CRAIG, P., MOVSISYAN, A., HODDINOTT, P., LITTLECOTT, H., O'CATHAIN, A., PFADENHAUER, L., REHFUESS, E., SEGROTT, J., HAWE, P., KEE, F., COUTURIAUX, D., HALLINGBERG, B. & EVANS, R. 2021. Adapting interventions to new contexts-the ADAPT guidance. *BMJ,* 374**,** n1679.

MOORE, S. M. & ROSENTHAL, D. A. 2007. *Sexuality in adolescence: Current trends*, routledge.

NG FAT, L., SCHOLES, S., BONIFACE, S., MINDELL, J. & STEWART-BROWN, S. 2017. Evaluating and establishing national norms for mental wellbeing using the short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS): findings from the Health Survey for England. *Qual Life Res,* 26**,** 1129-1144.

NHS. 2018. *Smoking, Drinking and Drug Use Among Young People,* Leeds, NHS Digital.

NIELSEN, P., CHRISTENSEN, M., HENDERSON, C., LIDDLE, H. A., CROQUETTE-KROKAR, M., FAVEZ, N. & RIGTER, H. 2021. Multidimensional family therapy reduces problematic gaming in adolescents: A randomised controlled trial. *J Behav Addict,* 10**,** 234-243.

NIHR 2022. NIHR Public Contributor Payment Policy. National Institute for Health and Care Research.

OHID. 2022. Young people's substance misuse treatment statistics 2020 to 2021. *In:* DISPARITIES, O. F. H. I. A. (ed.). London: HMSO.

PARLAR, M., MACKILLOP, E., PETKER, T., MURPHY, J. & MACKILLOP, J. 2021. Cannabis Use, Age of Initiation, and Neurocognitive Performance: Findings from a Large Sample of Heavy Drinking Emerging Adults. *J Int Neuropsychol Soc,* 27**,** 533-545.

PINTO, C., YATES, K., WESTON-STANLEY, P., D'ARCY, A., BENNETTO, R., CROWLEY, J., SAWDON, E., LAU, R. & KHAMBHAITA, P. 2024. Non-opiate and cannabis drug use in minority ethnic groups. London: Nat Cen.

REW, L. & WONG, Y. J. 2006. A systematic review of associations among religiosity/spirituality and adolescent health attitudes and behaviors. *Journal of Adolescent Health,* 38**,** 433-442.

RICKETT, B., JOHNSON, K., INGLE, H. & REYNOLDS, M. 2024. Support for parents/carers of primary school aged gender diverse children in England, UK: A mixed-method analysis of experiences with health services. *Social Perspectives on Trans Health.* Routledge.

RIGTER, H., HENDERSON, C. E., PELC, I., TOSSMANN, P., PHAN, O., HENDRIKS, V., SCHAUB, M. & ROWE, C. L. 2013. Multidimensional family therapy lowers the rate of cannabis dependence in adolescents: a randomised controlled trial in Western European outpatient settings. *Drug Alcohol Depend,* 130**,** 85-93.

RIGTER, H., PELC, I., TOSSMANN, P., PHAN, O., GRICHTING, E., HENDRIKS, V. & ROWE, C. 2010. INCANT: a transnational randomized trial of multidimensional family therapy versus treatment as usual for adolescents with cannabis use disorder. *BMC Psychiatry,* 10**,** 28.

SHIRK, S. & SAIZ, C. 1992. Clinical, empirical and developmental; perspectives on the therapeutic relationship in child psychotherapy. *Dev Psychopath,* 4**,** 713-721.

SIMON, K. M., LEVY, S. J. & BUKSTEIN, O. G. 2022. Adolescent Substance Use Disorders. *NEJM Evid,* 1**,** EVIDra2200051.

SMITH, D. & MCVIE, S. 2003. Theory and Method in the Edinburgh Study of Youth Transitions and Crime. *British Journal of Criminology,* 43**,** 169-195.

SOBELL, L. & SOBELL, M. 1995. *Alcohol Timeline Followback Users' Manual,* Toronto, ON, Addiction Research Foundation.

SOBELL, M. B., SOBELL, L. C., KLAJNER, F., PAVAN, D. & BASIAN, E. 1986. The reliability of a timeline method for assessing normal drinker college students' recent drinking history: utility for alcohol research. *Addict Behav,* 11**,** 149-61.

SOSU, E. M., DARE, S., GOODFELLOW, C. & KLEIN, M. 2021. Socioeconomic status and school absenteeism: A systematic review and narrative synthesis. *Review of Education,* 9**,** e3291.

TANNER-SMITH, E. E., WILSON, S. J. & LIPSEY, M. W. 2013. The comparative effectiveness of outpatient treatment for adolescent substance abuse: a meta-analysis. *J Subst Abuse Treat,* 44**,** 145-58.

VAN DEN BRINK, Y. 2022. Equality in the youth court: Meaning, perceptions and implications of the principle of equality in youth justice. *Youth Justice,* 22**,** 245-271.

VAN DER POL, T. M., HOEVE, M., NOOM, M. J., STAMS, G., DORELEIJERS, T. A. H., VAN DOMBURGH, L. & VERMEIREN, R. 2017a. Research Review: The effectiveness of multidimensional family therapy in treating adolescents with multiple behavior problems - a meta-analysis. *J Child Psychol Psychiatry,* 58**,** 532-545.

VAN DER POL, T. M., HOEVE, M., NOOM, M. J., STAMS, G. J. J. M., DORELEIJERS, T. A. H., VAN DOMBURGH, L. & VERMEIREN, R. R. J. M. 2017b. Research Review: The effectiveness of multidimensional family therapy in treating adolescents with multiple behavior problems - a meta-analysis. *Jnl of child psychol and psychiat and allied disciplines,* 58**,** 532-545.

WEINANDY, J. T. G. & GRUBBS, J. B. 2021. Religious and spiritual beliefs and attitudes towards addiction and addiction treatment: A scoping review. *Addictive Behaviors Reports,* 14**,** 100393.

WICKERSHAM, A., DICKSON, H., JONES, R., PRITCHARD, M., STEWART, R., FORD, T. & DOWNS, J. 2021. Educational attainment trajectories among children and adolescents with depression, and the role of sociodemographic characteristics: longitudinal data-linkage study. *The British Journal of Psychiatry,* 218**,** 151-157.

WOOLF INSTITUTE CENTRE FOR MENTAL HEALTH 2024. Muslim Mental Health Fact Sheet: Access, Experience & Outcomes. Woolf Institute.

WYNNE, B. 2015. Ghosts of the machine: publics, meanings and social science in a time of expert dogma and denial. *Remaking participation.* Routledge.

YEF 2024. Children, Violence and Vulnerability 2022. London: Youth Endowment Fund.

Appendix I: Theory of Change Narrative

Preconditions

Practitioners with a level 4 or equivalent qualification in psychology, social work, youth work, nursing or occupational therapy, post-graduate qualification, or equivalent, in therapeutic interventions. Experience in working with young people in a therapeutic environment. Staff are recruited and managed by Barnardo's who provide access to safe and supportive therapeutic spaces both those owned by Barnardo's and those accessed through existing community partnerships. Staff are managed by senior staff embedded within the proposed sites, Bristol and Newport.

