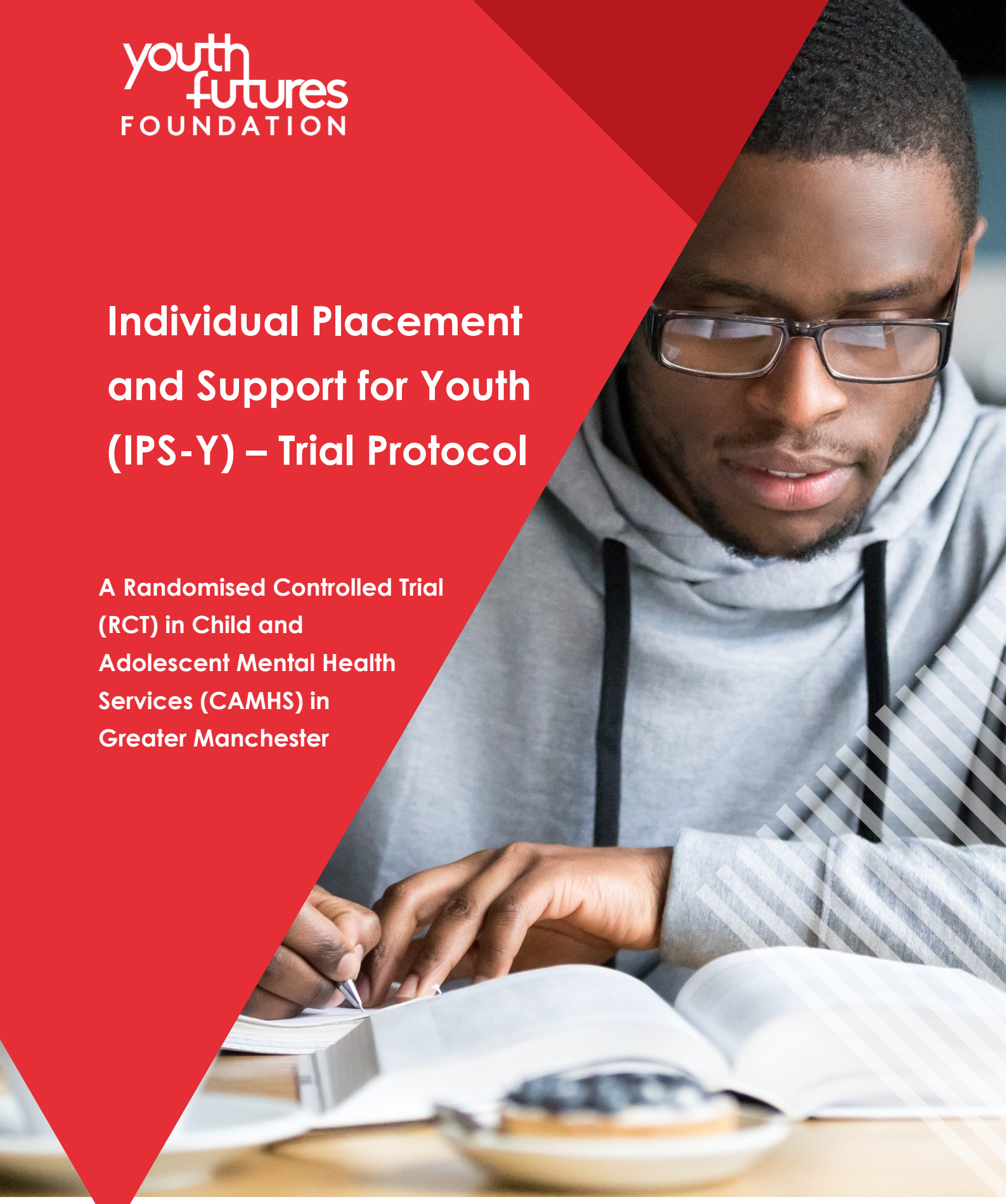
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Individual Placement and Support for Youth (IPS-Y) – Trial Protocol



A Randomised Controlled Trial (RCT) in Child and Adolescent Mental Health Services (CAMHS) in Greater Manchester

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Project overview

PROJECT TITLE	Individual Placement and Support for Youth (IPS-Y): A Randomised Controlled Trial (RCT) in Child and Adolescent Mental Health Services (CAMHS) in Greater Manchester
SHORT TITLE	IPS-Y RCT
DELIVERY ORGANISATION	Pure Innovations
EVALUATOR	Ipsos UK University of Strathclyde
PARTICIPATING ORGANISATIONS	Pennine Care NHS Foundation Trust (Pennine) Manchester University NHS Foundation Trust (MFT)
CHIEF INVESTIGATOR(S)	Joanna Hofman
PRINICPAL INVESTIGATOR	Co-PI Pennine: Professor Prathiba Chitasbesan & Dr Jennifer Kujacz Co-PI MFT: Dr Roshelle Ramkisson, Dr Vandna Saxena & Dr Shamik Chudasama

Evaluation plan version history

VERSION	DATE	REASON FOR REVISION	AUTHORS
5.0	27/08/2026	Updated following fourth review by YFF	As below
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3.0	09/07/2026	Updated following second review by YFF and comments from research lead at Pennine Care Foundation Trust	As below
2.0	22/06/2026	Updated following first review by YFF	As below
1.0 [ORIGINAL]	05/06/2026		Ipsos UK – Nicola De Waal, Facundo Herrera, Oliver Tee, Marina Leoni, Joanna Hofman University of Strathclyde – Professor Adam Whitworth

Study rationale and background

Young people with mental health difficulties are at increased risk of poor education and employment outcomes, including becoming not in education, employment or training (NEET), with longitudinal evidence showing that adolescent health and psychosocial factors are associated with later educational attainment and NEET status.[1,2,3] This risk is especially salient during late adolescence, when young people are navigating educational transitions, early labour-market decisions and increasing expectations of independence. For young people aged 16–17 with complex mental health needs, these transitions can coincide with movement through, or out of, Child and Adolescent Mental Health Services (CAMHS), creating risks of discontinuity in support. The transition from CAMHS to adult mental health services is recognised as a point of vulnerability, with evidence highlighting risks linked to fragmented pathways, variable eligibility thresholds and insufficient continuity of care.[4]

The resulting support landscape can leave young people and families navigating separate systems for mental health treatment, education support, careers advice and employment support, rather than receiving integrated assistance.[5] This fragmentation matters because being NEET during youth is associated with longer-term risks for health, wellbeing, social inclusion and labour-market participation.[6]

There is therefore increasing policy interest in interventions that can improve employment and education outcomes for young people with mental health difficulties.[7] Individual Placement and Support (IPS) is a well-established evidence-based model which integrates employment support within mental health care for adults.[8] The Individual Placement and Support – Youth (IPS-Y) model adapts IPS to meet the needs young people approaching adulthood, emphasising career exploration, education goals, family involvement, and developmentally appropriate supports. The model has been implemented internationally across a range of youth mental health settings, with evidence to suggest that IPS-Y can improve participation in employment and education among young people with mental health difficulties.[9] The SEED trial of IPS for young

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[1] APPG Mental Health Inquiry 2023: Report Final

[2] Hale, D. R., & Viner, R. M. (2018). How adolescent health influences education and employment: investigating longitudinal associations and mechanisms. *J Epidemiol Community Health*, *72*(6), 465-470.

[3] Milburn, A. (2026). Independent report: Young people and work: interim report. DWP.

[4] Hendrickx, G., De Roeck, V., Maras, A., Dieleman, G., Gerritsen, S., Purper-Ouakil, D., ... & Tremmery, S. (2020). Challenges during the transition from child and adolescent mental health services to adult mental health services. *BJPsych bulletin*, *44*(4), 163-168.

[5] Lanceley, L., Nancarrow, A., Williams, J., Campbell, B., Cook, J., Illidge, L. & Wong, K. (2025). Education to employment transitions: support in 2024. Youth Futures.

[6] Hofman, J, Zhang, K., Groom, M., Reed, M. & Angell, S. (2024). Variations in labour market outcomes for young people facing marginalisation: associated factors and explanations. Youth Futures.

[7] Alan Milburn calls for a 'movement' to address lost generation of young people not earning or learning as investigation opens - GOV.UK

[8] Whitworth, A., Baxter, S., Cullingworth, J., & Clowes, M. (2024). Individual Placement and Support (IPS) beyond severe mental health: An overview review and meta-analysis of evidence around vocational outcomes. *Preventive Medicine Reports*, *43*, 102786.

[9] See: Nicholas, J., Ardill-Young, O., Levy, P., Pearce, K., Chinnery, G., Sim, E., ... & Killackey, E. (2024). A supported education programme implemented in youth mental health services: Outcomes and lessons from the first year of COVID-disrupted delivery. *Early Intervention in Psychiatry*, *18*(8), 652-658; Hillborg, H., Lövgren, V., Bejerholm, U., & Rosenberg, D. (2024). Supporting education with IPS: Advancing a career-oriented model for integrating work and study support for young adults in Sweden. *Psychiatric rehabilitation journal*, *47*(1), 37; Sveinsdottir, V., Lie, S. A., Bond, G. R.; Ellison, M. L., Reeder, K. E., Stone, R., Hayes, M., Swanson, S. J., & Bond, G. R. (2023). Individual placement and support (IPS) for high school aged youth: Provider perspective and practice. *Community mental health journal*, *59*(3), 471-476.

people in Norway found that significantly more 18-29 year olds receiving IPS obtained employment compared to those receiving traditional vocational rehabilitation.[10] A 2023 meta-analysis of seven randomised controlled trials (RCTs) conducted internationally reported a significantly higher competitive employment[11] rate for young adults receiving IPS than the control group across all trials (58.3% compared to 32.4% overall).[12] However, four out of these studies focussed on people being treated for psychosis. Despite these promising results, the effectiveness of IPS-Y within NHS services in the UK has not been evaluated. This trial addresses this evidence gap by evaluating IPS-Y within CAMHS in Greater Manchester Integrated Care (GM IC).

Overview of the evaluation design

The evaluation will employ a mixed-methods design comprising three integrated components: (1) an impact evaluation, (2) an implementation and process evaluation (IPE), and (3) an economic evaluation.

The impact evaluation will use a two-arm, parallel-group randomised controlled trial (RCT) to estimate the causal effect of IPS-Y on education, employment or training (EET) outcomes for young people aged 16–17 receiving treatment within CAMHS. Eligible participants will be individually randomised to receive either IPS-Y or the control, which will be business-as-usual (BAU) services alone. Individual randomisation was selected because it provides the strongest basis for estimating causal impacts, minimises selection bias, and is feasible within participating CAMHS services. The trial is designed as a pragmatic effectiveness study, reflecting the intention to assess whether IPS-Y improves outcomes when delivered under routine service conditions within NHS settings.

The primary outcome is participation in EET during the 12 months following randomisation. This is defined as at least one of the following:

- in education (6+ hours/week) sustained for at least 4 consecutive weeks
- in paid employment (at least 1 day during the follow-up period)
- in accredited training (6+ hours/week), sustained for at least 4 consecutive weeks.

Secondary outcomes include the individual EET components during the 12 months following randomisation (education; employment; training), analysed separately, alongside mental wellbeing (SWEMWBS) and life satisfaction (ONS single item).

[10] Eriksen, H. R., Tveito, T. H., Grasdal, A. L., & Reme, S. E. (2020). Individual placement and support for young adults at risk of early work disability (the SEED trial). A randomized controlled trial. *Scandinavian journal of work, environment & health*, *46*(1), 50-59.

[11] As opposed to sheltered employment which refers to segregated work environments tailored for individuals with disabilities who face challenges finding work in the mainstream, competitive labour market.

[12] Bond, G, Al-Abdulmunem, M, Marbacher, J, Christensen, T, Sveinsdottir, V, Drake, R. (2023). A Systematic Review and Meta-analysis of IPS Supported Employment for Young Adults with Mental Health Conditions. *Adm Policy Ment Health*, 50(1), 160-172

Together, these outcomes reflect the intervention theory of change (ToC), which proposes that integrated vocational and educational support can improve participation in education and employment while also contributing to wider recovery, wellbeing and life chances.

Alongside the impact evaluation, a comprehensive IPE will examine how IPS-Y is delivered in practice, the extent to which delivery aligns with the intended model, and the barriers and facilitators influencing implementation. Drawing on quantitative monitoring data, fidelity assessments and qualitative interviews with young people, families, IPS-Y Specialists and CAMHS staff, the IPE will explore how contextual factors influence implementation and outcomes and will test the mechanisms proposed within the ToC. This component is particularly important given that IPS-Y represents a complex intervention requiring integration across health, education and employment systems.

An economic evaluation will assess the resources required to deliver IPS-Y and estimate its incremental cost-effectiveness relative to BAU. This will provide evidence on the affordability and value-for-money of IPS-Y alongside evidence on effectiveness and implementation.

The evaluation incorporates a nested pilot phase prior to progression to the main trial. The pilot will test key assumptions relating to recruitment, consent, randomisation, and intervention delivery. Findings from the pilot will be used to refine operational procedures and assess readiness for progression to the full effectiveness trial.

Taken together, this design will provide robust evidence on whether IPS-Y improves educational and employment outcomes for young people receiving CAMHS treatment, how and why any observed effects occur, the conditions under which the intervention is most effective, and the resources required to support wider implementation.

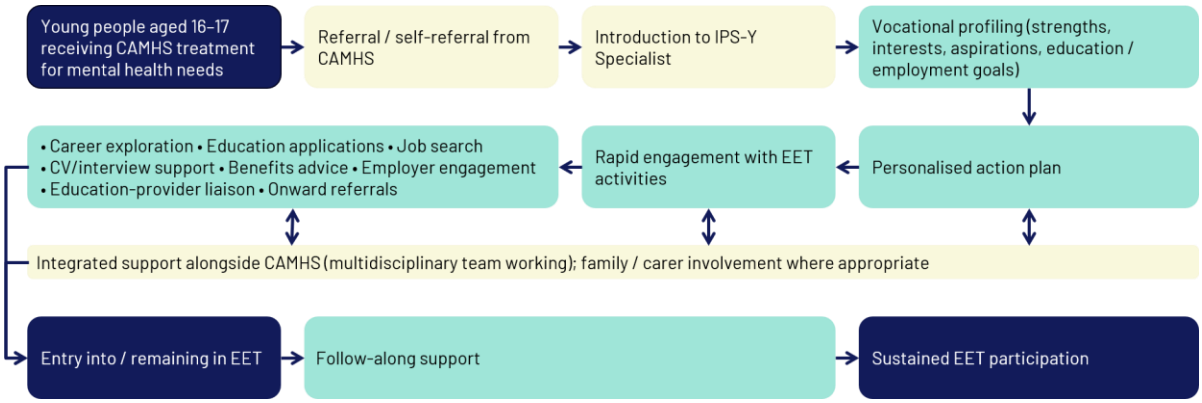
Intervention

Overview

The intervention is IPS-Y which is an adaptation of the established IPS model specifically designed to support the needs of transition-age young people experiencing mental health difficulties. IPS-Y integrates vocational and educational support alongside mental health care, enabling young people to access and sustain meaningful EET opportunities.

IPS-Y is delivered through a sequence of activities beginning with vocational profiling and goal setting, followed by rapid engagement with education, employment or training opportunities, and continuing with follow-along support once a young person enters EET. Support is delivered by an IPS-Y Specialist co-located in CAMHS and embedded within the CAMHS multidisciplinary team and includes vocational profiling, action planning, employer and education-provider engagement, supported education activities, and ongoing coordination with mental health care. **Error! Reference source not found.** illustrates the participant journey through the intervention.

Figure 1: IPS-Y participant journey



Brief name

Individual Placement and Support – Youth (IPS-Y)

Why (the rationale of the essential elements of the intervention)

Young people aged 16–17 receiving support from CAMHS are at increased risk of poor EET outcomes and of becoming NEET. IPS-Y was developed to address this by integrating vocational and educational support within mental health care.

IPS-Y is based on the premise that participation in EET is both an outcome of recovery and a contributor to recovery. Rather than requiring young people to achieve clinical stability before pursuing vocational goals, the intervention supports engagement with education and employment alongside ongoing mental health treatment. By embedding IPS-Y Specialists within CAMHS teams, IPS-Y seeks to reduce service

fragmentation, align vocational and clinical goals, and provide coordinated, person-centred support tailored to young people's educational, vocational, health and developmental needs and aspirations. Through supported education and employment activities, employer and education-provider engagement, family involvement where appropriate, and ongoing individualised support, IPS-Y seeks to increase participation in EET and improve longer-term outcomes related to independence, social inclusion, and wellbeing.

