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Interpersonal counselling for adolescent low mood

Submission date	Recruitment status
16/12/2019	No longer recruiting
Registration date	**Overall study status**
31/12/2019	Completed
Last Edited	**Condition category**
24/01/2024	Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Interpersonal Counselling (IPC) is a talking therapy for depression designed to be provided by staff who are not qualified mental health professionals. A version of IPC designed for young people (IPC for Adolescents: IPC-A) has been developed. Early work suggests that young people like IPC-A and it leads to reduced depressive symptoms. However, it is not known whether IPC-A is better at reducing depression symptoms than the normal support provided by non-specialist services, so the researchers to do a study to find out. Before they can do this, they need to run a smaller 'feasibility' study to answer questions about whether a larger study would be possible. This feasibility study will involve training local authority and charity staff members (without formal mental health qualifications) as IPC-A therapists.

Who can participate?
Young people aged 12-18 years seeking help for depression symptoms

What does the study involve?
Young people who consent are randomly allocated to receive either IPC-A or the support young people currently receive ("treatment as usual") because, in the future trial, the researchers will need to do this to test in a fair way whether IPC-A is better than the support young people currently receive. All participants are invited to meet with a researcher to answer questions about their mental health and relationships, and are asked to complete questionnaires regularly during the study. Some participants are also invited to take part in interviews to help the researchers understand their experience of taking part. The results of the study will be shared with young people, participating services and commissioners, and will be used to design a future study testing whether IPC-A delivered by this staff group is better than usual support at reducing young people's depressive symptoms.

What are the possible benefits and risks of participating?
Participants will receive a practical treatment for low mood (IPC-A) that would not otherwise be available to them. This treatment has been adapted from IPT which has been shown to be effective in other populations compared to TAU. However, because this revised version (IPC-A) has only recently begun to be explored, the researchers cannot guarantee that the therapy will benefit participants. Participants following the intervention will have access to usual care as

suggested through typical care pathways. 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 pilot work suggests that the intervention is safe and well accepted, the possibility of unintended consequences remains. All adverse events will be fully documented.

Where is the study run from?
Norfolk and Suffolk NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2019 to September 2022

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
268403

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 44035, IRAS 268403

Study information

Scientific Title
Interpersonal counselling for adolescent depression delivered by youth mental health workers without core professional training: a feasibility randomised controlled trial

Acronym
ICALM

Study objectives
It will be feasible to implement the IPC-A intervention and evaluate its effectiveness and cost-effectiveness in a randomised controlled trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/12/2019, East of England - Cambridge South Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; Tel: +44 (0)207 104 8134; Email: nrescommittee.eastofengland-cambridgesouth@nhs.net), ref: 19/EE/0300

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adolescent depression

Interventions
The ICALM study investigates the Interpersonal Counselling for Adolescents (IPC-A), a brief manualised psychological intervention, which 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 Interpersonal Counselling (IPC) designed to suit the needs of adolescents. The intervention is delivered over three to six (30-60 minute) sessions, depending on participant needs. This trial will investigate if IPC-A helps to reduce depressive symptoms of young people who participate in the study. As this is a feasibility study, we would also like to know if the methods employed in this trial can be used in a future larger trial.

To ensure we evaluate study outcomes in a fair and unbiased manner, young people who consent will be randomly allocated to receive either IPC-A or the support young people currently receive ("Treatment as Usual"[TAU]).
Eligible young people will complete a baseline assessment with the study research practitioner, including the other measures. Once the baseline assessment is complete, they will be randomly allocated to receive either IPC-A or TAU. 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. The Data Management Team at the Norwich Clinical Trials Unit (CTU) will manage allocation 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. 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).
All participants will be invited to meet with a researcher to answer questions about their mental health and relationships, and will be asked to complete questionnaires regularly during the study. Some participants will also be invited to take part in interviews to help understand their experience of taking part. All participants will be invited to complete a brief online assessment at 5 weeks post-randomisation and to take part in follow up assessments with a member of the research team at 10 and 23 weeks post-randomisation.

Intervention Type
Behavioural

Primary outcome(s)
This is a feasibility trial, and as such the primary output will be the design of the subsequent definitive trial. A number of feasibility outcomes will be assessed to facilitate this output, including recruitment and retention rates, fidelity of intervention implementation, degree of

contamination of the control arm, suitability of the proposed measures, and acceptability of IPC-A from the point of view of young people, parents, staff and other key stakeholders.
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:
1. Recruitment rate is at least 80% of target
2. At least 70% of those randomised to receive the intervention attend at least three therapy sessions within the 10-week treatment window
3. Follow-up assessments are completed by at least 80% of participants at 10 weeks and 70% of participants at 23 weeks
4. At least 80% of IPC treatment sessions reviewed meet treatment fidelity criteria
5. Contamination of the control arm can be sufficiently limited for individual randomisation to be justified
6. 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)

Key secondary outcome(s))
1. Presence of DSM depressive disorders measured using the Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS), depression section at baseline
2. Quality of family relationships of participants measured using the Family Assessment Device (FAD) at baseline, 5, 10, 23 weeks
3. Quality of peer relationships of participants measured using Cambridge Friendships Questionnaire (CFQ) at baseline, 5, 10, 23 weeks
4. Levels of inactivity amongst young people who are not in work, education or training measured using Employment, Education or Training in previous 4 weeks (NEET status) at baseline, 10, 23 weeks
5. Mental wellbeing of the research participants measured using the Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS) at baseline, 10, 23 weeks
6. Information on service utilisation, income, accommodation and other cost-related variables using the Modified Client Service Receipt Inventory(Modified-CSRI) at baseline, 10, 23 weeks
7. Health-related quality of life measured using the Child Health Utility 9D at baseline, 10, 23 weeks

Completion date
30/09/2022

Eligibility

Key inclusion criteria
Young people receiving treatment:
1. Aged 12-18 years
2. Seeking help for low mood (as the primary presenting difficulty)
3. Able to provide written informed consent or, for under 16s, written informed assent and parent/guardian consent
4. Of a level of illness where they would normally receive treatment from the service

Please note: this age range of 12-18 only applies to the young people receiving IPC. There will not be an age eligibility criterion for therapists/parents

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 years

Upper age limit
18 years

Sex
All

Total final enrolment
16

Key exclusion criteria
Young people receiving treatment:
1. Learning disability necessitating non-mainstream schooling
2. Current psychotic disorder
3. Current substance dependence
4. Current significant suicidal ideation (K-SADS-PL – 'suicidal ideation' threshold – 'often thinks of suicide and has thought of a specific method')

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.

Date of first enrolment
01/01/2020

Date of final enrolment
28/02/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Norfolk and Suffolk NHS Foundation Trust
Hellesdon Hospital
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Sponsor information

Organisation
Norfolk and Suffolk NHS Foundation Trust

ROR
https://ror.org/03400ft78

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 17/112/16

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to this being a feasibility trial; hence there will not be data that could be used for a useful and appropriately-powered secondary analysis.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/12/2020	11/12/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	qualitative mixed methods process evaluation	23/01/2024	24/01/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint (other)	Lessons learned from process evaluation	09/08/2023	14/08/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes