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Interpersonal Counselling for Adolescent Depression delivered by Youth Mental Health Workers without Core Professional Training: A Feasibility Randomised Controlled Trial

Short Title: ICALM (Interpersonal Counselling for Adolescent Low Mood)

- **This protocol has regard for the HRA guidance**

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NIHR HS&DR REFERENCE 17/112/16

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PROTOCOL VERSION 1.3

Version Control

Version No.	Date	Changes to previous version
1.1	26 July 2019	
1.2	2 Sep 2019	Clarifications at suggestion of NSFT internal peer review. Clarification of inclusion/exclusion criteria: - Study Summary - Section 5 Further details of process evaluation - Section 6.9
1.3	4 Nov 2019	Clarifications at suggestion of REC

KEY STUDY CONTACTS

Chief Investigator	Dr Paul Wilkinson, University of Cambridge Department of Psychiatry, Douglas House, 18b Trumpington Road, Cambridge, CB2 8AH, UK. Tel: 01223 465255, Mob: 07950 266742
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Funder	NIHR Health Services and Delivery Research
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Statistician	Prof Lee Shepstone, Professor of Medical Statistics, University of East Anglia

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STUDY SUMMARY

Title	Interpersonal Counselling for Adolescent Depression delivered by Youth Mental Health Workers without Core Professional Training: A Feasibility Randomised Controlled Trial
Internal ref. no. (or short title)	ICALM (Interpersonal Counselling for Adolescent Low Mood)
Design	Feasibility RCT with process evaluation using ethnographic methodology
Participants	Young people with depressive symptoms recruited from non-specialist community services. Inclusion criteria • Aged 12-18 years • Seeking help for low mood (as the primary presenting difficulty) • Able to provide written informed consent or, for under 16s, written informed assent and parent/guardian consent • Of a level of illness where they would normally receive treatment from the service Exclusion criteria • Learning disability necessitating non-mainstream schooling • Current psychotic disorder • Current substance dependence • Current significant suicidal ideation (K-SADS-PL – 'suicidal ideation' threshold – 'often thinks of suicide and has thought of a specific method')
Planned Sample Size	60 (30 per trial arm)
Treatment duration	Up to 6 sessions (estimated up to 10 weeks)
Follow up duration	23 weeks
Planned study period	24 Months (1st October 2019 – 30th September 2021)

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FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHR Health Services and Delivery Research	£382,870.76
Suffolk County Council Norfolk County Council Point 1 consortium Suffolk Young People's Health Project	Their staff will attend training and supervision in IPC; and deliver therapy in both arms

ROLE OF TRIAL SPONSOR

Norfolk and Suffolk NHS Foundation Trust will be the sponsor. Responsibility for all aspects of study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results will be delegated to the Chief Investigator.

ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS

Trial Management Committees

Three main groups will be convened to oversee the conduct of the study and ensure participant safety:

Trial Steering Committee (TSC)

The TSC will meet every 3-6 months throughout the study. It will be chaired by an independent expert. Other proposed members of the TSC will include experts in statistics, qualitative research and psychological therapy, the study chief investigator and members of our youth advisory group (young people with lived-experience of low mood/depression, with support from the trial PPI lead). At least 75% of members of the TSC will be independent of the trial management group (and our universities). The TSC will oversee the management of the trial and ensure its scientific integrity, reporting regularly to the Sponsor. In line with NIHR research governance guidelines, the TSC will have following main roles:

- To provide advice, through its chair, to the Trial funder, the Trial Sponsor, the Chief Investigator, the Host Institution and the Contractors on all appropriate aspects of the project
- To concentrate on progress of the trial, adherence to the protocol, patient safety and the consideration of new information of relevance to the research question
- The rights, safety and well-being of the participants are the most important considerations and should prevail over the interests of science and society
- To ensure appropriate ethical and other approvals are obtained in line with the project plan
- To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments
- To provide advice to the investigators on all aspects of the trial

The TSC will assess the success of the feasibility trial against the progression criteria and will make recommendations regarding the suitability of the proposed design for the full-scale trial.

Data Monitoring Committee (DMC)

The DMC will be composed of experienced trialists, including an independent statistician, who are independent of all staff and institutions involved in running the trial. The committee will meet bi-annually (just prior to TSC meetings) during the recruitment and follow-up phase to review accumulating data and report to the TSC regarding any safety or ethical concerns pertaining to the conduct of the research; if appropriate the TSC will report these to the sponsor. In line with NIHR research governance guidelines, the DMC will have following main roles:

- It is the only body involved in the trial that has access to the unblinded comparative data
- The role of the members is to monitor these data and make recommendations to the TSC on whether there are any ethical or safety reasons why the trial should not continue
- The safety, rights and wellbeing of the trial participants are paramount
- The DMC will consider the need for any interim analysis advising the TSC regarding the release of data and/or information
- The DMC may be asked by the TSC, Project Sponsor of Project Funder to consider data emerging from other related studies
- It is possible that the DMC chair may be asked by the Project Funder to provide a confidential interim or futility analysis if serious concerns are raised about the viability of the study or if the research team are requesting significant extensions.

Trial Management Group (TMG)

The TMG will be chaired by Dr Paul Wilkinson and will comprise core study team members, including clinical leads and co-investigators. The TMG will meet monthly throughout the study to monitor the day-to-day running of the study, ensuring that it is progressing well and being conducted in accordance with the protocol and GCP guidelines.

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STUDY FLOW CHART

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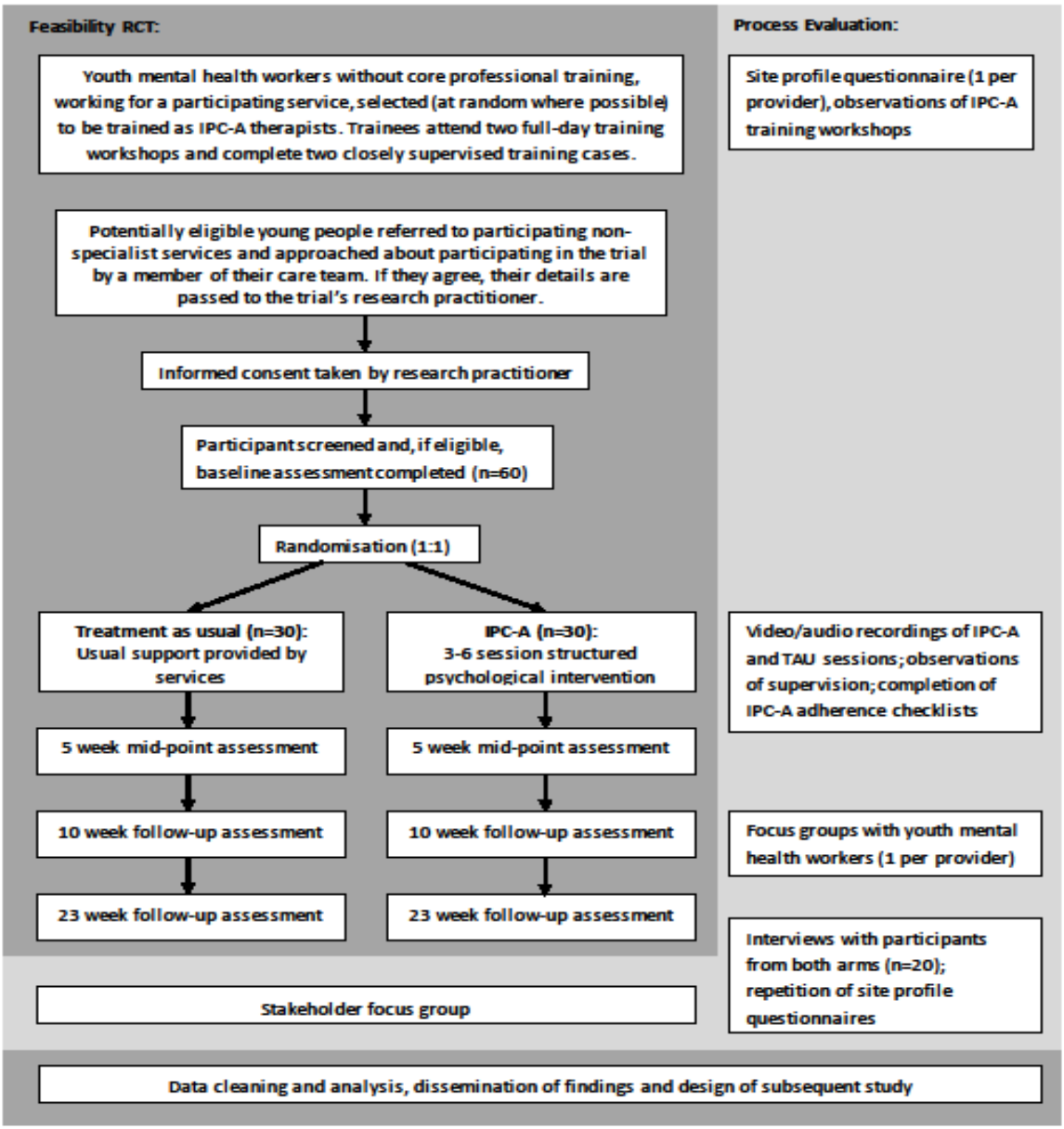
ICALM Study Flow Diagram, Version 2



1 BACKGROUND AND RATIONALE

There is extensive and growing demand for services to meet the needs of young people with poor mental health (1). Depression is a common health problem during adolescence. Adolescent lifetime prevalence of major depressive disorder (MDD) is 11-20% (2,3). However, mild/sub-threshold depression is much more common in adolescents than full MDD (4). Such mild depression is associated with significant personal and public health consequences (5) and is a strong predictor for future onset of full MDD (6). Depression in adolescence predicts a range of adverse outcomes in adulthood, including ongoing mental health problems (7), poorer physical health (8), and social, legal and financial problems (9), and is the most prevalent psychiatric disorder in young people who die by suicide (10). The total annual cost of depression in England has been estimated to be at least £20.2 billion (11). However, there is evidence that prompt psychological intervention can prevent relapse and recurrence (12) and therefore intervening early, before depression symptoms become severe, could generate substantial savings.

The majority of adolescents seeking treatment for depression have mild disorder (13). In the UK, such cases of mild depression are not likely to meet treatment thresholds for specialist (tier 3) child and adolescent mental health services (CAMHS). Instead, young people with mild depression are seen by staff working in local authority child and family services or tier 2 NHS-funded mental health services often delivered by third sector/voluntary agencies. Most of those working with depressed young people within these non-specialist services are not qualified mental health professionals and have no formal training in delivering evidence-based treatments for people with depression.

Current guidelines for the treatment of mild depression in children and young people (14) recommend simple non-specific psychosocial strategies, such as non-directive supportive therapy. A recent large network meta-analysis has shown that while non-directive supportive therapy is better than a waiting list (i.e. no treatment) for adolescent depression, it is not significantly better than placebo (15). It is important to note that the primary studies included in this meta-analysis took place in a range of services for a range of severities of depression. No randomised controlled trials have taken place in the services described above, where most cases of mild depression are treated in the UK. Thus there is a clear lack of evidence as to how to treat young people in these services (16–18).

Interpersonal psychotherapy (IPT) is a NICE-recommended first-line treatment for adolescents with moderate to severe depression. IPT helps patients to understand the two-way links between their depressive symptoms and current interpersonal relationships. It also helps patients to improve their interpersonal relationships. In doing so, it aims to reduce depressive symptoms. Whereas non-directive supportive therapy aims '*to help patients accommodate to existing reality rather than try to help them change it*' (19), IPT focuses on helping patients to take active steps to improve their relationships in order to decrease their depressive symptoms. Theoretical influences on IPT included Adolf Meyer's 'psychobiological' approach, which emphasized patients' current interpersonal and psychosocial experiences (20); and Harry Stack Sullivan's 'interpersonal' approach, which conceptualized psychiatry as the scientific study of people and interpersonal processes (21). Both approaches contrasted with the dominant psychoanalytic approach at that time, which emphasised intrapsychic processes over interpersonal relationships.

Meta-analyses have demonstrated IPT to be superior to control treatments for depression in both adults (22) and adolescents (15); and to lead to similar outcomes as cognitive-behaviour therapy in both age groups. Crucially, IPT has been shown to be significantly more effective than supportive counselling for depressed adolescents (23). Given the importance of interpersonal relationships in the causation of adolescent depression (16), and the developmental priority given to interpersonal relationships during adolescence, this approach has high face validity for this age group.

However, in common with other evidence-based treatments for adolescent depression, IPT must be delivered by a qualified mental health professional with extensive training. As such, it is unlikely to be a feasible treatment option outside of specialist CAMHS. Interpersonal counselling (IPC) is an adaptation of IPT with three main differences: the treatment duration is shorter (3-6 sessions); it is designed for clients with mild depression; and it can be delivered by non-mental health professionals after participation in a brief (two day) training course.

IPC has been found to be an effective treatment for adults with mild to moderate depression (24,25). An adapted form of IPC designed to meet the needs of young people (IPC-A) has recently been developed and piloted by members of the research team of this proposal (PW and VC), but its effectiveness as a treatment for adolescent depression has yet to be tested. Although there are many similarities between adult and adolescent depression, there are also important differences, particularly in treatment response (16). Adult and young people's services also differ in their organisation, ethos and staff training (26). Therefore, it cannot be assumed that an effective treatment for adult depression can be transferred to adolescents without evaluation.

This study is intended to provide the information needed to progress to a full-scale clinical trial of IPC-A delivered by staff without core professional training (referred to in this application as 'youth mental health workers'). The training (including subsequent supervised casework) required to deliver IPC-A can be completed by staff without prior mental health qualifications in less than 12 weeks. Therefore, if found to be an effective treatment, training existing workers as IPC-A therapists could facilitate a rapid and relatively low-cost expansion of the therapy workforce in line with NHS England and government commitments.

2 OBJECTIVES AND FEASIBILITY OUTCOMES

2.1 Aims and Objectives

The proposed research is designed to inform a future trial of the effectiveness and cost-effectiveness of the intervention (interpersonal counselling for adolescents with mild depression). The aim of the proposed research is to answer the following feasibility questions which arise from the variability in service models across providers of non-specialist mental health support for young people:

- Are trial procedures, including recruitment (of participants and therapists), randomisation, research assessments and follow-up, feasible and acceptable?
- How are IPC-A and treatment as usual (TAU) delivered and how and why does intervention delivery vary across differing service contexts?
- To what extent does contamination of the control arm occur and should it be mitigated against in a future trial?
- Does the interval estimate of benefit of IPC over TAU in depression scores at post-treatment include a clinically significant effect?

2.2 Feasibility Outcomes

The primary output of the research will be the design of the subsequent trial. The TSC will assess the trial against the following criteria and make recommendations regarding the suitability of the proposed design for the full-scale trial.

a) recruitment rate is at least 80% of target

b) at least 70% of those randomised to receive the intervention attend at least three therapy sessions within the 10 week treatment window

c) follow-up assessments are completed by at least 80% of participants at 10 weeks and 70% of participants at 23 weeks

d) at least 80% of IPC treatment sessions reviewed meet treatment fidelity criteria

e) contamination of the control arm can be sufficiently limited for individual randomisation to be justified

f) the mean RCADS depression scores of the IPC-A and TAU groups at 10 weeks are indicative of a clinically significant difference in depression (3 points).

Recruitment and retention rates. These will be estimated along with 95% CIs. If appropriate, time until drop-out will be estimated using a reverse Kaplan-Meier curve. Parameters required for the design of the subsequent study will also be estimated.

Feasibility of implementation and fidelity to the intervention model. Mixed-methods ethnographic process evaluation data will be collected to: (a) provide a description of how IPC-A and TAU are delivered, (b) assess implementation and theoretical fidelity to the IPC-A model over time, (c) observe how delivery is shaped by the context of differing service models, (d) identify any harms arising from treatment (including end of treatment) and (e) establish the extent and source of any contamination of the control arm. Data collection methods will include site profile questionnaires (one per provider administered at the

beginning and end of the trial, observations of IPC-A training workshops and supervision, video/audio recordings of treatment sessions (both IPC-A and TAU; all treatment sessions will be recorded, subject to consent), interviews with participants (young people and parents) from the IPC-A and TAU arms (n=20) and focus groups with youth mental health workers (one per provider) and wider stakeholders (n=1)). IPC sessions will be audiotaped and adherence marked using the IPC rating scale.

Degree of contamination in control arm. Qualitative process evaluation data on the experiences of the control arm and audiotapes of sessions (rated against the IPC rating scale) will be used to monitor contamination.

Suitability and acceptability of the proposed outcome and health economic measures. The rate of completion of each outcome measure will be calculated and acceptability assessed via the process evaluation. We shall estimate the expected cost of the intervention and likely drivers of cost.

3 STUDY DESIGN

Research question: Is a full-scale RCT of interpersonal counselling for young people with mild depression delivered in non-specialist community services feasible?

Design: Young people will be randomised to IPC-A or treatment as usual.

Sampling: Participants will be young people accessing participating services (for help with low mood) via the service's standard referral pathways.

Data collection: Quantitative outcome data will be collected by face-face interviews and online questionnaires. Qualitative data will be collected by site profile questionnaires, observations of IPC-A training workshops and supervision, video/audio recordings of treatment sessions (both IPC-A and TAU), interviews with participants (and parents) from the IPC-A and TAU arms and focus groups with youth mental health workers and wider stakeholders

Data analysis: A Statistical Analysis Plan (SAP) for quantitative data analysis will be written in accordance with Norwich CTU guidance and approved by the independent data monitoring committee prior to any formal statistical analysis. Transcriptions of recorded sessions, researcher's observational field notes and focus groups will be transcribed verbatim and thematically analysed with the aid of NVivo software.