What (materials)

IPS-Y is delivered using a combination of vocational support tools, educational planning resources, participant information materials, and case management systems. IPS-Y Specialists use structured vocational profiling and action-planning tools to identify young people's strengths, interests, aspirations and support needs. Support is guided by the IPS-Y fidelity framework and associated practice guidance.[13]

What (procedures)

IPS-Y is delivered in accordance with the core principles of IPS, which are associated with positive vocational outcomes and form the basis of the IPS fidelity framework. These principles include:

1. Competitive[14] employment
2. Eligibility based on client choice / zero exclusion
3. Integration of employment and mental health services
4. Attention to worker preferences
5. Personalised benefits counselling
6. Rapid job search
7. Systematic job development
8. Time-unlimited and individualised support.[15]

Support reflects IPS's distinctive "place–train–maintain" approach, whereby young people are supported to move quickly towards education, training or employment opportunities, with ongoing support provided before, during and after participation rather than requiring lengthy periods of preparation beforehand. Delivery is guided by the IPS-Y Fidelity Scale, a validated adaptation of the standard IPS Fidelity Scale developed specifically for transition-age young people.[16] The IPS-Y scale retains the core IPS principles, while placing greater emphasis on supported education, career exploration, family involvement and developmentally appropriate practice.

IPS-Y is delivered through a series of interrelated activities designed to support young people in achieving their EET goals while receiving ongoing CAMHS treatment (**Error! Reference source not found.**).

[13] Becker, D.R., Swanson, S.J., Reese, S.L., Bond, G.R. and McLeman, B.M., 2015. Supported employment fidelity review manual. *A companion guide to the evidence-based IPS Supported Employment Fidelity Scale*.

[14] As opposed to sheltered employment which refers to segregated work environments tailored for individuals with disabilities who face challenges finding work in the mainstream, competitive labour market.

[15] IPS Practice and Principles (English version) – The IPS Employment Center

[16] IPS-Y: IPS Fidelity Scale for Young Adults (Revised 10-7-23) available at: IPS-y revised 10-7-23

Who (provider)

IPS-Y is delivered by IPS-Y Specialists employed by Pure Innovations and embedded within participating CAMHS teams. In this case, the participating Trusts are Pennine Care NHS Foundation Trust (Pennine) and Manchester University NHS Foundation Trust (MFT). Therefore, the participating local authorities are Manchester, Trafford, Bury, Oldham, Rochdale, Salford, Stockport and Tameside. Pure Innovations is the lead IPS provider across Greater Manchester and has extensive experience delivering IPS services for adults with mental health conditions.

IPS-Y Specialists are practitioners whose role is to support young people to achieve their EET goals alongside ongoing mental health treatment. They work as part of a multidisciplinary team, collaborating closely with CAMHS clinicians, education providers, employers, families and other relevant services to provide integrated support.

IPS-Y Specialists will complete training covering IPS and IPS-Y principles, the IPS-Y fidelity model, supported education approaches, employer engagement, safeguarding, trauma-informed practice, neurodiversity-informed practice, research governance (such as Good Clinical Practice (GCP) consent training) and collaborative working within CAMHS settings. Ongoing supervision will be provided by Pure Innovations managers and through regular collaboration with CAMHS teams.

How

IPS-Y is delivered through a combination of one-to-one meetings, community-based support, employer and education-provider engagement, and multidisciplinary collaboration with CAMHS clinicians. Support is person-centred, strengths-based and guided by the young person's preferences, interests and aspirations. Interactions are tailored to individual needs. The model emphasises flexibility and accessibility to maximise engagement and responsiveness to young people's circumstances.

IPS-Y Specialists work closely with CAMHS clinicians as part of an integrated multidisciplinary approach. This includes regular communication, shared care planning, coordinated problem-solving and support during periods of fluctuating mental health or transition between services. Vocational and educational goals are considered alongside wider recovery and wellbeing objectives rather than being delivered as a separate or parallel service.

IPS-Y Specialists develop relationships with local organisations, identify opportunities aligned with young people's goals, facilitate introductions, support applications and interviews, and work with employers and educational settings to identify reasonable adjustments and address barriers to participation. Family members and other trusted adults may be involved in planning and support activities, where appropriate and with the young person's agreement.

Support continues after entry into education, training or employment and includes practical assistance, problem-solving, coaching and liaison with relevant stakeholders to help young people maintain participation and progress towards their longer-term goals.

Where

IPS-Y is delivered within CAMHS in participating NHS Trusts in Greater Manchester: Pennine Care NHS Foundation Trust and Manchester University NHS Foundation Trust, subject to completion of the necessary governance and implementation arrangements.

IPS-Y Specialists are co-located in CAMHS, embedded within CAMHS teams and work alongside clinical staff as part of an integrated model of support. Delivery occurs across a range of settings according to young people's needs and preferences, including CAMHS clinics, educational institutions, workplaces, community venues, other locations within the local community. Activities may also be delivered remotely through telephone, email, text messaging or video communication where appropriate.

When and how much (dosage)

IPS-Y support begins as soon as possible following enrolment and identification of the young person's EET goals. Support does not require completion of lengthy pre-vocational programmes or assessments before engagement with education, training or employment opportunities begins.

The frequency, duration and mode of contact are tailored to the young person's needs, preferences and stage of progression. Support intensity is expected to vary over time, with more frequent contact often required during periods of active job search, educational transition, entry into employment or education, or when additional support is needed to address barriers to participation.

Support continues for as long as the young person wishes to receive assistance. The duration and intensity of support received by individual participants will vary according to their goals, circumstances and timing of entry into EET. Trial participation and IPS-Y support for participants allocated to the intervention will continue if a young person is discharged from CAMHS during the trial. CAMHS discharge will be recorded, and the IPE will explore how transitions out of CAMHS affect IPS-Y delivery, continuity of support and participant experience.

Tailoring

IPS-Y is designed to be delivered flexibly within the boundaries of the IPS-Y fidelity framework. Whilst all participants receive an intervention grounded in the core IPS principles and youth-specific IPS-Y adaptations, the content, intensity and focus of support are tailored to individual circumstances, preferences and goals.[17]

Tailoring may include variation in the balance between education- and employment-related activities; the pace of progression towards vocational goals; the frequency and mode of contact; the level of family involvement; communication approaches; support for neurodivergent young people; and the nature of employer, education-provider or wider service engagement. The intervention may also be adapted in response to changes in mental health, educational status, employment circumstances or personal goals over time.

However, tailoring does not extend to modification of the core IPS-Y model. All participants receive support that remains consistent with IPS-Y fidelity principles.

Modifications

No modifications to the IPS-Y intervention are planned beyond those required to support delivery and evaluation within the trial context:

[17] Swanson, S.J., Becker, D.R., Bond, G.R., Reeder, K.E. and Ellison, M.L., 2020. IPS supported employment for transition age youth: Helping youth with serious mental health conditions to access jobs, education and careers. University of Massachusetts Medical School.

1. Whilst IPS-Y ordinarily operates according to the principle of zero exclusion, participation in the trial is restricted to young people who meet the study eligibility criteria and provide informed consent.
2. Whilst IPS principles advocate time-unlimited support based on individual need, support within the trial is limited by the funded delivery period and participants will be eligible to receive IPS-Y for a maximum of 13 months (consistent with other IPS trials and the IPS-LITE model)18 comprising up to nine months of pre-employment support and approximately four months of in-work support or up to 13 months of education support.

Any substantive modifications to intervention delivery identified during implementation will be documented through trial governance processes and reported as part of the IPE.

How well (planned)

Intervention quality and fidelity will be supported through a combination of supervision, internal self-assessments and external fidelity review:

- Supervision: IPS-Y Specialists will receive regular supervision from experienced Pure Innovations managers in line with established IPS service delivery arrangements.[19] Supervision will focus on case management, adherence to IPS-Y principles, integration with CAMHS teams, employer and education-provider engagement, safeguarding considerations, and problem-solving around implementation challenges.
- Internal self-assessments: Pure Innovations will undertake routine internal self-assessments using the IPS-Y Fidelity Scale.[20] This will assess adherence to the core IPS principles and youth-specific adaptations. Findings will be used to identify areas for improvement and inform supervision, training and service development.
- External fidelity reviews: These will be undertaken by trained third party reviewers using the IPS-Y Fidelity Scale. These reviews will provide an independent assessment of adherence to the model and identify any areas requiring corrective action. Where fidelity concerns are identified, improvement plans may include additional supervision, targeted training, service-level changes or other corrective actions to support consistent delivery across sites.

[18] See: Burns, T., Yeeles, K., Langford, O., Montes, M.V., Burgess, J. and Anderson, C., 2015. A randomised controlled trial of time-limited Individua Lplacement and Support: IPS-LITE trial. *The British Journal of Psychiatry*, *207*(4), pp.351-356; Marsden, J., Anders, P., Clark, H., Colocassis, K., Eastwood, B., Knight, J., Melaugh, A., Quinn, D., Wright, V. and Stannard, J., 2020. Protocol for a multi-centre, definitive randomised controlled trial of the effectiveness of Individual Placement and Support for employment support among people with alcohol and drug dependence. *Trials*, *21*(1), p.167.

[19] The supervision here is an equivalent of clinical supervision (where a healthcare or mental health professional meets regularly with a more experienced senior practitioner). It is not meant to replace the clinical supervision which will be provided separately by a designated clinician nominated in each Trust.

[20] See: Bond, Gary & Swanson, Sarah & Becker, Deborah & Ellison, Marsha & Reeder, Kimberly. (2021). The IPS-Y: IPS Fidelity Scale for Young Adults. American Journal of Psychiatric Rehabilitation. 22. 239-255; IPS-Y: IPS Fidelity Scale for Young Adults (Revised 10-7-23) available at: IPS-y revised 10-7-23

Theory of change (ToC)

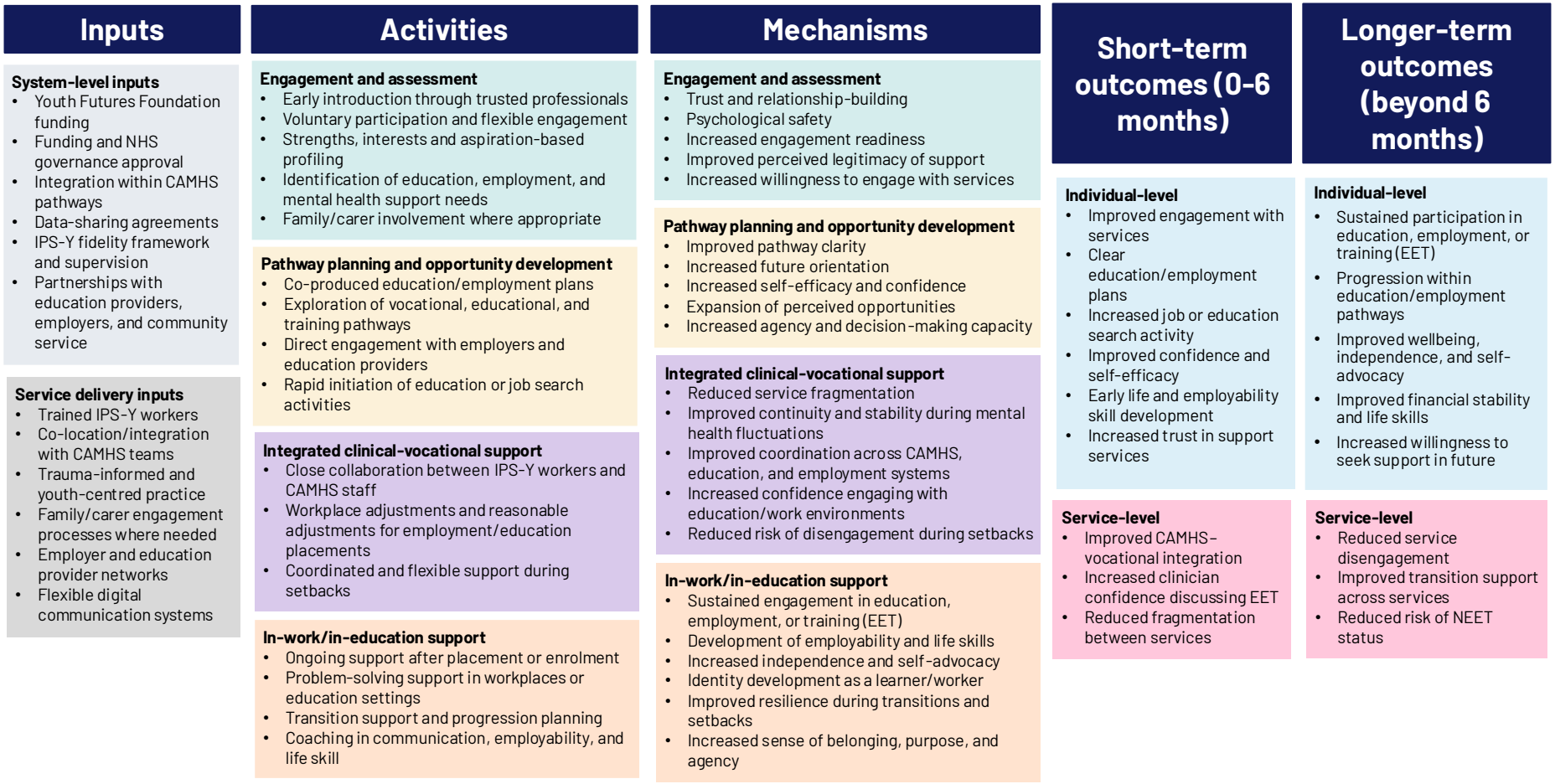
The intervention is expected to improve outcomes through several interconnected mechanisms. These include strengthening young people's confidence and aspirations, increasing access to education and employment opportunities, improving navigation of transitions and support systems, and reducing fragmentation between mental health, education and employment services. Through these mechanisms, IPS-Y aims to support greater participation in EET, while also contributing to wider outcomes such as increased independence, self-efficacy and social inclusion.

Figure 1 presents the ToC informed by IPS-Y literature, stakeholder engagement activities, and co-design work with young people and parents/carers. This ToC, which represents the intervention being trialled, will be reviewed and adjusted if needed during the trial as part of the IPE.

Period when the intervention is being delivered

1 March 2027 – 30 June 2028

Figure 1: ToC for the IPS-Y intervention within the trial context



Control conditions

Participants allocated to the control arm will receive BAU support during the 12-month follow-up period. BAU comprises the standard care and support available to young people receiving secondary care CAMHS services within participating NHS Trusts. This is expected to include ongoing mental health assessment, treatment and care coordination delivered through CAMHS, together with access to any education, employment, training or wider support services that would normally be available in the local area. The feasibility study determined that overall, the BAU was suitably distinct from IPS-Y (

Table 1).

Participants in the control arm (BAU) will not receive IPS-Y support from an IPS-Y Specialist before completion of the 12-month primary outcome measurement. However, they will receive an information sheet directing them to relevant services within their local authority. IPS (but not IPS-Y) currently forms part of the control conditions: IPS is provided by some organisations operating in Greater Manchester, such as 42nd Street and Groundwork. Control group participants may therefore independently access other statutory, voluntary, community or education-sector services available locally, including existing IPS services where these are offered outside the trial. These services form part of BAU and are therefore considered part of the control condition.

Table 1: Treatment contrast

Feature	IPS-Y	BAU
CAMHS treatment	✓	✓
Dedicated IPS-Y Specialist	✓	✗
Vocational profiling	✓	Variable
Individualised action plan	✓	Variable
Supported education	✓	Variable
Employer engagement	✓	Variable
Integrated multidisciplinary working around EET goals	✓	✗
Follow-along support after EET entry	✓	Variable

However, because awareness of local employment support services may increase through participation in the study, there is a possibility that some control group participants may independently seek out existing IPS provision during the follow-up period. To assess the extent of this, participant surveys at 6 and 12 months and the IPE will collect information on education, employment and vocational support received by participants in both trial arms, including the provider, duration and nature of support where possible. Particular attention will be paid to identifying any control participants who access existing IPS services or interventions closely aligned with the IPS model. These data will be used to describe service use across trial arms, assess the degree of differentiation between IPS-Y and BAU, and inform interpretation of the impact estimates. Trial recruitment materials and participant communications will not actively promote or signpost existing IPS services beyond the standard information on local support routinely provided to all participants.

Information on education, employment and mental health support received by participants in both trial arms will be collected through participant surveys and the IPE. This information will be used to describe the services accessed by participants as part of BAU provision and to identify any exposure among control-group participants to IPS-Y or services closely resembling IPS-Y that could reduce differentiation between trial arms. This will support interpretation of trial findings and assessment of the extent to which observed impacts reflect the added value of IPS-Y over and above existing support available within Greater Manchester.