Population need

Most adults with problematic substance use report that their substance use began in adolescence (Simon et al., 2022). Young people are much more vulnerable than adults to the adverse effects of substance use due to a range of physical and psychological factors that often interact and the differential impact of substances on the developing brain (Battistella et al., 2014, Copeland et al., 2013b, Parlar et al., 2021). In addition to an increased risk of accidents and injury (NHS., 2018), substance use in adolescence is also associated with poor educational performance and exclusion from education. Over the academic year 2015-16, almost 9% of permanent school exclusions in state secondary schools were due to alcohol and substance use (DFE., 2019).

While the relationship between offending behaviour and substance use is complex, evidence highlights that the prevalence of substance use is far higher in the youth offending population than the general youth population. Approximately 25% of young people in structured alcohol and drug treatment are referred from criminal justice (OHID., 2022) and data from the Youth Offending Team, ASSETPLUS, indicates that 76% of young people in the CJS use alcohol and other illicit substances.

There are few well-evidenced substance misuse programmes being delivered in England and Wales. In the areas targeted, Bristol and Newport, the treatment as usual consists of a combination of motivational interviewing and/ or motivational enhancement therapy, both interventions that focus on a single domain, substance use, with limited evidence of sustained effectiveness and no evidence of effectiveness in reducing offending.

Multidimensional family therapy (MDFT) is an integrative, family-based, multiple systems-oriented treatment specifically targeted at adolescent substance users (Liddle and Schwartz, 2002). The case for evaluating MDFT here is founded on:

- Strength of existing evidence and likely impact - MDFT is one of the most robustly evidenced substance misuse interventions globally, with several RCTs across the USA and Europe (Dakof et al., 2015, van der Pol et al., 2017a), and strong evidence ratings by the Early Intervention Foundation and several research clearing houses in the US. Unusually for a youth violence intervention it has been the subject of systematic review which concluded MDFT reduces drug use severity 6 months post-test, when compared to other treatments such as CBT (Dakof et al., 2015, van der Pol et al., 2017a). MDFT has been found to reduce rates of cannabis dependence and externalising behaviours

in a trial across Belgium, France, Germany, The Netherlands and Switzerland (Rigter et al., 2013). Collectively these studies establish MDFT as a promising programme that has shown impact in countries like the UK.

- Robust evidence of reducing offending - In the USA MDFT has demonstrated an impact on number of arrests 18 months after the intervention was delivered (Liddle et al., 2024a).
- Ability to get to trial - MDFT has undergone multiple evaluations in a range of geographies and delivery settings and developers show a strong commitment to robustly evaluating the programme in the UK.

Given the strength of evidence across a range of outcomes - as well as long-term impact on offending and the developers' commitment to evaluation, there is a strong case to trial this programme in the UK. Given the range of outcomes, it seeks to address, if effective, the impact of MDFT could extend beyond youth violence and be a part of government efforts to improve outcomes for vulnerable children, including through the Family Hubs initiative and the response to the Care Review.

In addition, there is strong demand in Bristol. A recent scrutiny report shows that Bristol has experienced an increase in the number of young people referred for services relating to extra-familial harm (up 18.3%) and an increase in child vulnerability due to poverty and inequality. The Children's Commissioner for England estimates that in 2019/20 there were 4,600 children and young people aged 0-17 living in households in Bristol with a parent who has alcohol or drug dependence. In Wales, substance misuse among children and young people represents a particular societal focus – figures from March 2022 for Newport show above average levels of substance misuse identified as a concern for YP receiving support and care: 10% (Wales average 7%) had their own substance misuse as a primary concern and 33% (Wales average 31%) had parental substance misuse as a primary concern.

Population

Inclusion criteria:

1. Young people aged 13-17 years inclusive.
2. Currently involved with the police or youth justice service or at risk of offending.

   At risk of offending defined as having at least one of the following risk factors, assessed on referral.

   Previously being in the secure estate.
   Currently, or previously, persistently absent from school (defined by DfE as 10% or more).
   Have been the victim of violence.
   Currently, or have attended alternative education provision.
   Received multiple suspensions from school or has been permanently excluded.
   Have a sibling or parent who has been involved in serious violence or identified as facing exploitation harm.
   Currently, or have been, in the care system.

   Have been identified as being at risk of criminal exploitation.

Currently or have had a social worker.

Have previously been in contact with youth justice services.

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.
4. Willing and able to provide informed consent or willing to provide assent with a parent/ carer willing to provide consent.

Exclusion criteria:

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

Inputs

In both sites, as a Strategic Partner for both LAs, Barnardo's has the local relationships to ensure effective referral pathways are put in place. It has been agreed that referrals will primarily come through the Front Door of each LA as well as through both Youth Justice Teams. In Bristol, the new MACE (Multi-Agency Child Exploitation) arrangement, which has oversight of young people at risk and those being harmed through exploitation, will also act as a key referrer.

MDFT will be adapted for delivery in the UK context. Adaption follows the ADAPT guidance (Moore et al., 2021) to ensure the intervention that aims to maximise the efficacy by ensuring they fit well within a UK delivery context.

Staff recruitment will recruit a broad, culturally diverse range of therapists by advertising roles in community venues and within local community networks. Barnardo's training offer for all staff supports culturally sensitive delivery. Where possible, consideration will be given to matching the young person and therapist. This might be along lines of shared protected characteristics, interests and when the therapist has a particular skill set that will meet the young person's needs. As part of induction, all staff undertake an equality, diversity and inclusion course, which includes discussions around culturally sensitive delivery, unconscious bias and understanding the experience of children from different backgrounds. Learning and Development is supported by SEEN (https://weareseen.org.uk/), the national resource centre to improve outcomes for children and young people of African, Asian and Caribbean heritage. As part of the support offered to all staff through SEEN, there is a knowledge bank containing resources such as: 'An emancipatory approach to cultural competency: The application of critical race, postcolonial, and intersectionality theories', 'Anti-racist supervision (for professionals)' and 'Being Black in rural spaces (UK Youth)'.

Therapists need access to safe, supportive and therapeutic spaces within the community in which they can build relationships with children and families. Barnardo's has access to community buildings through partnerships with the Local Authorities, VCSE networks and youth work providers across Newport and Bristol. Local management are embedded within both Newport and Bristol, and are fully cognisant of local factors including geography, demography, need and support services, allowing us to target and understand the background and support needs of children and families, and access resources as required.

In Bristol, Barnardo's own a building at Old Market (Bristol Centre), which is located for ease of access to children and families. It has been decorated in co-production with young people who use it to be welcoming, therapeutic and trauma-informed throughout, and contains dedicated safe spaces for therapeutic delivery.

The MDFT team in each site usually consists of 6-8 therapists, one who is trained to act in a supervisory role. Training in MDFT is provided by MDFT international who provide an intensive training package and full certification. Training includes the assessment of the needs of children and families and case formulation to meet those needs. All therapists have access to supervisory support from the site based MDFT supervisor and the wider MDFT international team. MDFT therapists have access to the MDFT portal to record planned and delivered sessions.

Activities

The specification with respect to number of adolescent alone session, parent sessions without their adolescent, family sessions are guidelines are not dictates or requirements. The exact configuration is very individualised to the need of the young person and family. MDFT is not a curriculum-based intervention but instead is a psychotherapy where the exact interventions applied, types of sessions, weekly dose, length of treatment episode is determined by the needs of the young person and family. A minimum dosage is considered 12 sessions over a 4-month period.

MDFT typically consists of 2 sessions per week lasting anywhere from 45 to 90 minutes. 90 minutes may be necessary for multipart family sessions. Individual sessions alone with the young person typically range from 45 – 60 minutes, sessions alone with the parents are usually 60 minutes.

Mechanisms

A key aspect of MDFT involves building a strong therapeutic alliance with young people and their parents/ carers as the foundation of achieving behaviour change. Therapeutic alliance is assessed using the Therapeutic Alliance Scale for Children (TASC-r; (Shirk and Saiz, 1992). Where young people feel included in decision making and experience a sense of positive collaboration with the therapist and families experience consistency in the support offered.

Young people develop an enhanced motivation to change their substance using behaviour, assessed using the readiness ruler (RR; (Maisto et al., 2011). They develop better strategies for managing situations where they would previously engage in substance use, assessed using the situational confidence questionnaire (SCQ; (Breslin et al., 1998) and they have a better understanding of their own strengths and a greater appreciation of the negative aspects of substance use, assessed using the substance use expectancy measure (SUE; (Montes et al., 2019). Families experience greater communication, less conflict and are empowered to solve problems

collaboratively, assessed using the brief family relationship scale (BFRS; (Fok et al., 2014)).

In the study the influence of these mechanisms on substance use and offending will be explored using a latent class mediation model approach that aims to identify implicit subgroups among the study population based on their response to a set of process (mechanistic) variables hypothesised to influence change. These variables are assessed at baseline, prior to randomisation and again at 6-months post-randomisation.

Short term outcomes

Short term outcomes are measured at baseline and again at 6-months post-randomisation.

Changes in the frequency, quantity and type of substances is assessed using the time line follow-back method over a 28-day retrospective period (TLFB 28; (Sobell and Sobell, 1995). Violent, non-violent and antisocial behaviour is assessed using the self-report delinquency scale (SRDS; (McAra and McVie, 2007). Emotional regulation, internalising, externalising and prosocial behaviours, and conduct issues are assessed using the strengths and difficulties questionnaire (SDQ; (Goodman, 1997)). Wellbeing and mental health are assessed using the Warwick Edinburgh mental wellbeing scale (WEMWBS; (Clarke et al., 2011)). The frequency of school attendance, exclusion, suspensions and involvement with the police and criminal justice system is assessed using a short form client service receipt inventory validated in other studies of adolescent substance using populations (CSRI; (Coulton S et al., 2023, Coulton et al., 2024)). Substance use related problems are assessed using the European School Project on Alcohol and Drugs problem domain (ESPAD; (Group, 2021).

Long term outcomes

Long term outcomes occur beyond the horizon of the trial. They are considered as longer-term impacts associated with changes observed in the short-term outcomes. Sustained reductions in substance use. Greatly reduced violent and non-violent offending due to reductions in risk factors associated with offending behaviour and fewer externalising and conduct behaviours. Improved educational attainment due to reduced absenteeism and less disengagement with education leading to increased propensity to remain in education or transition to employment. Improved physical and psychological health due to reduced substance use and fewer internalising behaviours and a more positive transition to adulthood.

Appendix II: Progression criteria from internal pilot

Project implementation

Area	Question	Assessment	Criteria	Rag rating
Therapist Recruitment	Have sufficient therapists been recruited	Number of therapists recruited	7	>6 in post
				<6 >4 in post
				<4 in post
Therapist Training	Have sufficient therapists been certified	% of therapists certified	75%	>75%
				60 – 74%
				<60%
Therapist Supervision	Do therapists attend planned supervision	% of therapist supervision sessions attended	75%	>75%
				60 – 74%
				<60%
Therapist Capacity	Is there sufficient capacity to provide MDFT	Model of randomisation/ capacity	100%	100%
				90-99% increase number of therapists by 1
				<90% increase number of therapists by required number
			80%	>80%

Dosage within 4-6 months 55% adolescent sessions 30% family sessions 15% parent alone sessions	Do participants comply with the minimal dose of MDFT	% participants receiving minimal dose		60-79%
				<60%
Eligible referrals	Are sufficient referrals eligible	% of eligible participants who consent	80%	>80%
				50 – 79%
				<50%
Acceptability of adaptions	Are the adaptions to MDFT acceptable to therapists and participants	Review of adaptions	Adaption should be acceptable	Acceptable
				Acceptable to some but not all revise adaption
				Not acceptable

Internal pilot evaluation

Area	Question	Assessment	Criteria	Rag rating
Participant recruitment	Have sufficient participants been recruited	Number of participants recruited	60	60
				42-60
				<42
Evaluation attrition	Have sufficient participants been	% of participants retained	90%	>90%
				70 – 89%

	retained at 6-months			<70%
Proportion with primary outcome recorded at month 6	Have sufficient participants provided a primary outcome	% of participants completing primary outcome	95%	>94% 75 – 94% <75%%
Proportion with secondary outcome recorded at month 6	Have sufficient participants provided a secondary outcome	% of participants completing secondary outcome	80%	>80% 60 – 79% <60%
Analysable primary and secondary outcome data	Proportion of participants who have provided primary and secondary outcomes that cab be analysed	% of participants providing usefull primary and secondary outcomes	80%	>80% 60 – 79% <60%
Randomisation	Are the groups allocated to MSFT and BAU of similar size	Difference in the proportion allocated to each group	2%	<2% 3-5% >5%
Randomisation	Are the groups allocated to MSFT and BAU of similar size by stratification	Difference in the proportion allocated to each group by stratification	5%	<5% 5-10% >10%

Appendix III: Equality Impact Assessment

The template form includes a comprehensive list of themes to consider in our approach to race equity diversity and inclusion across YEF projects. However, not all sections of this form will be equally relevant to all projects. Please agree which sections are focus areas for your project team to complete with the relevant project lead.

Section 1 - Overview			
Name of grantee	Prof Simon Coulton	**Name of evaluator**	University of Kent
Name of project	Multi-Dimensional Family Therapy (MDFT)		
YEF PM		**YEF EM**	
Section 1b – YEF review			
Reviewed by Race Equity Associate	Yes ☐ No ☐		
Do you recommend that we approve this EQIA?	☐ Yes ☐ Yes – with conditions ☐ No		
Narrative supporting the recommendation			
Section 2 – Evaluation details			
Type of evaluation	☐ Feasibility ☐ Pilot (pre-post) ☒ Pilot Efficacy (internal)		

	☐ Efficacy ☐ Effectiveness
Research question	Does Multidimensional Family Therapy reduce alcohol and drug use in adolescents.
Research design	Mixed method, individually randomised controlled trial with embedded internal pilot.
Research location	Newport and Bristol
Research period	April 2025 – March 2028
Number of participants	400
Characteristics of participants	Young people aged 13-17 years who are **at risk of offending** due to substance use or **have offended** and are involved with CJS. Screen positive for a substance use disorder. Resident within the research areas, Bristol & Newport. **'At risk of offending'** is defined as having at least one of the following risk factors, assessed on referral. Previously being in the secure estate. Currently, or previously, persistently absent from school (defined by DfE as 10% or more). Have been the victim of violence. Currently, or have attended alternative education provision. Received at least one suspension from school. Have a sibling or parent who has been involved in serious violence or identified as facing exploitation harm. Currently, or have been, in the care system. Have been identified as being at risk of criminal exploitation.