4 STUDY SETTING

Two agencies will be delivering treatment in Suffolk: Suffolk County Council Early Help and NEET teams; and Suffolk Young People's Health Project (4YP, a charity). Two agencies will be delivering treatment in Norfolk: Norfolk County Council Early Help; and MAP, a charity working within Point 1 (a charity). Staff delivering the IPC and TAU interventions will be employees of these organisations, doing this as part of their normal job (they will not receive additional payment). Further details are below.

In Suffolk, non-specialist mental health support for children and young people is provided by Suffolk County Council's Early Help and NEET (not in education, employment or training) teams. Referrals are received via the Common Assessment Framework (CAF) or the Suffolk Children and Young People's Emotional Wellbeing Hub. Referrals are received from professionals (including school/college staff, GPs and youth workers), families and young people and are triaged before being passed (if appropriate) to the Early Help team local to the area in which the young person lives. The Practice Lead for the team then then assigns the case to a Family Support Practitioner or Young Person's Worker. 4YP (https://www.4yp.org.uk/) take self-referrals and referrals from others, and provide a short course of counselling for young people with emotional problems.

In Norfolk, non-specialist mental health support for children and young people is provided by Point 1 (a consortium between local voluntary sector providers and the NHS) and Norfolk County Council Early Help teams. Referrals to Point 1 are received from professionals via a single point of contact (SPOC). The SPOC team screen referrals to ensure that they are directed to the right service and, if appropriate, conduct a more in-depth telephone assessment before sending appropriate referrals. Support for young people with emotional problems is provided by MAP, a charity working with Point 1 (https://www.map.uk.net/). MAP complete a more detailed assessment as part of the first session of the treatment package, during which a treatment plan is agreed in collaboration with the young person and his/her family. Referrals to the Early Help teams are received from professionals via the Family Support Process, or directly from young people and families.

While the sites are in the area served by one NHS mental health trust, the treatment is not delivered by this mental health trust, as the severity of illness of young people is generally below the thresholds for NHS specialist child and adolescent mental health services. Treatment at this level is delivered by a range of services locally: Suffolk County Council, 4YP, MAP (a voluntary sector funded via Point 1, a partnership between local voluntary sector providers and the NHS) and Norfolk County Council. These four organisations work in different ways in terms of service user selection and treatment as usual and will deliver a good amount of variety of service. This will give a good balance of generalisability while making the study feasible within the cost envelope.

5 PARTICIPANT ELIGIBILITY CRITERIA

Participants will be young people accessing participating services via the service's standard referral pathways as detailed above. Young people will be triaged and assessed according to each service's standard procedures. If this assessment identifies low mood as a presenting difficulty, the case will be discussed with a clinical member of the research team (without identifying the young person) to ascertain likely suitability for the trial. The service will have the option of using the RCADS depression scale to help determine suitability, with a cut-off of 11 or over suggesting suitability (this cut-off will not be an absolute).

Potentially suitable young people will be invited to participate and those who express an interest will meet with the trial's research practitioner who will carry out informed consent procedures and screen the young person to ensure they meet the following criteria. In line

with the approach used successfully in the pilot, eligibility criteria have been kept to a minimum to increase the external validity of the trial in the context of non-specialist services.

5.1 Inclusion criteria

- Aged 12-18 years
- Seeking help for low mood (as the primary presenting difficulty)
- Able to provide written informed consent or, for under 16s, written informed assent and parent/guardian consent
- Of a level of illness where they would normally receive treatment from the service

5.2 Exclusion criteria

- Learning disability necessitating non-mainstream schooling
- Current psychotic disorder
- Current substance dependence
- Current significant suicidal ideation (K-SADS-PL – 'suicidal ideation' threshold – 'often thinks of suicide and has thought of a specific method')

Excluded young people will be signposted to appropriate services. Young people will not be excluded on the basis of insufficient English language skills provided interpreting/translation services and foreign language RCADS are available.

Please note: there will not be a numerical upper severity threshold. The upper threshold comes under 'Of a level of illness where they would normally receive treatment from the service'. An interesting outcome of our initial IPC single-arm pilot was that some young people with severe depression (according to ratings questionnaires) are routinely treated by Suffolk Young Person's Services. Reasons are multiple. It is important to examine this in the wider range of services in the planned study. But the purpose of this study is not to examine/change referral thresholds but to investigate optimal treatments for young people in this service.

6 PROCEDURES

6.1 Overview of Study Procedures

Participants will be young people accessing participating services via the service's standard referral pathways as detailed above. Young people will be triaged and assessed according to each service's standard procedures. If this assessment identifies low mood as a presenting difficulty, the case will be discussed with a clinical member of the research team (without identifying the young person) to ascertain likely suitability for the trial. Potentially suitable young people (and/or parents/carers) will be invited to participate. If they express an interest, consent will be given to the service to pass on their details to the research team.

Those who express an interest will meet with the trial's research practitioner who will carry out informed consent procedures and screen the young person to ensure they meet the inclusion criteria.

Face-to-face quantitative assessment will take place at baseline, 10 weeks and 23 weeks. Online questionnaires will be completed by the participant at 5 weeks, with support from the research practitioner. Young people will be invited to take part in qualitative interviews at the end of treatment; up to 20 will take part in these. Staff and stakeholders will be invited to take part in focus groups.

6.2 Consent

The Chief Investigator will retain overall responsibility for taking informed consent but will delegate this responsibility to the study research practitioner who will be trained in taking informed consent according to the ethically approved protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki. The informed consent process will include a discussion with the potential participant (and his or her parent/carer if under 16) about the objectives of the study, what he or she will be asked to do if they choose to participate, and the possible risks and benefits of participation. Potential participants (and their parent/carer if applicable) will be provided with written information and will be given at least 48 hours to read and consider the information before being asked for consent. Young people and their parents/carers will be given the opportunity to ask questions and will have these answered in full.

If the young person wishes to participate following this process, they will be asked to complete a consent form (if 16 or over) or assent form (if under 16) to document the informed consent/assent process and their willingness to participate. For young people under 16, in addition to the child's assent to participation, the consent of a parent or carer (adult with parental responsibility) will be required for the young person to be included in the study. Consent to participate in an interview as part of the process evaluation will be sought during the main consent procedures. However, it will not be a requirement that a young person consents to a process evaluation interview in order to be included in the study.

We will not include individuals who do not have capacity to give their consent/assent to participation. During the consent process it will be made completely and unambiguously clear that the participant is free to refuse to participate in all or any aspect of the study, at any time, without giving a reason and without incurring any penalty. The participant's continued willingness to participate will be confirmed at each study contact before commencing any research procedures. Participants will be free to withdraw from the study at any time up until the time of data analysis without giving a reason and without prejudicing his or her further treatment. Data collected up to the point of withdrawal will be used if the participant (and their parent/carer in the case of participants under 16) consents to this. Every effort will be made to ensure that vulnerable young people are protected and participate voluntarily in an environment free from coercion or undue influence.

As the reading ages and levels of understanding of potential participants will vary and not necessarily mirror chronological age, and in line with PPI feedback, instead of preparing separate information sheets for children aged 13-15 years and young people aged 16-18 years, we have created an 'easier to read' version of the information sheet and a 'detailed' version. All young people will be provided with both versions of the participant information sheet and can choose to read the version they find more accessible, or to read both. Members of our Youth Advisory Panel (PPI group) have reviewed these information sheets to ensure the format and language used is appropriate for the target age group.

In the case of potential participants who have difficulty with the English language, information sheets and other materials will be translated into the preferred language of the potential participant where practically possible. In the case of potential participants with sensory impairment or mild learning disability, information sheets and other materials will be

converted into the preferred format (e.g. large print, audio recording, Easy Read) where practically possible. Where interpretation is necessary for informed consent or other aspects of the study, trained and accredited interpreters will be used wherever possible.

In addition, informed consent for staff participation will be sought prior to the training workshops. All staff members to be trained in the intervention will be given a verbal explanation of the objectives of the study, what he or she will be asked to do if they choose to participate, and the possible risks and benefits of participation. Staff will be provided with a written information sheet and will have the opportunity to ask questions and have these answered in full before deciding whether to participate. If the staff member decides to participate following this process, they will be asked to complete a consent form to document this process.

6.3 Randomisation scheme for feasibility RCT

Randomisation will be co-ordinated remotely by the Norwich Clinical Trials Unit (CTU). Participants will be randomised in a 1:1 allocation ratio, using a stochastic minimisation algorithm to minimise imbalance between groups in baseline symptom severity, gender and study site. Allocation will be managed by the Data Management Team at Norwich CTU via a web-based system; it will not be accessible by anyone outside of this team, including the research team, trial therapists and participants; thus allocation concealment will be maintained.