Participants

Study population

The study population comprises young people aged 16–17 receiving treatment within participating secondary care CAMHS services in Greater Manchester who express an interest in EET opportunities. Participants will be recruited from participating CAMHS teams within Pennine Care NHS Foundation Trust and Manchester University NHS Foundation Trust. A combined standing caseload across Pennine and MFT was estimated at approximately 3,413 young people and judged sufficiently large to support the trial sample size.[21]

Screening and recruitment procedures

The recruitment approach is based on the standing caseload of young people already receiving active CAMHS treatment, rather than the flow of newly referred patients. Recruitment will take place over a one-to-three-month period using batched randomisation during the recruitment window rather than a continuous rolling recruitment model.

Recruitment will proceed through the following stages.

Stage 1: Clinician pre-screening

Potential participants will be identified from routine CAMHS caseloads by members of the young person's direct care team, including CAMHS clinicians and multidisciplinary team members. As an initial pre-screening step, clinicians will review information already available within routine clinical records to identify young people who appear likely to meet the eligibility criteria. The pre-screening process is not a formal eligibility assessment and does not determine participation in the trial.

[21] See Hofman, J., Herrera, F., Tee, O., de Waal, N., Leoni, M., Snell, J., Stern, D., Whitworth, A. & Vallelyis, M. (2026). Individual Placement and Support – Youth (IPS–Y) Feasibility Report. Youth Futures Foundation (submitted to client).

Stage 2: Initial introduction to the study

Young person identified through clinician pre-screening will be approached by a member of their clinical team during one of their regular appointments and asked if they are interested in employment and/or education, and support to remain in, return to, or progress within EET. Where the young person expresses interest in hearing more either they will be introduced to an IPS-Y Specialist, and their contact details will be shared securely – and with permission – with an IPS-Y Specialist.

Young people may also express interest in the study through self-referral mechanisms publicised by participating CAMHS services and study partners. Self-referral does not constitute confirmation of eligibility or enrolment into the trial. Where a self-referral is received, the IPS-Y Specialist will provide information about the study and undertake an initial pre-screening which serves a similar function to the clinician pre-screen described above. Young people who continue to appear eligible following this assessment will proceed to formal eligibility assessment.

Stage 3: Formal eligibility assessment

The IPS-Y Specialist will provide a detailed explanation of the study, answer any questions, and undertake a formal eligibility assessment against the full study inclusion and exclusion criteria. For self-referred participants, this includes sharing their contact details – securely and with permission – with a member of their clinical team to confirm the eligibility and exclusion criteria.

Unlike the pre-screen, this assessment formally determines whether the young person is eligible to participate in the trial.

Stage 4: Participant information and consideration period

Young people who meet the eligibility criteria will be provided with the study leaflet, Participant Information Sheet, Privacy Notice and consent form. Participants will receive a clear explanation of:

- the purpose of the study
- what participation involves
- the randomisation process
- the intervention and control conditions
- any potential risks and benefits
- confidentiality and data protection arrangements, and
- their right to withdraw from the study at any time.

Participants will be given the opportunity to consider participation, ask questions about the study, and discuss participation with parents, carers or other trusted adults if they wish. However, the decision regarding participation remains entirely their own. Potential participants will normally be given at least 48 hours to consider participation, although they may choose to provide consent on the same day.

Stage 5: Informed consent

Informed consent will be obtained by a trained IPS-Y Specialist following confirmation of eligibility. Consent will include optional consent to be contacted about participation in the implementation and process evaluation (IPE).

No study procedures will occur before informed consent has been obtained, with the exception of the eligibility assessment described above.

Stage 6: Baseline assessment

Following informed consent, the IPS-Y Specialist will administer the baseline assessment and collect all required baseline data.

Following completion of these procedures, the IPS-Y Specialist will securely submit the participant's information to the independent Ipsos evaluation team for randomisation.[22]

Stage 7: Randomisation

The randomisation sequence will be generated in advance by an independent trial statistician and held securely by the Ipsos evaluation team (see Impact evaluation below for further detail). Participants who complete the baseline assessment will be randomised to either:

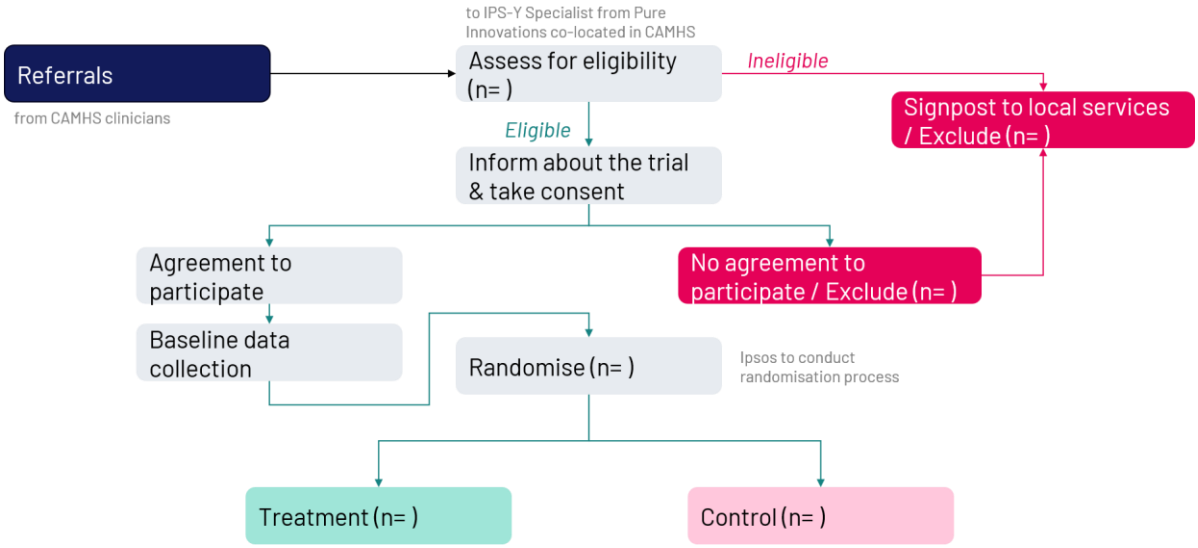
- treatment group (IPS-Y) or
- control group (BAU).

The Ipsos team will communicate the result to the IPS-Y Specialist, who will then inform the participant and initiate the appropriate pathway.

Figure 2 outlines the recruitment and randomisation process proposed, including organisational responsibilities.

Figure 2: Recruitment and randomisation process

[22] For randomisation purposes, the information shared with Ipsos will comprise the participant study ID, the randomisation stratification variables (NHS Trust site and diagnostic group), and confirmation that eligibility screening, informed consent and baseline data collection have been completed. Any sharing of identifiable information required for trial administration or follow-up activities will take place in accordance with approved privacy notices, data sharing agreements and information governance procedures.



A CONSORT participant flow diagram detailing numbers approached, screened, eligible, consented, randomised, retained and analysed will be included in the final trial report.

Recruitment will continue for up to two months or until the pre-specified target sample is reached, whichever occurs first. If the target sample size has not been achieved within two months, recruitment may continue for a further month. Recruitment will close at the end of the third month regardless of whether the target sample size has been reached. Any eligible young people identified after recruitment has closed will continue to receive routine CAMHS care. No changes to the sample size or allocation ratio will be made unless approved through a protocol amendment. Should recruitment close below the target of 304, the trial would be underpowered relative to the primary assumptions; the sample-size section sets out the minimum detectable effect across a range of achieved sample sizes, so that the smallest effect the trial could reliably detect under any given shortfall is transparent in advance.

Based on recruitment modelling, the principal constraint is the size of the eligible and consenting participant population that can be recruited within participating CAMHS services during the planned recruitment period. Accordingly, a 1:1 allocation ratio was judged to provide the most appropriate balance between statistical efficiency and operational feasibility. Furthermore, the intervention capacity of Pure Innovations (they can deliver IPS-Y to a maximum of ~160 young people) is a practical upper constraint on the trial sample.

Eligibility criteria

At point of randomisation:

1. Are aged 16–17 (including those still in compulsory schooling)
2. Are currently receiving active treatment for mental health in CAMHS secondary care in one of the participating Greater Manchester NHS Trusts
3. Have an identified mental health need (or mental health need and neurodiversity) for which they are receiving CAMHS treatment or support
4. Express interest in competitive employment and/or mainstream education, including special education needs and disabilities (SEND) provision and support to remain in, return to, or progress within EET

5. Are able to give informed consent to trial participation, with accessible information and reasonable communication support where required

Exclusion criteria

At point of randomisation:

1. Are currently receiving IPS or another specialist employment-support intervention that is judged to be sufficiently similar to IPS (i.e. WorkWell (if living in Thameside, Oldham and Rochdale), IPS PC, IPS-AD)
2. Had a recent suicide plan (past month)/attempt (past 6 months)
3. Are referred to CAMHS solely for autism/ADHD/neuro-developmental assessment, without concurrent CAMHS mental health treatment or support
4. Are unable to give informed consent, even with reasonable adjustments and supported decision-making
5. Are not yet in active in active mental health treatment or support (assessment-only, on a waiting list, or not accepted into CAMHS care)

Impact evaluation

Research question (RQ)

RQ1. What is the causal effect of IPS-Y, compared with business-as-usual (BAU), on participation in education, employment or training (EET) during the 12 months following randomisation?

Here, employment is defined as paid work in the open labour market, rather than sheltered or supported placements, consistent with IPS principles. Self-employment is excluded from this definition.

BAU comprises the mental health, education, employment and community support services that participants would ordinarily be able to access in Greater Manchester in the absence of IPS-Y. This includes CAMHS treatment, school or college support, careers advice, local authority services, voluntary and community sector provision, and any other routinely available support. BAU does not include support delivered by IPS-Y Specialists operating under the IPS-Y model and fidelity framework (see more in Control conditions above).

Trial design

The trial is justified on the basis of improving the evidence base for an intervention of which the emerging evidence is promising but not to a sufficient standard for policymaking. Although evidence from international studies suggests that IPS-Y may improve education and employment outcomes for young people with mental health difficulties, there remains uncertainty regarding its effectiveness when implemented within NHS CAMHS services in England. Random allocation is therefore necessary to determine whether IPS-Y provides benefits beyond BAU support and to inform future service commissioning decisions.

This study is a two-arm, parallel-group, individually randomised trial with 1:1 allocation and a nested pilot phase. The trial will compare IPS-Y plus usual CAMHS care against BAU support. The evaluation is designed as a pragmatic effectiveness trial, reflecting the intention to assess the impact of IPS-Y when delivered within routine NHS service settings rather than under tightly controlled efficacy conditions.

Table 2 summarises the trial design.

Table 2: Key elements of the trial design

TRIAL DESIGN, INCLUDING NUMBER OF ARMS	A two-arm, parallel-group, randomised controlled trial (RCT) with 1:1 allocation to intervention or control group with a nested pilot
TRIAL TYPE	Effectiveness
EVALUATION SETTING	CAMHS within: • Pennine Care NHS Foundation Trust (Pennine) • Manchester University NHS Foundation Trust (MFT)
TARGET GROUP / POPULATION	16–17-year-olds in active treatment in CAMHS care
INTERVENTION	IPS-Y
COMPARISON CONDITION	BAU
UNIT OF RANDOMISATION	Individual young person
STRATIFICATION VARIABLES	Randomisation will use randomly permuted blocks within each stratum defined by the variables below: 1) NHS Trust site (Pennine versus MFT); 2) mental health condition only versus mental health condition alongside neurodevelopmental needs Therefore, the allocation is balanced across arms within each stratum.
PRIMARY OUTCOME	EET status during the 12 months following randomisation Binary measure (in EET versus not in EET), defined as meeting at least one of the following during the 12 months following randomisation: • in education for at least 6 hours per week for at least 4 consecutive weeks • in paid employment for at least 1 day

	• in accredited training for at least 6 hours per week for at least 4 consecutive weeks. Self-reported across all outcomes, collected via online survey at 6 and 12 months following randomisation. Employment refers to competitive employment (paid work in the open labour market) excluding self-employment. The primary outcome (EET) is confirmatory and stands alone; the secondary outcomes are non-confirmatory and are organised into two pre-specified families as defined below.
SECONDARY OUTCOME(S)	**EET component outcomes** (during the 12 months following randomisation), analysed as one family of related binary measures: • in education (6+ hrs/week for 4+ consecutive weeks) • in paid employment (1 day) • in accredited training (6+ hrs/week for 4+ consecutive weeks) **Continuous wellbeing measures:** • Mental wellbeing (SWEMWBS) • Life satisfaction (ONS single-item) For multiple-comparison purposes, secondary outcomes are grouped into two pre-specified families: (i) the individual EET components, and (ii) the wellbeing measures (SWEMWBS and the ONS life-satisfaction item). Each family contains fewer than four outcomes, so no adjustment for multiple comparisons is required; the wellbeing measures are continuous and analysed accordingly. No secondary outcomes are designated as confirmatory. All secondary outcomes are exploratory and supportive. If multiplicity adjustment becomes necessary, the Romano-Wolf stepdown procedure will be used because it controls the family-wise error rate while retaining greater statistical power than conventional Bonferroni adjustments. Self-reported across all outcomes, collected via online survey at 6 and 12 months following randomisation.

Randomisation

Approach

Eligible participants who have provided informed consent and completed baseline data collection will be randomly allocated to either the IPS-Y intervention group or the BAU control group on a 1:1 basis. Individual-level randomisation is appropriate because IPS-Y is delivered directly to young people, and contamination risks can be managed through clear separation of IPS-Y delivery and BAU arrangements. Although intervention capacity allows up to 160 participants in the IPS-Y arm, the per-arm target under 1:1 allocation falls below this ceiling; recruitment, rather than intervention capacity, is therefore the binding constraint, and 1:1 allocation remains the most efficient choice.

Randomisation will be stratified by NHS Trust site and diagnostic profile (see below), using randomly permuted blocks within each stratum. The allocation sequence will be generated in advance by an independent trial statistician using Stata 17, prior to any recruitment, and held in a secure allocation spreadsheet exported from Stata. Within each stratum, block sizes are randomly varied[23] (for example, 2 and 4) and the order of allocations within each block is randomly permuted using Stata 17's random-number generator with a recorded seed, ensuring the sequence is reproducible for audit. Sufficient blocks are generated per stratum to cover the maximum anticipated recruitment. Full specification is provided in the statistical analysis plan.

As eligible participants complete screening, consent and baseline data collection, they will be allocated in sequence within their stratum according to this pre-generated list. Because allocation is determined in advance and held independently of the staff conducting recruitment, selection bias and foreknowledge of allocation are prevented.

Recruitment will take place over a one-to-three-month period from the standing CAMHS caseload, with participants randomised in batches following completion of recruitment, consent and baseline assessment.

Stratification

Randomisation will be stratified by:

1. NHS Trust site (Pennine versus MFT); and
2. Diagnostic profile (mental health condition only versus mental health condition alongside neurodevelopmental needs).

The use of stratified block randomisation is intended to maintain balance between trial arms across key participant and service characteristics. The trial includes four strata overall (2 NHS Trusts × 2 diagnostic groups), which is operationally manageable given the planned sample size of 304 participants.

- Site was selected as a stratification variable because IPS-Y will be delivered across two NHS Trusts that differ in organisational context, service configuration, referral pathways and BAU provision. These factors may influence implementation and participant outcomes. Stratifying by site helps ensure that participants from each

[23] Random variation in block size reduces the risk that future allocations could be predicted by recruitment staff while maintaining balance between trial arms within each stratum.

Trust are balanced across trial arms and reduces the risk that site-level differences confound estimates of intervention effectiveness.

- Diagnostic profile was selected because young people with co-occurring neurodevelopmental needs may experience different barriers to EET participation and may respond differently to vocational support. Stratification therefore helps ensure balance across an important prognostic characteristic identified during the feasibility study and stakeholder consultations.

Allocation and concealment

The allocation sequence will be generated and maintained by an independent trial statistician who will have no role in participant recruitment, consent, intervention delivery or outcome assessment. Within each stratum, participants will be allocated according to the pre-generated randomisation sequence.

Allocation concealment will be maintained through a secure centralised randomisation system. Eligibility screening, informed consent and baseline data collection will be completed before allocation is revealed. The allocation sequence will not be accessible to staff involved in participant recruitment, consent or intervention delivery.

