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**EARLY PARENT-BASED INTERVENTION FOR
CONDUCT PROBLEMS AND ADHD**

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Thesis submitted to Bangor University in fulfilment of the requirements
of the Degree of Doctor of Philosophy

School of Psychology, Bangor University

January 2008



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CONTENTS

| | |
|--|------|
| LIST OF TABLES | xii |
| LIST OF FIGURES | xiii |
| LIST OF APPENDICES | xiii |
| SUMMARY | xiv |
| | |
| 1. GENERAL INTRODUCTION | 1 |
| Substantial amendment to proposed study plan | 2 |
| General Introduction | 7 |
| The Incredible Years Series | 7 |
| Incredible Years Parent Training Programmes | 8 |
| Incredible Years BASIC Parent Training Programme | 8 |
| Structure and Content | 8 |
| Theoretical Grounding | 9 |
| Programme Delivery | 10 |
| Barriers to Attendance | 11 |
| Supporting Research | 12 |
| Implementation Fidelity | 13 |
| North Wales Sure Start Trial | 15 |
| Incredible Years Wales | 15 |
| Evaluation Aims | 15 |
| Methodology | 16 |
| Implementation Fidelity | 17 |
| Main Findings | 18 |
| Rationale for Examining the Efficacy of IY for ADHD symptoms | 19 |
| Structure of Thesis | 20 |
| Literature Review (Chapter 2) | 20 |
| Study One (Chapter 3) | 21 |
| Study Two (Chapter 4) | 22 |
| Study Three (Chapter 5) | 22 |

| | |
|--|----|
| 2. LITERATURE REVIEW: <i>Attention Deficit Hyperactivity Disorder (ADHD) in preschool children: Current findings, recommended interventions, and future directions</i> | 24 |
| Abstract | 25 |
| Introduction | 26 |
| ADHD | 26 |
| Developmental course | 26 |
| Co-Morbidity | 27 |
| ADHD in the Preschool Years | 27 |
| Aetiology of ADHD During the Preschool Years | 28 |
| Neuropsychological Models | 29 |
| Dual Pathway Model | 30 |
| Parenting Influences | 31 |
| Which Treatment is Appropriate for Preschool ADHD? | 32 |
| New Forest Parent-Training Package | 34 |
| Triple P Parent-Training Programme | 35 |
| Incredible Years Parent-Training Programme | 36 |
| Theoretical Grounding of PT programmes | 38 |
| Why are these interventions successful at Targetting Preschool ADHD? | 44 |
| Is the Evidence-Base which Supports ADHD Robust? | 45 |
| Moderators of Outcome | 48 |
| Mode of Delivery | 49 |
| Barriers to Implementation | 50 |
| Treatment Integrity and Implementation Fidelity | 51 |
| Future Directions | 52 |
| Conclusions | 54 |
| 3. STUDY 1: <i>Efficacy of The Incredible Years Basic Parent-Training Programme as an early intervention for children with conduct problems and ADHD</i> | 56 |
| Abstract | 57 |
| Introduction | 58 |
| Intervention | 59 |
| Evidence for Psychosocial Intervention for Preschool Children | |

| | |
|---|----|
| with ADHD | 60 |
| Rationale for Examining IY for ADHD | 61 |
| Aims of the Study | 62 |
| Methods | 63 |
| Participants | 63 |
| Measures | 64 |
| Screening: Parent Report Measures | 64 |
| Eyberg Child Behaviour Inventory | 64 |
| Strengths and Difficulties Questionnaire | 65 |
| Outcome: Parent Report | 65 |
| Conners Abbreviated Parent/Teacher Rating Scale | 65 |
| Observation of Mother and Child Behaviour | 66 |
| Design | 67 |
| Randomisation | 67 |
| Procedure | 68 |
| Intervention and Treatment Integrity | 68 |
| Results | 69 |
| Attrition | 69 |
| Attendance | 69 |
| Impact of Intervention on Conduct Problems | 69 |
| Preliminary Analysis (Equivalence) | 69 |
| Short-Term Intervention Effects | 70 |
| Short-Term Intervention Effects (Controlling for Change in Child Deviance) | 70 |
| Clinical Significance of Change | 72 |
| Discussion | 73 |
| Limitations | 73 |
| Clinical implications | 74 |
| Future studies | 74 |

| | |
|---|----|
| 4. STUDY 2: <i>Efficacy of the Incredible Years Programme as an early intervention for children with conduct problems and ADHD: Long-term follow-up</i> | 78 |
|---|----|

| | |
|--|----|
| Abstract | 79 |
| Introduction | 80 |
| Course | 80 |
| Co-Morbidity | 80 |
| Treatment | 81 |
| Parent-Training | 82 |
| The Incredible Years Basic Parent-Training Programme | 83 |
| Present Study | 85 |
| Methods | 86 |
| Participants | 86 |
| Measures | 88 |
| Screening: Parent Report Measures | 88 |
| Eyberg Child Behaviour Inventory | 88 |
| Strengths and Difficulties Questionnaire | 89 |
| Primary Outcome Measure | 89 |
| Conners Abbreviated Parent/Teacher Rating Scale | 89 |
| Observation of Mother and Child Behaviour | 90 |
| Procedure | 91 |
| Intervention and Treatment Integrity | 91 |
| Results | 92 |
| Attrition | 92 |
| Attendance | 92 |
| Impact of Intervention on Conduct Problems | 92 |
| Short-Term Findings: Impact of Intervention on | |
| ADHD Symptoms | 92 |
| Preliminary Analyses | 93 |
| Long-Term Findings | 94 |
| Long-Term Findings (Controlling For Observed Child | |
| Deviance Scores) | 95 |
| Clinical Significance of Change in Children's Disruptive | |
| Behaviour | 90 |
| Magnitude of Improvement | 90 |
| Discussion | 98 |
| Limitations | 99 |

| | |
|---|-----|
| Clinical Implications | 101 |
| 5. STUDY 3: <i>The Incredible Years Programme as an early intervention for children with conduct problems and ADHD: Moderators and mediators of outcome</i> | 102 |
| Abstract | 103 |
| Introduction | 105 |
| Interventions for Preschool ADHD | 105 |
| Moderators And Predictors of Outcome | 106 |
| Child-Specific Moderators | 107 |
| Parent / Psychosocial Factors | 108 |
| Mediators of Outcome | 109 |
| Background to Study | 110 |
| Present Study | 110 |
| Methods | 112 |
| Participants | 112 |
| Measures | 113 |
| Demographic information: The Personal Data and Health Questionnaire | 113 |
| Maternal Depression: The Beck Depression Inventory | 113 |
| Eyberg Child Behaviour Inventory | 114 |
| Conners Parent Rating Scale | 114 |
| Strengths and Difficulties Questionnaire | 114 |
| Observation of Mother and Child Behaviour | 115 |
| Randomisation | 115 |
| Procedure | 116 |
| Intervention and Treatment Integrity | 116 |
| Results | 118 |
| Attrition | 118 |
| Attendance | 118 |
| Equivalence | 118 |
| Predictor of Short-term Outcome (Baseline – Follow-up 1) | 119 |
| Intervention Group | 119 |
| Control Group | 119 |
| Predictors of Long-Term Outcome (Intervention Group at Follow-ups 2 and 3) | 121 |

| | |
|--|------------|
| Moderators | 122 |
| Mediators | 123 |
| Positive Parenting | 123 |
| Critical Parenting | 125 |
| Discussion | 126 |
| Predictors (Baseline to Follow-up 1) | 126 |
| Predictors of Long-Term Outcome (Intervention Group) | 127 |
| Moderators of Outcome | 129 |
| Mediators | 129 |
| Limitations | 130 |
| Clinical Implications | 131 |
| 6. GENERAL DISCUSSION | |
| Summary of main findings | 132 |
| Overview of Main Objectives | 133 |
| Study 1 | 133 |
| Study 2 | 134 |
| Study 3 | 136 |
| Methodological Issues | 141 |
| Clinical Implications | 146 |
| Future Directions | 147 |
| Conclusions | 149 |
| REFERENCES | 156 |
| APPENDICES | 189 |

Tables

| | | |
|------------------|--|-----|
| Table 1 | Demographic characteristics of participants | 57 |
| Table 2 | Equivalence of groups | 64 |
| Table 3 | Indices of clinically significant change | 89 |
| Table 4 | Standardised regression coefficients in the simultaneous regression of treatment outcome on candidate predictors (intervention & control group) | 112 |
| Table 5 | Standardised regression coefficients in the simultaneous regression of treatment outcome on candidate predictors (intervention group at follow-ups two and three) | 114 |
| Table 6 | Moderator analyses: association between improvements in ADHD symptoms and risk factors. | 115 |
| Table 7 | Correlations between Conners change scores and child deviance change scores at follow-ups one, two, and three | 204 |
| Table 8: | Correlations between Conners scores at baseline and follow-up 1 for intervention and control group | |
| Table 9: | Correlations between Conners scores at follow-up 1 and follow-up 2, and follow-up 2 to follow-up 3 (intervention group only)*. | |
| Table 10: | Correlations between Conners scores at baseline and follow-up 1, and observed positive parenting at baseline and follow-up 1 for all cases (intervention and control)* | |

Figures

| | | |
|-----------------|---|-----|
| Figure 1 | Parenting Pyramid (Webster-Stratton & Hancock, 1998) | 9 |
| Figure 2 | Short-term intervention effects for intervention and control groups (Controlling for change in observed child deviance) | 65 |
| Figure 3 | Flow of participants through trial | 79 |
| Figure 4 | Long-term intervention effects for intervention group from baseline to follow-up three. | 87 |
| Figure 5 | Standardised coefficient of intervention status on outcome | 116 |

Appendices

| | |
|---|-----|
| Appendix 1: Initial study protocol | 173 |
| Appendix 2: Ethics Application Cover Letters: | |
| 2 a. North West Wales Research Ethics Committee (CAMHS Study) | 183 |
| 2 b. School of Psychology, Bangor University (CAMHS Study) | 184 |
| 2 c. School of Psychology, Bangor University (School/Community Study) | 185 |
| Appendix 3: Letters of Invitation for Screening | |
| 3 a. CAMHS Study Parent Invitation Letter | 187 |
| 3 b. School Study Parent Invitation Letter | 188 |
| Appendix 4: Letter to School Headteachers | 189 |
| Appendix 5: Consent Forms (Screening) | |
| 5a. Screening Consent (CAMHS) | 192 |
| 5b. Screening Consent (School) | 194 |
| Appendix 6: Consent Forms (Research) | |
| 6 a. CAMHS Study Consent Form | 195 |
| 6 b. School Study Consent Form | 196 |
| Appendix 7: Information Sheets | |
| 7 a. CAMHS Study | 197 |
| 7 b. School Study | 201 |
| Appendix 8: Correlation Table (Relationship Between Child Deviance Change Scores and Conners Change Scores at Follow-ups one, two, and three). | 204 |
| Appendix 9: Tables of correlations between all measures that entered into the calculation of change scores in the findings of study 3 | |

Summary

Growing numbers of preschool children are being referred to mental health services with symptoms of Attention Deficit Hyperactivity Disorder (ADHD), and medication is increasingly being used to treat them (Zito, Safer, dosReis et al., 2000). However, there is limited evidence for the short- and long- term efficacy of medication (Greenhill, Kollins, Abikoff et al., 2006), concerns over adverse effects (Wigal, Greenhill, Chuang, et al., 2006) as well as ethical objections to medical intervention at such an early stage in development (Perring, 1997). Consequently, there is a need to provide effective psychosocial interventions for this population (Conners, March, Frances, Wells, & Ross, 2001).

A literature review of preschool ADHD (Chapter 2) identified three parent-training (PT) programmes that have demonstrated effectiveness in reducing ADHD symptoms, and concluded that PT may provide an effective first-line intervention for preschoolers with ADHD symptoms. The three empirical studies (Chapters 3, 4, and 5) evaluated the efficacy of one of these programmes – the Incredible Years (IY) BASIC PT programme – within a community sample of preschool children with signs of early emerging conduct problems and ADHD.

Study one (Chapter 3) examined the short-term efficacy of the IY intervention, using a randomised controlled group design. Following the delivery of the programme, the intervention group was associated with significantly lower levels of parent-reported ADHD symptoms, compared to a wait-list control group. The second empirical study (Chapter 4) examined the longitudinal stability of intervention-related gains. Results demonstrated that improvements were maintained at 12- and 18- month follow-ups.

The third study (Chapter 5) explored potential predictors, moderators, and mediators of outcome within this sample. Moderator analyses failed to uncover significant associations between risk factors and outcome, suggesting that the intervention was effective even for the most disadvantaged families. Predictor analysis suggested that those with the most severe levels of ADHD at baseline were most likely to benefit from intervention. Maternal depression was associated with poorer long-term outcome at 18-month follow-up, although it was not associated with initial treatment response. Mediator analyses indicated that enhanced positive parenting skill was a significant partial mediator of outcome, suggesting that positive parenting is one of the key mechanisms contributing to intervention success.

The short-term efficacy, longitudinal stability, and lack of outcome moderators suggest that the IY is a valuable and stable intervention when delivered as a preventive intervention for preschool children presenting with ADHD symptoms, even for families traditionally considered to be ‘hard to treat’.

CHAPTER 1

GENERAL INTRODUCTION

Substantial amendments to proposed study plan

Before introducing the thesis, the substantial amendments made to the Ph.D., from the initial proposed study to its current format, justifies further discussion. The study, in its present layout, eventually got off the ground after almost two years of frantically trying to recruit enough families, meeting a number of frustrating dead ends, and numerous applications for ethical approval that every change in the protocol warranted.

The original study plan, as outlined in the study protocol (Appendix 1), was to evaluate the efficacy of the Incredible Years (IY) BASIC parent-training (PT) programme (Webster-Stratton, 1989) using an intention to treat, randomised controlled design, with families of school-aged children referred to Bangor Child and Adolescent Mental Health Service (CAMHS) for ADHD assessment. Ethical approval was granted by North West Wales NHS Trust Research Ethics Committee (application cover letter is included in Appendix 2a), and by School of Psychology Ethics Committee, Bangor University (application cover letter is included in Appendix 2b). The aim was to recruit a total of 48 families, at two separate phases, and following the completion of baseline assessment, to randomly allocate the families to either a treatment group (IY) or a wait-list control group (WL).

At the first recruitment phase, prospective participants were drawn from a database of 38 children, aged between five and nine years, who were on the waiting list for ADHD assessment by the CAMH service. Families were initially contacted by the CAMH service by letter, explaining the purpose of the study (see Appendix 3a).

Families were asked to sign and return a consent form if they were willing for a researcher to contact them to arrange a screening interview to assess whether they were eligible to take part (see Appendix 5a). Eight families did not respond, and could not be contacted despite several attempts. Of the remaining 30 families, 25 gave consent for a screening interview, and five declined. Home visits were arranged with the 25 families.

