# Interpersonal counselling for adolescent depression delivered by youth mental health workers without core professional training: the ICALM feasibility RCT

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# Scientific summary

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# **Scientific summary**

## Background

Depression is a common mental health condition among young people, with estimated prevalence rates for major depressive disorder (MDD) in adolescents ranging from 11% to 20%. Despite high MDD prevalence in this age group, research highlights even higher mild/subthreshold depression rates. Untreated mild depression in adolescence is of major concern, often leading to a range of adversities in adulthood. As milder cases of adolescent depression do not meet treatment thresholds for specialist mental health services, young people often receive support from non-qualified mental health professionals in third-sector/voluntary agencies. Increasing rates of mild depression create an urgent need to find suitable early psychological interventions to address mild depression in non-specialist sectors and meet growing demand with limited resources.

Interpersonal counselling for adolescents (IPC-A) is an adapted form of interpersonal counselling (IPC) designed to meet the needs of young people. IPC was adapted from interpersonal psychotherapy (IPT), which is a National Institute for Health and Care Excellence-recommended first-line treatment for adolescents with moderate to severe depression. However, IPT must be delivered by a qualified mental health professional, which means it is unlikely to be a feasible treatment option outside of specialist Child and Adolescent Mental Health Services. IPC has a shorter treatment duration; it is designed for clients with mild depression; and it can be delivered by non-mental health professionals after participation in a brief (2-day) training course. IPC has been found to be an effective treatment for adults with mild to moderate depression.

The adapted intervention for adolescents was recently developed and piloted in a single-arm study by members of the research team. IPC-A was delivered by staff without prior psychotherapy training and was found to be well accepted by staff and young people, but its effectiveness as a treatment for adolescent depression has yet to be tested. The intervention was designed to be delivered over three to six (30- to 60-minute) sessions, depending on the participant's needs, by staff without core professional training. Practitioners delivering the intervention received training and supervision to promote adherence to the treatment manual.

#### Aims

The aims of this feasibility study were to (1) assess the feasibility and acceptability of trial procedures, (2) explore the delivery of IPC-A and treatment as usual (TAU) and how and why intervention delivery varies across differing service contexts, (3) evaluate the extent of contamination of the control arm and if it should be mitigated against in a future trial and (4) investigate if the interval estimate of benefit of IPC over TAU in depression scores post treatment includes a clinically significant effect.

## **Methods**

The feasibility randomised control trial involved 13 sites across two counties in England. Young people (age 12–18) who were seeking help for low mood (as their primary presenting difficulty) of a level of illness where they would normally receive treatment from the service were eligible to participate.

Participants were randomised in a 1 : 1 ratio using a stochastic minimisation algorithm to minimise imbalance between groups in baseline symptom severity, gender and study site to receive either IPC-A or TAU. Participants were assessed pre randomisation (baseline) and at 5, 10 and 23 weeks.

Mixed-methods process data were collected to understand how the intervention was implemented across settings, explore acceptability and monitor contamination.

#### **Progression criteria**

The primary intended output of the research was the design of a subsequent trial. The following criteria were set out at the beginning of the study to 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 attended 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 and (6) the mean Revised Children's Anxiety and Depression Scale (RCADS) depression scores of the IPC-A and TAU groups at 10 weeks are indicative of a clinically significant difference in depression (3 points).

## Results

The feasibility trial was disrupted by the COVID-19 pandemic, and recruitment was suspended from March 2020 to July 2020 due to the first lockdown of the COVID-19 pandemic, with recruitment recommencing in September 2020. In total, 32 referrals were received, with 16 eligible participants being recruited and randomised. Prior to suspension, the study had recruited two participants. These participants discontinued follow-up data collection with the research practitioner due to study suspension but continued with therapy (either IPC-A or TAU).

For those who were recruited after suspension (n = 14), the overall rate of recruitment was slower than anticipated: on average, 1.7 per month (18 months) versus a target recruitment rate of five participants per month (12 months). In response to COVID-19 and changing team responsibilities, it became necessary to recruit further teams alongside the original sites. However, alterations to the referral pathways did not increase the number of referrals made to the study. The recruitment rate of 80% of target set out in the progression criteria was not achieved.

Out of the 14 randomised participants, only 7 received an intervention (IPC-A or TAU), with 3 out of 6 participants receiving IPC-A and 4 out of 6 receiving TAU. The remaining seven participants either disengaged from therapy or were signposted due to risk. Of the six participants randomised to the IPC-A arm who had come to the end of the 10-week treatment window, three (50%) attended three or more treatment sessions, which was less than the target of 70% set out in the progression criteria. Participant retention was high, with 85.7% of participants reaching 23-week follow-up.

The retention of staff delivering IPC-A was fairly low. Of the 19 staff trained for IPC-A at the beginning of the study, only 8/19 remained in the study, with 4/8 being allocated a client. From those practitioners allocated a client on IPC-A, only two delivered the intervention. For the two practitioners who offered IPC-A but did not deliver the intervention, one client did not engage with the service nor attended IPC-A sessions, and the second was signposted due to complexity and risk and need for a more appropriate intervention.

Only four participants (three IPC-A and one TAU) consented to their session recordings being analysed for the process evaluation. Therefore, all recordings were rated and analysed to assess implementation and theoretical fidelity. From the four recordings reviewed, clear systematic use of the principles of IPC-A was identified; therefore, 100% of these sessions met the treatment fidelity criteria. There was no evidence of contamination effects from IPC-A training for TAU therapists for the recordings that were provided.

There was no clinically significant difference between the two interventions due to the study being underpowered. Health economic information was collected to inform a future trial. The Child Health Utility Index 9D (CHU-9D) and Client Service Receipt Inventory (CSRI) had high rates of completion and appeared to perform well. The CHU-9D showed possible improvement over time, suggesting it may be able to detect differences. The CSRI showed reduced healthcare use over time and would be a potential candidate for use in a future trial of ICALM, although it may benefit from simplification. The small recruitment rate means the potential cost of IPC-A remains unclear. Furthermore, high staff turnover means the benefits may be lost if IPC-A-trained staff leave their roles. A future trial may be feasible if challenges around staffing could be mitigated.

#### Conclusions

The findings of this feasibility study and the process evaluation indicate that conducting a randomised clinical trial of IPC-A in non-specialist services is not feasible in the current climate. It remains unknown if IPC-A is a useful therapeutic addition to universal and mild to moderate services for children and young people which should be recommended.

## **Trial registration**

This trial is registered as ISRCTN82180413.

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