ISRCTN25252940 https://doi.org/10.1186/ISRCTN25252940

Matching the therapeutic approach to childrens emotional and behavioural needs: a comparison of different ways of helping

Submission date 29/06/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 15/07/2010	**Overall study status** Completed	
Last Edited 12/09/2016	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MRD 12/36

Study information

Scientific Title
A pilot study of a new intervention for hard to treat children with conduct problems

Study objectives
The principal aim of the study is to examine whether children whose behaviours are not substantially improved by parent training, may be helped by a novel intensive treatment combining work with the child and the parents (Reflective Interpersonal Therapy for Children and Parents - RICAP).

We will carry out a pilot randomised controlled study of a novel treatment for conduct problems that have not responded to parent training. It is designed according to the MRC guidelines on Phase Two Exploratory Studies of complex interventions (MRC 2000) and the CONSORT statement (Altman, 1996; Moher, Schulz, Altman, Lepage & for the CONSORT Group, 2001). The main objectives are to establish the recruitment and attrition rate to a study with this design, to test whether the randomisation process is acceptable, to examine for differences in completion rates in the two arms of the randomised study (RICAP or clinical Treatment as Usual), to compare a range of outcome measures, and to generate data for a power calculation to provide the basis for an application to carry out a full scale randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Liverpool Children's Research Ethics Committee, 17/07/2003, ref: 03/05/051/C
2. Wirral Research Ethics Committee (LREC66/03), 20/08/2003, ref: 03/05/051C

Study design
Pilot single-centre single-blind randomised controlled trial with concealed allocation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Childhood conduct problems

Interventions

Phase 1 intervention: Parent-Training (Duration 12-14 sessions)
This social learning theory-based parent training package is well established and has been described in numerous publications (e.g. Webster-Stratton et al 1998, Scott et al 2001). It has an explicit structure described in a manual. The approach has proven effectiveness in UK community settings (Scott et al 2001).

Phase 2 interventions (Duration 16 weeks)

Control Group - clinical treatment as usual
Children randomised to the control group will receive further clinical treatment which is likely to vary naturally across child mental health teams, and will include further help with parenting skills, support for parents, family therapy and occasionally individual therapy for the child.

Reflective Interpersonal Therapy for Children and Parents (RICAP)
RICAP has been devised by Hermione Roff, senior research therapist. RICAP is a fourteen session structured treatment for children and their parents, usually delivered over 16 weeks. It comprises one set-up session, 12 weekly child sessions and one review session at the end. The parent receives 6 fortnightly sessions alongside the child sessions. The child is seen weekly, and the core activity is the creation and review of a notebook of childs drawings and a record of conversations between the child and the therapist. Conversation, based on the drawings and the childs commentary on them, focuses on the explanation of behaviours in terms of the childs emotions and beliefs about his/herself, and others in the family and the wider social world. There is a planned sequence of topics dealing with interpersonal understanding and behaviour. Each week the parent attends the beginning 10 minutes of the child's session to share with the childs therapist one good and one difficult interpersonal event that has occurred during the previous week. The child then commences 40 minutes alone with their therapist focussing on the co-creation of the book of drawings and reflections. The parent joins in the last 10 minutes at the end of the child's session to make plans for the forthcoming week often with reference to the events identified at the start of the session. This includes mother and child reflection, behavioural contracting and mutually agreed ideas for increasing the occurrence of good times. Running in parallel to the child's weekly sessions, the parent receives fortnightly sessions from a different therapist focusing on their understanding of the childs thoughts, feelings, and behaviours, and identifying ways of responding differently to the child in the light of new understandings. The focus for these discussions is the two specific interpersonal events - a good time and a difficult time during the past week - generated by the parent. A written record of these conversations, understandings and any plans for new parenting approaches to be tried in the light of new understandings, is summarised by the therapist in a letter to the parent after each session. This serves as a focus for discussion and review in subsequent sessions.

Therapeutic integrity
The child therapist and the parent therapist receive fortnightly supervision which will also serve as a check on adherence to the treatment. The content of the child's book and the letters to the parent enable therapist adherence to the therapeutic approach to be directly evaluated.

Duration of follow-up
Assessments of child behavioural functioning and parental mental health will be completed at baseline (pre-phase1 intervention), 4 months later (post-phase 1 intervention/pre-phase 2 intervention) and at 12 months post-baseline (post phase 2 intervention). All families will be followed up at 12 months post baseline regardless of whether they were randomised to phase 2 intervention or not.

Intervention Type
Behavioural

Primary outcome measure
This was a pilot RCT to establish feasibility and estimates of effect sizes on range of outcome measures.

Secondary outcome measures
1. Child Behaviour Checklist (CBCL) (Achenbach 1991a) parent version and Teacher Report Form (Achenbach 1991b). Extensively used questionnaire measure of a wide range of externalising and internalising behaviours.1.
2. Strengths and Difficulties Questionnaire (Goodman 1997). This is a widely used well validated brief measure of emotional and behavioural problems (Goodman 1997). Parent and teacher versions will be used.
3. The Parent Daily Report (Chamberlain and Reid 1987). This records 36 common problem behaviours as present or absent each day for week, and has been widely used as an alternative to direct observations in the home.
4. Teacher Report of Reactive/Proactive Aggression (Dodge and Coie 1987). This is a widely used 6-item teacher questionnaire which has excellent psychometric properties.
5. The General Health Questionnaire GHQ-28 (Goldberg and Hillier 1979). This is a widely used, reliable and valid brief measure of current adult anxiety and depression. GHQ-28 scores predict psychiatric disorder identified by standardised interview (Goldberg et al 1997), and the depression sub-scale shows moderately good agreement with current DSM depression Koeter (1992).

Overall study start date
01/09/2003

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Phase 1: Children aged 5-10 years of age, rated in the clinical range on the Strengths and Difficulties Questionnaire (SDQ) conduct problems subscale or the Child Behaviour Checklist (CBCL) externalising subscale by either their parent or teacher
2. Phase 2: All children who remain in the clinical range of either of these scales according to one or more informant at the end of phase 1 intervention (parent training)

Browne (1995) recommends that in a pilot study 30 are needed in each group to provide reasonably narrow confidence intervals for the standard deviations required for a power calculation. The 80% upper one-sided confidence limit will be used when determining power for a full scale RCT.

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
We aim to recruit 160 families initially. 140 are estimated to complete post-phase 1 intervention assessments and 120 will complete one year assessments. 60 will be eligible for randomisation.

Key exclusion criteria
Phase 1: Non-English speaking families
Phase 2: Moderate learning disability which indicated RICAP would not be an appropriate intervention

Date of first enrolment
01/09/2003

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Manchester Children's Hospital
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
http://www.alderhey.nhs.uk/

ROR
https://ror.org/00p18zw56

Funder(s)

Funder type
Government

Funder Name
NHS National R&D Programme on Forensic Mental Health (UK) - Psychological vulnerabilities in antisocial children (Ref: MRD 12/36)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration