

# Early intervention for at-risk children: three-year follow up

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| <b>Submission date</b><br>28/06/2008   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
|  |   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>29/08/2008 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>08/08/2011       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |

**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**  
N/A

# Study information

## Scientific Title

School-based indicated prevention: two and three year follow up of a randomised trial of group therapy

## Study objectives

The hypothesis was that drama group intervention would reduce symptoms of mental disorder among children teacher-identified children meeting a number of criteria. These were:

1. Scholastic under-performance
2. Known major family problems
3. Ill-nourished or poorly cared for appearance
4. Impaired peer relationships
5. Behavioural or emotional difficulties

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the Newcastle upon Tyne Ethics Committee in 1995.

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Prevention

## Participant information sheet

## Health condition(s) or problem(s) studied

Mental disorder in children and young people

## Interventions

Interventions comprised drama group therapy (DGT), comprising reflective discussion and role play conducted by a drama therapy trained teacher. The role play was central to the drama therapy and involved mini-plays using themes suggested by the children themselves such as disciplinary episodes involving teachers or police, family difficulties and peer issues, seeking for alternative practicable routes to more satisfactory solutions from the participants' perspectives.

The control curriculum studies (CS) comparison involved teaching mathematics and English also delivered in the children's school. The CS group was encouraged in the formation of a positive

peer group that focused on developing skills in mathematics and English. During the sessions no attempt was made to investigate any emotional/behavioural issues, but the pedagogy was strongly inclusive and supportive, with clear expectations for conduct. The group leader used focused praise for achievement of task outcome and collaborative behaviours shown by the group.

The two groups each ran for an hour a week over a 12 week period and were conducted during school hours. The follow up took place over three years.

Please note that the sponsor and funder of this trial, Northern and Yorkshire Research and Development Directorate (UK), does not exist any more due to restructuring in the NHS.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

Scores on behaviour parent- teacher- and self-report mental health questionnaires:

1. The Child Behaviour Checklist
2. Teacher Report Form
3. Youth Self Report

Data were gathered three months pre-intervention and at the start of intervention (waiting list control), at the end of intervention (+three months), six months, one year, two years and three years post-intervention.

## **Secondary outcome measures**

No secondary outcome measures.

## **Overall study start date**

15/09/1996

## **Completion date**

15/04/2001

# **Eligibility**

## **Key inclusion criteria**

1. Children of either sex
2. Scholastic under-performance
3. Known major family problems
4. Ill-nourished or poorly cared for appearance
5. Impaired peer relationships
6. Behavioural or emotional difficulties

## **Participant type(s)**

Patient

## **Age group**

Child

**Sex**

Both

**Target number of participants**

122

**Key exclusion criteria**

Not at school.

**Date of first enrolment**

15/09/1996

**Date of final enrolment**

15/04/2001

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Fleming Nuffield Unit**

Newcastle upon Tyne

United Kingdom

NE3 4EX

## **Sponsor information**

**Organisation**

Northern and Yorkshire Research and Development Directorate (UK)

**Sponsor details**

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United Kingdom

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paul.mcardle@ntw.nhs.uk

**Sponsor type**

Government

# Funder(s)

## Funder type

Government

## Funder Name

Northern and Yorkshire Research and Development Directorate (UK)

# 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

## Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/09/2002   |            | Yes            | No              |