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TIGA-CUB-manualised psychoanalytic child psychotherapy versus treatment as usual for children aged 5–11 with treatment-resistant conduct disorders and their primary carers: results from a randomised controlled feasibility trial

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Background: Parenting programmes are recommended for conduct disorders in 5–11 year olds, but ineffective for 25–33%. A feasibility trial was needed to determine whether a confirmatory trial of second-line, manualised short-term psychoanalytic child psychotherapy (mPCP) versus treatment as usual (TaU) is practicable.
Method: This was a two-arm, pragmatic, parallel-group, multi-centre, individually-randomised controlled feasibility trial with blinded outcome assessment. Child–primary carer dyads were recruited from National Health Service Child and Adolescent Mental Health Services and mPCP delivered by routine child psychotherapists.
Results: Thirty-two dyads (50% of eligible, 95% CI 37 to 63%) were recruited, with 16 randomised to each arm. Eleven (69%) completed ≥50% of 12 week mPCP and 13 (81%) . Follow-up was obtained for 24 (75%) at 4 months and 14/16 (88%) at 8 months. Teacher follow-up was 16 (50%) ≥1 session. Manual adherence was good. Baseline candidate primary outcomes were 37.4 (SD 11.4) and 18.1 (SD 15.7) on the Child Behaviour Checklist/Teacher Report Form externalising scale and 102.8 (SD 28.4) and 58.8 (SD 38.9) on the total score. Health economics data collection was feasible and the trial acceptable to participants.
Conclusion: Recruitment, teacher follow-up and the manual need some refinement. A confirmatory trial is feasible, subject to funding of research child psychotherapists.

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Background

Conduct disorders (CDs) — "repetitive and persistent patterns of antisocial, aggressive or defiant behaviour that amounts to significant and persistent violations of age-appropriate social expectations" (NICE, 2013) — affect 5% of 5–10 year olds, with prevalence expected to rise

(NICE, 2013). CDs are the most common reason for referral to Child and Adolescent Mental Health Services (CAMHS), with incidence higher in boys (7%) than girls (3%) (NICE, 2013). Risk of adverse outcomes is high, including poor educational achievement, long-term physical and mental illness, criminality, unemployment, teenage parenthood, and poor subsequent parenting (Healey, Knapp, & Farrington, 2004; Kim-Cohen et al., 2003; Knapp, King, Healey, & Cicely, 2011; Koning, Webbink, Vujic, & Martin, 2010; Odgers et al., 2007; Odgers et al., 2008; Piquero, Farrington, Nagin, & Moffitt, 2010; Sainsbury Centre for Mental Health, 2009). Children with CDs cost public services up to ten times more than those without, and typically represent 30% of GP child consultations (NICE, 2013; Romeo, Knapp, & Scott, 2006; Scott, Knapp, Henderson, & Maughan, 2001). Up to 50% of children and young people with CDs develop antisocial personality disorder (NICE, 2013).

First-line parenting programmes are effective, but do not benefit 25–33%, and 30–40% drop out (NICE, 2013; Scott, 2008; Scott & Dadds, 2009). Group or individual social and cognitive problem-solving programmes are recommended for 9–14 year olds and multi-modal interventions for 11–17 year olds, but there are few alternatives for 5–11 year olds (Bakker, Greven, Buitelaar, & Glennon, 2016; NICE, 2013).

Clinical experience, small-scale studies, and theoretical research suggest that psychoanalytic child psychotherapy (PCP), delivered by child and adolescent psychotherapists (CAPTs), might be a suitable second-line treatment. CAPTs address complex problems, particularly where first-line treatments have failed (Kam & Midgley, 2006; Kennedy, 2004). There have been several small-scale studies of PCP for CDs, but with small sample sizes and/or not conducted in UK CAMHS (Eresund, 2007; Fonagy & Target, 1994; 1996; Szapocznik et al., 1989; Winkelmann et al., 2005). PCP is available in the NHS for children with CDs, but is usually only provided after several years in CAMHS, and often for at least a year. Theoretical research indicates that PCP, with its attachment focus, might benefit children with CDs. Large meta-analyses have found correlations between CDs and insecure (particularly disorganised) attachment (Fearon, Bakermans-Kranenburg, van Ijzendoorn, Lapsley, & Roisman, 2010; Groh et al., 2014; Hoeve et al., 2012; van Ijzendoorn, Schuengel, & Bakermans-Kranenburg, 1999), and other studies have found links between CDs and primary carer (particularly maternal) attachment difficulties (DeKlyen, 1996; Madigan et al., 2006; Madigan, Moran, Schuengel, Pederson, & Otten, 2007; Marchand, Schedler, & Wagstaff, 2004). Such difficulties are liable to inter-generational transmission (Kelly, Slade, & Grienenberger, 2005; van Ijzendoorn, 1995; Verhage et al., 2016) and have been linked to problems in parental reflective functioning, i.e. understanding behaviour in terms of underlying thoughts and feelings. Attachment difficulties have been linked to adult mental health difficulties, which can in turn contribute to children's CDs (G. Goodman & Bartlett, 2013; Luyten, Mayes, Nijssens, & Fonagy, 2017; NICE, 2013). Attachment security can be earned (R. Saunders, Jacobvitz, Zaccagnino, Beverung, & Hazen, 2011) and PCP is effective in improving attachment between primary carers with mental health problems and young children (Cicchetti, Toth, & Rogosch, 1999).