	Are engaged with the Supporting Families Programme. Currently or have had a social worker. Have previously been in contact with youth justice services. Have been arrested and released by the police with no further action. Participants must evidence alcohol or substance use on at least 4 occasions in the past 28 days, assessed using a single substance use frequency question and be willing and able to provide informed consent or willing to provide assent with a parent/ carer willing to provide consent.
Key aims and benefits of the research	**Short term outcomes** Short term outcomes are measured at baseline and again at 6-months post-randomisation. Changes in the frequency, quantity and type of substances is assessed using the time line follow-back method over a 90-day retrospective period (TLFB90; (Sobell and Sobell, 1995). Violent, non-violent and antisocial behaviour is assessed using the self-report delinquency scale (SRDS; (McAra and McVie, 2007). Emotional regulation, internalising, externalising and prosocial behaviours, and conduct issues are assessed using the strengths and difficulties questionnaire (SDQ; (Goodman, 1997)). Wellbeing and mental health are assessed using the Warwick Edinburgh mental wellbeing scale (WEMWBS; (Clarke et al., 2011)). The frequency of school attendance, exclusion, suspensions and involvement with the police and criminal justice system is assessed using a short form client service receipt inventory validated in other studies of adolescent substance using populations (CSRI; (Coulton S et al., 2023, Coulton et al., 2024)).

	Long term outcomes Long term outcomes occur beyond the horizon of the trial. They are considered as longer-term impacts associated with changes observed in the short-term outcomes. Sustained reductions in substance use. Greatly reduced violent and non-violent offending due to reductions in risk factors associated with offending behaviour and fewer externalising and conduct behaviours. Improved educational attainment due to reduced absenteeism and less disengagement with education leading to increased propensity to remain in education or transition to employment. Improved physical and psychological health due to reduced substance use and fewer internalising behaviours and a more positive transition to adulthood.
Previous equality related research or consultation relevant to this research	The proposed research is to explore the adaptation of MDFT for young people and families in the UK, regardless of their background or self-identification as belonging to any group whereby their protected characteristics would suggest belonging to any marginalised group by virtue of such characteristics. As can be seen below, a consideration of previous relevant research pertaining to equality has been included as it relates to the individual characteristics of potential participants. This has been done to aid consideration of these issues in turn. The importance of intersectionality is also considered throughout this assessment, and this will be explored in further detail in the section entitled '**Summary of the main equality issues'.** In preparation for the completion of this EIA, consultation with a group of young people has been ongoing where consideration of key equity-related issues have been discussed. To augment

	these discussions, two members of this group have also been involved in helping to prepare this document.
Section 3 - Identify who from the protected characteristic groupings or other relevant disadvantaged communities will or may be affected and how	
Age	☒ Positive impact ☐ Negative impact ☐ No impact ☐ Impact not known Narrative: The research study and delivery of the MDFT intervention is likely to have a positive impact on participants of all ages, but particularly those individuals eligible to take part according to their age (13-17). However, as MDFT also includes family members/carers/appropriate adults that are associated with the young participants in question, this research study is also likely to have benefits for individuals outside of the 13-17 age bracket of young people. Given the range of outcomes it seeks to address, if effective, the impact of MDFT could extend beyond youth violence and be a part of government efforts to improve outcomes for vulnerable children, including through the Family Hubs initiative and the response to the Care Review. Through consultation with young people as part of the co-design process, questions were asked about the freedom of young people under the age of 16 to take part in the study if their parents or carers were opposed to the idea, and if a lack of parental/carer support would be a barrier to their taking part.

	Mitigation: Regarding young people's concerns, the involvement of a specific adult is not required for participation in the study. This is because 'family' involvement could be an adult other than a parent/carer with involvement in the young person's life. Initial sessions of MDFT are often directed at identifying such an adult who is then able to provide consent for continued involvement in the study.
Disability	☒ Positive impact ☒ Negative impact ☐ No impact ☒ Impact not known Narrative: Overall, it is expected that the impact of the study on participants identifying as having a disability will be positive. This is expected to be particularly true of individuals who are experiencing issues surrounding their mental health, as the process of engaging in MDFT has been shown to improve mental health outcomes for those experiencing a range of mental health issues, even in instances of comorbidity (Liddle, 2016). A further positive impact of the proposed research is that participants will not only have the opportunity to access MDFT, but also to reflect on this process with the evaluation team afterwards, thus providing a further opportunity to examine their participation and have their voices heard about the future development and implementation of the intervention. This is true both of recipients of MDFT and the delivery team. As with many research projects of this nature, there is the potential for negative impact for those whose specific disabilities may make it more difficult to access this kind of study. Furthermore, for those experiencing mental health

	difficulties, there is the possibility that both sessions and interviews may prove challenging. Mitigation: To mitigate any potential negative impact, it is essential that any and all reasonable adjustments to the delivery and evaluation process of MDFT are made to ensure that equitable participation is possible for all participants, regardless of their disability status. This will be achieved through the development of both sensitivity and safeguarding protocols for participants and a focus on appropriate signposting for all participants.
Sexual orientation	☒ Positive impact ☐ Negative impact ☐ No impact ☒ Impact not known Narrative: Research has shown that adolescence is a period in which one's sexual identity is often uncertain and that furthermore that this can be made especially challenging in connection with a range of wider social determinants (Moore and Rosenthal, 2007). However, there is evidence that also suggests that MDFT can help to navigate these issues and provides a positive space in which to negotiate the complex relationships between adults and young people as they transition from adolescence into young adulthood (Liddle et al., 2024b) Mitigation: Whether or not the UK specific context of the study will also allow positive interactions to develop when encountering issues around sexual orientation and identity is largely unknown at present, but the evaluative process will

	provide an opportunity for all participants to explore this notion. Additionally, the training provided to all delivery staff will make them both aware and well-equipped to deal with such issues within a safe therapeutic environment. Individual sessions held with young people will also afford the opportunity to discuss anything that young participants may feel uncomfortable speaking about with their family/appropriate adult which can then (depending on the wishes of the young person in question) be introduced in a safe and supportive environment.
Ethnicity	☒ Positive impact ☒ Negative impact ☐ No impact ☐ Impact not known Narrative: The over-representation of individuals belonging to marginalised ethnicity groups within youth justice settings is a global issue, and so too is this the case in the UK (Van den Brink, 2022). Similarly, there are marked differences in outcomes across a wide range of health and social indicators that are directly linked to the ethnicity or race of individuals. As part of the study is to explore the adaptability of the MDFT intervention to the UK context and as such will examine any barriers or facilitators to access and engagement of the MDFT intervention, such barriers if encountered can be identified through evaluation and addressed – leading to positive future outcomes. There may be the possibility of a negative impact for those potential participants whose first language is not English when engaging with either the intervention or evaluative interviews as part of the project, even if this is a reduction in efficacy of communication linked to needing to use one's non-native language.

	Young people consulted as part of this process raised concerns around engaging with therapists or researchers that were of different ethnicities or cultural backgrounds, as they felt that this may lead to a lack of understanding of the issues that they faced. This was highlighted by several young people from a variety of backgrounds. When the notion of training and education for all prospective staff was discussed, many of the young people expressed that this would help to form the trusting relationships required for such a process to work. They were however keen to point out that they felt using the phrase 'cultural competency' suggested that one could attain a level or 'certificate' in this area, when this was only something that would work with a sustained and ongoing interest and willingness to learn about the experiences of individuals from other ethnic and cultural backgrounds. This move away from the notion of 'cultural competency' is something that is echoed in relevant research literature (Fisher-Borne et al., 2015). Mitigation: Data around those individuals who both do and do not engage or continue to engage will be collected throughout the project to be able to identify any trends within groups. Should it be necessary, the research team will explore any access needs (availability of further tailored resources etc.) that may be required moving forward. The intervention provider, Barnardo's has experience in recruiting, training and retaining interventionists who are representative of the ethnic diversity of the areas they serve. As stated above, the introduction of culturally relevant and sensitive training to individuals on the research and delivery teams were welcomed by young people, but with the caveats described above.

Sex	☒ Positive impact ☒ Negative impact ☐ No impact ☒ Impact not known Narrative: Previous studies of MDFT have indicated that it is an effective treatment for substance use in both male and female participants (Greenbaum et al., 2015) and thus there is the likelihood of a positive impact in this regard. In the UK, female involvement in crime (particularly for young people) is still not as well understood as that of their male counterparts. Despite accounting for 13% of proven youth offenses is 2022, their involvement in violence remains largely invisible and support services are rarely specifically catered to girls and young women (Local Government Association, 2024). Due to the nature of identification of eligibility for the study and the referral pathways thereof, there is the possibility that young women and girls that may benefit from involvement in the study could be missed through the ways in which eligibility is defined. Mitigation: Although some areas of eligibility may lead to an under-representation of female participants in the study, when all criteria are taken into account, it is felt that this risk is sufficiently minimised through multiple points of identification for eligibility and inclusion in the study. Moreover, delivery teams will work closely with organisations that currently work with prospective participants to fully explain the process and support them where necessary to aid them.
Religion or belief	☒ Positive impact ☒ Negative impact

	☐ No impact ☒ Impact not known Narrative: Despite research investigating the link(s) between religion/belief and substance use more generally (Weinandy and Grubbs, 2021) a consensus as to the role that religion and belief play in the appearance of substance use disorders remains unclear. Critics of current research point to a lack of an agreed upon definition of religious belief and how this is measured (Rew and Wong, 2006), as well as conflicting approaches to the inclusion of spiritual (but not necessarily formal) beliefs (Galanter et al., 2024). In the UK context, it is worth noting that individuals from the Muslim community report a significantly negative perception and experience of formal and structured counselling services, with a survey conducted by the Lantern Initiative finding that 1 in 5 people felt judged or dismissed as a Muslim when attending such services (Woolf Institute Centre for Mental Health, 2024). Young people involved in the consultation that identified as belonging to non-Christian religious communities also stated that they would have possible concerns about the discussion of cultural or religious norms if there was the possibility that these may clash with the theory underpinning the therapeutic intervention. This worry was more acute if these issues were raised in sessions with parents/carers. Broadly speaking, some of the concerns raised in connection with religion and belief were similar to those highlighted in discussions around ethnicity and cultural considerations detailed above. Mitigation: Working with religious communities in a way that makes them feel both seen and heard and values the importance of their beliefs is of paramount importance to

	ensure equitable access to the study. To achieve this, close working and an iterative approach to delivery and evaluation will be required. Both delivery and evaluation teams will undergo training and guidance to ensure they are confident in delivering their tasks in a culturally sensitive and aware way. This will also be monitored through regular consultation with an equity advisory group when formed.
Gender reassignment	☐ Positive impact ☒ Negative impact ☐ No impact ☒ Impact not known Narrative: There is a general paucity of literature pertaining to non-binary gendered individuals and both alcohol and substance misuse. However, where studies do exist, evidence suggests that individuals identifying as non-binary experience higher prevalence of alcohol and substance use compared to other groups (Meads et al., 2023). The current situation in the UK – especially for young people – for transgender individuals is one characterised by the problematisation and pathologisation of childhood gender diversity and an environment in which both gender diverse young people and their parents/carers feel increasingly isolated (Rickett et al., 2024). This feeling of isolation is especially pronounced when engaging with health service providers (Horton, 2022). Mitigation: Additional care in involving non-binary gendered participants and their families/carers will need to be taken

	throughout the intervention and evaluation process, taking into account that trust may be more difficult to develop. Knowledge of issues currently facing non-binary or transgendered individuals will be of importance and further work as part of the project will need to be conducted to measure any potential impact as this is currently largely unknown.
Marriage and civil partnership	☐ Positive impact ☐ Negative impact ☒ No impact ☐ Impact not known Narrative: It is anticipated that the impact on individuals in this group is likely to be neutral (no impact). Mitigation:
Pregnancy and maternity	☐ Positive impact ☐ Negative impact ☒ No impact ☐ Impact not known Narrative: Again, the likely impact upon individuals in this group is expected to be neutral or have no impact. Mitigation:

Social class	☒ Positive impact ☐ Negative impact ☐ No impact ☐ Impact not known Narrative: Studies have previously shown that social class and socioeconomic status can lead to an over-representation of individuals from lower income groups across a number of the inclusion criteria for the proposed study (Sosu et al., 2021). Furthermore, the impact of factors such as persistent absenteeism at school have also been demonstrated to have significantly more detrimental effects when coupled with socioeconomic factors and the presence of mental health conditions (Wickersham et al., 2021). As such, the research project is expected to have a positive impact on mitigating the impact of such adverse impacts upon those participants currently experiencing inequality and inequity that is related to social class/socioeconomic status. Mitigation:
Other	☐ Positive impact ☐ Negative impact ☒ No impact ☐ Impact not known Narrative: Mitigation:

Section 4 – Summary and references	
Summary of the main equality issues	In addition to the issues highlighted above in relation to specific characteristics, the concept and impact of intersectionality is also of import to this study. Examining the interplay between characteristics and how they may combine to exacerbate equity concerns will be also be part of any equity considerations throughout this project. The impact of intersectionality notwithstanding, it is anticipated that this project will lead to broadly positive impacts for marginalised groups engaging with the study, due to their over-representation in many of the eligibility criteria due to systematic inequity. However, in terms of both the MDFT intervention and the evaluative work surrounding this, there is the possibility of negative consequences in situations where there may be barriers to access for the study. However, as is detailed in the EIA above and the action plan below, actions to mitigate these potential negative impacts will be taken.
How will the equality impact of the study be monitored and evaluated?	As well as the collection of data pertaining to the characteristics of participants in the research study by the evaluation team (via collection of relevant protected characteristic data) and the monitoring of data that will be routinely collected by the implementation team (through extraction of this data) the following actions will also be undertaken: • Use of this EIA as a basis for subsequent equity focussed discussion of the project, amending and adding to this as necessary as new learning is gained. • Completing a formal review of the EIA every 3 months in consultation with the evaluation and implementation teams, alongside input from young people engaged in the advisory group.

	• Conduct a literature review of relevant equity-related research and compile a data pack specific to the two implementation sites (Newport and Bristol) • Monitor ongoing research examining the role of diversity within research studies of this kind and integrate new findings, if necessary, within research project. • Ensure ongoing engagement with community members through the young person's advisory group, seeking feedback and further guidance from individuals with lived and living experience relevant to the project. • Continue to monitor, and if necessary, implement any changes that relate to additional or unmet needs of prospective or actual participants in regard to equity of access to the project. This may include, but is not limited to issues arising due to spoken or written communication due to language or disability or to amend any procedures or protocols that may have been identified as presenting barriers to participation. **For more detail on the above measures, see the Action Plan below.**
References	Clarke, A., Friede, T., Putz, R., Ashdown, J., Martin, S., & Blake, A. (2011). Warwick-Edinburgh Mental Well-being Scale (WEMWBS): validated for teenage school students in England and Scotland. A mixed methods assessment. *11*, 487. https://doi.org/10.1186/1471-2458-11-487 Coulton S, Nizalova O, Pellatt-Higgins T, Stevens A, Hendrie N, Marchand C, Vass R, Deluca P, Drummond C, Ferguson J, Waller G, & D., N.-B. (2023). *A multicomponent psychosocial intervention to reduce substance use by adolescents involved in the criminal justice system: the RISKIT-CJS RCT.* . NIHR. Coulton, S., Hendrie, N., Vass, R., Gannon, T., Wooton, A., Rushworh-Claeys, J., & Sinetos, J. (2024). Randomized controlled internal pilot trial of a diversion programme for adolescents in police custody who possess illicit substances. *J Public Health (Oxf)*, *46*(2), e269-e278. https://doi.org/10.1093/pubmed/fdae017

Fisher-Borne, M., Cain, J. M., & Martin, S. L. (2015). From mastery to accountability: Cultural humility as an alternative to cultural competence. *Social Work Education*, *34*(2), 165-181.

Galanter, M., White, W. L., Khalsa, J., & Hansen, H. (2024). A scoping review of spirituality in relation to substance use disorders: Psychological, biological, and cultural issues. *Journal of addictive diseases*, *42*(3), 210-218.

Goodman, R. (1997). The Strengths and Difficulties Questionnaire: a research note. *J Child Psychol Psychiatry*, *38*(5), 581-586. https://www.ncbi.nlm.nih.gov/pubmed/9255702

Greenbaum, P. E., Wang, W., Henderson, C. E., Kan, L., Hall, K., Dakof, G. A., & Liddle, H. A. (2015). Gender and ethnicity as moderators: Integrative data analysis of multidimensional family therapy randomized clinical trials. *Journal of Family Psychology*, *29*(6), 919.

Horton, C. (2022). " Of Course, I'm Intimidated by Them. They Could Take My Human Rights Away": Trans Children's Experiences with UK Gender Clinics. *Bulletin of Applied Transgender Studies*, *1*(1-2), 47-70.

Liddle, H. A. (2016). Multidimensional family therapy: Evidence base for transdiagnostic treatment outcomes, change mechanisms, and implementation in community settings. *Family process*, *55*(3), 558-576.

Liddle, H. A., Dakof, G., Rowe, C., Mohamed, A. B., Henderson, C., Foulkrod, T., Lucas, M., & DiFrancesco, M. (2024). Multidimensional family therapy for justice-involved young adults with substance use disorders. *The journal of behavioral health services & research*, *51*(2), 250-263.

Local Government Association. (2024). *Girls Involved in Youth Violence: Key Findings and Recommendations*. https://www.local.gov.uk/publications/girls-involved-youth-violence-key-findings-and-recommendations

McAra, L., & McVie, S. (2007). Youth justice? The impact of system contact on patterns of desistance from offending. *European Journal of Criminology*, *4*, 315–345.

Meads, C., Zeeman, L., Sherriff, N., & Aranda, K. (2023). Prevalence of alcohol use amongst sexual and gender

minority (LGBTQ+) communities in the UK: a systematic scoping review. *Alcohol and alcoholism*, *58*(4), 346-356.

Moore, S. M., & Rosenthal, D. A. (2007). *Sexuality in adolescence: Current trends*. routledge.

Rew, L., & Wong, Y. J. (2006). A systematic review of associations among religiosity/spirituality and adolescent health attitudes and behaviors. *Journal of Adolescent Health*, *38*(4), 433-442. https://doi.org/10.1016/j.jadohealth.2005.02.004

Rickett, B., Johnson, K., Ingle, H., & Reynolds, M. (2024). Support for parents/carers of primary school aged gender diverse children in England, UK: A mixed-method analysis of experiences with health services. In *Social Perspectives on Trans Health* (pp. 9-24). Routledge.

Sobell, L., & Sobell, M. (1995). *Alcohol Timeline Followback Users' Manual*. Addiction Research Foundation.

Sosu, E. M., Dare, S., Goodfellow, C., & Klein, M. (2021). Socioeconomic status and school absenteeism: A systematic review and narrative synthesis. *Review of Education*, *9*(3), e3291.

Van den Brink, Y. (2022). Equality in the youth court: Meaning, perceptions and implications of the principle of equality in youth justice. *Youth Justice*, *22*(3), 245-271.

Weinandy, J. T. G., & Grubbs, J. B. (2021). Religious and spiritual beliefs and attitudes towards addiction and addiction treatment: A scoping review. *Addictive Behaviors Reports*, *14*, 100393.

Wickersham, A., Dickson, H., Jones, R., Pritchard, M., Stewart, R., Ford, T., & Downs, J. (2021). Educational attainment trajectories among children and adolescents with depression, and the role of sociodemographic characteristics: longitudinal data-linkage study. *The British Journal of Psychiatry*, *218*(3), 151-157.

Woolf Institute Centre for Mental Health. (2024). Muslim Mental Health Fact Sheet: Access, Experience & Outcomes. In: Woolf Institute.

Section 5 - Action plan

Actions should be SMART and progress on the action plan should be monitored as part of routine quarterly monitoring. Equality actions may arise during the research process, these should also be recorded and actioned.