Participants will be enrolled by a trained IPS-Y Specialist following confirmation of eligibility and completion of baseline measures. The secure randomisation procedure will be overseen by an independent member of the Ipsos evaluation team, who has no role in recruitment, consent or intervention delivery, and will follow a documented standard operating procedure. Once eligibility and baseline data collection are confirmed, the independent team member will determine the participant's allocation from the pre-generated sequence and inform the IPS-Y Specialist of the outcome. The IPS-Y Specialist will then inform the participant. For participants allocated to BAU, the IPS-Y Specialist will provide information about support available through usual care and will have no further role in their support, nor further contact with the BAU participants. For participants allocated to IPS-Y, the IPS-Y Specialist will arrange the first appointment and commence delivery in accordance with the IPS-Y model. Similar procedures have been used successfully in previous IPS trials, including the Health-Led Trials evaluation.[24]

This approach separates eligibility assessment, consent and baseline data collection from allocation, maintaining concealment until the point of randomisation. The progress of randomisation will be monitored throughout the recruitment intake period. Randomisation records, allocation status and trial participation logs will be maintained securely and audited throughout the study to ensure compliance with trial procedures.

Blinding

Given the nature of the intervention, participants, IPS-Y Specialists and CAMHS practitioners cannot be blinded to allocation status. However, outcome data collection will be conducted independently of intervention delivery, and statistical analyses will be undertaken using anonymised datasets with allocation status masked where feasible until primary analyses have been completed.

To reduce the risk of bias, treatment allocation will be masked (coded as neutral group labels) during data preparation and initial analysis, with allocation revealed only when

[24] Newton, B., Gloster, R. & Hofman, J. (2022). Health-led Employment Trial Evaluation: Synthesis report. DWP

the pre-specified primary analysis is conducted. Outcome data collection will be conducted independently of intervention delivery.

Sample size calculations / power

The sample size for this trial was determined a priori through a combination of statistical power calculations and feasibility modelling. The calculations were informed by evidence on the size of the eligible population within participating CAMHS services, expected recruitment volumes from the standing CAMHS caseloads of 16–17-year-olds (3,413),[25] evidence from previous IPS studies, and the minimum effect size considered policy-relevant for the Youth Futures Foundation and NHS stakeholders.

The trial is powered to detect differences in the primary outcome of EET status during the 12 months following randomisation. The key parameters underpinning the power calculation are summarised in

Table 3.

Table 3: Power calculations

PARAMETER		VALUE
MINIMUM DETECTABLE EFFECT SIZE (MDES)		Absolute difference of approximately 20 percentage points in EET participation during the 12 months following randomisation (25% control vs 45% intervention in base case)
PRE-TEST / POST TEST CORRELATIONS	LEVEL 1 (PARTICIPANT)	The power calculation is based on an unadjusted two-proportion comparison and does not benefit from baseline covariate adjustment. Any covariate adjustment in the primary model (e.g. baseline EET status, where available) will tend to increase precision, so the reported sample size is a conservative upper bound.
ALPHA		0.05

[25] See Hofman, J., Herrera, F., Tee, O., de Waal, N., Leoni, M., Snell, J., Stern, D., Whitworth, A. & Vallelyis, M. (2026). Individual Placement and Support – Youth (IPS–Y) Feasibility Report. Youth Futures Foundation (submitted to client).

POWER		0.8
ONE SIDED OR TWO SIDED		Two-sided
NUMBER OF PARTICIPANTS	Intervention	152 recruited (approximately 91 retained at 12 months)
	Control	152 recruited (approximately 91 retained at 12 months)
	TOTAL	304 recruited (approximately 182 retained at 12 months)

The study is designed as a two-arm individually randomised trial with equal (1:1) allocation between IPS-Y plus BAU and BAU alone. The power calculation assumes a two-sided significance level (α) of 0.05, statistical power of 80%, individual-level randomisation, a binary primary outcome (EET status during the 12 months following randomisation), and equal allocation between arms. It assumes an absolute improvement of approximately 20 percentage points in EET participation, based on a control-group EET rate of 25% and an intervention-group rate of 45%.

The recruitment target is 304 participants (152 per arm). Allowing for 40% attrition by the primary endpoint, this is expected to yield an analytical sample of approximately 182 participants (91 per arm). This target is inclusive of the approximately 30 participants (15 per arm) recruited during the nested pilot phase, who will be retained in the main analysis provided no substantive changes to the trial design are required following the pilot.

A 20 percentage-point improvement was selected because it represents a meaningful reduction in the risk of becoming NEET among a population facing substantial barriers to EET participation. Published IPS studies have reported larger effects — a meta-analysis of IPS for young adults[26] found a pooled difference of 25.9 percentage points — so the assumed effect is both substantively meaningful and plausible while remaining below the meta-analytic estimate, reflecting the uncertainty in transferring evidence from older IPS populations to a 16–17-year-old CAMHS cohort.

The assumed 40% attrition rate reflects loss to follow-up on the participant survey (rather than disengagement from the intervention itself) by the 12-month primary endpoint. It is applied equally to both arms for the purposes of the power calculation. This figure is consistent with comparable trials: the most analogous evidence, the DWP Health-Led

[26] Bond, G. R., Al-Abdulmunem, M., Marbacher, J., Christensen, T. N., Sveinsdottir, V., & Drake, R. E. (2023). A systematic review and meta-analysis of IPS supported employment for young adults with mental health conditions. Administration and Policy in Mental Health and Mental Health Services Research, 50(1), 160-172.

Trials, reported follow-up attrition of around 54%,[27] while systematic reviews of school-based interventions showed a range from 3.4% to 42.5%[28] and meta-analytic estimates from mental-health intervention studies are in the region of 17–26%.[29] The 40% assumption sits between these and reflects the 12-month follow-up window and reliance on self-report, alongside compromising with practical constraints, such as intervention capacity and cost (see below).

Although the Health-Led Trials reported differential attrition between trial arms, there is currently insufficient evidence to support robust assumptions about the direction or magnitude of any difference for IPS-Y. Applying a common attrition rate is therefore considered the methodologically neutral approach at this stage. The trial will implement identical follow-up procedures, reminder schedules and financial compensation for participants in both arms to minimise differential loss to follow-up. Attrition rates will be monitored throughout the trial, and any emerging differential attrition will be reviewed by the Trial Management Group and Trial Steering Committee. The potential for differential attrition between arms, and its implications for bias rather than power, is addressed in the missing-data section.

The recruitment target also reflects the planned intervention delivery capacity available within the study budget. Based on current workforce planning, Pure Innovations is expected to have capacity to deliver IPS-Y to approximately 160 participants allocated to the intervention arm during the trial period. Under the planned sample size of 304 and 1:1 allocation, approximately 152 participants would be allocated to IPS-Y, which remains within this planned capacity. Recruitment, rather than intervention capacity, is therefore expected to be the principal constraint on sample size. The relevant capacity consideration relates to the number of participants randomised to the IPS-Y arm rather than the number who subsequently engage with or complete the intervention. Recruitment is targeted at 304 participants and will not be capped below this figure. The total recruitment will not exceed 320 participants (equivalent to approximately 160 allocations to the intervention arm under 1:1 randomisation). Recruitment numbers will be monitored regularly in order not to exceed the intervention capacity.

We note that the primary outcome is measured by self-report, which introduces a degree of measurement error (for example through recall bias or reluctance to report being NEET). In addition, as an outcome measuring entry into qualifying EET during the 12-month follow-up period, it does not capture the subsequent persistence of EET participation. Self-report measurement error is expected to attenuate observed effects and reduce effective power; it cannot be quantified in advance but is recognised as a threat to power and is recorded in the risk register..

Power sensitivity analyses

The required sample size is sensitive to the assumed effect size and to the control-group EET rate. **Table 4** shows the recruited sample required across a plausible range of control-group rates (rows) and intervention-group rates (columns), holding power at 80%, a at 0.05 two-sided, attrition at 40% and allocation at 1:1.

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[27] Crowley, J., Martin, I., Weston-Stanley, P., Lau, R., Khambhaita, P., Newton, B., Gloster, R., (2023). *Survey findings: Health-led Employment Trial Evaluation*. DWP research report no.1035.
[28] Clarke, A., Sorgenfrei, M., Mulcahy, J., Davie, P., Friedrich, C., & McBride, T. (2021). *Adolescent mental health A systematic review on the effectiveness of school-based interventions*. Early Intervention Foundation
[29] Prior E, Dorstyn D, Taylor A and Rose A (2023). 'Attrition in Psychological mHealth Interventions for Young People: A Meta-Analysis', Journal of Technology in Behavioural Science, 9 (1), pp. 639-651.

The power calculation assumes a control-arm EET rate of 25% and an intervention-arm rate of 45%, corresponding to a 20-percentage-point absolute intervention effect. The assumed control rate is informed by a systematic review of IPS for young adults with mental health conditions, in which baseline EET rates across the included studies ranged from approximately 20% to 33%.[30] The populations, interventions and settings in these studies are not directly equivalent to those in the proposed trial. However, in the absence of robust UK evidence for a closely comparable population, the review provides the most relevant empirical basis available for informing this assumption.

The 25% control-group rate used in the power calculation therefore draws on the estimated baseline EET rate in the relevant evidence base, on the assumption that, in the absence of IPS-Y, the control-group outcome rate would be of a similar order.

Reading across each row of Table 4 shows how the required sample increases as the absolute difference between the assumed control- and intervention-group rates narrows. Under the base-case assumptions of 25% in the control group and 45% in the intervention group, a 20-percentage-point difference requires 304 recruited participants. Smaller differences require substantially larger samples. The sensitivity analysis therefore demonstrates the importance of both the assumed control-group rate and the magnitude of the anticipated intervention effect, and provides the basis for reviewing these assumptions during the pilot before committing to full recruitment.

Table 4: Recruited sample size required, by control-group (CG) and intervention-group (IG) EET rate

IG → CG ↓	**32%**	**34%**	**36%**	**38%**	**40%**	**42%**	**45%**
20%	717	540	420	340	280	234	187
22%	1,054	750	564	440	354	290	224
25%	2,214	1,370	937	684	520	410	**304**
28%	6,940	3,154	1,810	1,180	834	620	427
30%	28,137	7,187	3,257	1,864	1,214	854	557

Because this is an individually randomised trial, intra-cluster correlation assumptions are not required for the primary power calculation. The trial is powered to detect the overall intervention effect and is not powered to detect differences within subgroups or interactions between treatment and participant characteristics.

[30] Bond, G. R., Al-Abdulmunem, M., Marbacher, J., Christensen, T. N., Sveinsdottir, V., & Drake, R. E. (2023). A systematic review and meta-analysis of IPS supported employment for young adults with mental health conditions. *Administration and Policy in Mental Health and Mental Health Services Research*, *50*(1), 160-172.

Nested pilot

The trial includes a nested pilot phase intended to test recruitment pathways, consent procedures, randomisation processes, and implementation arrangements prior to progression to the full trial.

The pilot will run across both participating NHS Trusts, so that mobilisation, cross-site randomisation and the integration of IPS-Y Specialists within CAMHS teams are tested at each site before full commitment. Approximately 30 young people will be recruited and randomised on a 1:1 basis (around 15 per arm) to the intervention and control arms. This figure is not powered to detect an intervention effect; it follows established guidance for pilot and feasibility trials, which recommends approximately 15 participants per arm for a definitive trial anticipating a medium effect size,[31] and is consistent with the typical size of UK two-arm pilots.[32] The per-arm target is set to give a stable read on the key feasibility parameters — recruitment, consent and early retention — and to exercise every stratum across the participating site or sites; it does not depend on the number of sites confirmed.

The pilot is intended to test the feasibility of recruitment, screening, consent, randomisation, intervention delivery, safeguarding and governance procedures, and the mobilisation and integration of IPS-Y Specialists within CAMHS teams, rather than to assess intervention effectiveness. Pilot participants are randomised using the same stratified procedure (by diagnosis and site) as the main trial, drawn from the same pre-generated allocation sequence, so they are fully compatible with the main analysis. Accordingly, the recruitment target of 304 is inclusive of the approximately 30 participants recruited during the pilot: provided no substantial changes to the trial design are required following the pilot, these participants are retained and included in the final intention-to-treat analysis. Retention of the pilot sample in the main analysis therefore depends on the pilot confirming the design rather than prompting substantial revision to it.

Because the baseline EET rate cannot be firmly established from existing data for the intended trial population, the observed baseline EET rate among pilot participants will be reviewed as an empirical check on this assumption. Baseline characteristics associated with EET participation will also be considered descriptively as contextual evidence. A materially higher baseline EET rate would not establish the subsequent control-group outcome rate, but would provide a reason to scrutinise the 25% assumption more closely. The pilot will not directly estimate the 12-month control-group outcome rate; rather, this evidence will inform consideration of whether the original assumption remains plausible or warrants reconsideration before the full sample is committed.

The pilot will also be used to review the proposed approach to defining compliance for the Complier Average Causal Effect (CACE) analysis. Routine monitoring data will be examined to understand patterns of intervention uptake, engagement and dosage, including the number, duration and type of contacts received by participants. These data will be used to assess whether the proposed compliance definition appropriately reflects meaningful exposure to IPS-Y and to explore dose-response patterns. Where pilot findings indicate that an alternative threshold would provide a more valid

[31] Whitehead, A. L., Sully, B. G., & Campbell, M. J. (2014). Pilot and feasibility studies: is there a difference from each other and from a randomised controlled trial? Contemporary clinical trials, 38(1), 130-133.
[32] Billingham, S. A., Whitehead, A. L., & Julious, S. A. (2013). An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. BMC medical research methodology, 13(1), 104.

representation of intervention receipt, the compliance definition may be refined prior to progression to the main trial. Any such refinement will be agreed through the trial governance structure, documented in the Statistical Analysis Plan, and finalised before any outcome analyses are undertaken.

Progression from the pilot to the main trial is assessed against the criteria below. The recruitment criterion is anchored to a quantitative threshold — the pilot's recruitment against its pro-rata target — which determines the initial Green/Amber/Red rating. Because recruitment to trials of this kind typically builds gradually as sites mobilise and referral pathways establish, rather than proceeding at a constant rate, an Amber or Red rating on the threshold alone does not automatically halt the trial: it triggers a structured judgement of whether the full sample remains credibly achievable, drawing on the qualitative picture of referral flow, consent uptake and site readiness. The threshold focuses the decision; the judgement governs it.

1. Recruitment and consent

- Green: the pilot recruits ≥80% of its pro-rata recruitment target[33], with a credible route to the full sample; consent procedures acceptable and feasible.
- Amber: the pilot recruits 50–79% of its pro-rata target, but credible remedial actions are identified that are judged likely to achieve the full sample; consent procedures require only minor modification.
- Red: the pilot recruits <50% of its pro-rata target with no credible route to the full sample; or significant concerns about the acceptability or feasibility of consent.

2. Randomisation and trial procedures

- Green: randomisation, consent, safeguarding and data collection procedures operate as intended with no major ethical or operational concerns.
- Amber: minor issues identified requiring modification.
- Red: major concerns regarding acceptability, ethics or operational feasibility.

3. Intervention implementation

- Green: IPS-Y established in pilot sites and delivered as intended, with no major concerns.
- Amber: minor implementation issues identified that can be addressed before the main trial.
- Red: significant implementation failures or inability to deliver core IPS-Y components.

Overall progression decision

- Proceed: all criteria Green, or minor Amber issues with agreed mitigations.
- Proceed with modifications: one or more Amber ratings requiring protocol or operational changes.

[33] The pro-rata recruitment target is the number of participants the pilot would be expected to recruit if the trial were on track to reach its overall target of 304 within the planned recruitment window — that is, the share of the total anticipated during the pilot phase.

- Do not proceed: any red rating, or combination of issues indicating a definitive trial is not feasible.

Outcome measures

Primary outcome

The primary outcome is participation in EET during the 12 months following randomisation.

The primary outcome was selected because increasing participation in EET is the principal objective of IPS-Y and represents the most direct test of the intervention ToC. IPS-Y is designed to support young people with mental health difficulties to access and sustain meaningful educational and vocational opportunities through integrated support embedded within CAMHS. Participation in EET therefore represents the most policy-relevant and intervention-specific measure of success.

The primary outcome is operationalised as a binary measure EET status (in EET vs not). Participants will be classified as being in EET if, at any point during the 12-month follow-up period, they meet at least one of the following criteria:

- Participation in education for at least 6 hours per week sustained for a minimum of 4 consecutive weeks
- Participation in paid employment (excluding self-employment) for at least one day
- Participation in accredited training, apprenticeship or recognised vocational training for at least 6 hours per week sustained for a minimum of 4 consecutive weeks.

EET status counts education, employment and training together because IPS-Y is designed to support young people into whichever of these pathways fits their circumstances, rather than steering everyone toward a single destination. A young person who moves into employment, returns to education, or takes up accredited training has each achieved a successful outcome under the intervention's theory of change. Measuring participation in any of these pathways — rather than one alone — therefore captures the full range of outcomes IPS-Y is intended to produce.

The outcome is analysed as a binary measure (in EET versus not in EET), since the primary question is whether IPS-Y increases participation in any meaningful EET activity relative to BAU. Following an intention-to-treat principle, it is analysed using a linear probability model in line with YFF guidance,[34] with effects reported in percentage points and as risk ratios. Full model specification is set out in the Analysis section. This approach is consistent with the intervention ToC and with previous IPS evaluations that have focused on participation in education and/or employment as key indicators of success.[35]

[34] Youth Futures Foundation (2026) *Statistical Analysis and Trial Design Guidance*. April 2026. Internal guidance for YFF evaluators (unpublished).
[35] Bond, G. R., Al-Abdulmunem, M., Marbacher, J., Christensen, T. N., Sveinsdottir, V., & Drake, R. E. (2023). A systematic review and meta-analysis of IPS supported employment for young adults with mental health conditions. *Administration and Policy in Mental Health and Mental Health Services Research*, *50*(1), 160-172.

The thresholds differ by pathway by design: the education and training thresholds (6 hours per week over at least 4 consecutive weeks) distinguish sustained participation from brief engagement, while the employment threshold of at least one day reflects the entry-focused definition used in the IPS-AD trial[36] and common across the IPS literature.[37]

EET status will be measured through participant self-report collected via online surveys administered at 6 and 12 months following randomisation, with the 12-month assessment constituting the primary endpoint.

Secondary outcomes

Secondary outcomes comprise the individual components of EET participation together with measures of mental wellbeing and life satisfaction.[38] They are intended to provide a more detailed understanding of the pathways through which IPS-Y influences young people's educational and vocational trajectories, and to complement interpretation of the primary outcome. Secondary outcomes are pre-specified but non-confirmatory, and the trial is powered for the primary outcome only; secondary analyses are therefore interpreted as supportive rather than definitive. To manage multiple comparisons, secondary outcomes are organised into two pre-specified families — the EET component outcomes and the wellbeing measures — as set out in the Analysis section.

The first family consists of the individual components of the primary EET measure, each analysed as a separate binary outcome capturing participation in:

1. Education (at least 6 hours per week sustained for a minimum of 4 consecutive weeks);
2. Paid employment, excluding self-employment (at least one day);
3. Accredited training, apprenticeship or recognised vocational training (at least 6 hours per week sustained for a minimum of 4 consecutive weeks)

Analysing the components separately allows the evaluation to determine whether any overall effect on EET participation is driven primarily by education, employment or training. This is particularly important given the developmental stage of the target population, for whom continued education may be as significant an outcome as entry into employment, and it provides a more nuanced understanding of the intervention's effects to inform future implementation and policy decisions.

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[36] Marsden, J., Anders, P., Shaw, C., Amasiatu, C., Collate, W., Eastwood, B., Horgan, P., Khetani, M., Knight, J., Knight, S. and Melaugh, A., 2024. Superiority and cost-effectiveness of Individual Placement and Support versus standard employment support for people with alcohol and drug dependence: a pragmatic, parallel-group, open-label, multicentre, randomised, controlled, phase 3 trial. *EClinicalMedicine*, *68*.

[37] Burns, T., Yeeles, K., Langford, O., Montes, M.V., Burgess, J. and Anderson, C., 2015. A randomised controlled trial of time-limited individual placement and support: IPS-LITE trial. *The British Journal of Psychiatry*, *207*(4), pp.351-356.

[38] Alternative outcomes including earnings, hours worked and sustained employment were considered. However, these were not selected as primary or secondary outcomes because many participants are expected to remain in full-time education throughout follow-up, employment participation may be intermittent and developmentally appropriate, and reliable earnings data would require either administrative linkage or detailed self-report with substantial risk of missingness and recall error. Participation in education, employment or training was therefore considered the most appropriate and policy-relevant outcome for this age group. Longer-term sustainability of EET outcomes may also be examined through administrative data linkage, where these outcomes are captured in the relevant datasets, subject to data availability, access and relevant approvals.

The second family comprises two measures of subjective wellbeing:

4. Mental wellbeing, measured using the Short Warwick–Edinburgh Mental Wellbeing Scale (SWEMWBS);
5. Life satisfaction measured using the Office for National Statistics (ONS) single-item life-satisfaction question.

Wellbeing is included because the intervention theory of change proposes that greater participation in EET contributes to wider improvements in wellbeing, confidence, independence and social inclusion. Two complementary measures were selected to balance measurement quality against participant burden. SWEMWBS is a brief, validated measure of mental wellbeing widely used with young people, capturing a multi-dimensional construct (covering aspects of psychological functioning and emotional wellbeing) in seven items. The ONS single-item life-satisfaction question provides a parsimonious, nationally benchmarked measure that maps directly to wellbeing-adjusted life years (WELLBYs) and, in turn, to monetised benefits in the economic evaluation. Together they allow wellbeing to be assessed both as a richer psychological construct (SWEMWBS) and as a single comparable metric suitable for economic valuation (ONS). Other psychological measures were considered but not adopted, in order to keep the survey short and proportionate for this age group given the ethical imperative to minimise questionnaire burden.

SWEMWBS will be scored using the standard metric-converted summed score, and the ONS item on its 0–10 scale; full scoring and analysis details are set out in Analysis section and statistical analysis plan.

All secondary outcomes will be measured through participant self-report collected via online surveys administered at 6 and 12 months following randomisation. The 6-month assessment provides information on early intervention effects and trajectories of change, while the 12-month assessment provides longer-term follow-up and contributes to assessing EET entry and other outcomes over the full follow-up period.

Baseline measures

Baseline data will be collected prior to randomisation and will serve three purposes: to describe the trial population, to assess balance between arms following randomisation, and to improve statistical precision through covariate adjustment in the outcome analyses.

Baseline measures will include:

- Participant characteristics: age, gender, ethnicity, sexual orientation, socioeconomic circumstances, living arrangements, NHS Trust site, CAMHS team, mental health diagnosis, neurodevelopmental diagnosis and assessment status, educational status, employment status, previous qualifications and attainment, and previous experience of employment.
- Baseline outcome status: current EET status and baseline wellbeing (SWEMWBS and ONS life satisfaction).

Baseline EET status will be measured as point-in-time status at the date of randomisation (whether the young person is in education, employment or training at that point), rather than using the 12-month look-back window applied to the primary outcome. A current-status measure is used because the great majority of participants will recently have been subject to compulsory education or training, so a 12-month look-back would classify almost all participants as having been in EET and would provide little discriminating information at baseline.
Baseline EET status and baseline wellbeing will be included as covariates in the corresponding primary and secondary outcome models to improve precision. The power calculation does not, however, take any credit for this adjustment: it is based on an unadjusted two-proportion comparison, so the reported sample size is a conservative upper bound and any precision gain from baseline adjustment is additional.

Outcome data collection

All outcome data will be collected via online self-completion surveys (with telephone follow-up), administered and managed by trained Ipsos researchers who are independent of intervention delivery.

Survey administration will be supported through:

- Email invitations
- SMS reminders
- Telephone follow-up for participants who have not responded after two reminders, and face to face option for those with a preference for this or who have literacy issues
- Participant compensation at each survey wave (£25 at baseline, £50 at 6 month follow-up and £100 at 12 month follow-up).

Automated scoring procedures will be used where possible to minimise data-entry error. Researchers involved in data collection will have no role in intervention delivery, and statistical analyses will be conducted on anonymised datasets with treatment allocation masked during initial data preparation, in line with the blinding arrangements set out above.

Intention-to-treat, compliance and treatment effects

The primary analysis follows the intention-to-treat (ITT) principle: every participant is analysed according to their randomised allocation, regardless of whether or to what extent they took up IPS-Y. The ITT estimate is the headline result, as it reflects the effect of offering IPS-Y under real-world implementation conditions and preserves the benefits of randomisation.

Because IPS-Y is voluntary and individually tailored, some young people allocated to the intervention will engage little or not at all. For the purposes of the impact evaluation, compliance is therefore defined as a single binary indicator: a participant is classified as a complier if they engaged with an IPS-Y Specialist on at least one occasion following randomisation (that is, they began the programme). This deliberately pragmatic

definition reflects the nature of IPS-Y, which has no fixed curriculum, session count or dosage threshold that could be applied uniformly across participants. Where feasible, a continuous measure of intervention exposure (for example, the number and duration of contacts with an IPS-Y Specialist) will additionally be derived from Pure Innovations' routine monitoring data and may be used to explore dose-response patterns during the nested pilot.

To estimate the effect of receiving rather than being offered IPS-Y, a Complier Average Causal Effect (CACE) analysis will be pre-specified as a secondary analysis, using random allocation as an instrument for take-up. ITT and CACE estimates will be presented side by side in the main results tables, and the analysis will make explicit how patterns of take-up attenuate the ITT estimate relative to the CACE.

Interpretation of the CACE rests on the exclusion restriction — the assumption that randomisation affects outcomes only through take-up of IPS-Y. In this trial that assumption requires caution. Control-arm participants will continue to access the mental health, education, employment and community support ordinarily available through usual care, some of which is substantively similar to IPS, while some intervention-arm participants will not take up the programme. This gives rise to two-sided non-compliance, in which both arms receive a mixture of IPS-Y-like and BAU support. Two-sided non-compliance weakens the exclusion restriction and means CACE estimates must be interpreted, and labelled, with appropriate caution. The estimator is the standard instrumental-variables CACE (equivalently the LATE), using random assignment as the instrument for IPS-Y take-up; under two-sided non-compliance its interpretation as a clean complier effect depends on the exclusion restriction, which is why the estimate is reported with caution rather than as a headline result.

The trial will therefore monitor for two-sided non-compliance throughout, and the statistical analysis plan will specify the data collected to allow an informed assessment of the plausibility of the exclusion restriction, together with pre-specified sensitivity analyses probing that assumption. The implications of take-up for policy — including whether low take-up is itself decision-relevant, or whether programme modifications to improve take-up are warranted — will be discussed alongside the results.

Detailed specification of the compliance indicator, the CACE estimator and the associated sensitivity analyses will be set out in the statistical analysis plan.

Contamination

Potential contamination will be monitored throughout the trial. In this context, contamination refers to exposure of control-group participants to IPS-Y intervention components or practices that arises as a consequence of trial implementation, rather than through normal access to BAU services. Access to services ordinarily available in Greater Manchester — including the employment, education and vocational support available as part of BAU — is not treated as contamination.

The principal potential source of contamination is the integrated delivery model. IPS-Y Specialists will work exclusively with participants allocated to the intervention arm but will collaborate closely with CAMHS clinicians as part of routine multidisciplinary working. There is therefore a possibility that knowledge, approaches or practices associated with IPS-Y could influence the support that CAMHS staff provide to control group participants. The IPE will explore this through interviews with staff and examination of service-delivery practices.

A second route is the unintended receipt of IPS-Y support by control arm participants — for example through administrative error, referral pathways or other unforeseen

implementation issues. Such occurrences will be documented through routine monitoring systems and reported descriptively. Because this route involves receipt of the actual intervention rather than of similar provision, it is treated as a threat to the exclusion restriction and to treatment differentiation, not as non-compliance; any non-trivial occurrence will be examined in sensitivity analysis rather than absorbed into the CACE.

Distinct from contamination, some control-arm participants may access IPS or IPS-equivalent provision through other Greater Manchester services (for example other supported-employment programmes). This is not trial-induced contamination, nor is it ordinary BAU; it is a form of two-sided non-compliance, in which both arms receive a mixture of IPS-Y-like and business-as-usual support. It is monitored through the support-received data described below and reflected in the cautious interpretation of the CACE analysis, as set out in the Intention-to-treat, compliance and treatment effects section.

To assess whether the intervention and control conditions remain differentiated throughout the trial, information on the support received by participants in both arms will be collected. This will be captured through a services-received module within the participant surveys at each follow-up wave and, for the intervention arm, through Pure Innovations' routine monitoring data. These data will be used to assess treatment differentiation and to support interpretation of the trial findings.

The possibility of spillover through informal social routes — for example contact between participants via local youth, parent or community networks — is also recognised. This risk is considered low: IPS-Y is delivered individually rather than through group settings, caseloads are dispersed, and participants across arms are unlikely to be in regular contact. Such informal spillover cannot be directly monitored or controlled in an individually randomised trial; however, the support-received data would be expected to reveal any substantial erosion of the difference between arms.

Analysis

All primary and secondary analyses follow the intention-to-treat (ITT) principle: participants are analysed according to their randomised allocation, regardless of intervention uptake or completion. All analyses are pre-specified in the statistical analysis plan (SAP). Two-sided tests are used throughout at a 5% significance level, and all effect estimates are presented with 95% confidence intervals.

Primary outcome analysis

The primary analysis compares the proportion of participants in EET during the 12 months following randomisation between arms. In line with YFF guidance, the primary model is a **linear probability model (LPM)** estimated by ordinary least squares, with heteroskedasticity-robust (Huber–White) standard errors. The model takes the form:

$$EET_i = \beta_0 + \beta_1 Treatment_i + \beta_2 BaselineEET_i + \gamma Diagnosis_i + \delta Site_i + \theta X_i + \varepsilon_i$$

where, for participant i:

- $\boldsymbol{EET_i}$ is the binary primary outcome (1 = in EET during the 12 months following randomisation, 0 = not)
- $\boldsymbol{Treatment_i}$ indicates randomised allocation (1 = IPS-Y plus BAU, 0 = BAU alone)
- $\boldsymbol{BaselineEET_i}$ is baseline EET status

- $\boldsymbol{Diagnosis_i}$ is the diagnosis-category stratifier (mental health only versus mental health plus neurodevelopmental condition)
- $\boldsymbol{Site_i}$ is the NHS Trust site stratifier, entered as a fixed effect
- $\boldsymbol{X_i}$ is a vector of other pre-specified baseline covariates correlated with the outcome
- $\boldsymbol{\varepsilon_i}$ is the error term.

The coefficient of interest is β_1, which estimates the adjusted risk difference — the absolute change in the probability of being in EET attributable to being offered IPS-Y, expressed in percentage points. The treatment effect is reported as this risk difference with a 95% confidence interval, and as a risk ratio derived from the model's predicted probabilities. The model adjusts for the randomisation stratifiers (diagnosis and site) and for baseline EET status; adjusting for the stratification variables is necessary because the trial is stratified on them, and failing to do so would yield invalid (conservatively biased) standard errors.

Choice of model

The LPM is adopted as the primary specification for three reasons. First, its coefficients are directly interpretable as risk differences in percentage points — the metric YFF expects for headline reporting and the most policy-meaningful expression of effect for a binary EET outcome. Second, because the trial is individually randomised, a single-level OLS specification is appropriate: there is no clustering or multi-site sampling structure requiring a multilevel or random-effects model, and site is therefore handled as a fixed effect, giving inference conditional on the participating sites. Third, the LPM avoids the well-documented difficulties of interpreting interaction terms on the odds-ratio scale, which is important because the pre-specified subgroup analyses rest on treatment-by-covariate interactions.

A logistic regression specification may be reported as supporting information, with effects expressed as average marginal effects in percentage points; odds ratios will not be presented as the headline result, given their interpretability limitations. The LPM can in principle produce predicted probabilities outside the [0,1] range and assumes a constant additive effect across covariate values; these are recognised limitations.

If the primary outcome is observed in fewer than 10% or more than 90% of participants across the trial as a whole (that is, across both the intervention and control groups combined), we will use logistic regression instead, reporting average marginal effects in percentage points. These are the conditions under which a linear probability model (LPM) is more likely to produce predicted probabilities outside the 0-1 range and less reliable estimates. This decision rule has been specified in advance, so the choice of analytical model will not be influenced by the trial findings.

Secondary outcome analysis

The secondary outcomes are analysed under the same intention-to-treat principle and with the same covariate adjustment as the primary analysis.

Binary EET component outcomes (education, employment, training)

Each component is analysed as a separate binary outcome using a linear probability model of the same form as the primary analysis:

$$Y_i = \beta_0 + \beta_1 Treatment_i + \beta_2 BaselineEET_i + \gamma Diagnosis_i + \delta Site_i + \theta X_i + \varepsilon_i$$

where Y_i is the binary component outcome (e.g. in education, 1/0) and all other terms are as defined for the primary model. As with the primary outcome, β_1 is reported as an adjusted risk difference in percentage points and as a risk ratio, each with a 95% confidence interval.