Rather than waiting until children with CDs are older, more treatment resistant, and require long-term treatment, it seemed logical to explore a shorter, more intensive version of PCP with a particular focus on addressing inter-generational attachment difficulties earlier in children's CAMHS trajectories. A feasibility randomised control trial (RCT) was required to determine the practicality and design of a confirmatory trial of the clinical and cost-effectiveness of manualised PCP (mPCP) compared with heterogeneous treatment as usual (TaU) for this patient group.

Aims and objectives

The aims and objectives of the feasibility RCT were to:
• Establish screening and recruitment procedures;
• Assess acceptability of randomisation;
• Collect baseline and blinded follow-up data to estimate follow-up and data quality;
• Collect CAMHS treatment data to characterise co-interventions and TaU;

- Assess feasibility and methods for collecting clinical data, adverse events, and quality of life to assess short- and long-term cost-effectiveness;
- Assess feasibilty of keeping researchers blinded;
- Establish procedures to assess treatment attendance and adherence; and
- Confirm variability and clustering of outcomes to inform sample size calculations for a fully powered confirmatory RCT.

Method
Design
Trial on improving inter-generational attachment for children undergoing behavioural problems (TIGA-CUB) was a multi-centre, two-arm, pragmatic, parallel-group, individually randomised (1:1) controlled feasibility trial. The protocol is published online (https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-2166-2). The study was approved by Yorkshire and the Humber Bradford Leeds Research Ethics Committee (reference 16/YH/0055) and local NHS Trusts.

Setting
Four NHS Trusts (eight CAMHS) in Yorkshire and the Midlands were selected to provide a range of participants and service configurations to test recruitment feasibility and maximise generalisability. One CAMHS was subsequently unable to take part because no eligible CAPTs were available to participate at the time of recruitment.

Eligibility
Eligible dyads were identified by National Institute of Health Research (NIHR) funded Clinical Studies Officers (CSOs) and CAMHS practitioners undertaking routine screening of initial referrals and re-referrals within CAMHS.

Main inclusion and exclusion criteria (see protocol for full details, published online at https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-2166-2)

Inclusion criteria:
- Child aged 5–11 years old;
- Presenting to or re-presenting within CAMHS with a clinical level of CD ≥4 on the Strengths and Difficulties Questionnaire (SDQ) conduct sub-scale (R. Goodman, 1997);
- Primary carer previously offered a first-line group or individual parenting programme or other structured parenting intervention, and attended at least one session of this first-line intervention, but child's CD persists.

Exclusion criteria
- Child with clinical diagnosis of autistic spectrum disorder (ASD) or severe learning difficulties;
- Child medicated for attention deficit hyperactivity disorder (ADHD), unless on stable medication for ≥ 3 months;
- Looked after child (LAC) unless in stable (≥6 months) adoption, foster care or special guardianship – all kinship;
- Child under/at risk of safeguarding or court procedures;
- Primary carer with severe mental health difficulties likely to impact on primary carer or child session attendance – as determined by usual CAMHS procedures using clinical judgement;
- Primary carer with severe adverse parental functioning, e.g. alcohol dependence (≥20 on Alcohol-Use Disorders Identification Test) (AUDIT-C) (J. Saunders, 1993) or drug dependence (≥3 on Drug Abuse Screening Test) (DAST-10) (Skinner, 1982).

Participant identification and recruitment
CAPT availability and clinical practice dictated that dyad recruitment mirrored school terms (allowing a minimum of three sessions before a school holiday to establish therapeutic alliance). Following participant identification and confirmation of CAPT capacity, a CAMHS practitioner introduced the

trial to the dyad. If interested, patient information leaflets (PIS) were provided, and consent gained for researcher contact. Consent was taken for the qualitative process evaluation and the primary carer was asked to complete questionnaires about recruitment experience and trial understanding.

After a minimum of 24 hours, consenting primary carers were re-contacted and, if still interested, a meeting scheduled. A researcher explained the trial and confirmed eligibility using the AUDIT-C and DAST-10 (primary carer), and the SDQ (child). Anyone declining or scoring outside thresholds was offered non-trial TaU. Formal written consent was taken (primary carer consented for the child, unless they objected, then reason for trial non-participation was recorded).

Randomisation
Dyads were randomised (1:1) to mPCP or TaU by the CTRU via an automated 24-hour randomisation system. A minimisation programme incorporating a random element was used, stratifying for (1) site and (2) child's gender. In CAMHS with more than one trial CAPT, dyads allocated to mPCP were randomly allocated to the CAPT delivering the child's intervention, proportionate to CAPT availability. CAMHS were informed of allocation and contacted the primary carer to schedule treatment. Participants and clinicians were, of necessity, aware of treatment allocation. Researchers were not informed, to maintain blinding of outcome assessment.

Interventions
Manualised psychoanalytic child psychotherapy (mPCP)
Qualified CAPTs working in CAMHS delivered mPCP using the TIGA-CUB manual, a shortened version of current NHS practice written by CAPTs at the Northern School of Child and Adolescent Psychotherapy, drawing on psychoanaltyic theory and practice appropriate to this patient group and to undertaking short-term work. The intervention comprised 12×50-minute weekly sessions for the child and 12×50-minute weekly sessions for the primary carer(s), running concurrently. The child and primary carer were seen by one CAPT at separate times or by two CAPTs at the same or different times, depending on practicality. Primary carer sessions commenced prior to the child's where possible, to help the primary carer prepare the child. Following usual CAPT practice, the day, time, and location of sessions was consistent unless there were exceptional circumstances, to maximise continuity and containment. A break of a maximum of two weeks, where possible, was incorporated into the intervention to provide the dyad with a 'practice run' at a therepeutic ending. Intervention and supervision sessions were audio-recorded with consent.