Families were eligible for inclusion in the study if their child scored above the clinical threshold on the Hyperactivity Subscale of the Parental Account of Children's Symptoms (PACS; Taylor, Schachar, Thorley, & Wieselberg, 1986). Families who met this criterion were given a detailed information sheet, explaining the purpose of the study (Appendix 7a), and signed a consent form if they were willing to take part (Appendix 6a). The full assessment battery was subsequently administered to eligible families, which examined the following outcome domains: Demographic information; parenting competencies; parental mental health; child symptoms; child IQ; and parent-child interaction. These participant characteristics were assessed using a combination of assessment techniques, including direct behavioural observation, semi-structured interview, intelligence tests, neuropsychological tests, and ratings scales, which are listed in the protocol (Appendix 1).

Despite being on the current ADHD waiting list, only eight out of the twenty-five families met inclusion criteria following the administration of the PACS.

Furthermore, because Bangor CAMH service covers a large, predominantly rural area, five of these families lived quite a distance away from the clinic where the intervention was to be delivered, with some living as far as 70 miles away

(approximately a 2 hour drive by car, and longer by public transport).

Understandably, these families could not commit to attending the group on a weekly basis. From a clinical viewpoint, this highlights the difficulties faced by some families in rural areas in terms of accessing much needed services.

In an attempt to increase the number of participants, the aims of the study as well as the recruitment difficulties encountered were presented to paediatricians working at the local hospital, who were asked to forward potentially suitable cases on to the research team. Unfortunately, this failed to yield any additional participants. As the Ph.D. was partially funded by NWW NHS Trust, it was not possible to recruit participants from other health trusts.

The intervention was subsequently delivered to the three participating families at the CAMHS clinic. Follow-ups were not conducted due to low numbers, and because the children of two of these families had been prescribed medication to treat their ADHD symptoms before the parents completed the PT intervention.

In a further effort to run a prospective evaluation of the IY PT programme, an attempt was made to recruit a community sample of families of children displaying symptoms of ADHD, through local primary schools. Ethical approval was granted by School of Psychology, Bangor University (application letter is included in Appendix 2c).

Letters, addressed to head teachers, were sent out to twelve local schools (Appendix 4). The schools selected were within a ten-mile radius of the proposed intervention venue, in a pre-emptive effort to reduce potential time and transport difficulties. Ten of these schools agreed to distribute letters and screening questionnaires to the parents

of all children in years 1 to 6 (aged 5-11 years). One thousand one hundred and seven letters were distributed to parents, explaining the purpose of the research (Appendix 3b), together with a screening questionnaire (the Strengths and Difficulties Questionnaire [SDQ; Goodman, 1997]), to be returned, together with a consent form (Appendix 5b) to the research team if they wished to take part. Families were eligible for a further screening interview (using the PACS) if they rated their child's behaviour as being above the level of clinical concern on the Hyperactivity Subscale of the SDQ (≥ 7 ; Goodman, 1997). The response rate to the letters was exceptionally low, with only 12 respondents, and only four of these families met criteria for further screening. Letters were sent out to the four eligible families explaining that although the number of responses were too low for the evaluation to continue, they could still join an IY PT group, that was shortly due to commence at the local CAMH service.

By this point, almost two years had elapsed since the start of the Ph.D., and it seemed implausible, given the limited time remaining, to embark on yet another recruitment campaign.

Thankfully, however, the availability of a large data set following the North Wales Sure Start Trial provided an opportunity to run a secondary re-analysis of this data. The trial was headed by Professor Judy Hutchings, one of my Ph.D. supervisors, and it was a trial that I had been involved with for two years as a Research Assistant prior to commencing the Ph.D. The Sure Start trial evaluated the IY as a preventive intervention with a community sample of disadvantaged families of preschool children identified as being at risk of developing conduct problems (for more details, see Hutchings, Eade, Jones, & Bywater, 2004).

As inattention and hyperactivity/impulsivity frequently co-occur with conduct problems during the preschool years (Barkley, 1998; Biederman Newcorn, & Sprich, 1991; Conners & Ehrdart, 1998), the Sure Start trial assessment battery included measures of ADHD. Exploratory analysis of the data demonstrated that a large proportion of the children within this sample also scored above the clinical cut-off on measures of ADHD. This afforded a unique opportunity to examine the efficacy of the IY for this co-morbid sub-group of children. Thus, a preschool (as opposed to school aged), community (as opposed to clinic) sample of families of children displaying signs of co-morbid conduct problems and ADHD formed the basis of the current thesis.

A secondary re-analysis of this data was considered to be an appropriate basis for the Ph.D. given: i) the substantial level of cost and time dedicated to recruiting the existing Sure Start sample; and ii) the considerable difficulties encountered in attempting to recruit a new, prospective sample.

General introduction

The introduction begins with an overview of the Incredible Years (IY) series, followed by a summary of the IY BASIC Parent Training (PT) programme, which outlines information relevant to the structure and content of the programme, the theoretical background, and programme delivery. A summary of supporting research, and issues relating to implementation fidelity are also included. Secondly, an overview of the North Wales Sure Start Trial, highlighting the objectives, methodology, and key findings, is provided. Thirdly, a brief rationale for examining the efficacy of the IY in reducing ADHD symptoms is presented. Finally, an introduction to the structure of the thesis is given, which includes a summary of the literature review chapter, and highlights the key objectives of the three empirical chapters.

The Incredible Years Series

The evidence-based IY programmes were initially developed as treatment interventions for families of children with Conduct Disorder (CD), though they have subsequently been implemented, and researched, in community as well as clinic settings. The IY series provides comprehensive training for parents (Webster-Stratton, 1989), children (Webster-Stratton, 1990, revised 2003), and teachers (Webster-Stratton, 1995, revised 2003) in behaviour management strategies. The programmes have been rigorously researched over the last 20 years, using randomised controlled trials (e.g. Reid & Webster-Stratton, 2001; Webster-Stratton, 1998; Webster-Stratton, Reid, & Hammond, 2004). The accumulated research evidence converges on the effectiveness of these programmes in enhancing parental

competencies, reducing conduct problems, and increasing child social competence.

The programmes have been identified in many systematic reviews of effective evidence-based interventions for reducing and preventing violence (e.g Brestan & Eyberg, 1998; Mihalic, Fagan, Irwin et al., 2002; Taylor & Biglan, 1998).

The Incredible Years Parent Programmes

There are three parent-focused programmes. The first to be developed was the BASIC programme (Webster-Stratton, 1989), which has since been supplemented by the ADVANCE, and the SCHOOL (Supporting Your Child's Education) programme.

The ADVANCE programme was developed to address other family risk factors, such as depression, marital distress, poor coping skills, and lack of support (Webster-Stratton & Hancock, 1998). The SCHOOL programme was developed to address risk factors associated with children's lack of academic readiness and poor home-school connections (Webster-Stratton & Hancock, 1998).

Incredible Years BASIC Parent-Training Programme:

Structure and Content

The IY BASIC PT Programme consists of 12, two-hour, weekly sessions for parents, involving facilitator-led group discussion, videotape modelling and rehearsal of taught intervention techniques. The programme is delivered in a collaborative group format with groups of up to 12 parents.

The first half of the programme focuses on play and relationship building, and teaches effective use of praise and rewards. The objective is to promote a positive relationship between parent and child, and to help parents encourage more appropriate social

behaviours in their children (Webster-Stratton & Hancock, 1998). These early sessions enable parents to establish a positive base upon which strategies to reduce inappropriate behaviour can be built. Parents are reminded of the importance of this base throughout the subsequent sessions by referring to the parenting pyramid (Figure 1). The remaining sessions focus on clear instruction giving, effective limit setting, and strategies for managing non-compliance (including ignoring, time out and the use of natural and logical consequences).

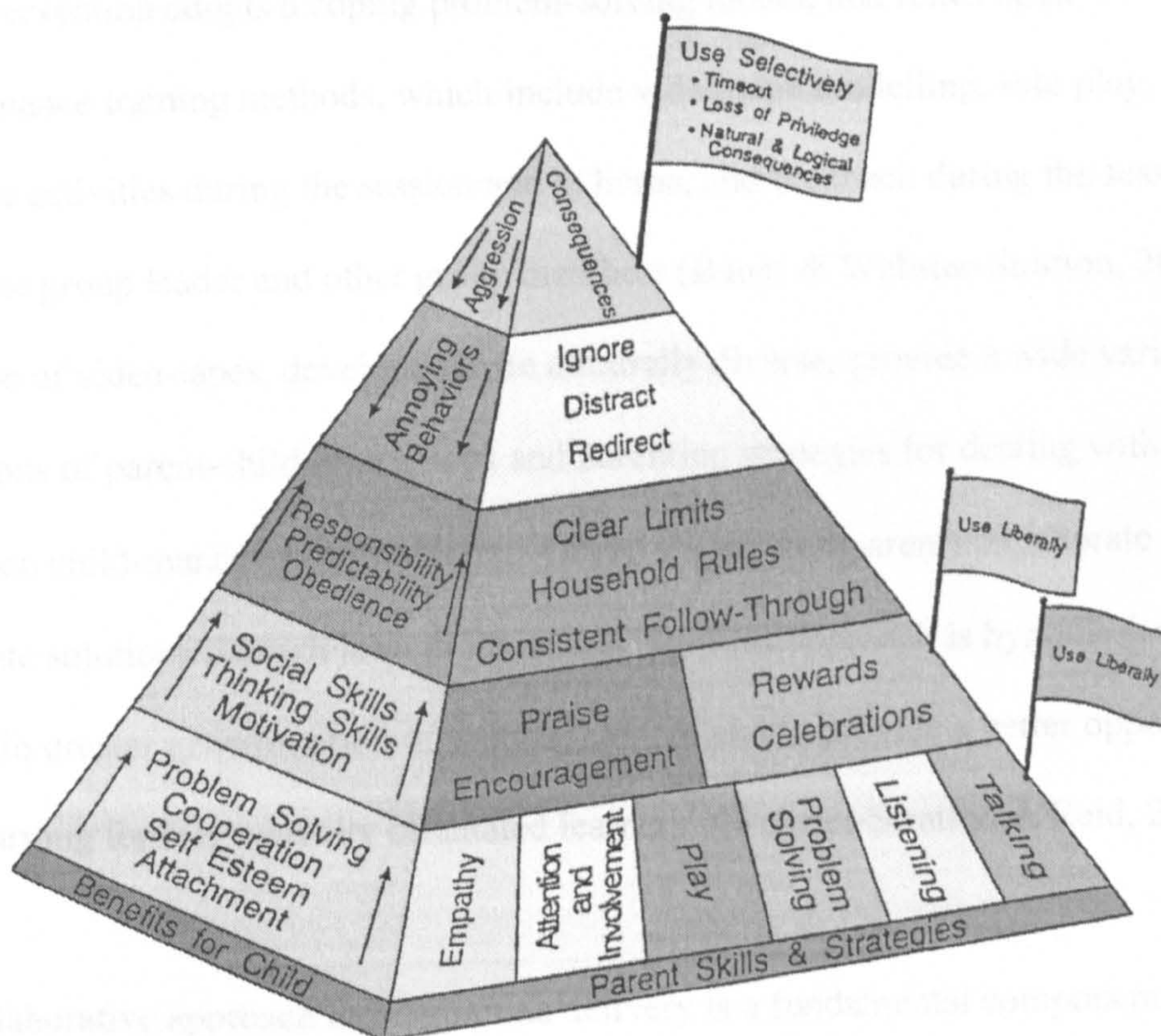


Figure 1. The Parenting Pyramid (Webster-Stratton & Hancock, 1998).

Theoretical Grounding

The intervention is grounded in extensively researched models of parent-child interactions. The IY programme is strongly influenced by Patterson's model of

coercive interaction (Patterson, 1982), and Social Learning Theory (Bandura, 1977).

The primary goal of IY is to provide parents with strategies to change the antecedents that are eliciting, and the consequences that are maintaining, the child's negative behaviours, and to develop techniques to maintain and increase positive behaviours. Effective use of these strategies is hypothesised to promote the child's social and emotional competence (Patterson, 1982).

Programme Delivery.

The intervention adopts a coping problem-solving model, and relies upon performance training methods, which include video-tape modelling, role-play, practice activities during the session and at home, and feedback during the session from the group leader and other group members (Bauer & Webster-Stratton, 2006).

The use of video-tapes, developed to be culturally diverse, provide a wide variety of situations of parent-child interactions and parenting strategies for dealing with common child-management problems. Group leaders and parents collaborate to generate solutions through joint problem solving. This approach is hypothesised to result in greater generalisation of training content and to provide a better opportunity for learning for less 'verbally orientated learners' (Webster-Stratton & Reid, 2001).

A collaborative approach to programme delivery is a fundamental component of the IY programme, as therapeutic alliance is one of the most important determinants of positive outcomes in children with oppositional, aggressive, or anti-social behaviour (e.g. Kazdin & Wassell, 1999). This approach is described in detail by Webster-Stratton and Herbert (1994). When delivering the IY programme, the group leaders seek to utilise, equally, their own expertise and the parents' unique strengths and

perspectives. Respect for each individual's contribution is essential to promote a non-blaming relationship built on trust and open communication. Due to the reciprocal nature of the approach, both parents and group leaders have important roles in facilitating change and, consequently, a share in the outcome (Webster-Stratton & Herbert, 1994).

Barriers to Attendance.

Much research has been conducted within the field of PT to examine factors that predict engagement with the intervention, adherence, and drop out. Factors identified include parental characteristics (e.g. high parent stress), family factors (e.g. socio-economic disadvantage; work commitments), and those centred on the child (e.g. co-morbidity) (Kazdin, 1997). Currently, a great emphasis is placed on addressing these factors in order to improve engagement, adherence, and to improve treatment response (Kazdin, 1997)

The IY programme includes strategies that facilitate the engagement of socio-economically disadvantaged families, such as the provision of child care, the provision of meals and snacks, transport to and from parent groups, and holding groups in highly accessible locations (e.g. schools, churches). In addition to these incentives, tangible benefits (such as prizes for attendance and completion of homework) are also incorporated into the weekly sessions (Webster-Stratton & Hancock, 1998).

Supporting Research.

Over the past 20 years, the IY BASIC PT Programme has been evaluated extensively, initially as a treatment programme for children referred with conduct disorders and more recently as a prevention programme with high-risk families. The efficacy of the BASIC programme has been strongly supported by the programme developer, with findings from randomised controlled trials (RCT) in both clinic and community settings (e.g. Webster-Stratton, 1998; Webster-Stratton, Reid & Hammond, 2004).

When used as a treatment programme, results have demonstrated significant improvements in parent-child interaction, reductions in parents' use of violent forms of discipline, and reductions in child conduct problems (Webster-Stratton, 1984, 1990, 1994; Webster-Stratton & Hammond, 1997; Webster-Stratton, Kolpacoff, & Hollinsworth, 1988). There is also evidence for the long-term stability of intervention gains. In a three-year follow-up of 83 families who had received the BASIC intervention, approximately two-thirds of the children previously assessed showed clinically significant behavioural improvements (Webster-Stratton, 1990).

Similarly, when used as a preventive intervention with multi-ethnic, socio-economically disadvantaged families, results demonstrated positive outcomes in terms of parent-child interaction, parental discipline strategies, parent involvement in child's education, child conduct problems, and child social competence, both at home and at school. These improvements were maintained at one-year follow-up (Webster-Stratton, 1998; Webster-Stratton, Reid, & Hammond, 2001).

The programme has also been demonstrated to be effective with different cultural groups in the United States (Caucasian, African, Asian, and Spanish Americans; Reid, Webster-Stratton, & Beauchaine, 2001), and for families of children entering foster care (Linares, Monalto, Li, & Oza, 2006).

A number of independent replication studies have demonstrated the efficacy of the IY BASIC PT programme, with both clinic and community samples. These studies have been conducted in England, Wales, and Norway, and have reported improvements in child conduct problems and parental competencies (Gardner, Burton, & Klimes, 2006; Hutchings, Bywater, Daley et al., 2007; Morch, Clifford, Larsson et al., 2004; Scott, Spender, Doolan, Jacob, & Aspland, 2001).

The BASIC parenting programme (Webster-Stratton, 1989) has been identified as one of eleven 'Blueprint' interventions by the Center for Violence Prevention at the University of Colorado (Mihalic et al., 2002), having satisfied stringent scientific criteria, including the use of RCTs, long-term follow ups, independent replications, and by providing sufficient detail to enable faithful replication by others.

Implementation Fidelity

When evidence-based interventions are delivered in regular service settings, by non-specialist staff, it is often difficult to replicate the established findings (Mihalic et al., 2002; Olds, Mihalic, & O'Brien, 1998; Henggeler, 1999). This failure can be due to the fact that the programme developer has not supplied the necessary tools, such as manuals, adherence checks, training, and access to supervision to enable faithful replication (Durlak, 1997; Gresham, Cohen, Rosenblum, Gansle, & Noell, 1993;

Moncher & Prinz, 1991; Peterson, Homer, & Wonderlich, 1982; Shapiro & Shapiro, 1983; Skiba & Casy, 1983; Durlak & Wells, 1998). Another reason is that, even when programmes provide the tools for fidelity, services may not follow the programme faithfully, by adding or discarding components, by using insufficiently trained staff, or by lacking some of the required resources (Chen, 1990; Mihalic et al., 2002; Vermilyea, Barlow, & O'Brien, 1984; Bond, Evans, Salyers, Williams, & Hea-Won, 2000; Mills & Ragan, 2000).

A core component of the IY programmes, that contributed to their Blueprint status, is the attention given to ensuring that the programmes can be implemented with fidelity (Mihalic et al., 2002). This includes a rigorous certification process for leaders starting with an initial three-day basic training followed by supervision. Once a certain level of expertise has been developed, a videotape of a two-hour parent session demonstrating both knowledge of the content and the collaborative leader skills is submitted and reviewed by a mentor or trainer. This generally receives extensive feedback and suggestions of how to further develop collaborative leader skills. If this advice is followed, a subsequent tape is likely to be approved, after which the leader submits the records from two full programme sequences, including leader checklists and participant feedback. This process can take one or two years to complete but ensures that a certified leader is delivering the programme in a way that should achieve similar results to those obtained in the research evaluations. Other tools for fidelity include participant books, detailed manuals, vignettes, parent handouts, and evaluation checklists.

The North Wales Sure Start Trial

Incredible Years (IY) Wales

The IY Wales Centre was founded by Professor Judy Hutchings, as a collaborative venture between the North West Wales NHS Trust, and Bangor University. The main objectives of the centre are to promote evidence-based practice in clinical and preventive work with children with conduct problems, and to disseminate training and research about the IY programmes. The IY programmes have been delivered and researched in Wales over the last ten years.

Although the IY parenting programme was initially implemented locally as a CAMHS intervention, the increased availability of training in Wales, together with the impressive evidence base led to an increased interest in the programme across different services, including Social, Health, Education and Sure Start services. It was in the context of these developments that a proposal to evaluate the BASIC parenting programme in Sure Start areas across North- and Mid-Wales originally emerged. This proposal received grant funding from the Health Foundation (formerly the PPP Health Care Trust) in 2002.

Evaluation Aims

The trial was designed as a replication of Webster-Stratton's evaluation of the BASIC PT Programme delivered as a selective prevention intervention to 'at risk' families from Head Start Centres in Seattle (Webster-Stratton, 1998). Although an evaluation of the BASIC programme with clinically referred populations had been undertaken in the UK by Scott and colleagues (Scott et al., 2001), there had been no examination of

the programme as an early preventive intervention, and no evaluation of the particular challenges posed to programme implementation with a largely bi-lingual, rural population. The aims of the trial were therefore to examine whether the efficacy of the IY PT programme could be transported to a rural Welsh setting, with an 'at risk' population, using health, social services, and voluntary sector staff (Hutchings, Eade, Jones, & Bywater, 2004; Hutchings, Bywater, Daley, et al., 2007). The trial ran from October 2002 to June 2006.

Methodology

The trial recruited in eleven Sure Start areas across North and Mid-Wales and the borders, from January 2003 to September 2004. Ethical approval was granted by North West Wales NHS Research Ethics Committee. Prospective families were recruited by health visitors, who administered the Eyberg Child Behaviour Inventory (ECBI; Eyberg & Ross, 1978) to socially disadvantaged families with a child aged between 36-48 months. Families were eligible for inclusion if the parent rated their child's behaviour as being above the clinical cut-off on either the problem or intensity subscale of the ECBI, and if the primary carer was able to attend the parenting groups. Of the two hundred and fifty-five families identified by health visitors, one hundred and thirty three met inclusion criteria, and consented to take part in the study.

The full assessment battery was administered to eligible families and included measures of social and demographic factors, child mental health, child behaviour, sibling behaviour, parenting style, parenting stress, parental depression, as well as direct observation of parent-child interaction by trained observers who were blind as to group status of families. The study employed an intention to treat, randomised

controlled trial. Following the collection of baseline measures, families were randomly allocated on a 2:1 basis to intervention or control condition, after stratification by age and sex. Eighty-six of these families were in the intervention and 47 in the control condition (see Hutchings et al., 2007 for details).

The full assessment battery was administered again to all families at follow-up one (six months after baseline assessment). The intervention was delivered during the intervening period between baseline and follow-up, and control families were offered a place on an IY PT programme after follow-up one data was collected. Families in the intervention condition were also followed up at 12- and 18-months after baseline. As families in the control condition were offered the intervention after initial follow-up, comparison with a control group was not possible at these stages.

All parenting groups took place in regular service settings in North- and Mid-Wales. Groups were delivered in services managed by two different national children's charities, local health trusts, a local education authority and a local community group. Each group had two leaders, employed by health, education and voluntary sector organisations.

Implementation Fidelity

The intervention was delivered by experienced and certified group leaders, who received 3-hour weekly supervision by an IY mentor, where videotapes of weekly sessions were reviewed to ensure leaders were using a collaborative approach as well as covering the session-specific content. In addition, the trial addressed fidelity by providing all course materials (CDs, handouts, books, raffle prizes etc.), completion

of a Peer and Self Evaluation questionnaire by group leaders (to monitor treatment exposure, adherence, and delivery); parent completed satisfaction questionnaires; completion of Session Specific Checklists to monitor treatment integrity, participant responsiveness, treatment delivery, and treatment differentiation by group leaders.

Main Findings

Main evaluation results reported by Hutchings and colleagues (2007) found robust improvements following intervention on multiple measures of child conduct problems and parent characteristics, including parental skill, stress, and depression, using both parent-report and direct observation of parent-child interaction, compared to a wait-list control group. The examination of the longitudinal stability of treatment outcome found that improvements were maintained at 12- and 18-month follow-ups (Bywater, et al., submitted). A recent study reported by Gardner and colleagues (submitted) examined the moderators and mediators of outcome, and found that children who were boys, who were younger and who had mothers with higher levels of stress and depression at baseline, demonstrated the best treatment response. Risk factors, including teen or lone parenthood, and low income showed no predictive effects, suggesting that the intervention was an effective intervention even for the most disadvantaged families. Mediator analysis demonstrated that improvement in positive parenting skill predicted change in child conduct problems, suggesting that positive parenting is a key mechanism contributing to intervention success. A bolt-on economic evaluation of the programme reported the cost-effectiveness of the intervention (Edwards, O Ceilleachair, Bywater, Hughes, & Hutchings, 2007).

Rationale for Examining the Efficacy of IY for ADHD Symptoms

As previously noted, the present thesis is based on the secondary re-analysis of a subgroup of families from the North Wales Sure Start Trial, whose children displayed signs of ADHD as well as conduct problems. The primary objective is to examine the efficacy of the IY intervention in reducing symptoms of ADHD within this co-morbid sample of children.

There is growing evidence in the literature demonstrating the efficacy of PT programmes for reducing ADHD symptoms, and these interventions appear to be notably successful for families of preschool children (e.g. Pisterman, McGrath, Firestone et al., 1989; Sonuga-Barke, Daley, Thompson, Weeks, & Laver-Bradbury, 2001). These findings are particularly salient given the current concerns regarding the use of medication (such as methylphenidate) to treat ADHD symptoms in preschool children (e.g. Greenhill et al., 2006; Perring, 1997).

Whilst the IY programme has a strong evidence-base, the intervention was developed to treat and prevent conduct problems, and does not therefore draw from theoretical models of ADHD. However, recent studies have reported that the IY programme appears to be equally effective for children with ADHD as they are for children with conduct problems (Hartman, Stage, & Webster-Stratton, 2002; Scott et al., 2001).

This success may be attributed to the underlying theoretical model of the programme.

The IY draws extensively from social learning theory, and provides parents with strategies for effective use of reinforcement; clear instruction-giving, and effective

limit setting, within the context of sensitive and responsive parenting. Responsive and sensitive parenting during the early years provides the foundation for the development of child self-regulation skills (Hughes, Dunn, & White, 1998). Children with ADHD have particular difficulties with self-regulation skills (e.g. low frustration tolerance, following instructions etc). American Psychiatric Association [APA], 1994; 2000). As a result, providing parents with strategies that promote self-regulation might be effective in reducing the behavioural difficulties associated with ADHD symptoms.

Structure of Thesis

This thesis is structured as a series of four papers, which follow a logical sequence: a literature review paper, followed by three empirically based papers that evaluate the efficacy of the IY BASIC PT programme for families of children who display signs of conduct problems and ADHD.

The first objective was to provide a review of preschool ADHD, and evaluate current parenting programmes that have demonstrated efficacy in the treatment of preschool children with ADHD. The second was to examine the efficacy of the IY BASIC PT programme with families of children with signs of early emerging conduct problems and ADHD. Following on from this, the third aim was to establish the long-term stability of treatment related effects. The final objective was to examine potential moderators and mediators of outcome within the sample.

Literature Review (Chapter 2)

The first paper (Chapter 2) provides a review of the literature of preschool ADHD, outlining the presentation, aetiology and treatment of the disorder in the early years, and examines effective parent-training programmes available for this population.

Three programmes were evaluated: The New Forest Parent-Training Package (NFPT; Weeks, Thompson, & Laver-Bradbury, 1999); the Triple-P – Positive Parenting Programme (Triple - P; Sanders, Markie-Dadds, & Turner, 1998; 2000); and the Incredible Years PT Programme (IY; Webster-Stratton, 1989). The evidence base supporting the efficacy of each intervention in reducing ADHD symptoms is appraised, and issues relating to moderators, barriers to attendance, and mode of delivery are discussed in relation to each intervention. Clinical implications and the future directions of parent-training research are discussed accordingly.

Study 1 – Chapter 3

Due to the current concerns about offering medical intervention to treat ADHD (Perring, 1997), there is a need to provide effective psychosocial interventions with this population (Conners, 2001). There is growing evidence in the literature to support the efficacy of PT programmes for preschool children with ADHD (e.g. Pisterman et al., 1989; Sonuga-Barke et al., 2001; Bor et al., 2002). There is also evidence that the IY is equally effective for children with ADHD as it is for conduct problems. In light of these factors, the first empirical study (Chapter 3) was designed to evaluate the short-term efficacy of the IY programme for a community-based sample of families with preschool children at risk of developing conduct problems and ADHD. The evaluation adopted an intention-to-treat randomised controlled design. The 79 eligible families had previously been randomly allocated to either IY intervention group, or to a waiting list (WL) control group. Fifty families were in the intervention

and 29 in the control group. Child ADHD symptoms and conduct problems were assessed at baseline and at follow-up, the intervention being delivered in the interim. The outcomes for the intervention group are compared with the control group using Analysis of Covariance. Clinical as well as statistical significance are also investigated. The findings are discussed in relation to the literature, and methodological considerations, clinical implications and future directions are outlined.

Study 2 (Chapter 4)

It is often documented that the benefits of intervention are not always successful in the long-term (Serketich & Dumas, 1996; Webster-Stratton & Hooven, 1998). The positive effects of intervention can decline quite rapidly after the delivery of intervention. Consequently, after evaluating the short-term efficacy of the intervention, the second empirical paper (Chapter 4) examined whether these intervention gains were stable in the long-term. The fifty intervention families were followed up at 12- and 18- months after baseline assessment. Comparison with a control group was not possible at these follow-ups, as the families in the control condition were offered the intervention after post-intervention follow-up.

Study 3 (Chapter 5)

Within the field of PT intervention outcome research, there is currently a great emphasis to identify particular subgroups of families with a particular good (or poor) response to treatment, and exploring the mechanisms that contribute to the success of intervention. As a result, study 3 (Chapter 5) examined predictors, moderators, and mediators of intervention outcome within the community sample of disadvantaged

families with children who display signs of ADHD and conduct problems. Child and family risk factors, as well as parenting skill were assessed using a combination of parent-report and direct observational measures.

The first empirical study (Chapter 3) has been published, and the second study (Chapter 4) has been accepted for publication in a peer-reviewed journal. The literature review (Chapter 2) and the third study (Chapter 5) have been submitted to academic journals, and are currently under review (the paper resulting from each study is indicated at the foot of each respective title page). Referencing within the text of each manuscript therefore conforms to the requirements of each respective journal.

Chapter 6 (general discussion) summarises the findings from each study in relation to the current literature. Methodological issues, including study limitations, are presented accordingly, as well as a summary of theoretical and clinical implications of collective findings. To conclude the discussion, the future research and clinical directions are delineated.

CHAPTER 2

LITERATURE REVIEW

Attention Deficit Hyperactivity Disorder (ADHD) in preschool children: Current findings, recommended interventions and future directions.¹

¹ This review formed the basis of a paper submitted to Child: Care, Health and Development. (Daley, D., Jones, K., & Hutchings, J. Attention Deficit Hyperactivity Disorder (ADHD) in preschool children: Current findings, recommended interventions and future directions.

Abstract

This paper outlines the presentation, aetiology, and treatment of Attention Deficit Hyperactive Disorder (ADHD) in preschool children. A review of current parenting training interventions demonstrates that there is good evidence for their efficacy in reducing symptoms of ADHD in preschool children, and three interventions are evaluated: The New Forest Parent Training Programme (NFPT; Weeks et al., 2001); the Triple P - Positive Parenting Programme (Triple - P; Sanders et al., 1998; 2000); the Incredible Years Parent Training Programme (IY; Webster-Stratton, 1982). The evaluation of the NFPT provides strong evidence demonstrating its effectiveness for preschool children with ADHD (Sonuga-Barke et al., 2001), while the efficacy of the Triple - P and the IY programme have, to date, only been demonstrated on children with conduct problems and co-morbid ADHD (Bor et al., 2002; Jones et al 2007). It is suggested that parent training should be the first choice treatment for preschool children presenting signs of ADHD, and medication introduced only for those children where parent training is not effective. Few moderators of outcome have been identified for these interventions, with the exception of parental ADHD (Sonuga-Barke et al., 2002). Barriers to intervention and implementation fidelity will need to be addressed to achieve high levels of attendance, completion and efficacy. The IY programme is a good model for addressing fidelity issues and for overcoming barriers to intervention. The future directions for parent training are also discussed.