Continuous wellbeing outcomes (SWEMWBS and ONS life satisfaction)

Each is analysed using a linear regression (ANCOVA) model adjusting for the baseline value of the same measure and the stratification variables:

$$W_i = \beta_0 + \beta_1 Treatment_i + \beta_2 W0_i + \gamma Diagnosis_i + \delta Site_i + \theta X_i + \varepsilon_i$$

where W_i is the follow-up wellbeing score, $W0_i$ is the corresponding baseline score, and β_1 estimates the adjusted mean difference between arms. Effects are reported as adjusted mean differences with 95% confidence intervals, and standardised effect sizes (Hedges' g) are reported alongside, using the control-group post-test standard deviation as the denominator. Where useful, repeated-measures models may be used to examine change across the 6- and 12-month follow-up points.

Multiplicity across the secondary outcomes is handled as set out in the Multiple outcomes and multiplicity section.

Missing data

Given the anticipated level of attrition, missing data are a central analytical concern and are addressed as follows.

First, the extent and pattern of missing data will be described, and missing outcome data will be distinguished from missing covariate data, since these warrant different treatment: imputing missing covariates is generally reasonable, whereas imputing missing primary-outcome data is more debatable and is therefore not used in the primary analysis.

Second, the primary analysis uses complete cases (participants with observed primary-outcome data), analysed under ITT. The plausibility of the missing-at-random (MAR) assumption will be examined by modelling missingness as a function of baseline characteristics and treatment arm (a "drop-out model"), and by comparing baseline characteristics between completers and non-completers, and between arms, at baseline and at the primary endpoint. Particular attention will be paid to differential attrition between arms, which threatens internal validity rather than merely reducing power.

Third, sensitivity analyses will probe robustness to departures from MAR. Multiple imputation will be used as a MAR-based sensitivity analysis (not as the primary estimate), and the robustness of conclusions to data that are missing not at random (MNAR) will be assessed using bounding approaches (for example, Manski-style bounds and a tipping-point analysis), with full specification in the SAP. Possible reasons for missingness at the primary endpoint, the patterns they may generate, and the resulting threats to the reliability of the trial will be set out in the SAP, together with the full specification of these analyses.

If follow-up rates differ materially between the intervention and control groups, the primary analysis will continue to use participants with observed outcome data (complete cases), but the results will be interpreted with additional caution. We will examine whether participants who do not complete follow-up differ systematically from those who do by comparing baseline characteristics and modelling factors associated

with non-response. This will help assess whether attrition may have introduced bias into the results.

We will also conduct sensitivity analyses using alternative assumptions about missing data. These analyses will assess whether the conclusions change when different plausible scenarios are considered for participants who do not provide follow-up data.

If the estimated treatment effect remains similar across these alternative analyses, this will increase confidence that the findings are robust and not being driven by missing data. If the estimated effect changes substantially under reasonable alternative assumptions, this will suggest that attrition may have influenced the results. In that situation, the findings will be interpreted more cautiously and any limitations arising from missing data will be reported transparently.

Subgroup analyses

The following subgroup analyses are pre-specified: diagnosis category (mental health only versus mental health plus neurodevelopmental condition); gender; school Year-11 vs. post-secondary school; and baseline EET status. Each is a binary split, so each is examined through a single interaction term. NHS Trust site is not analysed as a subgroup: with only two participating sites such an analysis would be severely underpowered, would collapse entirely under a single-site scenario, and the question of whether IPS-Y performs differently between Trusts is not of substantive interest. Site is retained as a fixed-effect adjustment in all models.

These subgroup analyses are exploratory and not individually powered; they must be interpreted with caution as hypothesis-generating rather than confirmatory. The trial is powered for the overall treatment effect only and is not powered to detect interactions; results are therefore interpreted with caution and treated as a basis for generating hypotheses rather than drawing firm conclusions about differential effects.

Two complementary quantities are reported for each subgroup. First, **subgroup-specific effect estimates** — the adjusted treatment effect within each category, with 95% confidence intervals — provide an interpretable description of the effect in each group. Second, a **treatment-by-subgroup interaction term**, included in a model fitted to the full sample and adjusted for the same covariates as the primary analysis, provides the formal test of whether the effect differs between groups. Any claim that the intervention works differently across subgroups rests on this interaction term, not on a comparison of whether the effect is statistically significant in one group but not another, since a difference in significance is not itself evidence of a difference in effect.

Because the primary model is a linear probability model, each interaction term is interpreted directly on the risk-difference (percentage-point) scale, avoiding the difficulties of interpreting interactions on the odds-ratio scale.

Gender is recorded at full granularity at data collection. For the subgroup analysis it is operationalised as a binary split, as cell sizes for smaller categories are too small to support stable interaction estimates; the precise operationalisation is set out in the statistical analysis plan, and smaller categories are reported descriptively where numbers allow.

Interim analyses

No formal interim analysis of the primary outcome or intervention effectiveness is planned. Six-month outcome data will be analysed descriptively and exploratorily as set out below, primarily to inform the IPE.

Longitudinal follow-up

Outcome data will be collected at three time points as shown in **Table 5**.

Table 5: Outcome data collection points for the trial

TIME POINT	DATA COLLECTED
Baseline	Participant characteristics, baseline EET status and baseline wellbeing measures
6 months post-randomisation	Secondary outcomes, implementation measures and mechanism indicators
12 months post-randomisation	Primary outcome and all secondary outcomes

The 6-month follow-up will provide information regarding early intervention effects, engagement and potential mechanisms of change, primarily to inform the IPE. **EET information collected at 6 months will also be used, alongside the 12-month follow-up, to establish whether participants entered qualifying EET at any point during the 12 months following randomisation.** Six-month data will additionally inform the missing-data analysis, including as predictors in the drop-out model and multiple imputation for participants who respond at 6 months but not at 12 months. The 12-month follow-up provides the final assessment within the trial follow-up period and captures subsequent EET experiences and other outcomes. The primary outcome is **entry into qualifying EET at any point during the 12 months following randomisation**, reflecting the trial's aim of establishing whether IPS-Y increases young people's entry into employment, education or training.

Multiple outcomes and multiplicity

The trial has a single primary outcome (EET status during the 12 months following randomisation), and no adjustment for multiple testing is applied to the primary analysis.

Secondary outcomes are pre-specified but non-confirmatory and are organised into two families: the EET component outcomes (education, employment, training) and the wellbeing measures (SWEMWBS, ONS life satisfaction). Multiplicity is governed by confirmatory status rather than by the number of tests: as both families contain fewer than four non-confirmatory outcomes, no formal adjustment for multiple comparisons is required. Outcomes within each family will be hierarchically ordered in the statistical analysis plan to aid interpretation.

Should any secondary outcome be designated as confirmatory, or should a family come to include four or more outcomes, multiplicity adjustment will be applied using the Romano-Wolf stepdown procedure, with both adjusted and unadjusted results reported. Subgroup and interaction analyses are exploratory and hypothesis-generating; these are described separately and are not subject to multiplicity adjustment.

Implementation and process evaluation (IPE)

Research questions

The IPE will be embedded within the trial and will seek to understand how IPS-Y was delivered, experienced and implemented across participating CAMHS sites, alongside exploring the mechanisms through which the intervention influences outcomes. The IPE is informed by the UK Medical Research Council guidance for process evaluations of complex interventions. It examines implementation, mechanisms of impact and contextual influences, drawing on the Consolidated Framework for Implementation Research (CFIR)[39], and a realist-informed perspective to understand how IPS-Y operates across different CAMHS contexts.[40]

The IPE will address the following high-level research questions:

- RQ2: To what extent was IPS-Y implemented as intended, and what barriers and facilitators influenced its delivery?
- RQ3: How did young people, families, IPS-YEE Specialists and CAMHS staff experience IPS-Y, and what factors influenced engagement with the intervention?
- RQ4: How did local contextual factors influence implementation, fidelity, recruitment, engagement and outcomes?
- RQ5: Through what mechanisms did IPS-Y influence participants' EET outcomes?

Research methods

A mixed-methods IPE will run alongside the impact evaluation. The IPE will combine quantitative implementation data, fidelity assessments, routine monitoring information and qualitative interviews to provide a comprehensive understanding of delivery processes and contextual influences.

The evaluation will focus on six key implementation domains:

- Reach and recruitment
- Fidelity to the IPS-Y model
- Participant engagement and retention
- Acceptability and experience
- Contextual influences
- Mechanisms of change.

The table below outlines the research methods, participants and data sources, analysis approach and associated research questions for the IPE approach:

[39] Damschroder, L.J., Reardon, C.M., Widerquist, M.A.O. and Lowery, J., 2022. The updated Consolidated Framework for Implementation Research based on user feedback. *Implementation science*, *17*(1), p.75.
[40] Pawson, R., & Tilley, N. (1997). Realistic evaluation. Sage Publications

Table 6: IPE methods overview

RESEARCH METHOD	PARTICIPANTS/DATA SOURCE	ANALYSIS	RESEARCH QUESTIONS
Monitoring information and recruitment data	All trial participants	Descriptive statistics	RQ2, RQ4
6-month participant survey	Trial participants	Descriptive and exploratory analysis	RQ3, RQ5
Interviews with young people	25-35 participants	Framework analysis	RQ3, RQ5
Interviews with parents/carers	10-15 participants	Framework analysis	RQ3, RQ5
Interviews with IPS-Y and CAMHS staff	25-35 participants	Framework analysis	RQ2, RQ3, RQ5
Employer/education partner interviews	5-10 participants	Framework analysis	RQ2, RQ4
Documentary review	Site documents and implementation records, fidelity reviews	Documentary analysis	RQ2, RQ4

Routine monitoring and participant survey data

Implementation metrics will be collected throughout the trial from routine monitoring information systems maintained by Pure Innovations, participating NHS Trusts and the research team. These data will include:

- Numbers screened, eligible, recruited and randomised
- Recruitment source and referral pathway
- Uptake and participation rates
- Retention and attrition rates
- Intervention dosage (number, duration and mode of contacts)
- Timing of key intervention milestones
- Fidelity assessment scores
- Service utilisation and referral pathway data.

Routine monitoring information will be collected primarily from existing management information systems (MIS) used by Pure Innovations to support IPS-Y delivery, supplemented where necessary by routinely collected NHS administrative data and trial

management records maintained by the research team. A small number of implementation variables not routinely captured within existing systems (e.g. recruitment source or reasons for ineligibility) will be recorded using standardised data collection templates integrated into routine trial procedures. To minimise burden on CAMHS and IPS-Y Specialists, additional data collection requirements will be kept to a minimum and aligned with existing documentation wherever possible. Standardised data definitions, collection guidance and quality assurance procedures will be agreed across delivery partners to ensure consistency and completeness of monitoring information throughout the trial. Participant survey data collected from all trial participants at the six-month follow-up will contribute to both the impact evaluation and the IPE. In addition to outcome measures, the survey will include questions on participants' experiences of support received, engagement with IPS-Y (intervention arm only), perceived usefulness of different intervention components, and hypothesised mechanisms within the Theory of Change (e.g. confidence, self-efficacy, understanding of education and employment pathways, and perceived coordination of support). The intervention-arm survey will also include a small number of open-ended questions to capture participants' reflections on what aspects of IPS-Y were most and least helpful and any barriers to engagement.

High response rates will be promoted through multiple contact attempts using participants' preferred communication methods (e.g. email and SMS), automated reminders, flexible online completion, participant compensation (as outlined above), and follow-up by the independent research team where appropriate. Survey findings will be analysed alongside routine monitoring information and qualitative interview data to strengthen understanding of implementation, engagement and mechanisms of change.

Qualitative interviews

Semi-structured interviews will be conducted with a purposive sample of key stakeholder groups across participating sites:

- young people receiving IPS-Y
- parents or carers
- IPS-Y Specialists and managers
- CAMHS clinicians and operational leads
- education, training or employer partners.

Sampling will seek maximum variation across sites, gender, ethnicity, diagnosis, neurodivergence status, engagement levels and EET outcomes.

Interviews will explore experiences of recruitment, consent, intervention delivery, engagement, barriers and facilitators, contextual influences, perceived impacts and mechanisms of change, as well as costs (see Economic evaluation).

Documentary review

The IPE will incorporate review of implementation documents and contextual materials, including:

- Standard operating procedures
- Training materials
- Fidelity reports and internal self-assessment records
- Supervision records

- Site implementation plans and costs
- Local service pathway documentation.

Contextual data will also be collected regarding workforce changes, service pressures, referral pathway developments and local policy factors that may influence implementation.

Instrument piloting

All qualitative instruments will be piloted and refined prior to full implementation. Topic guides are informed by the ToC, CFIR domains and findings from the feasibility study.

Data collection and quality assurance

Qualitative data collection will be undertaken by trained Ipsos researchers independent of intervention delivery. Researchers conducting interviews will receive training in:

- Safeguarding procedures
- Trauma-informed interviewing
- Working with young people
- Neurodiversity-informed communication
- Qualitative interviewing techniques.

To minimise bias, interviewers will not be involved in intervention delivery or participant support. Standardised protocols, interviewer training and regular quality assurance reviews will be used throughout the study.

Analysis

The IPE will use an integrated mixed-methods analytical approach designed to explain implementation variation and understand how IPS-Y influences outcomes.

Quantitative analysis

Implementation metrics will be analysed descriptively to examine:

- Recruitment performance
- Reach and representativeness
- Uptake and retention
- Intervention dosage
- Fidelity scores
- Site-level implementation variation.

Relationships between implementation measures and trial outcomes will be explored using appropriate descriptive and exploratory statistical analyses.

Qualitative analysis

Interview data will be audio-recorded, transcribed and analysed using framework analysis.[41] Coding will adopt a mixed deductive-inductive approach:

- Deductive coding informed by the ToC, implementation research questions and CFIR domains
- Inductive coding to identify emergent themes and unexpected findings.

Coding will be conducted by multiple researchers, with regular review meetings to enhance consistency and analytical rigour.

ToC and mechanism testing

Analysis will explicitly examine the extent to which observed implementation and participant experiences support the proposed ToC. Quantitative and qualitative findings will be integrated to explore:

- Whether implementation occurred as intended
- Which implementation components were most influential
- How contextual factors shaped delivery and outcomes
- Which mechanisms appeared to contribute to EET outcomes
- For whom IPS-Y appeared most effective and under what conditions.

Particular attention will be given to hypothesised mechanisms identified during the feasibility study, including:

- Trusting relationships with IPS-Y Specialists
- Increased confidence and self-efficacy
- Improved navigation of education and employment systems
- Enhanced coordination between educational, vocational and clinical support
- Improved continuity during periods of mental health instability
- Increased access to opportunities and reasonable adjustments
- Unintended (positive or negative) consequences.

Integration with impact evaluation

IPE findings will be integrated with the impact evaluation using a convergent mixed-methods design,[42] whereby quantitative and qualitative data are collected and analysed in parallel and brought together during interpretation. As part of this integrated analysis, EET status at the 12-month follow-up will be examined alongside EET experiences reported across the follow-up period to explore patterns of entry into,

[41] Gale, N. K., Heath, G., Cameron, E., Rashid, S., & Redwood, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC medical research methodology*, *13*(1), 117.
[42] Moseholm, E., & Fetters, M. D. (2017). Conceptual models to guide integration during analysis in convergent mixed methods studies. *Methodological Innovations*, *10*(2), 2059799117703118.

persistence in and movement out of EET. These trajectories will be interpreted alongside qualitative evidence on participants' experiences and the factors influencing EET engagement. IPE should also capture material changes in BAU, particularly any expansion of IPS or closely aligned provision that could reduce the distinction between IPS-Y and BAU and affect interpretation of trial findings.

This integration will support interpretation of trial outcomes by explaining:

- Variation in implementation across sites
- Differential engagement and retention
- Mechanisms underlying observed effects and patterns of EET engagement over time
- Contextual factors influencing effectiveness, including changing policy/service landscape
- Considerations for future scale-up and implementation.

The combined analysis will provide evidence not only on whether IPS-Y is effective, but it will also point to how, for whom and under what conditions it achieves its intended outcomes. Interpretation will consider different patterns of impact findings. Where positive effects are observed, IPE evidence will be used to examine the mechanisms and implementation conditions associated with these effects. Where effects are null or limited, the analysis will explore whether this is consistent with challenges in implementation, fidelity or engagement, contextual constraints, or whether IPS-Y was delivered as intended without producing the hypothesised effects. Where findings vary across sites or participant groups, IPE evidence will be used to explore potential explanations for this variation.