Action	Completion date	Owner	Monitoring	Impact	Status
Formation of equity team This team will be comprised of members of the evaluation team but will primarily be the responsibility of A Divers. In addition to members of the evaluation team, this equity team will also include 6-8 young people that will attend co-design sessions. From these 6-8 individuals, 2 will be invited to act as youth co-researchers to engage more regularly and who will provide feedback on documentation and materials to ensure equity	Prior to commencement of research project	Evaluation team/ A Divers	This EIA and its monitoring has been added as a monthly task for the evaluation team (with equity considerations led by A Divers) and two youth co-researchers will continue to work upon with this with the evaluation team	By creating an equity team, this will ensure that all equity issues that may arise within the project will receive appropriate attention and weighting within the project as a whole. This will also give a clear point of contact for the rest of the team to raise any issues pertaining to equity should they arise.	Completed/Ongoing

considerations are addressed.					
Discussion of equity and community engagement The equity team will host a series of collaboration and consultation events with young people. As members of the evaluation team are also involved in a number of other projects with marginalised communities, any learning from these projects that is relevant to the current project will be used.	Prior to commencement of research project	Evaluation team/ A Divers	Although these meetings will not be recorded, notes will be taken to ensure salient points are captured and reflected in this EIA.	Regular discussions with young people from a range of backgrounds ensures that a wide knowledge base is drawn upon regarding equity considerations. The inclusion of youth co-researchers further strengthens this commitment to ensuring equitable access to the project.	Completed/Ongoing 3 meetings with young person's advisory group have been conducted as of 31/1/25. 2 youth co-researchers have met with A Divers separately on 3 further occasions to provide feedback on screening tools and other research documentation. Recommendations have been incorporated into this EIA, which has also been supported with input from youth co-researchers.
Literature review of equity relevant research and data pack of two study sites As stated above, a review of relevant	Prior to commencement of research project	Evaluation team/A Divers	To support both the delivery and evaluation team(s), an overview of relevant	Although it is the case that the delivery team in either site are well-connected and have deep	To be completed in advance of study beginning.

literature (some of which has been cited in preparation of this EIA) will be conducted that will cover relevant research on a range of equity and access issues and potential barriers. Where possible, this will be project specific to both the geographic areas of the chosen sites, and of the intervention, highlighting any recommendations for best practice.			literature will be composed detailing the main considerations pertaining to equity and diversity. In addition to this, a data pack giving a demographic overview of the two delivery sites (Newport and Bristol) to assist these teams in providing an overview of the local population.	knowledge of their local communities, the proposed literature review and data pack will provide additional insight of the local communities and may highlight any hidden communities in the local area(s).	
Ensure equity considerations are built into research design To ensure equity learning and an exploration of barriers and facilitators to participation in the study amongst diverse groups, monitoring of this will be built into	Upon creation of research materials	Evaluation team/A Divers	Ongoing throughout project, and to be discussed explicitly within 'Reflexivity' action	Building equity at a fundamental level within research methods and design will allow the research team to assess any equity impact of the work itself but will also allow for monitoring of any barriers that may exist	Ongoing

the design of the study. Necessary sociodemographic information will be asked of all participants (though they may choose not to provide this) and additional equity-related questions will be added to interview schedules to explore engagement with both the intervention and evaluation.				to engagement with either the intervention or evaluation.	
Investigate feasibility of any required reasonable adjustments to materials	Ongoing throughout the project as necessary	All	If/when issues surrounding accessibility are highlighted, these will be passed on to the evaluation team. Options of amending or providing additional formats for study documentation will be		This will enable exploration of feasibility and resources available to improve accessibility of research documents and data collection. This is in addition to reviewing the documents considering best practice for accessibility relating to design and literacy Assess through equity and barrier to engagement monitoring. Where there are resources available

			assessed and actioned where necessary. This assessment may include (but is not limited to) the provision of resources in other languages, easy-read formats. In each instance, an assessment of additional time/cost for implementing amendments will be made.		to support reasonable adjustments, these will be implemented. If it is not possible to develop more accessible documents to match the needs of the participants, this will be flagged up for future iterations of implementation of the intervention and service evaluation.
Reflexive practice and monitoring The evaluation team will be proactive in regularly inviting feedback and discussion around the accessibility of the project and any other equity concerns that may be raised by participants or the delivery team. Wider researcher discussion will also	Throughout the duration of the project	Evaluation team/A Divers	The evaluation team will engage in monthly discussions to monitor equity and access. Evaluation team will also ensure ongoing learning around equity and incorporate learning from other projects.	Research team will demonstrate best practice around qualitative work, ensuring that evaluation team engage in reflexive process around acknowledging bias around data collection and analysis.	Ongoing throughout project.

take place with the team, such as exploring and mitigating for bias when analysing research data and when discussing equity in meetings.					
Next steps Both delivery and evaluation teams will highlight any relevant next steps in relation to further research or practical implications for the implementation of MDFT that are linked to equity.	Throughout study and recommendations formulated for any further work.	All		Definitive tasks around next steps pertaining to equity in future research and implementation will ensure that any potential gaps in representation of under-served groups are minimised both in relation to the current project and other future work.	Ongoing

Please share your completed form with the evaluation manager for your project.

Appendix IV: Outcomes not contained with YEF Core Outcome Dataset

GAIN-SS – Substance Use

The following questions are about common psychological, behavioral, and personal problems. These problems are considered **significant** when you have them for two or more weeks, when they keep coming back, when they keep you from meeting your responsibilities, or when they make you feel like you can't go on. After each of the following questions, please tell us the last time, if ever, you had the problem by answering whether it was in the past month, 2 to 3 months ago, 4 to 12 months ago, 1 or more years ago, or never.	Past month	2 to 3 months ago	4 to 12 months ago	1+ years ago	Never
	4	3	2	1	0

When was the last time that…

a. you used alcohol or other drugs weekly or more often?	4	3	2	1	0
b. you spent a lot of time either getting alcohol or other drugs, using alcohol or other drugs, or recovering from the effects of alcohol or other drugs (e.g., feeling sick)?	4	3	2	1	0
c. you kept using alcohol or other drugs even though it was causing social problems, leading to fights, or getting you into trouble with other people?	4	3	2	1	0
d. your use of alcohol or other drugs caused you to give up or reduce your involvement in activities at work, school, home, or social events?	4	3	2	1	0
e. you had withdrawal problems from alcohol or other drugs like shaky hands, throwing up, having trouble sitting still or sleeping, or you used any alcohol or other drugs to stop being sick or avoid withdrawal problems?	4	3	2	1	0

DUE – Drug Use Expectancy

Positive and negative expectancies

For each of the following questions, circle the answer closest to how you think?

Q1. Using substances can have a lot of positive effects, such as having fun and being popular

Strongly disagree Disagree Agree Strongly agree

Q2. Using substances can have a lot of negative effects, such as being bad for your health and getting into trouble

Strongly disagree Disagree Agree Strongly agree

Situational Confidence – SCQ8

PART 2: SITUATIONAL CONFIDENCE QUESTIONNAIRE

Imagine yourself, as you are right now, faced with in each of the following trigger situations. Place an **X** along the line in the scale provided to show how confident you feel **right now** that you would be able to resist problem drinking or other drug use. In the example below, the person feels that he or she is about 48% confident—a little less than halfway—about resisting in this situation.

I feel . . .

0% 25% **X** 50% 75% 100% = 48%

Not at all confident — Totally Confident

Right now, I feel I would be able to resist the urge to drink or use other drugs in situations involving . . .

1. *Unpleasant emotions*

0% 25% 50% 75% 100% = %

Not at all confident — Totally Confident

2. *Physical discomfort*

0% 25% 50% 75% 100% = %

Not at all confident — Totally Confident

3. *Pleasant emotions*

0% 25% 50% 75% 100% = %

Not at all confident — Totally Confident

4. *Testing personal control*

0% 25% 50% 75% 100% = %

Not at all confident — Totally Confident

5. *Urges and temptations*

0% 25% 50% 75% 100% = %

Not at all confident — Totally Confident

6. *Conflict with others*

0% 25% 50% 75% 100% = %

Not at all confident — Totally Confident

7. *Social pressures*

0% 25% 50% 75% 100% = %

Not at all confident — Totally Confident

8. *Pleasant times with others*

0% 25% 50% 75% 100% = %

Not at all confident — Totally Confident

Adapted from: H.M. Annis and G. Martin, Inventory of Drug-Taking Situations *(4th ed.). Toronto: Addiction Research Foundation* © *1985*

Wellbeing – SWEMWBS

Below are some statements about feelings and thoughts.

Please select the answer that best describes your experience of each over the last 2 weeks.

	None of the Time	Rarely	Some of the Time	Often	All of the Time
I've been feeling optimistic about the future	**1**	**2**	**3**	**4**	**5**
I've been feeling useful	1	2	3	4	5
I've been feeling relaxed	1	2	3	4	5
I've been dealing with problems well	1	2	3	4	5
I've been thinking clearly	1	2	3	4	5
I've been feeling close to other people	1	2	3	4	5
I've been able to make up my own mind about things	1	2	3	4	5

C21 **How likely is it that each of the following things would happen to you personally, if you drink alcohol?**

Mark one box for each line.

	Very likely	Likely	Unsure	Unlikely	Very unlikely
a) Feel relaxed	☐	☐	☐	☐	☐
b) Get into trouble with police	☐	☐	☐	☐	☐
c) Harm my health	☐	☐	☐	☐	☐
d) Feel happy	☐	☐	☐	☐	☐
e) Forget my problems	☐	☐	☐	☐	☐
f) Not be able to stop drinking	☐	☐	☐	☐	☐
g) Get a hangover	☐	☐	☐	☐	☐
h) Feel more friendly and outgoing	☐	☐	☐	☐	☐
i) Do something I would regret	☐	☐	☐	☐	☐
j) Have a lot of fun	☐	☐	☐	☐	☐
k) Feel sick	☐	☐	☐	☐	☐
	1	2	3	4	5

C22 **BECAUSE OF YOUR OWN ALCOHOL USE, how often during the LAST 12 MONTHS have you experienced the following?**
If you haven't used alcohol the last 12 months, please mark zero occasions on all questions.

Mark one box for each line.

	Number of occasions						
	0	1–2	3–5	6–9	10–19	20–39	40 or more
a) Physical fight	☐	☐	☐	☐	☐	☐	☐
b) Accident or injury	☐	☐	☐	☐	☐	☐	☐
c) Serious problems with your parents	☐	☐	☐	☐	☐	☐	☐
d) Serious problems with your friends	☐	☐	☐	☐	☐	☐	☐
e) Performed poorly at school or work	☐	☐	☐	☐	☐	☐	☐
f) Victimized by robbery or theft	☐	☐	☐	☐	☐	☐	☐
g) Trouble with police	☐	☐	☐	☐	☐	☐	☐
h) Hospitalised or admitted to an emergency room	☐	☐	☐	☐	☐	☐	☐
i) Engaged in sexual intercourse without a condom	☐	☐	☐	☐	☐	☐	☐
j) Engaged in sexual intercourse you regretted the next day	☐	☐	☐	☐	☐	☐	☐
	1	2	3	4	5	6	7

Motivation – Readiness Ruler

Single item readiness ruler

On the scale below enter how you feel right now about your substance use

1	2	3	4	5	6	7	8	9	10
I never think about my substance use		Sometimes I think about using substances less often		I have decided to use substances less often			I am already trying to use fewer substances		My substance use has changed I use less than before

Family Relationships – Brief Family Relationship Scale

Responses True or False

Cohesion

1. In our family we really help and support each other.
2. In our family we spend a lot of time doing things together at home.
3. In our family we work hard at what we do in our home.
4. In our family there is a feeling of togetherness.
5. My family members really support each other.
6. I am proud to be a part of our family.
7. In our family we really get along well with each other.

Expressiveness

8. In our family we can talk openly in our home.
9. In our family we sometimes tell each other about our personal problems.
10. In our family we begin discussions easily.

Conflict

11. In our family we argue a lot. (R)
12. In our family we are really mad at each other a lot. (R)
13. In our family we lose our tempers a lot. (R)
14. In our family we often put down each other. (R)
15. My family members sometimes are violent. (R)
16. In our family we raise our voice when we are mad. (R)

Time Line Follow-Back – TLFB28 – completed using interview rather than self-complete

To help us evaluate your drug use, we need to get an idea of what your use was like in the past ____ days. To do this, we would like you to fill out the attached calendar.

- ✓ Filling out the calendar is not hard!
- ✓ Try to be as accurate as possible.
- ✓ We recognize you won't have perfect recall. That's OKAY.

✓ WHAT TO FILL IN

- The idea is that for **each day** on the calendar we want you to indicate whether you "used" or "did not use" drugs.
- On days when you **did not use drugs**, you should write a "0" in the box.
- On days when you **did use drugs**, you should put a "✓" in the box.

It's important that something is written for <u>every</u> day, even if it is a "0".

✓ YOUR BEST ESTIMATE

- We realize it isn't easy to recall things with 100% accuracy.
- If you are not sure whether you used a certain drug on a Thursday or a Friday of a certain week, **give it your best guess!** The goal is to get a picture of how many days you were using drugs and your patterns of use.

✓ HELPFUL HINTS

- Holidays such as Thanksgiving and Christmas are marked on the calendar to help you better recall your use. Also, think about whether you used drugs on personal holidays and events such as birthdays, vacations, or parties.
- If you have **regular drug use patterns** you can use these to help you recall your use. For example, you may have weekend/weekday changes in your drug use or your drug use may be different depending where you are or whom you are with.

✓ COMPLETING THE CALENDAR

- A blank calendar is attached. **Each day** should contain a "0" for no drug use or a **"✓" for drug use**.
- The time period we are talking about on the calendar is

  from _____ **to** _____.
- In estimating your drug use, be as accurate as possible.
- **DOUBLE CHECK THAT <u>ALL</u> DAYS ARE FILLED IN BEFORE RETURNING THE CALENDAR.**
- Before you start look at the **SAMPLE CALENDAR** on the next page.

✓ **SAMPLE CALENDAR**

2000	SUN	MON	TUES	WED	THURS	FRI	SAT
						1 0	2 0
S	3 0	4 Labor Day 0	5 ✓	6 ✓	7 ✓	8 0	9 ✓
E	10 ✓	11 ✓	12 0	13 ✓	14 ✓	15 0	16 ✓
P	17 ✓	18 0	19 0	20 0	21 0	22 ✓	23 ✓
T	24 0	25 0	26 ✓	27 0	28 0	29 0	30 ✓

Substance Use Screening Questionnaire – SUSQ

"On how many days in the past 28 days have you used alcohol or other illegal substance (list prompt)?"

YOUTH ENDOWMENT FUND

Impetus

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The Youth Endowment Fund Charitable Trust

Registered Charity Number: 1185413