6.4 Blinding

Research practitioners collecting follow-up data will be blind to the participant's treatment allocation. Another member of the research team will contact the randomisation centre and pass details of allocation to the clinical service. Given the nature of the intervention, it will not be possible for participants and those involved in delivering the intervention to remain blind. Following allocation, all participants in the study and therapists will be asked not to reveal the group to which the participants were randomised to the research practitioner. Participants will be reminded at the beginning of each contact with the research practitioner post-randomisation not to disclose their allocation. Any potentially unblinding data will be stored separately in a database to which the research practitioner will not have access.

6.5 Emergency Unblinding

As the study's Chief Investigator and participants' responsible clinicians will be unblind to treatment allocations, no emergency unblinding procedures are required for this study.

6.6 Baseline data

The following participant data will be collected at baseline (face-face interview):

- Demographic characteristics of young person
- Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS), depression section (27,28)
- Revised Children's Anxiety and Depression Scale (29)
- Family Assessment Device (30)

- Cambridge Friendships Questionnaire (31)
- Employment, Education or Training in previous 4 weeks (NEET status)
- Short Warwick-Edinburgh Mental Wellbeing Scale (32)
- Modified Client Service Receipt Inventory (33)
- Child Health Utility 9D (34)

6.7 Follow-up assessments

The following participant data will be collected at 5 week follow-up (online with telephone support):

- Revised Children's Anxiety and Depression Scale (29)
- Family Assessment Device (30)
- Cambridge Friendships Questionnaire (31)

The following participant data will be collected at 10 &23 week follow-up (face-face interview):

- Revised Children's Anxiety and Depression Scale (29)
- Family Assessment Device (30)
- Cambridge Friendships Questionnaire (31)
- Employment, Education or Training in previous 4 weeks (NEET status)
- Short Warwick-Edinburgh Mental Wellbeing Scale (32)
- Modified Client Service Receipt Inventory (33)
- Child Health Utility 9D (34)

The primary outcome measure for the study is the Revised Children's Anxiety and Depression Scale (RCADS), which is a continuous self-rated questionnaire of depressive and anxiety symptoms, with six sub-scales, including for depression. The RCADS is used as the primary outcome measure for emotional disorders in Child and Adolescent Mental Health Services in England, as recommended in the Department of Health Children and Young People's Improved Access to Psychological Therapies (CYP-IAPT) programme. This results from this feasibility study could potentially be benchmarked against results from country-wide CAMHS services. The RCADS is also used as the primary measure in routine English interpersonal psychotherapy for adolescents practice – the depression scale is used at each session as part of routine IPT-A. We extended this to IPC-A in our pilot(35) and weekly RCADS-depression was a useful part of therapy and certainly acceptable to young people and therapists; and it was a highly useful primary outcome scale in the research evaluation. The chief investigator was part of a review of adolescent depression measures published in 2015 and we found the RCADS to have good psychometric properties(36).

We are using the observer-administered Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS) at baseline to test for presence of DSM depressive disorders. While not an outcome measure, we are using this to help us to describe the sample, in particular what proportion of participants have major depressive disorder. The K-SADS is the gold standard diagnostic interview schedule in adolescents, with excellent validity and reliability(28).

6.8 Attendance Data

Information about gender of therapist, attendance/non-attendance at planned therapy sessions, and location of sessions will be collected by therapists in both treatment arms.

6.9 Process Evaluation

Mixed-methods ethnographic process evaluation data will be collected to: (a) provide a description of how IPC-A and TAU are delivered, (b) assess implementation and theoretical fidelity to the IPC-A model over time, (c) observe how delivery is shaped by the context of differing service models, (d) identify any harms arising from treatment (including end of treatment) and (e) establish the extent and source of any contamination of the control arm.

Data collection methods will include:

- Site profile questionnaires (one per provider administered at the beginning and end of the trial)
- Observations of IPC-A training workshops and supervision
- Video/audio recordings of treatment sessions (both IPC-A and TAU; all treatment sessions will be recorded, subject to consent)
- Interviews with participants (young person and a parent/carer) from the IPC-A and TAU arms (n=20)
- Focus groups with youth mental health workers (one per provider)
- Focus group with wider stakeholders

Therapy sessions will be recorded in both arms (subject to consent of young people and therapists). A random selection (15% of therapy sessions in each arm) will be rated according to the IPC Audio Recording Rating Scale by one of the supervisors. A random selection of all sessions audiorecorded will be selected (therapists will not be able to select their 'best cases'), and selection of cases will be ongoing regularly through the study. Feedback will be given to the therapist from the supervisor for IPC cases, to aid continued development. This process will be ongoing through the study so such feedback is timely. Audiotaped sessions will also be subject to qualitative analysis by the post-doctoral process evaluation researcher. We accept that therapists in the TAU arm are less likely to submit sessions, but we shall regularly meet with teams and explain the importance of us rating sessions from both arms of the study - and that the aim of this is to check what TAU is, and whether it contains IPC - the purpose is not to rate the quality of their therapy.

6.9.1. Young Person/Parent Interviews: Twenty young people participating in the RCT (10 per arm) will be invited to take part in in-depth interviews to help us understand their experience of taking part. A separate interview will happen with a parent/carer (all parents whose child participates will be invited). These parents/carers will complete a separate consent form for this. Participants will be asked about their experience and views of the process of accessing help, the content of sessions, staff contacts had in addition to study therapy sessions, how they feel they have benefitted or not from receiving the intervention, the experience of ending therapy, and suggestions for improvement.

6.9.3 Staff Focus Groups: Focus groups will take place in participating services to understand staff perspectives of delivering the intervention. Discussions will focus on barriers and facilitators to successful delivery, experiences and views of intervention sessions, additional work required to support delivery of IPC, and suggestions for improvement. This

will include a discussion of how TAU is delivered and how this differs to IPC. Separate focus groups will take place for staff who delivered IPC and TAU.

6.9.4 Focus Group with Professional Stakeholders: At the end of the study, an additional focus group will be conducted with commissioners, education representatives, and service managers to review study findings and discuss implementation barriers and sustainability of implementation. The research team will contact managers within the organisations providing study treatment, NHS child and adolescents mental health, the local education authorities and commissioners in both counties towards the end of the study to explain the study and ask for people who would be willing to take part in the focus group.

6.10 Risk Protocol

The research practitioner will follow the Norfolk and Suffolk NHS Foundation Trust (NSFT) Research Department's set guidelines for assessing and managing risks. The guidelines are designed to help the research practitioner make appropriate risk management decisions. Risk assessment will consider, physical, psychological, emotional, sexual, financial risks alongside safeguarding issues. The research practitioner (who will be conducting the 1:1 quantitative interviews, where it is most likely that young people will reveal risks) is a registered mental health nurse (RMN) and so has experience of managing patients in distress and facing significant risks.

In the unlikely case that a young person (research participant) experience any distress during the consent process or during quantitative or qualitative interviews, the research practitioner will conduct a risk assessment of the situation and determine the appropriate measures to follow. Such measures include ensuring if participants are still happy to continue the assessment or interview, reassuring the client, allowing comfort breaks, or terminating the visit altogether. Where there are any concerns regarding a client's mental state, the respective Young Person's Worker (or other professional providing IPC or TAU, hereafter caller YPW) will be informed for the appropriate measures to be put in place. The researcher will make every effort to ensure that risks are minimised through liaison with the YPW (and parent or guardian where appropriate), before and after visits to young people. All participants will also be provided with contact details of the research practitioner and will likewise be advised to contact their YPW for any concerns they may have concerning the study.

It is important that unblinding is avoided where possible. If liaison is needed with the YPW and the assessment was conducted by the treatment-blind research practitioner before the final assessment, one of two processes will be used: a clinical member of the research team will liaise with the YPW; or the research practitioner will liaise with a named member of the YPWs team who will pass this information on.

The adopted procedures for assessing risk in NSFT's Research Department puts potential and actual risk situations into four main categories: Imminent, Urgent, Major and Emergent.

Imminent risk: There will be definite risk of harm if nothing is actioned immediately.

This will include when a participant informs the research practitioner that they have taken an overdose, serious self-harm, a serious accident or participant is immediate danger.

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Research practitioner will dial 999 for help immediately. This may involve the ambulance taking the young person to the A&E or the police getting involved. The chief investigator will be told at the earliest opportunity.

In these cases, a parent or guardian will be informed straightaway; given the strong risk to life, it is appropriate to over-ride any wish for confidentiality.

Urgent: Significant risk of harm if nothing is actioned within a very short time frame

(same working day).

Urgent risk includes situations when someone has been physically or sexually abused and are at significant risk if they remain where they are. It also includes when someone has a strong intent to take their life; or someone is hearing voices telling them to harm themselves or others, and they think they are likely to act on it.

The research practitioner will as soon as can do so contact the relevant agency(ies), this may include emergency services, GP, social services, crisis team, and the YPW's team. This will also require the research practitioner to contact their line manager or the Chief investigator where appropriate to discuss further actions.

In these cases, a parent or guardian will be told if the young person is under 16. If they are 16 or over, the research practitioner will try to persuade them for permission to contact a parent or guardian. If consent is withheld, the research practitioner will discuss this with the Chief investigator (or other clinical member of the research team).