All eligible CAPTs (qualified members of the Association of Child Psychotherapists) working within a recruiting CAMHS were involved and received training from the chief investigator and members of the trial management group (TMG) in manual use and trial processes. CAPTs received fortnightly, small group supervision from supervisors experienced in working with children with CDs, to facilitate manual adherence and care quality. All copies of the manual were traceable to prevent unauthorised circulation and potential treatment contamination. Manual adherence was checked using a trial-specific tool and the manual subsequently reviewed by the TMG to ensure suitability for the confirmatory trial.

TaU
TaU comprised usual care offered by CAMHS practitioners from a range of professional backgrounds and was unconstrained and monitored for therapeutic modality, duration, frequency of sessions, and supervision provision.

Both groups
Both arms had access to CAMHS child psychiatrists if medication, other specialist services, or hospitalisation were clinically necessary, with routine care outside CAMHS unaffected.

Data collection
Participant assessments were undertaken at baseline by researcher visits to participants' homes prior to randomisation, and at four months post randomisation (and eight months for those recruited

within the first four months of the trial), by researcher visit or by phone or postal follow-up if needed. The child's teacher completed the TRF (Child Behavior Checklist Teacher Report Form) by post at baseline and four months post randomisation.

Measures
- For full details, see protocol at https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-2166-2
- Child Behavior Checklist (CBCL* and TRF) (Achenbach & Rescorla, 2000; 2001; Thomas, 1991) (parental rating of child's problem behaviours and competencies;* teacher rating of academic achievement, class behaviour, attendance)
- Parental Reflective Functioning Questionnaire (PRFQ) (Fonagy et al., 2016; Luyten et al., 2017) (reflective functioning, related to both child and adult attachment)*
- General Health Questionnaire 12 (GHQ-12) (Goldberg & Williams, 1988) (parental mental health)
- Parenting Stress Index (PSI) (Abidin, 1995) (primary carer rating of level of stress in primary carer-child relationship)
- Beck Depression Inventory (BDI) (v2.0) (Beck, 1961) (screening for adult depressive symptoms)
- EuroQol 5 Dimension (EQ-5D™, 3-level version) (The EuroQoL Group, 1990) (parental health-related quality of life)
- EuroQol 5 Dimension Youth (EQ-5D-Y™, 3-level version) (The EuroQoL Group, 1990) (child health-related quality of life; primary carer proxy respondent*, and child reported where able).

Note: *Questionnaires additionally collected at eight months post randomisation.

Treatment data (care-pathway, referrals and re-referrals within CAMHS and to other services, adverse events, supervision and therapist details) were also collected from CAPTs and CAMHS practitioners up to four months post randomisation.

Qualitative process evaluation
This assessed acceptability of randomisation to dyads and CAPTs using questionnaires, semi-structured interviews (primary carers and children, where possible) and focus groups (CAPTs), which were audio-recorded.

Analysis
Sample size
We planned to recruit 60 dyads over eight months, randomised equally between intervention and control arms, to obtain four-month follow-up data on a minimum of 54 dyads (loss to follow-up ≤10%) to establish robust recruitment and retention strategies, estimate variability in outcomes, and inform the power calculation for a confirmatory trial. As the current study was a feasiblity trial, it was not powered to evaluate effectiveness (see protocol for full details at https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-2166-2).

Statistical analysis
Quantitative analyses were performed on an intention-to-treat basis. As this was a feasibility study, formal hypothesis testing was not conducted. Summary statistics (with 95% CIs) are reported for recruitment, therapeutic delivery, retention in treatment and follow-up outcome data and outcomes. To inform the sample size calculation for a confirmatory trial, we assessed the variability (SD) of the CBCL total and externalising score and the difference in outcomes between the control and intervention arms at four months (with 95% CI).

Health economics analysis
Data completeness was evaluated to inform the methodology and perspective to be used for the confirmatory trial. Indicative costs for both arms were calculated through direct observation of treatment provided and the structured participant-reported resource use questionnaire. Unit costs for resources were obtained from the 2016 Personal Social Services Research Unit (Curtis &

Burns, 2016) and the NHS Electronic Drug Tariff (NHS Business Services Authority, n.d.). Utlity was calculated using EQ-5D-Y as reported by the child and proxy primary carer (Brooks, Rabin, & de Charro, 2013) and discrepancies between the two were evaluated. Within trial sensitivity analyses were undertaken.

Process evaluation analysis
Questionnaires were analysed using descriptive statistics to summarise views regarding the trial/ intervention, participation, treatment drop out, and trial withdrawal. Semi-structured interviews with participants and focus groups with CAPTs were transcribed verbatim. Qualitative data were analysed thematically (Braun & Clarke, 2006) by two researchers coding the data independently to develop a coding frame, and to allow for comparisions across cases. Data collection and analysis were conducted in parallel to identify the point of data saturation (not reached).

Results
Screening and recruitment
From 23 August 2016 to 7 April 2017, 106 dyads were screened, 64 (60%, 95% CI 50% to 70%) deemed eligible, and 32 (50% of eligible, 95% CI 37% to 63%) recruited (Figure 1).

Recruitment was relatively stable, with two key recruitment periods aligned with school terms. In all but one CAMHS, recruitment rates suggest a ceiling of eligible consenting dyads was not reached; rather, recruitment was limited by the need to convert consenting dyads to participants by CAPT deadlines and by remaining availability of CAPT capacity.

Participants were identified a median 5.4 months after referral to CAMHS, with ~50% having previous referral(s). At baseline, child mean age was 7.7 (SD 1.8) years, 69% male, mean SDQ conduct score 7.4 (SD 2.2), with 26% in the 'high' and 71% in the 'very high' problems category; 19% were on psychotropic medication (ADHD stimulant medication and/or hypnotics); for all but two

Table 1: Participant baseline characteristics

|	mPCP *n* = 16	TaU *n* = 16	Total *N* = 32
Trust			
Trust A	5 (31.3%)	3 (18.8%)	8 (25.0%)
Trust B	9 (56.3%)	9 (56.3%)	18 (56.3%)
Trust C	2 (12.5%)	2 (12.5%)	4 (12.5%)
Trust D	0 (0.0%)	2 (12.5%)	2 (6.3%)
Child gender (male)	11 (68.8%)	11 (68.8%)	22 (68.8%)
Child age			
Mean (SD)	7.8 (1.91)	7.6 (1.71)	7.7 (1.79)
Median (range)	7.5 (5, 11)	7.5 (5, 10)	7.5 (5, 11)
Child treated for another health condition (current or historic) (not mutually exclusive)			
Physical health condition (asthma, eczema)	3 (18.8%)	5 (31.3%)	8 (25.0%)
Neurological condition (epilepsy)	1 (6.3%)	1 (6.3%)	2 (6.3%)
Mental health condition (anxiety, ADHD, mutism, attachment disorder)	1 (6.3%)	4 (25.0%)	5 (15.6%)
Other – sleep disturbance	2 (12.5%)	6 (37.5%)	8 (25.0%)
Child currently taking psychotropic medications	1 (6.3%)	5 (31.3%)	6 (18.8%)
Primary carer relationship to child			
Mother	15 (93.8%)	15 (93.8%)	30 (93.8%)
Father	1 (6.3%)	1 (6.3%)	2 (6.3%)
Primary carer health (not mutually exclusive)			
Physical health condition	6 (37.5%)	11 (68.8%)	17 (53.1%)
Mental health condition	6 (37.5%)	10 (62.5%)	16 (50.0%)
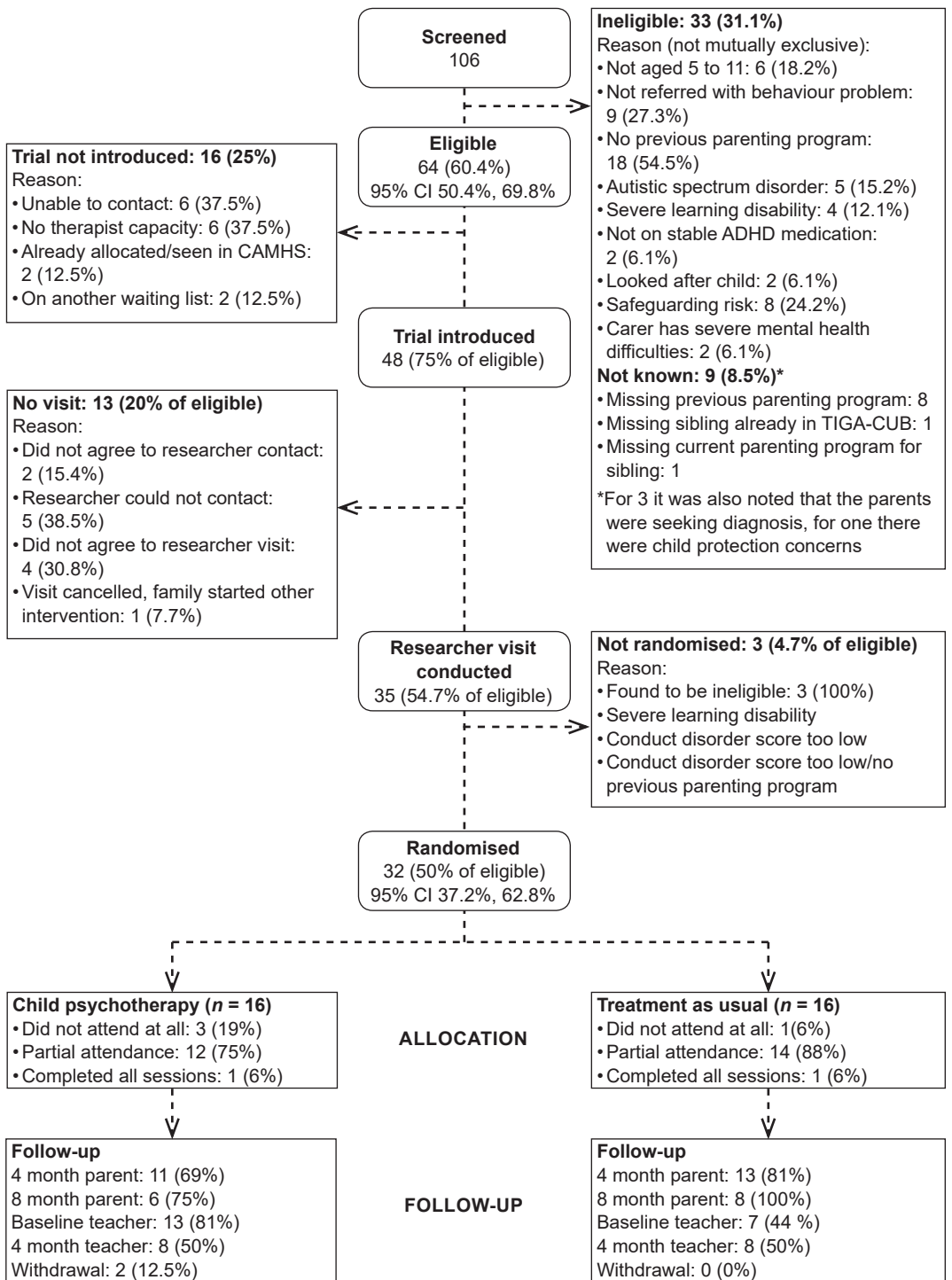
Figure 1: CONSORT diagram for child and primary carer dyads

participants, the birth mother was the consenting primary carer, and 50% of primary carers had a historic or current mental health condition (Table 1).

Study conduct

The first child entered had a sub-threshold CD screening score due to researcher error using the SDQ. Two TaU dyads withdrew from postal and researcher follow-up, none from clinical data collection. The two trial researchers were unblinded for four (13%) dyads: two in mPCP via CAMHS clinician, and two in TaU via CSO and primary carer.

CAPTs

Sixteen CAPTs consented to participate and attended mPCP training; 12 were allocated mPCP participants during randomisation (ten dyads allocated via further CAPT randomisation, six based on availability). Twelve (75%) CAPTs were allocated to the child and/or primary carer for the 16 participant dyads allocated to mPCP, while four CAPTs were trained but not allocated to participants – three in one CAMHS in which no participants were randomised to receive mPCP, and one due to lack of subsequent availability. The majority of dyads were allocated different CAPTs for child and primary carer sessions, while three were allocated the same CAPT, resulting in a total of 11 different CAPT child and primary-carer dyad combinations. There were no deviations from allocated CAPT. Due to CAMHS workloads, three CAPTs were unavailable during the second recruitment wave and one could only see primary carers.

Therapeutic delivery

mPCP

Of the 16 participants allocated mPCP, 13 (81%, 95% CI 54% to 96%) attended a minimum of one session, and one (6%, 95% CI 0.2% to 30%) attended all 12 child and 12 primary carer sessions; 11 (69%, 95% CI 41% to 89%) attended over 50% of sessions offered. A median of ten child and nine primary carer sessions were attended; the duration of treatment was three (range 0.2 to 3.9) months; the session duration mean was 50 minutes. One child was deemed unsuitable for mPCP by CAPTs and re-referred. On completion, five dyads were referred for further PCP and three for other treatment.

Two supervisors held 26, ~fortnightly 90 minute supervisions, involving median five CAPTs, and focussing on one to three dyads per session. Fourteen CAPTs attended median 10 supervisions, and each dyad featured in median two supervisions (range 0 to 8). Manual adherence, assessed via review of sessions #1, #6, #11 and the relevant supervisions, occurred for five randomly selected cases – three child and two primary carer – for different CAPTs across five CAMHS. Total adherence scores ranged from 12–18/18, with non-adherence for two cases in session #11 on reflecting on endings. As the manual had not allowed for two CAPTs co-working a case in concurrent slots, some saw the primary carer only, but not the child during the first week to enable discussion of how to prepare the child for attendance.

TaU

Of 16 dyads allocated TaU, 15 (94%) attended one or more sessions, median 2.5 (range 0 to 21). One (6%) dyad completed treatment, treatment was ongoing for nine (56%), and for five (31%), there was assessment with treatment yet to start. Therapeutic orientation varied, comprising family work, psycho-education, integrative-systemic and psychodynamic work, child-focussed social and cognitive problem-solving, play therapy, art therapy, and generic therapy/counselling. Sessions started median 8.3 weeks post randomisation in TaU, compared with 3.5 weeks in mPCP (Table 2).

Follow-up

Four-month follow-ups were completed by 24 (75%) primary carers, and eight-month by 14/16 (88%). Follow-up was face-to-face for all but one primary carer who returned their eight-month questionnaire by post. Estimated loss to follow-up was 25% (95% CI 11.5% to 43.4%) at four months and 13% (95% CI 1.6% to 38.3%) at eight months. Twenty teachers (62.5%) completed

Table 2: Participant treatment receipt

	mPCP (*n* = 16)	TaU (*n* = 16)
Any sessions attended		
Yes	13 (81.3%)	15 (93.8%)
No	3 (18.8%)	1 (6.3%)
Summary of attendance		
Completed all sessions	1 (6.3%)	1 (6.3%)
Negotiated ending – end of TIGA-CUB treatment phase	8 (50.0%)	
Negotiated ending – non-attendance/drop-out	4 (25.0%)	
No treatment (drop-out, CAPT decision, moved area)	3 (18.8%)	1 (6.3%)
Treatment not yet started/assessment only		5 (31.3%)
Treatment ongoing		9 (56.3%)
Overall number of sessions attended		
Mean (SD)	13.8 (8.92)	4.9 (5.60)*
Median (range)	17.5 (0, 23)	2.5 (0.0, 21.0)
Time from randomisation to start of treatment		
N	13	15
Mean (SD)	0.8 (0.48)	1.9 (1.40)
Median (range)	0.8 (0.3, 1.9)	1.6 (0.4, 5.2)
Treatment duration (first to last session – months)		
N	13	15*
Mean (SD)	2.9 (0.90)	2.1 (2.21)
Median (range)	3.0 (0.2, 3.9)	1.5 (0.0, 7.5)
Referred for other treatment within CAMHS		
Yes	9 (56.3%)	NA
Reason for referral (of those referred)		
TIGA mPCP end – continuation of PCP	5 (55.6%)	NA
TIGA mPCP end – other treatment	3 (33.3%)	
TIGA mPCP unsuitable	1 (11.1%)	
Therapeutic orientation of TaU (not mutually exclusive)		
Play therapy	NA	3 (18.8%)
Other family work		6 (37.6%)
Art Therapy		1 (6.3%)
Therapy/counselling		1 (6.3%)
Psycho-education		2 (12.6%)
Integrative – systemic & psychodynamic		1 (6.3%)
Child-focused social & cognitive problem solving		1 (6.3%)
Assessment only		5 (31.3%)
No attendance		1 (6.3%)

Note: *The number and duration of sessions attended in TaU include only those attended during the four-month follow-up; the majority of participants had not yet started treatment, or treatment was ongoing.

questionnaires at baseline, and 16 (50%) at four months. Questionnaires were well completed with minimal missing data, and outcome scores for all returned questionnaires could be generated.

Variability of outcomes
There were four candidate primary outcomes: the CBCL/TRF total score and externalising score, each rated by the primary carer and teacher respectively. At baseline, the total scores were 102.8 (SD 28.4; 95% CI 22.8 to 37.7) (primary carer) and 58.5 (SD 38.9; 95% CI 29.6 to 56.9) (teacher) and the externalising scores were 37.4 (SD 11.4; 95% CI 9.1 to 15.1) (primary carer) and 18.1 (SD 15.7; 95% CI 11.9 to 22.9) (teacher). The four-month follow-up mean difference in total score between arms, adjusted for baseline, was 2.4 (95% CI −10.2 to 15.0) (primary carer) and −27.0 (95% CI −68.6 to 14.7) (teacher), while the four-month follow-up mean difference in externalising score between arms, adjusted for baseline, was −2.3 (95% CI −8.3 to 3.8) (primary carer) and

Table 3: Baseline and four-month candidate primary outcome measures – CBCL and TRF

	Baseline			Four months		
	mPCP Mean (SD)	TaU Mean (SD)	Total Mean (SD)	mPCP Mean (SD)	TaU Mean (SD)	Total Mean (SD)
CBCL[1]						
n	16	16	32	13	11	24
Total problems						
Raw score (0 – 240)	97.5 (32.47)	108.1 (23.47)	102.8 (28.38)	89.9 (37.85)	92.7 (20.66)	91.2 (30.58)
95% CI	(80.2, 114.8)	(95.6, 120.6)	(92.6, 113.0)	(67.0, 112.8)	(78.9, 106.6)	(78.3, 104.1)
Adjusted difference between treatment arms (95% CI)	2.38 (−10.2, 14.98)					
Deviant (Clinical)	15 (93.8%)	16 (100.0%)	31 (96.9%)	12 (92.3%)	11 (100.0%)	23 (95.8%)
Internalising subscale						
Raw score	20.3 (10.36)	21.8 (11.07)	21.1 (10.57)	19.1 (13.46)	16.1 (8.95)	17.7 (11.47)
95% CI	(14.8, 25.9)	(15.9, 27.7)	(7.3, 24.9)	(10.9, 27.2)	(10.1, 22.1)	(12.9, 22.6)
Deviant (Clinical)	12 (75.0%)	13 (81.3%)	25 (78.1%)	10 (76.9%)	7 (63.6%)	17 (70.8%)
Externalising subscale						
Raw score	34.0 (12.70)	40.8 (8.97)	37.4 (11.37)	30.3 (12.48)	38.6 (8.71)	34.1 (11.47)
95% CI	(27.2, 40.7)	(36.1, 45.6)	(33.3, 41.5)	(22.8, 37.9)	(32.7, 44.4)	(29.3, 39.0)
Adjusted difference between treatment arms (95% CI)	−2.25 (−8.34, 3.84)					
Deviant (Clinical)	16 (100.0%)	16 (100.0%)	32 (100.0%)	12 (92.3%)	11 (100.0%)	23 (95.8%)
TRF[1]						
n	7	13	20	8	8	16
Total problems						
Raw score (0 – 240)	54.7 (52.89)	61.0 (31.40)	58.8 (38.93)	51.4 (53.54)	86.5 (26.35)	69.0 (44.62)
95% CI	(5.8, 103.7)	(42.0, 80.0)	(40.6, 77.0)	(6.6, 96.2)	(64.5, 108.6)	(45.2, 92.7)
Adjusted difference between treatment arms (95% CI)	−27.0 (−68.6, 14.72)					
Deviant (Clinical)	2 (28.6%)	8 (61.5%)	10 (50.0%)	3 (37.5%)	8 (100.0%)	11 (68.8%)
Internalising subscale						
Raw score	10.1 (11.96)	10.9 (7.02)	10.7 (8.75)	9.7 (10.40)	13.7 (7.81)	11.7 (9.12)
95% CI	(−0.9, 21.2)	(6.7, 15.2)	(6.6, 14.8)	(1.0, 18.4)	(7.2, 20.2)	(6.8, 16.6)
Deviant (Clinical)	3 (42.9%)	6 (46.2%)	9 (45.0%)	3 (37.5%)	5 (62.5%)	8 (50.0%)
Externalising subscale						
Raw score	14.9 (19.84)	19.8 (13.54)	18.1 (15.68)	15.4 (21.11)	27.9 (17.27)	21.6 (19.71)
95% CI	(−3.5, 33.2)	(11.6, 28.0)	(10.7, 25.4)	(−2.3, 33.0)	(13.4, 42.3)	(11.1, 32.1)
Adjusted difference between treatment arms (95% CI)	−9.60 (−25.1, 5.93)					
Deviant (Clinical)	3 (42.9%)	8 (61.5%)	11 (55.0%)	3 (37.5%)	6 (75.0%)	9 (56.3%)

[1]High scores indicate greater deviance

−9.6 (95% CI −25.1 to 5.9) (teacher) (Table 3). Cluster sizes were small (1–3 dyads per CAPT), suggesting a small clustering effect in a confirmatory trial (see Appendix for other outcomes).

Safety
No deaths, related unexpected serious adverse events, or expected serious adverse events (self-harm/risk-taking behaviours leading to medical attention) were reported.

Health economics
Sixty-six per cent of children completed the EQ-5D-3L youth version at baseline, and 34.4% at follow-up. There was no proxy-respondent missing data at baseline, but 25% missing at follow-up. Age appeared unrelated to child completion, and children and primary carers were concordant for child health. Over four months, quality of life appeared to increase across trial arms. Overall, 24 (75%) dyads reported using a minimum of one healthcare service, most commonly a GP, with an average of two visits. Use of CAMHS and family support workers was commonly reported across arms. Patterns of health care use were also very similar. Average total reported use over four-month follow-up was estimated at £542.74 (SD 682.27) in TaU and £602.48 (SD 745.11) in mPCP. The treatment cost of mPCP, including session attendance, CAPT supervision and CAMHS re-referral, was estimated at £1 479 (SD 877.75), while TaU was £429.65 (SD 463.41); however, TaU was mostly ongoing or yet to start at data collection. Two carers reported personal expenses, including damage to home or school property related to their child's behaviour. Six carers reported related work absence and provided estimated lost earnings.

Qualitative process evaluation feedback
Primary carer interviews
Lack of knowledge of CAMHS and therapies available was a key issue. Despite a stated preference for mPCP, primary carers across trial arms described positive aspects of therapy, or could also explain why, where therapy was less successful. Questionnaires, researcher visits and qualitative interviews were well received and some children could discuss their experience of therapy.

CAPT focus groups
Most CAPTs felt mPCP constrained usual practice, but that the theoretical basis was familiar from previous clinical training. Due to trial design, the usual three to five session assessment of dyad suitability for PCP prior to treatment could not occur, so CAPTs felt cases were not sufficiently 'worked up' prior to intervention commencement. Other research processes worked better than expected, e.g. audio recording of therapy. CAPTs felt the trial impacted negatively on CAPT waiting lists, and that screening did not always accurately identify cases needing referral elsewhere, e.g. for ADHD diagnosis. CAPTs found supervision beneficial but wanted it monthly. CAPTs felt that where two CAPTs co-worked in concurrent sessions, the manual needed to allow the primary carer's first session to occur prior to the child's, within the timeframe.

Patients and public involvement (PPI)
It was difficult to interest non-participant primary carers in joining the PPI group. Potential reasons included difficulty finding ad hoc childcare even when paid for, and payment for PPI risking reduced/delayed benefits. We therefore had a small PPI group and supplemented this with ad hoc email and face-to-face input from other non-trial parents who provided specific input, e.g. feedback on PIS and topic guides. Meetings were short (20–30 minutes) and payment not requested. Existing PPI members found it difficult to attend trial meetings but agreed to meet separately. Project rationale and plans were explained, written feedback on PIS obtained, PPI members informed of trial developments, and advice on expanding the PPI group sought. Key results were shared and contributions invited for a participant newsletter.

Discussion

This feasibility RCT identified challenges in recruitment, primary carer and teacher follow-up, and trial design allowing for usual CAPT assessment. It nevertheless demonstrated the practicability of delivering the intervention and of data collection, and has provided information to enable the research team to design and implement an optimal confirmatory trial. The majority of feasibility criteria were met and, by refining processes based on our findings, the remainder are deemed achievable. It is therefore intended to apply for funding to undertake a large-scale confirmatory trial to establish the clinical and cost-effectiveness of mPCP versus TaU for children aged 5–11 with treatment resistant CDs, and their primary carers.

In relation to self-reported outcomes, while the study was not powered to evaluate outcomes, summary measures indicate a more promising effect according to the CBCL as rated by teachers as compared to the CBCL as rated by primary carers. While it is not unusual with this patient group for parents to rate their children's progress as being relatively poor, particularly where parents have mental health difficulties, it is difficult to interpret these initial results meaningfully, give the relatively low return rate from teachers.

Limitations

We did not meet our target recruitment of 60 dyads for four main reasons. Delays in the Health Research Authority (HRA) approval system during set-up led to delays in establishing CAMHS internal pathways and therefore screening procedures. A late change of Trust and early loss of a CSO meant that a second researcher and experienced CSO were not in place at trial commencement. A further Trust had considerable operational difficulties and felt unable to prioritise CD cases given existing waiting lists and targets. We had to use phased rather than rolling recruitment due to limited CAPT capacity, existing CAMHS workloads, and CAPT conventions, such that once a critical point was reached, further randomisation of available eligible and consenting dyads could not take place lest they were randomised to mPCP. To maximise confirmatory trial recruitment, we recommend revising the timing of screening to ensure a supply of eligible dyads more robust to delays, using experienced CSOs, ensuring appropriate clinicians to maximise screening accuracy, and, where possible, tailoring recruitment processes to local circumstances. Consideration is also being given to specific funding for research therapists (used in a CAMHS-related context to ensure a pragmatic trial), so as to prevent the diversion of limited CAMHS CAPT capacity. Despite or perhaps because of these difficulties, we were nevertheless able to establish successful screening and recruitment processes for use in the confirmatory trial. We therefore deem it possible to address these recruitment difficulties, especially as we were in the unusual position of being limited by therapist capacity, rather than any shortage of eligible cases.

Our four-month follow-up rate was lower than our 90% target, although our follow-up rate at eight months was higher than expected. Our loss to follow-up at four months was 25% for primary carers and 50% for teachers. Previous literature indicates that loss to follow-up in this population has ranged from 8% to 38% at 12 months and we were therefore within acceptable limits for participant loss to follow-up with this hard-to-retain patient group. Possible reasons for the higher than anticipated teacher loss to follow-up include the timing of requests for return of teacher data (usually at the end of term, as dictated by the timing of delivery of the intervention) and possible concerns about confidentiality of data. In a confirmatory trial, we recommend including email as well as telephone reminders for teachers, possible use of secure on-line questionnaire completion to make it easier for teachers to return data, and a letter utilising a CAMHS-related letter heading (with permission), to improve teacher confidence in data confidentiality. Where data was returned, it was of high quality, with sufficient questionnaire completion to calculate all required outcomes. Data on treatment received in CAMHS was collected and heterogeneity of TaU confirmed. Improvements might have been seen if TaU data had been collected over a longer period and procedures for collecting details of waiting lists and intended end of treatment optimised. Particularly where treatment may take time to initiate, fully involving experienced CSOs and clinicians is also recommended, given the challenges in obtaining clean and complete data, particularly when collected retrospectively.

With the aim of being inclusive, we included looked after children in stable kinship care. The feasibility of collecting data on age of placement and length of placement at time of recruitment was not collected. This data would need to be collected in any confirmatory trial as age of placement and length of placement, as well as possible interaction between them, would potentially impact on treatment outcomes.

Similarly, as this was a feasibility study, the diagnostic co-morbidity of the children recruited was not addressed as part of this trial. It would nevertheless be important to address this in a large-scale confirmatory trial, especially given the high levels of co-morbidity in children with CDs, and this could potentially be achieved by conducting sub-group analyses of treatment outcomes on the CBCL by making use of the SDQ data.

Strengths

Randomising dyads to treatment was found to be acceptable to primary carers and clinicians. Primary carers used the trial to expedite treatment access. CAPTS would have preferred to follow usual practice of a specialist assessment for mPCP, which would be challenging in a confirmatory trial for timing of randomisation, potential drop out, and differential drop out across arms. Possibilities include a run-in phase where dyads receive formal assessment prior to randomisation, and stratification of randomisation by CAPT outcome prediction prior to formal assessment. Careful consideration of relative advantages and disadvantages of complication to trial design would be needed.

Assessment of treatment attendance and adherence was made via trial forms and session review. As stated above, previous literature has shown drop out from parenting programmes to be 30–40%. Taking drop out to be attendance at <50% of sessions, this trial found a 31% drop out (95% CI 11% to 59%); taking drop out to be non-attendance at any sessions, this trial found a 19% drop out (95% CI 4% to 46%). We therefore deem that drop out for any confirmatory trial would be likely to be within acceptable boundaries for this patient group. Primary carers had to have attended at least one session of a first-line intervention such as a parenting programme or other structured parenting intervention to be eligible for the feasibility study. Although this might seem low, the bar was set at this level because the literature indicates that drop out from treatment often occurs very early on with this patient group. Consideration must also be given for this second-line intervention to the potential challenges of achieving significant change in relatively few sessions, particularly where drop out occurs in the context of a short-term psychoanalytic intervention. Nevertheless, drop-out rates are likely to be high for this patient group whatever the intervention. CAPTs routinely receive training in how to engage hard to retain patients, and this patient group might in any case find it difficult to tolerate a longer-term intervention.

CAPTs and dyads tolerated audio-recording sessions well and the questionnaire burden was also considered acceptable. Only minor amendments to the manual adherence tool are required. Both structural and minor amendments will be made to the manual (without substantially changing the nature of the intervention), to improve accessibility, practicability of usage (especially the first primary carer and child sessions), and flexibility for CAPTs. Training will be optimised and supervision frequency amended to reflect CAPT views.

A number of procedures were assessed to be feasible, e.g. methods for collecting clinical data, adverse events, and quality of life data to assess short- and long-term cost-effectiveness, and to keep researchers blinded, with only one unblinding by primary carer considered unavoidable. Additional training of clinicians during site initiation and refining processes for the confirmatory trial should avoid future incidents.

Variability of outcomes has been successfully established to inform sample size calculations for the confirmatory trial, but estimation of the clustering of outcomes by clinician was not possible. A total of 12 CAPTs were allocated to the 16 child-primary carer dyads randomised to mPCP. CAPTs therefore saw just one to three child participants each and estimation of intra-class correlation coefficient (ICC) was not possible. The very small cluster size means the clustering effect is likely to be minimal and reasonably robust across estimates of the ICC, but if a confirmatory trial employed

a smaller number of dedicated CAPTs, the impact on the clustering effect and sample size would be evaluated.

PPI confirmed that families of children with CDs can have chaotic lives, making it difficult for them to engage with long-term PPI. Short, targeted involvement using virtual technology where appropriate, focussing on practical issues and offering vouchers rather than monetary recompense, might facilitate engagement.

Conclusion

This feasibility RCT demonstrated that, with appropriate refinements, it is practicable to undertake a large-scale confirmatory trial to establish the clinical and cost-effectiveness of mPCP versus TaU for children aged 5–11 with treatment-resistant CDs, and their primary carers. Nevertheless, this patient group is notoriously hard to recruit and engage, and undertaking a large-scale RCT in CAMHS – especially with the current transformation agenda – has specific challenges. Working with CAPTs – who are mostly unfamiliar with RCT methodology and with participating in this type of research – can also prove challenging. Yet with ever-increasing referral rates and a welcome current political focus on children's mental health, the need for robust evidence of the clinical and cost-effectiveness of interventions has never been more pressing. Given the particularly adverse long-term outcomes of this often neglected patient group, there is probably none more deserving of research into effective mental health interventions – or more liable to result in substantial cost savings to the public purse if they are established – than children with treatment-resistant CDs, and their primary carers.

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