Economic evaluation

Research question

RQ6. What is the cost-effectiveness and wider economic value of IPS-Y compared with BAU — in terms of the cost per EET outcome, the monetised value of wellbeing impacts, and indicative longer-term benefits — over the 12 months following randomisation?

Approach

The economic evaluation has four focal points. Throughout all of the economic evaluation analyses assumptions, uncertainty and data limitations will be clearly reported. The table below outlines the components and data sources included in the economic evaluation.

Table 7: Summary of economic evaluation approach

COMPONENT	RESEARCH QUESTION	COSTS/BENEFITS INCLUDED	DATA SOURCE	OUTPUT

Cost of IPS-Y delivery	What resources are required to deliver IPS-Y?	IPS-Y Specialist time, management, supervision, training, fidelity monitoring, CAMHS staff time and overheads required for implementation (excluding trial set-up costs)	Pure Innovations management information, cost-return templates, NHS staff input and stakeholder interviews	Total cost Cost per participant receiving IPS-Y
Cost per EET outcome	What is the cost of generating additional EET outcomes?	IPS-Y delivery costs and trial outcome data	Trial cost data and primary outcome analysis	Cost per EET outcome and cost per additional EET outcome attributable to IPS-Y
Estimating wellbeing benefits	What is the monetary value of wellbeing gains?	Changes in life satisfaction and wellbeing	Baseline and 12-month participant surveys	WELLBYs and monetised wellbeing benefits
Estimating indicative longer-term economic benefits	What longer-term value could be generated if impacts are sustained?	Lifetime earnings, tax revenues, welfare costs, economic productivity and wellbeing impacts	Trial impact estimates combined with published Milburn Review estimates	Illustrative estimates of longer-term economic and fiscal value

The total cost of IPS-Y delivery will be estimated as:

Total IPS-Y cost = staff costs + supervision costs + training costs + management costs + fidelity monitoring costs + associated NHS implementation costs.

Average cost per participant will be calculated by dividing total IPS-Y delivery costs by the number of intervention participants receiving IPS-Y.

1. Estimating the cost of delivering IPS-Y

The first component of the economic evaluation will estimate the resources required to deliver IPS-Y within participating CAMHS services. We will separate trial and delivery cost and exclude costs related to the trial to inform future roll-out estimates.

We adopt a public-sector perspective, extended to include the monetised wellbeing benefits to participants. We count costs wherever they fall across the delivering organisations. These are principally Pure Innovations' direct delivery costs, together with the NHS Trust resources the model draws on, notably extra CAMHS clinician and supervision time. The aim is the economic cost of replicating IPS-Y under routine conditions rather than the cost of running the trial, so we exclude evaluation activities, trial administration, and research data collection. Costs falling on participants and their families, such as travel to work or study, are out of scope, and we note this as a limitation.

We exclude shared organisational overheads that are not attributable to IPS-Y delivery, rather than apportioning them, because the aim is the resource cost of replicating IPS-Y rather than a full accounting allocation. We include overheads directly attributable to IPS-Y, namely management, supervision, and administrative support, estimated from the cost-return templates completed by Pure Innovations and the participating Trusts.

Cost data will be collected using structured cost-return templates completed by Pure Innovations and participating NHS Trusts. Information will be supplemented through qualitative interviews with delivery staff and review of routine management information systems.

The following resource categories will be included:

- IPS-Y Specialist salaries and on-costs
- supervision time
- management and leadership time
- staff recruitment and training
- fidelity monitoring and quality assurance activities
- administrative support
- additional CAMHS clinician time required to support integration of IPS-Y within services and
- implementation-related overheads where directly attributable to IPS-Y delivery.

Costs will be estimated by identifying the quantity of resources used (for example staff hours) and multiplying these by appropriate unit costs (for example salary costs or nationally published NHS reference costs where appropriate).

Shared organisational overheads will not be estimated in detail where they are unrelated to IPS-Y delivery. However, implementation costs directly attributable to IPS-Y

(for example management, supervision and administrative support) will be included using information provided by participating organisations.

2. Estimating the cost per EET outcome

This component estimates what it costs to generate EET outcomes. We will report two measures, both using the primary binary EET outcome:

- Cost per EET outcome: total IPS-Y delivery cost divided by the number of intervention-arm participants in EET during the 12 months following randomisation.
- Cost per additional EET outcome: total IPS-Y delivery cost divided by the number of additional EET outcomes attributable to IPS-Y. We calculate this by applying the trial's estimated impact on the primary outcome, the adjusted risk difference in percentage points, to the number of participants randomised to the intervention arm.

The second measure is the policy-relevant one, because it nets off the outcomes that would have occurred under BAU. We will report it with a confidence interval derived from the interval around the primary impact estimate, so that uncertainty in the impact estimate carries through to the cost figure. Where the trial does not detect a statistically significant impact, the interval rather than the point estimate governs interpretation.

Both measures use participants randomised to IPS-Y as the denominator, consistent with the intention-to-treat basis of the primary analysis. We will also report a supplementary figure using only those who engaged with an IPS-Y Specialist at least once, as this is the more useful figure for a provider planning delivery.

3. Estimating wellbeing benefits

The second component of the economic evaluation will estimate the monetary value of any wellbeing improvements associated with IPS-Y.

Participants in both trial arms will complete the ONS life satisfaction measure at baseline and follow-up. The economic evaluation will estimate whether changes in life satisfaction differ between the intervention and control groups.

We will convert differences in life satisfaction between arms into WELLBYs. One WELLBY is a one-point change on the 0 to 10 life satisfaction scale sustained for one year. The calculation needs three parameters. We state each here and test each in sensitivity analysis:

- the monetised value of one WELLBY, taken from current HM Treasury Wellbeing Guidance. This is £13,000 in 2019 prices, uprated to 2027 using the GDP deflator, consistent with the price used for the delivery cost[43]
- the assumed persistence of the effect. The trial observes a difference during the 12 months following randomisation. Following the approach taken in the Health-Led Trials economic evaluation, the base case assumes the year 1 difference is sustained into years 2 and 3 without decay. Sensitivity analyses assume the effect falls by 50% a year and rises by 50% a year, giving a lower and upper bound[44]

[43] HM Treasury (2021) Wellbeing Guidance for Appraisal: Supplementary Green Book Guidance. *London: HM Treasury*

[44] Edney, C., Gray, H., Muir, D., Newton, B. and Gloster, R. (2023) Health-led Employment Trial Evaluation: 12-month outcomes report: Economic evaluation, DWP Research Report No. 1036

- the discount rate applied to wellbeing effects[45] which is 1.5% as set out in the Green Book.[46]

Because the persistence assumption drives the estimate, we report the base case, the range tested, and the basis for both.

The primary wellbeing valuation will be based on differences between baseline and 12-month follow-up outcomes, although 6-month data will be used descriptively to understand trajectories of change.

4. Estimating indicative longer-term benefits

This component will not generate trial-based estimates of long-term outcomes directly. Instead, the analysis will combine:

1. trial estimates of the impact of IPS-Y on EET participation; and
2. published evidence from the Milburn Review regarding the longer-term consequences of being NEET estimated as up to £300,000 in lost lifetime earnings and chronic damage to confidence and mental health.[47]

The analysis will estimate the potential implications of the observed IPS-Y impact for:

- lifetime earnings
- tax receipts
- welfare expenditure
- economic productivity
- wider public expenditure and
- wellbeing.

We apply published per-person estimates from the Milburn Review to the trial's estimated impact on EET status. We will state the time horizon over which we estimate lifetime earnings, the discount rate we apply, and the assumed duration of NEET status avoided over 3 years. In line with the time horizon set out above.

Lifetime earnings, tax receipts, welfare expenditure, productivity, and wellbeing partly capture the same underlying gain. We therefore report them separately rather than summing them, and we identify the overlaps. Any headline figure uses a non-overlapping subset.

The same persistence assumptions discussed above for wellbeing apply to all estimates projected into years 2 and 3, including earnings, tax receipts and welfare expenditure, and not only to wellbeing: the base case assumes the year 1 difference is sustained without decay, with sensitivity analyses assuming a 50% annual fall and a 50% annual rise.

Assumptions

The modelling assumes:

[45] The discount rate for health and wellbeing is 1.5% while for the rest of dimensions is 3.5%. This will be considered in our estimations.
[46] HM Treasury (2021) *Wellbeing guidance for appraisal: Supplementary Green Book guidance. London: HM Treasury*
[47] Young people and work: interim report - GOV.UK

- observed improvements in EET status represent reductions in the risk of becoming NEET
- the longer-term relationships reported within the Milburn Review are broadly applicable to the trial population and
- published per-person estimates can be used to illustrate the potential value associated with observed trial impacts.

These estimates should be considered indicative and illustrative rather than predictive.

Limitations

The first two components of the economic evaluation (delivery costs and wellbeing valuation) will be based directly on data collected during the trial.

The longer-term economic modelling is more uncertain because it relies on combining trial findings with evidence from external sources. Consequently, estimates of lifetime earnings, fiscal impacts and wider economic benefits should be interpreted as illustrative scenarios rather than projections of actual future outcomes.

Ethics and registration

Informed consent

Participants must be fully informed about the nature and implications of the trial, including what participation involves. They must understand that they are taking part in a RCT and provide informed consent before participating. As participants are aged 16–17 years, they will normally provide consent for their own participation. Young people will be encouraged to discuss participation with parents, carers or other trusted adults if they wish, but the decision to participate will remain their own.

The trial will embed obtaining consent within the role of the IPS-Y Specialist. IPS-Y Specialists will receive training from Ipsos on how to gain informed consent, and research governance and will undertake Good Clinical Practice (GCP) consent training. Particular attention will be paid to minimising therapeutic misconception. Young people may understandably focus on the opportunity to access education and employment support and may not fully appreciate the implications of random allocation. Information materials and consent discussions will therefore emphasise that access to IPS-Y is determined through randomisation, that not all participants will receive IPS-Y, and that declining participation will not affect access to routine CAMHS care or other services.

Participants will be informed that participation in the study is entirely voluntary and that they may withdraw at any stage without giving a reason and without any impact on their current or future care, treatment or access to services. Clear procedures will be in place to support withdrawal, including provision of a withdrawal form and direct contact details for the evaluation team. Contact details for the evaluation team and information about participants' rights will be included in all participant information sheets, consent forms and privacy notices.

Risk of harm to participants

Whilst the risks associated with participation in IPS-Y and the trial are expected to be low, the evaluation team recognises that some participants may experience distress when discussing their mental health, education, employment experiences or future aspirations. Appropriate safeguards will therefore be implemented throughout the study.

All IPS-Y Specialists and researchers involved in participant-facing activities will hold enhanced DBS clearance and receive training in safeguarding, trauma-informed practice, youth-centred engagement and working with neurodivergent young people.

All members of the research and delivery teams will be required to follow study-specific safeguarding procedures and relevant NHS and local safeguarding policies.

Research activities and study materials are designed to be developmentally appropriate, accessible and sensitive to participants' needs. Participants will be reminded that their involvement is voluntary and that they may decline to answer any question, pause an interview or survey, or withdraw from the study at any time without consequence.

The study will seek to ensure equitable participation through reasonable adjustments for participants with additional communication, accessibility or neurodevelopmental needs. Information materials will be provided in accessible formats and engagement approaches adapted where appropriate.

Confidentiality will be maintained in accordance with applicable legal and ethical requirements. However, participants will be informed that confidentiality may be breached where there are concerns regarding serious risk of harm to the participant or others, or where safeguarding concerns require escalation.

Any disclosures relating to participant safety, self-harm, suicidality, abuse, neglect or exploitation will be managed in accordance with the study safeguarding policy and established NHS safeguarding procedures. Clear safeguarding procedures will set out reporting and escalation pathways, including referral to appropriate clinical, safeguarding or emergency services where required.

Ethical approval

HRA and REC approvals will be obtained prior to recruitment. Ipsos will prepare the application (and core study documents) for this and submit it via the Integrated Research Application System (IRAS). Ipsos will coordinate with the participating Trusts to ensure the relevant Trust-specific information is included and accurate.

Trial registration

The trial will be prospectively registered prior to participant recruitment. Registration details will be made publicly available through the International Standard Randomised Controlled Trial Number (ISRCTN) and any additional registry required by the funder or ethics committee. A registration number will be provided when available.

Data protection

Data protection statement

All personal data collected for this trial will be processed and stored in accordance with the GDPR and DPA 2018. The procedures detailed in this protocol are designed to protect the rights and privacy of participants and ensure that data are used solely for the purposes of this research project. The aim of the research is to understand whether IPS-Y is effective in supporting young people with mental health difficulties into employment or education. The purpose of data processing is strictly limited to the research activities specified in privacy notices.

Participant data will be pseudonymised using unique study identification numbers. Personally identifiable information required for participant contact and follow-up will be stored separately from research datasets. Only authorised members of the research team will have access to identifiable information.

Electronic data will be stored on secure password-protected systems with role-based access controls. Any transfer of identifiable data between organisations will use secure encrypted channels and be governed by formal Data Sharing Agreements.

Legal basis for data processing

For the purposes of this trial, the legal basis for processing personal data is Legitimate interest (Article 6(1)(f)) and for processing special category data is Scientific research purposes (Art 9(2)(j)).

Participants will be provided with privacy notices that detail the purpose of the data collection, how their data will be used, who will have access to it, and their rights regarding their data.

GDPR compliance

Information on data protection is included in the trial-wide and research-activity-specific privacy notices. This information will be shared with young people and their parents when they sign up to the trial, and with relevant stakeholders prior to any research activity. The privacy notices will set out how their data will be used and their rights in relation to this.

The trial data will be submitted to the YFF archive within 6 months of study completion (expected April 2029) and securely destroyed at Ipsos.

Participants will be informed of their rights under UK GDPR, including rights relating to access, rectification, restriction of processing and complaints. Contact details for the Ipsos UK Data Protection Officer and the Information Commissioner's Office (ICO) will be provided within privacy notices.

Data processing roles

Ipsos UK is the data controller for personal data collected and processed for the purposes of the trial and associated research. Where Pure Innovations staff undertake trial-specific activities on behalf of Ipsos, including eligibility screening, obtaining and documenting informed consent, and baseline data collection, Pure Innovations will process the relevant trial data on Ipsos's documented instructions.

Processing for the purposes of the trial and associated research will include:

- Eligibility screening and confirmation against the trial inclusion and exclusion criteria
- Obtaining and documenting informed consent to participate in the trial
- Collecting baseline data
- Conducting randomisation
- Analysing baseline and relevant IPS-Y service management information provided to the research team for trial analysis
- Collecting and analysing follow-up survey data at 6-months and 12-months
- Facilitating approved linkage of participants' data to administrative data sources, where applicable and subject to the necessary approvals and data-access arrangements
- Contacting research participants (trial participants, CAMHS staff, Pure Innovations staff) to arrange interviews
- Collecting and analysing qualitative data from interviews
- Collecting and analysing cost data from Pure Innovation.

Pure Innovations is the data controller for personal data collected and processed for the purposes of delivering the IPS-Y service and associated service management information. This includes information required to deliver, manage and monitor IPS-Y support. Pure Innovations is also the data controller for personal information relating to its staff involved in IPS-Y delivery.

Processing for these purposes will include:

- Delivering and managing IPS-Y support
- Recording participants' engagement with and receipt of IPS-Y support
- Recording employment, education and training activity and outcomes required for service delivery and monitoring
- Maintaining service management information
- Processing relevant information about IPS-Y staff for service management purposes.

Participating Trusts is the data controller for:

- Routinely collected NHS administrative data
- Personal information of staff.

Processing will include:

- Referring patients to IPS-Y
- Sharing CAMHS risk assessments and relevant data with Pure Innovations to support determination of eligibility and with Ipsos UK to support decisions about the safe approach of trial participants for interviews.

Stakeholders and interests

This study is conducted by evaluators in the Ipsos UK, working in partnership with University of Strathclyde. NHS Trusts are participating organisations and host IPS-Y Specialists employed by Pure Innovations who delivers the intervention. The study is funded by the Youth Futures Foundation.

Ipsos evaluation team

- Susan Mackay, Director and Head of Employment and Skills Evaluation, will be responsible for second-level quality assuring deliverables during trial delivery.
- Karl Ashworth, Director and Head of Data Analytics, will provide oversight and quality assurance of all analysis undertaken to undertake the RCT.
- Joanna Hofman, Director of Research and Evaluation in the Employment, Skills and Welfare team, will be the Project Director and named Chief Investigator responsible for overseeing delivery and quality assuring all elements of trail delivery and evaluation.
- Oliver Tee, Associate Director, will manage the study and lead on the IPE.
- Dr Facundo Herrera, Associate Director and Senior Economist, will oversee and manage the delivery of the impact evaluation and support economic evaluation.
- Emily Newport, Senior Consultant, will be the Trial Manager and provide support to both the impact and economic evaluation.
- Nicola de Waal (Associate Consultant) and Fred Smith (Graduate Research Assistant) will provide support both the impact evaluation and the IPE.

University of Strathclyde

- Professor Adam Whitworth, Professor of Work, Employment and Organisation at the University of Strathclyde, will lead on the economic evaluation and provide consultation to the evaluation.
- Dr Michael Vallely, University of Strathclyde, will provide support on the economic evaluation.

Young People Advisory Board (YPAB) and Parents/Carers Advisory Board – engaged by the Centre for Mental Health team:

- Juliet Snell (lead)
- Dani Stern (support)
- Julie Baile (support).

Pure Innovations Delivery Team

- Louise Parrott Bates, CEO, will have oversight of IPS-Y delivery
- Danielle Sidderly, Director of Employment, will manage the recruitment, training and ongoing support for IPS-Y Specialists.
- Ben Moloney, IPS contract manager, will help to manage the delivery of IPS-Y delivery.
- Natalie Irvine, IPS quality lead, will quality assure IPS-Y delivery.

Participating Trusts

Pennine

- Professor Prathiba Chitasbesan, Principal Investigator at Pennine
- Dr Jennifer Kujacz, co-Principal Investigator at Pennine and CAMHS research fellow, will be the research lead at Pennine to support with coordination and delivery of the trial
- Neryssa Charman, Commissioning and Implementation Manager at Pennine, will support with coordination and governance of IPS-Y delivery across the participating Trusts (Pennine and MFT).

MFT

- Roshelle Ramkisson, Principal Investigator at MFT
- Dr Vandna Saxena, co-Principal Investigator at MFT
- Dr Shamik Chudasama co-Principal Investigator at MFT.

Trial governance

The proposed governance structure is based on established arrangements used in UK publicly funded randomised controlled trials, adapted to reflect the relatively low-risk nature of the IPS-Y intervention. We have adopted a two-tier model comprising a Trial Management Group (TMG) and an independent Trial Steering Committee (TSC), as this provides a clear separation between operational delivery and independent oversight. The TMG will be responsible for the day-to-day management and delivery of the research. Membership will include the Chief Investigator, Co-Investigators, Trial Statistician, Trial Manager, representatives from YFF, Pure Innovations, and participating NHS Trusts. The TMG will meet monthly to oversee recruitment, data collection, protocol adherence, safeguarding, risk management, data quality and study timelines. The TMG will maintain the study risk register and oversee implementation of mitigation actions.

The TSC will provide independent oversight of the trial and will be established prior to recruitment. The Committee will comprise an independent Chair, an independent statistician, and independent experts with relevant expertise in areas such as child and adolescent mental health, vocational support, trial methodology and implementation. The Committee will also include a public contributor with relevant lived experience. The Chief Investigator and other members of the study team may attend meetings to provide updates but will not form part of the independent membership. The TSC will

meet approximately every six months, or more frequently if required, to review trial progress, recruitment and retention, protocol adherence, participant safety, emerging risks, and any proposed protocol amendments. The TSC will advise on progression from the pilot phase to the main trial and make recommendations regarding the continuation, modification or termination of the study.

Risks

Overview

A risk management approach will be applied throughout the trial. Risks will be reviewed regularly by the TMG and escalated to the TSC where appropriate. Risk monitoring will draw on routine project management information, recruitment and retention metrics, implementation monitoring, fidelity assessments and stakeholder feedback.

The risks presented below will be reviewed and updated throughout the study lifecycle.

Table 8: Risk register for the trial including mitigation strategies

RISK	LIKELIHOOD	IMPACT	MONITORING	MITIGATION
Delays in obtaining research approvals (HRA, NHS R&D, Capacity and Capability approvals)	Medium	High	Approval milestones monitored through project governance meetings	Early submission of approvals; dedicated project management; contingency built into recruitment timeline; phased site activation where appropriate
Insufficient participant recruitment	Medium	High	Monthly recruitment monitoring against site-level targets; screening and eligibility logs	Recruitment pathways embedded within CAMHS teams; multiple referral routes; clinician engagement; recruitment materials co-produced with young people; pilot phase used to refine recruitment processes
Lower than anticipated	Medium	High	Monitoring of screening	Recruitment targets reviewed

proportion of eligible young people interested in EET participation			outcomes and reasons for non-participation	regularly; recruitment period extension considered if required
True baseline EET rate is materially higher than the assumed 25%	Medium	High	Review pilot baseline EET rate and relevant baseline characteristics as contextual evidence on the plausibility of the assumption	Review and, if necessary, revise the power assumptions before committing to full recruitment
Participant attrition and loss to follow-up	Medium	High	Follow-up completion rates monitored monthly	Multi-modal contact methods; participant compensation; regular reminders; collection of multiple contact routes; engagement strategies informed by YPAG recommendations; linking participants to known administrative data sources
Differential attrition rates (e.g. participants in the control group are less likely to complete follow-up surveys than those receiving IPS-Y, introducing attrition bias and reducing statistical power)	Medium	High	Monitor follow-up completion rates by trial arm at regular intervals (e.g. monthly), with oversight by the Trial Management Group. Review reasons for non-response where available and compare baseline characteristics of completers and non-completers.	Apply identical follow-up procedures, compensation and communications across both trial arms; maintain participant engagement through regular contact and multiple reminder methods (email, SMS, telephone); collect multiple contact details and preferred communication methods at baseline;

				implement targeted retention strategies if differential attrition emerges. These may include additional reminder contacts, verification and updating of participant contact details, greater use of preferred communication channels (e.g. SMS, email or telephone), flexible options for survey completion, and tailored engagement approaches for participant groups demonstrating lower response rates. Address remaining missing data using pre-specified statistical methods (e.g. multiple imputation and sensitivity analyses) detailed in the Statistical Analysis Plan.
Variation in recruitment and implementation across NHS Trust sites	Medium	Medium	Site-level recruitment, fidelity and implementation monitoring	Standardised operating procedures; site initiation training; regular implementation meetings; stratification by site in randomisation and analysis

Challenges embedding IPS-Y Specialists within CAMHS teams	Medium	High	Staff feedback, implementation monitoring and fidelity assessments	Clear governance arrangements; co-location where feasible; agreed referral pathways; senior clinical sponsorship within participating Trusts
Delays recruiting and onboarding IPS-Y Specialists	Medium	High	Workforce recruitment tracking and vacancy monitoring	Early workforce planning; phased recruitment; contingency staffing arrangements; support from Pure Innovations senior management
Variation in intervention fidelity across sites and staff	Medium	Medium	Fidelity assessments, supervision records and monitoring data	Standardised IPS-Y training; ongoing supervision; fidelity reviews; corrective action plans where required
Contamination between intervention and control groups	Low	Medium	Participant surveys, service mapping and monitoring information	Clear separation of IPS-Y delivery from usual care; documentation of alternative vocational support received; sensitivity analyses where necessary
Poor quality outcome data (e.g. inaccurate or incomplete self-reported EET status, leading to outcome misclassification and reduced validity of trial findings)	Medium	High	Monitor survey completeness, item non-response and response patterns throughout data collection. Conduct routine data quality checks, including validation of inconsistent responses	Use clear, plain-English survey questions with defined eligibility thresholds and examples of education, employment and training. Test the questionnaire with young people prior to the trial, incorporate automated validation and routing within the online survey, and

			(e.g. reporting employment but zero hours worked) and review missing data by trial arm.	provide participants with contact details for clarification if needed. Where feasible, compare self-reported outcomes with other available information (e.g. implementation records or administrative data) and undertake pre-specified sensitivity analyses to assess the robustness of findings to potential outcome misclassification.
Poor quality or incomplete monitoring data	Medium	Medium	Routine data quality checks and audit processes	Standardised data collection templates; staff training; regular validation and cleaning procedures
Changes to CAMHS structures, referral pathways or workforce during the study period	Medium	Medium	Context monitoring through IPE	Documentation of contextual changes; adaptation of operational procedures where necessary; inclusion of contextual factors in analysis
Participant distress during research activities	Low	High	Safeguarding reporting procedures and researcher supervision	Trauma-informed research protocols; safeguarding training; clear escalation pathways; ability to pause or discontinue participation at any time
Information governance or	Low	High	Compliance monitoring,	GDPR-compliant systems; secure

data security breaches			audits and incident reporting procedures	storage and transfer protocols; role-based access controls; staff training and Data Protection Impact Assessments
Lower than expected intervention uptake or engagement	Medium	Medium	Monitoring of referral acceptance, attendance and dosage data	Flexible engagement approaches; youth-centred communication methods; family involvement where appropriate; ongoing implementation review
Failure to meet progression criteria following pilot phase	Low-Medium	High	Assessment against pre-specified progression criteria	Pilot phase used to identify and resolve operational challenges; progression decisions informed by recruitment, retention, fidelity and implementation data

Risk review and escalation

Risks will be reviewed monthly by the Trial Management Group and formally reported to the Trial Steering Committee at scheduled oversight meetings. Recruitment, retention, fidelity, safeguarding incidents, implementation progress and data quality metrics will be reviewed routinely.

Where risks exceed agreed thresholds, corrective action plans will be developed collaboratively with participating NHS Trusts, Pure Innovations and Youth Futures Foundation. Significant protocol deviations or emerging risks with implications for participant safety, study integrity or delivery feasibility will be escalated promptly to the Trial Steering Committee, sponsor and relevant ethics and governance bodies as appropriate.

Timeline

The tables below outline the timeline for each strand of the study (RCT, IPE and economic evaluation). These timelines are brought together in the diagram that follows.

Table 9: RCT timeline

DATES	ACTIVITY	LEAD
Jul – Dec 2026	Trial set up: HRA submission and approvals	Ipsos
By 30 Nov 2026	Completion of IPS-Y study training for CAMHS and Pure Innovations	Ipsos
Dec 2026 – Mar 2027	Trust Capacity and Capability checks	Participating Trusts
Mar 2027	Recruitment to trial pilot phase: test referral pathways, validate assumptions	Pure Innovations / Ipsos
31 May 2027	Go/No-Go decision on progression to main trial	Ipsos and Youth Futures Foundation
Jun – Jul 2027	Recruitment to main trial: randomisation and baseline data collection	Pure Innovations / Ipsos
Sep 2027	6 months follow-up data collection (for pilot phase cohort)	Ipsos
Dec 2027 – Feb 2028	6 months follow-up data collection (for main trial cohort)	Ipsos
Mar 2028	12 months follow-up data collection (for pilot phase cohort)	Ipsos

Jun - Aug 2028	12 months follow-up data collection (for main trial cohort)	Ipsos
Sep 2028	12 months follow-up data collected and locked	Ipsos
Oct – Nov 2028	Data analysis	Ipsos
30 Nov 2028	Impact evaluation report	Ipsos

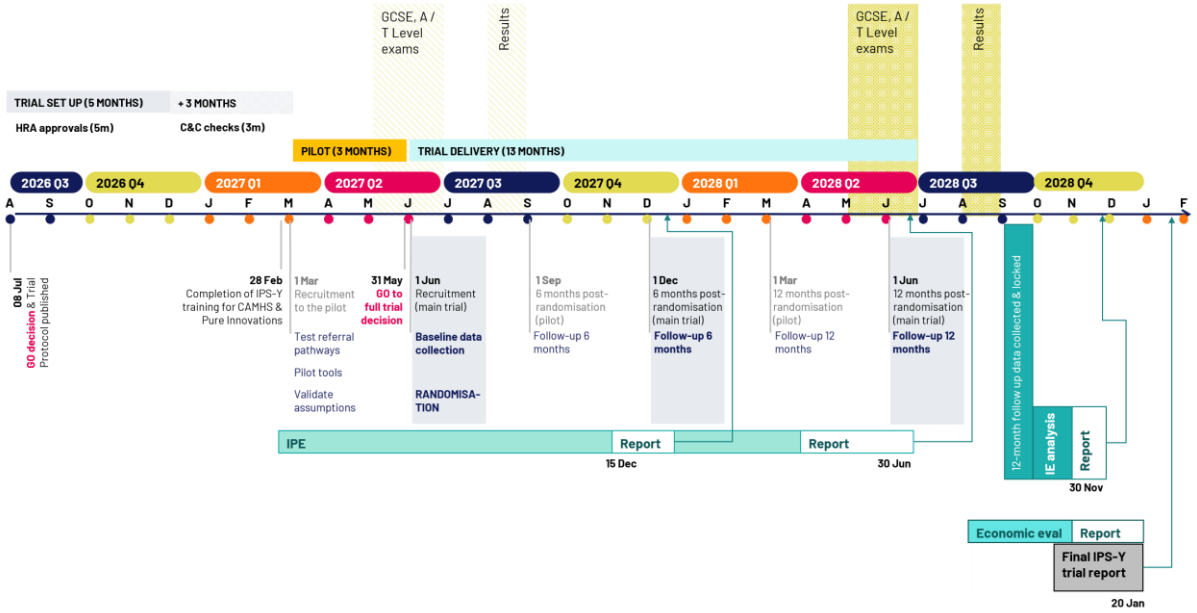
Table 10: IPE timeline

DATES	ACTIVITY	LEAD
Mar – Dec 2027	IPE data collection, analysis and reporting	Ipsos
15 Dec 2027	Interim IPE report delivery	Ipsos
Jan – Jun 2028	IPE data collection, analysis and reporting	Ipsos
30 Jun 2028	Final IPE report	Ipsos

Table 11: Economic evaluation timeline

DATES	ACTIVITY	LEAD
Aug – Dec 2028	Economic evaluation data analysis	University of Strathclyde
20 Jan 2029	Economic evaluation reporting	University of Strathclyde / Ipsos

Figure 3: Proposed timelines (combined)



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Appendix

BAU services for control group

The table below outlines the core BAU services on offer in each of the GM boroughs. Where there is the potential for significant overlap with IPS-Y, control group participation will be monitored. This is indicated where relevant in the table.

Table A1: BAU services by LA

Area	Services
City of Manchester	• **Powerhouse Youth Zone:** Multiservice youth hub providing careers advice and NEET support, located centrally in Manchester. • **Career Street (Part of IPS):** Part of 42nd Street, providing employment support for 16–25-year-olds with mental health difficulties. **(participation to be monitored)**
Salford	• **Career Connect Salford:** Provides local careers advisor or engagement coach to NEET young people, promoted via the Connexions website. • **Career Street (part of IPS):** Provides employment support for young people facing mental health difficulties. **(participation to be monitored)**
Trafford	• **Connexions Trafford:** Provides advice, guidance, and mental health support for13-25-year-olds. Through qualified Careers Advisors and drop in Talkshop sessions. • **Engage Trafford:** Offers broad mentoring for children and young people with various needs, including NEET status. • **Career Street (part of IPS):** Provides employment support for young people facing mental health difficulties. **(participation to be monitored)**
Stockport	• **Stockport Family's ECAS:** Supports NEET 16-17-year-olds with ongoing careers guidance. • **WorkWell:** Provides a triage service to navigate work and skills support.
Tameside	• **Stockport Family's ECAS:** Supports NEET 16–17-year-olds with ongoing careers guidance. • **WorkWell:** Provides a triage service to navigate work and skills support. • **IPS available**: Through Groundwork offering support to young people involved or at risk of being involved in serious violence. **(participation to be monitored)**
Oldham	• **Positive Steps - Empower Oldham:** Mentoring and wellbeing support for young people. • **Get Oldham Working:** Part of Work Well offer; specific youth offer with one-to-one guidance. • **IPS available**: Through Groundwork offering support to young people involved or at risk of being involved in serious violence. **(participation to be monitored)**

Heywood, Middleton and Rochdale	• **Positive Steps - Engage Rochdale:** Mentoring and wellbeing support for up to 19-year-olds. • **IPS available**: Through Groundwork offering support to young people involved or at risk of being involved in serious violence. **(participation to be monitored)**
Bury	• **Connexions Bury:** Provides qualified personal advisers for young people aged 15-18 (or up to 25 if NEET).
Wigan	• **Aspiring Futures**: Employment support from Progression Advisors as part of Wigan Council's Employment and Skills team • **WorkWell** offer for residents delivered via Ingeus and the Growth Company
Bolton	• **Connexions/Next Generation:** bespoke mentoring to improve mental health and wellbeing and increase employability skills • **WorkWell Bolton:** Personalised support from a Work and Health coach • **Genuine Futures**: Youth led social enterprise offering a 12-weekprogramme "Boss Your Future"