Major: Significant risk of harm if nothing is actioned within a short time frame (days). This may include situations where a young person is expressing suicidal ideations, where the research practitioner has safeguarding concerns about the social environment. E.g. Risk of neglect, grooming (adult and child), exploitation, forced criminality, signs of abuse of participant or others, trafficking, domestic servitude/modern slavery, forced marriage, GFM etc. [NB Some risks may be categorised as Urgent].

The research practitioner will contact the relevant agency(ies); this may include emergency services, social services, crisis team, young people's team, and GP services. This will also require the research practitioner to contact their line manager or the Chief investigator (or other clinical member of the research team) where appropriate to discuss further actions.

In these cases, a parent or guardian will be told if the young person is under 16. If they are 16 or over, the research practitioner will try to persuade them for permission to contact a parent or guardian. If consent is withheld, the research practitioner will discuss this with the Chief investigator (or other clinical member of the research team).

Minor/Emergent: Potential or likelihood of risk of harm in the future if not action/support offered

These are potential risk factors and may not require urgent action, but when dealt with will prevent significant risks later. This may include some mild concerns about young people's

physical health, mental health, home environment, social network, and possibly some extreme views or ideologies. As young people involved in the study will not be receiving care from NSFT, the research practitioner will liaise with YPWs and their teams to discuss such risks.

Some important emergency numbers to note.

Police: 999 or non-emergency: 101

Fire brigade or Ambulance: 999

NSFT Switchboard: 01603 421421

7 TREATMENTS

7.1 Intervention: Interpersonal Counselling for Adolescents (IPC-A)

IPC-A is a brief manualised psychological intervention, derived from IPT. IPC helps clients to identify the reciprocal interaction between their current depressive symptoms and interpersonal relationships, with a focus on one of four domains: grief, relationship disputes, big changes and loneliness & isolation. The therapist works with the client to identify effective strategies to deal with their interpersonal problems, which should improve depressive symptoms.

IPC-A is an adapted form of IPC designed to suit the needs of adolescents. The intervention is delivered over three to six (30-60 minute) sessions, depending on participant needs. There is often (but not always) and assessment session first. IPC-A is based on the manual developed by Weissman et al. (37), with minor modifications to make it suitable for young people. IPC-A arm participants will also have access to standard health and care provision throughout their participation; the extent to which provision of IPC-A alters use of these services will be monitored using the Client Service Receipt Inventory (CSRI).

Staff to be trained as IPC-A therapists will receive two full-days of initial training. Prior to delivering IPC-A to trial participants, trainees will need to achieve adequate scores on audiotaped ratings of two therapy sessions for each of two cases, write an adequate reflective log of the two cases, and attend supervision regularly. Attendance at and costs of training will be recorded as a therapy cost.

If a greater number of therapists will put themselves forwards for the study than required in this feasibility RCT, we shall select trial therapists at random from volunteering potential therapists, separately in Norfolk and Suffolk. People who volunteer to be IPC therapists in Norfolk but who are not selected to take part in the study will be offered training in the next wave of training, if this trial is successful and services want to continue to train staff in IPC.

Randomisation to IPC will not preclude other interventions being offered to young people that the service thinks are appropriate, such as family work.

Randomisation to IPC will not limit the number of sessions of treatment given: if the clinical team think there should be more than 6 sessions, then they should provide this treatment, as per normal practice.

7.1.1 Supervision and adherence

Following successful completion of the training, therapists will receive monthly clinical supervision. Supervision will be provided in a group format to allow therapists to explore the theory and practice of IPC through engaging in shared discussion of real world cases. Each supervision session will last up to 1.5 hours. There are a number of trained IPC supervisors in the local area who have expressed an interest in supervising the delivery of the intervention within the trial, including three members of the research team (PW, VC and ST). If required, further appropriately qualified supervisors will be recruited from local CAMHS services. They will be trained to supervise IPC in accordance with the treatment manual by Viktoria Cestaro, IPT supervisor and trainer, who will have overall responsibility for co-ordinating the provision of clinical supervision.

All sessions will be audiotaped/videotaped (if young people consent). 15% of total sessions will be rated using the interpersonal counselling audiorecording rating scale by VC.

7.2 Control: Treatment as Usual

The control arm will receive ‘treatment as usual’ (TAU): the standard support provided by services. It is important to state there that unlike a lot of NHS treatment services, there is no accepted (let alone recognised gold standard) treatment as usual that is delivered systematically in non-specialist adolescent mental health services. So there is not a simple definition of treatment as usual; and staff are not told they must deliver a specific intervention. What is offered varies based on the ethos of the organisation, the background of the staff members and the problems/wishes of the young person and their family – it is often (but not always) what is loosely called counselling (active listening to help a young person talk about their problems). Discussions by the study team with professionals and managers of the organisations involved in the study about their TAU has led to a large range of answers including ‘we cannot really say what treatment as usual is in our service’. Indeed this study aims to address the issue of treatment as usual in two ways: the process evaluation will find out more about what TAU actually is (especially important if we find zero difference between outcomes); the study is the first test of a manualised formal therapy in this setting, and will test whether IPC could be better than TAU. We shall describe below some of the treatment approaches used by some professionals in the partner organisations.

It is also important to state that participants will not be denied access to any treatment option available as part of current provision. It is also crucial to state that professionals treating young people in the study have received safeguarding and risk assessment training as part of their jobs, and will continue to follow standard escalation procedures if they have concerns, and this study will not change this. However staff providing individual support to TAU participants will not have attended any IPC-A training and will not receive any IPC-A supervision, to minimise contamination. Staff to be trained as IPC-A therapists will be required to contract not to discuss any aspect of their training or supervision with colleagues

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not trained in IPC-A. The interventions that constitute TAU for this group will be monitored via the CSRI and process evaluation. Randomisation to TAU will not limit the number of sessions of treatment given: if the clinical team think there should be more than 6 sessions, then they should provide this treatment, as per normal practice.

In Suffolk County Council, support is provided by a member of the Early Help team or NEET (not in education, employment or training) team (Family Support Practitioner or Young Person's Worker). Many practitioners work with young people using the Signs of Safety approach. The Signs of Safety approach is a strengths-based, safety-organised approach grounded in partnership and collaboration, originally developed for child protection cases. At the heart of the approach is a risk assessment framework which is designed to be used together with the families and their support people. A comprehensive risk assessment, assessing for danger and strengths/safety is incorporated within the one page Signs of Safety assessment protocol. Practitioners can also utilise series of tools which have been created and designed to get the children's voice and get children to talk about their experiences. Once a plan has been agreed, practitioners meet with families weekly, or as frequently as they feel is appropriate, until the safety goals have been met. 4YP uses a counselling approach to young people.

In Norfolk, Point 1 offers counselling, themed group sessions, advice and information for parents/carers, and telephone support. Early Help Family Practitioners offer direct work to children and young people and their families which may focus on building self-esteem, supporting access to other services, supporting re-integration into education (if applicable) and working with the young person and families to understand and prevent risk. Treatment options offered vary by team and locality but include monitoring, active listening, group psychoeducation, and guided self-help using online resources.

Although the practitioners delivering these services in both IPC and control arms are not qualified mental health professionals, they may consult with or offer a joint appointment with a mental health professional (e.g. primary mental health worker or clinical psychologist) or signpost/refer the young person to other local services.

7.2.1 Supervision and adherence

Supervision will be provided as per usual service protocols. All sessions will be audiotaped/videotaped (if young people consent). 15% will be rated using the interpersonal counselling audiorecording rating scale by VC.

8 STATISTICS AND DATA ANALYSIS

8.1 Sample size calculation

60 eligible participants will be randomised. The sample size is not based upon estimation of efficacy but is in keeping with published suggestions (e.g. 32) and

believed to be practically possible within the limits of the project. Further, it should enable us to assess rates of recruitment and retention to a reasonable degree of precision. Assuming an attrition rate of around 20%, a sample of 60 would provide a 95% confidence interval of width 20% (i.e. +/- 10%). For a recruitment rate of around 50% the interval width would be around 25% (i.e. +/- 12.5%).

8.2 Planned recruitment rate

The planned recruitment period for the feasibility RCT is Jan 2020 – December 2020 (12 months). In order to recruit the target 60 participants, it would be necessary to recruit an average of five participants per month across all sites; this is likely to be lower in early stages of the study and higher in later stages, as more therapists complete training. We aim to have six IPC therapists trained in each of Norfolk and Suffolk, and they would each need to treat two-three young people with IPC. With IPC taking around 10 weeks (taking into account holidays), this means that on average, they will have one ongoing IPC case for half of this recruitment year.