ADHD

Attention Deficit Hyperactivity Disorder (ADHD) is currently one of the most common reasons for referral to specialist child mental health services (Barkley, 1998; Jensen et al., 1999). Epidemiological studies indicate that ADHD is a prevalent disorder, affecting between three and six per cent of school aged children (Szatmari, 1992; American Psychiatric Association [APA], 1994; 2000). The central feature of the disorder is a persistent pattern of inattention, impulsivity, and hyperactivity that is inconsistent with the child's developmental stage (APA 1994; 2000). Symptoms typically arise in early childhood, and cause cross-situational impairment (e.g. at home and at school). Within the current Diagnostic and Statistical Manual of Mental Health Disorders (4th ed: DSM-IV, 2000), three sub-types of ADHD are stipulated: predominantly inattentive, predominantly hyperactive-impulsive, and a combined subtype.

Developmental Course of ADHD

The natural course of ADHD is discouraging for many individuals. As well as the primary deficits of inattention, impulsivity, and hyperactivity, associated difficulties often include problems with motor coordination, poor regulation of emotion, and low frustration tolerance (APA, 2000). Children with elevated levels of ADHD are at risk of developing significant impairments in social, academic, and personal functioning (Daley, 2006), and these impairments can often persist into adulthood (Biederman et al., 1991; Taylor et al., 1996).

Co-morbidity

Epidemiological studies have reported that ADHD is also associated with substantial rates of co-morbidity with other psychiatric and developmental disorders (Szatmari et al., 1989a; Bird et al., 1993). Chief among these co-morbidities are conduct problems, prevalent in 30-70% of children diagnosed with ADHD (Barkley, 1998; Biederman et al., 1991; Conners & Ehrhart, 1998). Children with co-morbid conditions are more likely to have poorer outcomes, experience more impairment, more peer rejection, and their parents are also more likely to meet higher levels of psychosocial adversity (Hinshaw & Melnick, 1995; Lynham, 1996; Abikoff & Kline, 1992).

ADHD in the preschool years

A notable increase, over recent years, in the number of preschool children coming to clinical attention with ADHD symptoms (Zito et al, 2000), has driven research to examine the validity of ADHD in the preschool period (e.g. Barkley, 1998; Stevenson & Goodman, 2001). Findings from this research suggest that children with a preschool variant of ADHD share many of the characteristics associated with their school-aged counterpart. Typically, preschool children present with the same symptom structure (Gadow & Nolan, 2002); experience similar associated impairment, co-morbidity, and developmental risk (Gadow & Nolan, 2002; Lahey et al., 1988); as well as similar neuropsychological deficits (Sonuga-Barke et al., 2003).

Several studies have examined the longitudinal stability of preschool ADHD (e.g. von Stauffenberg & Campbell 2007; Speltz et al., 1999), and results generally converge on the developmental persistence of early ADHD symptoms. Typically, children

characterised as hyperactive during the preschool years continue to manifest problems with impulsive behaviour, aggression, and social adjustment in primary school (Campbell et al., 1986). Pierce et al. (1999) found that symptoms of ADHD identified in hard-to-manage preschool boys predicted continuing problems in middle childhood. Consistent with these findings, Lahey et al. (2004) examined the three-year predictive validity of ADHD in children diagnosed between four and six years of age using DSM-IV criteria, and found that children who met full diagnostic criteria during their first assessment were likely to continue to meet diagnostic criteria for ADHD over the subsequent three years. A number of studies have also documented a similar pattern of impairment in preschool children with ADHD, with symptoms being associated with profound impairment in academic and social functioning (Campbell et al., 2006) as well as long-term educational failure, social exclusion, delinquency and substance abuse (Swanson et al., 1998). Evidence of impairment has also been reported at follow-up for both community (Sonuga-Barke et al., 1994) and clinical samples (DuPaul et al., 2001).

Aetiology of ADHD During The Preschool Years,

Although there has been extensive research investigating the aetiology of ADHD (e.g. Castellanos & Acosta, 2002; Stevenson et al, 2005), the precise cause of the disorder continues to remain unclear (Durstun, 2003). Whilst genetic factors (Thapar et al., 2007) and environmental factors (Dekker & Koot, 2003) both go some way in explaining why some children are at greater risk for the development of ADHD, neither can independently provide a full account for the cause of the disorder (Daley, 2006). ADHD is therefore best viewed as a gene x environment interaction (Larsson et al., 2004).

Neuropsychological Models

However, there are currently two predominant theoretical models that seek to explain the development, and maintenance, of ADHD in individuals with a genetic predisposition for ADHD. Each model focuses on a distinct neuropsychological deficit: Firstly, executive dysfunction underpinned by deficient inhibitory control mechanisms (Barkley, 1997); and secondly, delay aversion (Sonuga-Barke, 1994), underpinned by disturbances in motivational processes (Sagvolden et al., 1998; Antrop et al., 2006)

Within the first theoretical framework, an underlying inhibitory dysfunction specifies that a child's ADHD symptoms result from insufficient forethought, planning and control due to cognitive dysregulation (Schachar et al., 2000). This model is supported by evidence from a wealth of studies that consistently demonstrate significantly poorer performance on tests that measure executive function in children with ADHD when compared to non-ADHD matched control groups (Nigg et al., 2005; Pennington & Ozonoff, 1996; Sergeant et al., 2002).

The second theoretical model views ADHD, not as a disorder of cognitive dysregulation, but as a motivational style and therefore as a *functional* response by the child to their environment (Sonuga-Barke et al., 1994). Within this motivational model, children with ADHD are thought to behave impulsively, not because of deficient inhibitory mechanisms, but in order to avoid delay. The delay aversion hypothesis characterises the influence of delay on behaviour as being dependent upon whether the child has control over their environment or not. For example, when a

child with ADHD is in control of their environment they can choose to minimise delay by acting impulsively. When the same child is not in control of their environment, or at least where they are expected to behave in a certain way or face sanctions, they will choose to distract themselves from the subjective experience of delay by either spending time off-task by, for instance, daydreaming (inattention), or by increasing their level of stimulation by fidgeting or moving about (hyperactivity). The Delay Aversion hypothesis is supported by studies demonstrating that children with ADHD show greater sensitivity to delay than their normally developing peers, typically choosing immediate over large delay rewards (Kuntsi et al, 2001; Solanto et al, 2001).

The Dual Pathway Model

These distinct theoretical formulations have been represented within the dual pathway model of ADHD (Sonuga-Barke 2002). Evidence to support these two developmental pathways exist for preschool children with ADHD, as well as school-aged children (Solanto et al., 2001). For example, Sonuga-Barke, et al., (2003) examined the independent contribution that executive dysfunction (working memory, planning and set shifting) and delay aversion (delay of gratification and preference for large rewards) made to ADHD symptoms in preschool children. Their results demonstrated that when other factors such as age, IQ and conduct problems were controlled, both executive dysfunction and delay aversion made significant independent contributions to the prediction of ADHD symptoms, suggesting two independent early-emerging pathways to ADHD. Thorell & Wahlstedt (2006) examined the relationship between executive functioning (inhibition, working memory and verbal fluency) and ADHD symptoms in a large sample of preschool children. Their results demonstrated that

preschool children with high levels of ADHD symptoms exhibited greater severity of executive dysfunction compared to children with low levels of ADHD. Sonuga-Barke et al., (2003) examined associations between executive dysfunction (planning, working memory and inhibitory control and individual differences in preschool children's symptoms of ADHD). No specific associations were found between ADHD symptoms and working memory or planning, but a significant negative association existed between inhibition and ADHD symptoms. Sonuga-Barke et al (2003) concluded from these findings that specific deficits in inhibitory control rather than general executive dysfunction underpinned the symptoms of ADHD during the preschool years.