8.3 Statistical analysis plan

Recruitment and retention rates will be estimated with 95% confidence intervals (CIs). Assuming sufficient information, time until drop-out will be analyzed using 'time-to-event' methods, i.e. in an effort to identify baseline factors likely to be related to drop-out. The proposed primary outcome measure for the definitive RCT is the RCADS depression score at 10 weeks. Although the proposed study is not designed to assess efficacy, the mean between-group difference will be estimated using a general linear model including baseline RCADS depression score and treating therapist as a random effect. A 95% CI will be constructed to assess whether the treatment benefit is feasibly greater than the minimal clinically significant difference, i.e. whether or not it is included within the CI. A similar approach will be undertaken for the secondary outcome measures. The rate of completion of each outcome measure will be reported. If appropriate, depending on the proportion of missing values, multiple imputation will be undertaken and between-group differences re-estimated as a sensitivity analysis. Further parameters, such as within group variation, needed for the design of a subsequent full-scale trial, will also be estimated.

A Statistical Analysis Plan (SAP) will be written in accordance with Norwich CTU guidance and approved by the independent data monitoring committee prior to any formal statistical analysis.

8.4 Economic evaluation

As this is a feasibility study, it will not be possible to demonstrate the cost-effectiveness of the intervention because the study will not be powered to demonstrate effectiveness. However, we shall collect information to inform the design of the economic evaluation planned for the future definitive trial. This will yield useful information, such as the likely cost of the intervention and key components of resource use. It will also inform the design of health economic data collection instruments in the future fully-powered trial.

The resources required to provide the interventions (IPC and TAU) will be recorded. These would include: training; ongoing clinical supervision; staff time required to provide the

intervention; consumables and materials required; any other necessary expenditure. Each session offered (and its location) in both arms will be explicitly recorded. Recording of all events will be built into the design of the study and study CRF. These will be combined with appropriate unit cost data to provide an estimate of the cost of providing IPC-A. It will also be possible to conduct scenario analyses to estimate changes in the cost of provision if any assumptions about how the service is provided are changed. It will be important to measure any resources related to participants' mental health in both the intervention and control groups. This will be conducted by means of a modified CSRI conducted at baseline, 10, and 23 weeks. The time frame requested for the baseline and 10 week CSRI will be any use of services in the last 10 weeks. For the 23 week assessment the time frame will be the last 13 weeks. To reduce burden on participants the a priori aim is to make the modified CSRI as simple as possible but to still capture relevant and important service use. Any modifications made will be made in consultation with other ICALM investigators. The CSRI will be collected by means of a face-to-face interview.

Resource use data will be analysed to highlight any potential areas of differences between trial arms in use of NHS and social care services, including emergency department attendances. The measure of health related quality of life (HRQoL) used in this study will be the CHU-9D. One important outcome of the feasibility study will be an assessment of the suitability of this instrument for use in a future full scale trial. This will be assessed by looking at measures of correlation with other outcome measures.

8.5 Process evaluation

A linguistic ethnographic methodology (39) will be employed to analyse how relationships, roles and moments of intervention delivery are organised within the contexts of delivery. This will be achieved by: 1) setting out macro, meso and micro contextual features relevant to implementation within each provider; 2) targeting where likely tensions in implementation are likely to occur at each contextual level; then 3) searching for 'disruptions' to targeted activities involved in intervention delivery; and 4) considering the consequences of these disruptions for how the intervention was implemented and the implications of these for scaled up implementation in a future definitive trial.

The linguistic ethnographic process evaluation methodology combines strengths of linguistics and ethnography to systematically investigate human behaviour within context. A particular strength is that it provides methodological tools for empirically exposing relationships between talk, non-verbal behaviour and the contexts in which such behaviour is produced. This is particularly helpful for evaluating the interpersonal counselling intervention, which trains local authority teams to communicate effectively with adolescents. The process evaluation design, using linguistic ethnography, is an approach that has been developed by Co-Applicant Murdoch(40) to facilitate detailed investigation of complex healthcare interventions, and already applied in a range of research projects, including an ongoing study of a counselling intervention delivered in schools to support young people with borderline personality disorder.

To manage the quality and range of data collected as part of the process evaluation, analysis will involve working laterally across data types. We will seek to provide a broad

description of intervention delivery but, instead of allocating equal time to the analysis of each case, we will focus on identifying 'telling cases', triangulating and looking for connections between data. The analysis of qualitative data will be iterative, moving between data collection and data analysis to test emerging theories. Care will be taken to identify and follow up deviant cases which do not fit into emerging theories. Emerging theories and the relationship of the data to the conceptual literature underpinning the intervention will be discussed and refined at team meetings throughout the research.

Researchers' field notes from observations of training and supervision of IPC-A therapists will be analysed thematically to provide a detailed description of process and content of staff training and supervision. Interviews with individual pupils, and focus groups with staff and stakeholder will be transcribed verbatim and thematically analysed with the aid of NVivo software. For intervention arm participants, we will then develop a coding scheme to evaluate how the process and content of IPC-A as delivered by the youth mental health workers have functioned from the participants' perspective. In the control arm, we will assess how participants experienced the treatment as usual provided by their youth mental health worker and any other sources of support used. A constant comparison approach will be adopted, working iteratively between data obtained from different interviewees within and between implementation sites.

A randomly selected sample of 15% of recorded IPC-A and TAU sessions will be rated against the IPC-A adherence checklist (used in the pilot and approved by IPT-UK) by a member of the research team. These ratings will be used to monitor fidelity to the IPC-A treatment model and to assess the degree of contamination. If contamination of the TAU arm is identified, data generated through observations, interviews and focus groups will be used to explore the mechanisms by which contamination occurs and how this might be mitigated against in a future trial. In addition, a purposive sample of 5 hours of extracts of recorded IPC-A sessions will be transcribed according to Jefferson conventions and subject to conversation analysis in order to investigate how the intervention plays out in terms of interactional sequences.

By framing the analysis of intervention implementation within a macro, meso and micro contextual framework, we will be able to make the transition from the identification of routines and patterns of use in the specific services participating in the current study, to theoretical explanations of how different structural relations and mechanisms of the intervention organise moments of delivery, which then impact on specific outcomes. In drawing case comparisons across participating services, we will develop hypotheses about why the intervention is linked to outcomes which we can test in a future definitive trial. This may lead us to identify factors which are plausibly and/or consistently related to successful or unsuccessful delivery of the components of the intervention. Emerging theories and the relationship of the data to the theory underpinning IPC-A will be discussed and refined in team meetings throughout the research.

9 DATA MANAGEMENT

9.1 Data collection and storage

Data will be collected and stored in accordance with the Data Protection Act (2018) and Good Clinical Practice Guidelines. The Chief Investigator will be the data custodian. Quantitative data will be captured using standardised assessment tools as detailed in section 7. Hard copies of these assessment measures will be completed by the research practitioner and stored securely in locked filing cabinets at Trust premises. Data on the young person's attendance will be requested from the therapy teams. Interviews, focus groups and observations of intervention delivery will be (audio/video) recorded and transcribed verbatim. We shall be using a transcription service that the team have worked with in the past (https://catranscriptionservices.wordpress.com/) and they will have to complete a confidentiality agreement. This will include permanently destroying audiofiles after transcription and destroying the transcription after it has been sent back to the ICALM team. Data will be transferred securely. Each participant will be allocated a study identification code on entry to the study which will be used to identify data relating to that participant. Consent forms and other documents containing person-identifiable information will be stored separately from participant data. Personally-identifiable data will be destroyed 6-12 months after the end of the study, and anonymous data will be destroyed 10 years after the end of the study. Recordings and transcripts will be stored securely on Trust and/or University computer systems. If data need to be transported, password-protected encrypted memory sticks or the NHS Mail secure file transfer system will be used.

All data will be entered into the study's database by the research practitioner. Periodically and at database lock the data will be further validated for errors and inconsistencies. The database will be password protected to prevent unauthorised access and will only be accessible to members of the research team and authorised representatives of external regulators.

9.2 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections. Participant consent for this will be obtained as part of the informed consent process for the trial.

9.3 Archiving

The investigators agree to archive and/or arrange for secure storage of trial materials and records for 10 years after the close of the trial unless otherwise advised by the Sponsor.

10 ETHICAL AND REGULATORY CONSIDERATIONS

10.1 Research Ethics Committee (REC) review and reports

Before the study begins, approval will be sought from a REC for the protocol, participant information sheets, informed consent/assent forms and other relevant documents. The study will not begin until REC and all other regulatory approvals have been received. Substantial amendments that require review by REC will not be implemented until the REC grants a

favourable opinion. All correspondence with the REC and HRA will be retained in the Study Master File. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. The Chief Investigator will notify the REC of the end of the study and within one year after the end of the trial, the Chief Investigator will submit a final report with the results (including any publications/abstracts) to the REC.

The research raises a number of ethical issues that will be fully addressed in the application for ethics approval.

The involvement of children and young people in research requires special ethical consideration. For participants under the age of 16, informed consent will be sought from an adult with parental responsibility. However, no young person under the age of 16 will be included in the trial unless they themselves also assent to take part. We will work closely with the study's Youth Advisory Group to ensure that all information sheets, consent and assent forms are written in way that can be easily understood by the target age group. Confidentiality (and it limits) will be clearly explained to young people during the informed consent process. Research procedures will be conducted in a place familiar to the young person (e.g. their home address, youth service base or alternative community venue according to the young person's preference) and participants will be invited to ask a parent/carer or other trusted adult to attend appointments with them for support if they wish.

Participation in the research will involve thinking and talking about topics that some young people might find distressing, including difficult emotions and problems in their relationships with others. To reduce the risk of distress, research staff and those delivering the intervention will be trained in how to introduce potentially difficult topics sensitively, how to manage distress if it occurs and safeguard the safety and wellbeing of participants. While our pilot work suggests that the intervention is safe and well accepted, the possibility of unintended consequences remains. All adverse events will be fully documented and serious adverse events will be reported to the Sponsor and DMC. The DMC will have the authority to initiate an interim analysis if there are concerns about the research causing harm and to stop the study prematurely if deemed necessary.

The research will involve randomising some participants to receive IPC-A in place of the standard treatment offered by participating non-specialist services. Since IPC-A has not yet been formally trialled, we cannot be sure that it will be effective. However, as outlined in section 1 of this proposal, there are currently no interventions for adolescent depression/low mood which have been demonstrated to be effective in the context of these non-specialist services. Potential participants will be given information about IPC-A and standard treatment and will be supported to make an informed decision on whether to take part in the trial or access treatment as usual. Young people who choose to participate and continue to require support for low mood/depression after receiving IPC-A will continue the standard treatment pathway and have access to all currently available interventions. There is the possibility that randomisation will lead to disappointment among young people randomised to the treatment as usual group or their parents. This will be mitigated against by emphasising during the informed consent process that this is a new treatment that we cannot be sure is preferable to treatment as usual.

10.2 Peer review

The study protocol has been peer reviewed by independent experts as part of the NIHR funding application process.

10.3 Public and Patient Involvement

This proposal has been informed by two PPI events attended by 14 young people, most with personal experience of accessing mental health services. The first event was held at a local school and the second with members of Suffolk Children & Young People, Action and Transformation (CAT) group. The young people we consulted stressed the inadequacy of current mental health provision for young people and supported the idea of extending access to treatment by training existing staff working with young people to deliver IPC-A. They told us that knowing workers have appropriate training is important to building trust and that they would prefer to be treated somewhere familiar to them rather than attend a specialist clinic.

We intend to form a Youth Advisory Group for this study made up of young people with personal experience of low mood to be involved in key decisions regarding the conduct of the trial, interpretation of the results, and dissemination of the findings. There will be two sub-groups, one based in each of Norfolk and Suffolk, each of 4-5 members. Involving this number of young people will increase the breadth of experience and skills, allow for group members to support and encourage each other, while ensuring that all members are able to contribute meaningfully; it will also allow for attrition, as young people choose to leave the group. Members will be recruited from among existing members of Norfolk and Suffolk NHS Foundation Trust's research involvement panel (INSPIRE) and users of participating services.

The Youth Advisory Group will be facilitated by Susie Tulk who will be the dedicated PPI lead co-applicant for the trial. Susie Tulk is a Co-Production Advisor who works as part of Suffolk County Council's Engagement Hub. She is passionate about empowering young people to have a voice in shaping and evaluating the services that impact them, and is skilled in facilitating the engagement of young people with mental health needs. Susie will act as a point of contact for the young people involved and ensure their welfare by offering emotional support and signposting to appropriate services if young people need further support as a result of the sensitive nature of the research. In addition, group members will receive on-going training and support via INSPIRE.

The Youth Advisory Group will meet regularly throughout the trial; we intend to be flexible about the meeting times, which will be arranged outside of school/college hours when possible. We shall offer videoconferencing as a way to attend meetings, if preferred. In addition, we will seek group member's views on their preferred methods of communication outside of meetings, which may include text, phone or online communication, to enable them to input in a way that suits their needs and preferences. Two representatives of the Youth Advisory Group will be invited to sit on the trial steering committee (TSC). They will be supported by Susie Tulk to prepare for and attend these meetings.

Based on our experience in previous trials, we anticipate that involving young people with relevant lived-experiences as members of the research team will enhance our ability to successfully recruit and retain participants, and to effectively communicate the study's findings to a broad range of stakeholders. The Youth Advisory Panel will be involved in hosting the public dissemination event and in preparing reports of the findings for trial participants and the public.

10.4 Protocol compliance

Every effort will be made to ensure protocol compliance. Accidental protocol deviations will be fully documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol which are found to frequently recur will be acted on immediately and could potentially be classified as a serious breach.

10.5 Notification of Serious Breaches to GCP and/or the protocol

A "serious breach" is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the trial; or
(b) the scientific value of the trial

The sponsor will be notified immediately of any case where the above definition applies during study conduct phase.

10.6 Financial and other competing interests for the chief investigator and committee members for the overall trial management

The co-applicants have no competing interests that might influence trial design, conduct, or reporting.

All members of the trial management and oversight committees will be required to disclose any potentially competing interests including (but not limited to):

- ownership interests that may be related to products, services, or interventions considered for use in the trial or that may be significantly affected by the trial
- commercial ties requiring disclosure include, but are not restricted to, any pharmaceutical, behaviour modification, and/or technology company
- any non-commercial potential conflicts e.g. professional collaborations that may impact on academic promotion.

These will be recorded by the Study Co-coordinator and reported in all publications resulting from the study.

10.7 Indemnity

The sponsor, Norfolk and Suffolk NHS Foundation Trust, is covered by NHS Indemnity arrangements for any negligent harm caused by the design and conduct of the research study as a non-clinical trial once HRA and Ethical approval has been obtained. Any activity taking place on non-NHS sites will be covered by individual organisational indemnity arrangements.

10.8 Amendments

The responsibility for decisions to amend the protocol and for deciding whether an amendment is substantial or non-substantial will be the Chief Investigator's. Amendments will be approved by the REC prior to implementation. Once approved, amendments will be communicated to all trial personnel via email correspondence and team meetings. A version tracking document will be used to track amendment history and allow staff working on the trial to identify the most recent version of the protocol and other documents.

10.9 Post trial care

The sponsor will not continue to provide any intervention to participants (beyond those offered as part of standard care) after the study is completed.

10.10 Access to the final trial dataset

All co-applicants will have access to the full dataset. Other individuals will be able to request access to trial data and these will be considered, and approved in writing where appropriate, after formal application to the TSC, in accord with Open Science principles. Participants will be asked explicitly to consent to this.

11 SAFETY REPORTING

11.1 Definitions of harm

Adverse event definitions to be used in this study are given in Table 1.

Table 1. Adverse event definitions

Adverse Event (AE)	Any untoward medical occurrence in a participant (which does not necessarily have a causal relationship with the trial treatment). Adverse events include: • an exacerbation of a pre-existing illness • an increase in the frequency or intensity of a pre-existing episodic event or condition • a condition (regardless of whether PRESENT prior to the start of the trial) that is DETECTED after trial intervention administration. (This does not include pre-existing conditions recorded as such at baseline.) • continuous persistent disease or a symptom present at baseline that worsens following administration of the trial treatment
Adverse Reaction (AR)	Any untoward and unintended response to a trial intervention.
Unexpected Adverse Reaction (UAR)	An adverse reaction, the nature or severity of which is not consistent with the applicable intervention information.
Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR)	Any AE or AR that at any dose: • results in death • is life threatening* • requires hospitalisation or prolongs existing hospitalisation** • results in persistent or significant disability or incapacity • is a congenital anomaly or birth defect • or is another important medical condition***
* the term life threatening here refers to an event in which the patient is at risk of death at the time of the event; it does not refer to an event that might hypothetically cause death if it was more severe (e.g. a silent myocardial infarction) ** Hospitalisation is defined as an in-patient admission, regardless of length of stay, even if the hospitalisation is a precautionary measure for continued observation. Hospitalisation for pre-existing conditions (including elective procedures that have not worsened) do not constitute an SAE *** Medical judgement should be exercised in deciding whether an AE or AR is serious in other situations. Important AEs or ARs that may not be immediately life threatening or result in death or hospitalisation, but may seriously jeopardise the participant by requiring intervention to prevent one of the other outcomes listed in the table.	

11.2 Researcher responsibilities relating to safety reporting

When an adverse event occurs, the member of the study team who first becomes aware of the adverse event must assess whether or not the event is serious using the definition given in Table 2. If the event is classified as serious, the team member must notify the Study Coordinator within 1 working day and complete an SAE form. The completed and signed SAE form should be emailed to the Study Coordinator (or delegated person in the absence of the Study Coordinator).

All adverse events assessed as non-serious, whether expected or not, should be recorded in the participant's medical notes (if applicable) and recorded on the study database within 7 days.

11.3 Research practitioner responsibilities relating to safety reporting

The research practitioner will review the SAE form and disseminate to the CI and and sponsor representative within 72 hours of being informed. The DMC and REC will be informed by the Study Coordinator of SAEs periodically unless the CI or sponsor representative escalates the SAE or deems necessary.

11.4 Study co-ordinator responsibilities relating to safety reporting

The Chief Investigator (or a clinically qualified delegate) will review all SAE reports received. The CI must assess the causality of all serious events or reactions in relation to the trial intervention using the definitions in Table 2. If there is at least a possible involvement of the trial procedures (including any comparators), the investigator and sponsor must assess the expectedness of the event. If a SAR is assessed as being unexpected it becomes a SUSAR (suspected, unexpected, serious adverse reaction). The CI is responsible for the reporting of SUSARs and other SARs to the REC as appropriate. Fatal and life threatening SUSARs must be reported to the competent authorities within seven days of the Chief Investigator becoming aware of the event; other SUSARs must be reported within 15 days.

Table 2. Causality definitions

Relationship	Description	Event Type
Unrelated	There is no evidence of any causal relationship	Unrelated SAE
Unlikely to be related	There is little evidence to suggest that there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial medication). There is another reasonable explanation for the event (e.g. the participant's clinical condition or other concomitant treatment)	Unrelated SAE
Possibly related	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial medication). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition or other concomitant treatment)	SAR
Probably related	There is evidence to suggest a causal relationship and the influence of other factors is unlikely	SAR
Definitely related	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.	SAR

12 DISSEMINIATION

12.1 Dissemination plan

The primary output of the research will be the design of the subsequent trial. The TSC will assess the trial against the following criteria and make recommendations regarding the suitability of the proposed design for the full-scale trial.

a) recruitment rate is at least 80% of target

b) at least 70% of those randomised to receive the intervention attend at least three therapy sessions within the 10 week treatment window

c) follow-up assessments are completed by at least 80% of participants at 10 weeks and 70% of participants at 23 weeks

d) at least 80% of IPC treatment sessions reviewed meet treatment fidelity criteria

e) contamination of the control arm can be sufficiently limited for individual randomisation to be justified

f) the mean RCADS depression scores of the IPC-A and TAU groups at 10 weeks are indicative of a clinically significant difference in depression (3 points).

If the above criteria are met, we will apply for funding to progress to a multi-site, assessor-blind, RCT of the effectiveness and cost-effectiveness of IPC-A in comparison to TAU for adolescents presenting to non-specialist services with depressive symptoms, informed by our feasibility results. The decision to include clear criteria on which to base the decision of whether to progress to a definitive RCT as planned was based on RDS guidance. However, in line with the CONSORT statement for randomised pilot sand feasibility trials (41), these criteria will not be treated as deterministic thresholds for progression. Instead, they will be used to guide the decision about the feasibility of the proposed design and practicality and value of progressing as planned. If problems are encountered in this feasibility study that would make our proposed definitive trial design unfeasible, we will first look for solutions to overcome the barriers encountered. If suitable solutions to these problems cannot be identified, we will consider alternative study designs. For instance, if contamination cannot be sufficiently limited for individual randomisation to be justified then a cluster randomised design will be considered.

If proven effective, training for youth mental health workers to deliver IPC-A could be implemented nationally. This would facilitate rapid expansion of the therapy workforce, dramatically increasing access to evidence-based treatment for adolescent depression. The understanding of implementation across contexts generated by the process evaluation nested within the feasibility trial will be invaluable to successful translation. IPC-A complements the current CYP-IAPT programme of training staff in brief-evidence based interventions, and could be integrated within this programme. Norfolk and Suffolk services are active members of the South-East and London CYP-IAPT collaborative and have been successful in implementing the programme locally. We would use these established links to ensure IPC-A is successfully translated from research to practice.

Findings of the feasibility trial will be disseminated to trial participants, commissioners, service managers, service users and their parents, clinicians and academics. Dissemination vehicles will include regular study newsletters, a public dissemination event, publications in peer-reviewed journals and presentation at scientific conferences. Additionally, we will disseminate the findings through networks of which the research team are established members, including the East of England Mental Health Clinical Network, the Future in Mind steering groups for the East of England, RCPsych, BPS, IPT-UK and CYP-IAPT. Study results will also be shared with the National Children and Young People's Mental Health improvement team.

We shall work with our young advisors to disseminate findings to the public in a way that is accessible to young people, perhaps using YouTube/Instagram/other social media. Young people will be involved in hosting our public dissemination event.

Suffolk County Council have an established communication cascade associated with their Emotional Wellbeing Transformation Plan to improve access to mental health support and interventions for children and young people. This includes the Suffolk Parent Carer Network, Parents and Children Together, Suffolk Assembly of Youth, Suffolk Community Foundation – all of which are actively participating in disseminating information to their networks.

All service review and development associated with CYP emotional wellbeing and mental health is reported through the Children's Emotional Wellbeing Group (CEWG) to the STP Boards covering the county and the associated Alliances and associated governance within the developing Integrated Care Systems (Local Development Board for Waveney). The CEWG is a multi-agency, commissioner and provider Forum responsible for the oversight and delivery of the Transformation Plan for CYP mental health. Sharon Jarrett, one of the study PIs, is a member of the CEWG, putting us in a good position to utilise this for dissemination.

The CEWG report to the organisational senior leaders through their Governance structures to ensure that they are sighted on initiatives and will then incorporate good practice that is identified. This includes linking in to CYP and system-wide workforce development – a key home for the findings of this research.

Improving mental health for all ages is one of the four priorities for Suffolk Health and Wellbeing Board with at least quarterly reports on progress against transformation initiatives as a requirement. Representatives from the CEWG attend the regional clinical network meetings of Future in Mind and associated working groups, linking in with commissioners across the Eastern region to share good practice, including liaison with Anna Freud centre, CYP IAPT and educational settings developments.

The CEWG also work closely with Suffolk HealthWatch who are an active partner in our CYP mental health work who cascade information and collate feedback and have a voice nationally to raise the profile of the work we are doing. Susie Tulk, our PPI lead, has strong links with youth councils and also works closely with the Suffolk parent/carer network. She also facilitates other PPI groups of young people (SEND YP network and Care leavers) through schools and colleges. This puts us in a strong position to discuss and disseminate results.

Readily accessible information for the public, young people, parent, carers and practitioners is held on a number of web-based portals, including The Source for young people, Emotional Wellbeing Gateway, Healthy Suffolk, HealthWatch Suffolk.

The Norfolk members of the team have ongoing strong links with children's and young people's services across Norfolk, and will use these networks to disseminate results. Norfolk commissioners actively support this research and fully support implementing learning from this study. They have also suggested that the intervention, if feasible, acceptable and effective would be integrated in to local CYP MH transformation.

PW has strong links with a charity called Innovations for Young People's Mental Health (iYPMH), which strongly support the development of IPC. This charity is supporting the bringing together of disparate groups, including researchers, primary care, schools,

commissioners, young people and families, to take forwards innovations in YP mental health. This will include support in dissemination to wide-ranging audiences and implementation.

12.2 Publications

The following key publications are planned. All individuals named as study team members above will be credited as authors of these publications provided they meet the authorship criteria. The proposed primary author is stated below. Other authors will be listed according to the size of their contribution to that particular paper (in the case that two or more authors have contributed equally, their names will be listed alphabetically), with the exception that the last author will be PW if not primary author. The order of authors should be proposed by the primary author and agreed by the TMG.

- The study protocol. Primary author: PW
- Main trial outcome paper covering key feasibility outcomes and health economic data. Primary author: PW
- Report of process evaluation findings. Primary author: JM

It is anticipated that a number of other publications may be produced based on study data. Proposals for additional publications will be circulated to all study team members, who will be asked to comment, offer participation and indicate the extent of their availability to participate. The TMG will review proposals and comments. The presumption is that all proposals will be agreed provided the proposed authorship has sufficient resources to deliver the study, appropriate ethical permission is obtained, and unless there are perceived problems with overlap with ongoing projects or lack of availability of data.

The agreed primary author of each manuscript is responsible for ensuring:

- timely circulation of all drafts to all co-authors during manuscript development. The final draft should be circulated to all co-authors (and the TMG) at least 14 days prior to the proposed submission date
- timely circulation of reviewers' comments to all co-authors
- incorporation of comments by authors and reviewers into subsequent drafts

12.3 Authorship and acknowledgments

In line with International Committee of Medical Journal Editors and NSFT guidelines, only individuals who meet **all** of the following criteria will be named as authors on publications resulting from the study:

- conception and design, or acquisition of data, or analysis and interpretation of data
- drafting the article or revising it critically for important intellectual content
- final approval of the version to be published

The Chairs and Independent members of the TSC and Data Monitoring and Ethics Committee (DMEC) will be acknowledged, but will not qualify for full authorship, in order to maintain their independence. The following should also be acknowledged:

- The funders (NIHR)

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- All study participants, including therapy staff involved in delivering the intervention.
- Research staff who do not meet the above criteria for authorship, named individually if they give permission.
- Members of the Youth Advisory Panel who do not meet the criteria for authorship, named individually if appropriate and they give permission.

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