Parenting Influences

As previously highlighted, ADHD is best viewed as a gene x environment interaction (Larsson et al., 2004). In this context, children with a biological predisposition will manifest the disorder when placed in the correct environment, typically one characterised by chaotic parenting (Johnston & Mash, 2001).

Negative parenting, including coercive, over-stimulating, intrusive and inconsistent parenting, expressed as early as the first year has been identified as being associated with preschool hyperactivity (Jacobvitz & Sroufe, 1987). Longitudinal studies suggest that such parenting also contributes to early delays in executive functioning and to later hyperactivity (Olson et al., 2002 Morrell & Murray, 2003;). It is important to note, however, that children with ADHD are genetically predisposed to be more negative, poorly regulated, and more challenging to parent. For example, preschoolers meeting DSM-IV criteria for ADHD were found to display high levels

of non-compliance during parent-child interactions (DuPaul et al., 2001). The association between parenting and ADHD is therefore best viewed as reciprocal. The child's difficult temperament might elicit ineffective parenting and poor coping, leading to a coercive cycle (Patterson, 1982), which maintains, and ultimately might exacerbate the behavioural symptoms of ADHD.

In addition, because of the high heritability rates associated with ADHD (Biederman et al., 1992; Smalley et al., 2000), children with ADHD are more likely to have a parent with the disorder, which typically interferes with consistent and appropriate parenting. For example, evidence suggests that parental ADHD prevents effective parental monitoring (Evans et al., 1994), and is associated with lax discipline (Harvey et al 2003).

Which Treatment is Appropriate for Preschool ADHD?

As preschool children with ADHD are most at risk for future problems (Sonuga-Barke et al., 2005) the provision of interventions that ameliorate ADHD symptoms are strongly recommended for this population (McGoey et al., 2002). The treatment of ADHD during the preschool period, however, is a relatively controversial topic and one that is largely dominated by the results of a recent American medication trial, the Preschool ADHD Treatment Study PATS (Kollins et al 2006).

PATS was the first controlled trial to assess the safety and efficacy of methylphenidate (MPH) in 183 children aged between three and five years. The trial was designed to evaluate the short term efficacy (5 weeks) and long term safety (40 weeks) of methylphenidate in preschoolers with ADHD (Kollins *et al.*, 2006).

Throughout the medication period, the presence of treatment related adverse events (AE) were noted at each stage. Thirty per cent of parents reported moderate to severe AE's, including emotional problems, sleep disturbance, appetite decrease, and irritability, and 11 percent discontinued treatment due to these events (Wigal *et al.*, 2006). This proportion is considerably higher than those reported in similar trials with school aged children. For example, the Multimodal Treatment Study of Children with ADHD (MTA Cooperative Group, 1999) reported less than 1 per cent discontinuation rate due to adverse effects. In terms of efficacy, significant improvements in ADHD symptoms were found following MPH treatment in PATS compared with a placebo control group with some, but not all doses. However, effect sizes were notably smaller than those reported in the MTA study, suggesting that MPH is not as effective with preschool children as it is for their school-aged counterparts (Greenhill *et al.*, 2006). Furthermore, the sample size was too small to effectively attest to the safety of MPH with preschool children (Wigal *et al.*, 2006). Purely pharmacological interventions for ADHD preschoolers are therefore less than desirable due to: i) lack of evidence for short-term or long-term effectiveness (Greenhill *et al.*, 2006); ii) concerns about side effects (Wigal *et al.* 2006); and iii) ethical objections to the use of medication to modify child behaviour (Perring 1997); highlighting the need to offer effective psychosocial interventions for preschool ADHD.

As an alternative to drug therapy, psychosocial treatment with parent training (PT) is considered a suitable first-level treatment for young children presenting with signs of ADHD (Conners, *et al.*, 2001). Due to some evidence of the efficacy of these interventions with school-age children with ADHD (e.g. Anastopououlos *et al.*, 1993;

Pollard et al., 1983), an increasing number of empirical studies have, over the last two decades, evaluated the outcomes of PT intervention for preschool age children with ADHD, and such interventions appear to be notably successful for this age group (Erhardt & Baker, 1990; Chronis et al 2006; Hartman et al., 2003). Following PT intervention, improvements have been found in parent-child interaction (Pisterman, *et al.*, 1989), in compliance and on-task behaviour (Sonuga-Barke *et al.*, 2001), and in parent-reported ADHD symptoms and child behaviour problems (Sonuga-Barke, 2001; Bor *et al.*, 2002; Jones et al 2007; Jones et al, in press).

The particular success of PT for preschool children most likely reflects the premise that early intervention, before the child's transition to school, and before the child's symptoms become associated with secondary problems such as academic failure, aggressive behaviour, and conduct problems, provides the best opportunity to alter the developmental course of the disorder (Daley 2006).

When considering effective PT treatments for ADHD during the preschool period three interventions have been shown to be effective and are worthy of further discussion.

New Forest Parent Training Package (NFPT; Weeks et al., 1999)

The NFPT is a parent-based intervention package specifically designed to address the core symptoms of ADHD, as well as target key parenting skills. The intervention entails eight 1-hour individual sessions delivered by specially trained therapists, and focuses on four intervention components: i) Psycho-education; ii) Parent-child relationships, including positive parenting, extension of language to promote

emotional self-regulation, and play; iii) Behaviour training to encourage consistent limit setting; and iv) Attention training to help parents work on improving their child's attention. Sonuga-Barke et al (2001) evaluated the intervention outcomes associated with NFPT compared with a parent counselling and support group (PC&S), which provided no specific strategies for parents, and a waiting list control group (WL). Results of the evaluation indicated that, following intervention, parent training significantly reduced ADHD symptoms as measured by questionnaires, clinical interview and direct observation of child on-task behaviour and improved mothers sense of well-being, when compared to the PC&S and WL group, and showed clinically reliable change. Reductions in ADHD symptoms in the PT were maintained at follow-up 15 weeks after completion of intervention. The effect size for PT in this preschool sample was comparable to those achieved using stimulant medication with older children (Daley & Thompson, 2007).

The Triple P Positive Parenting Programme. (Triple - P; Sanders et al., 1998; 2000)

The Standard Behavioural Family Intervention (SBFI) consists of an average of 10 one-hour sessions with a practitioner on an individual basis. This programme teaches 17 core child management strategies including 10 strategies to promote child competence and development (e.g. physical affection, attention, and praise), and seven strategies to promote effective limit setting and managing disruptive behaviour (e.g. rule setting, directed discussion, and time-out). A six-step planned activities routine is also introduced to parents to promote the generalization and maintenance of parenting skills (e.g. planning ahead and joint decision making). The Enhanced Behavioural Family Intervention (EBFI) includes the same strategies as the SBFI,

with the addition of strategies on partner support and coping skills (10 sessions; total duration 12 hours).

In a sample of families of preschool children with co-morbid attentional/hyperactive difficulties and disruptive behaviour, Bor et al (2002) compared standard and enhanced behavioural versions of the Triple - P family intervention with WL control group. The trial assessed a community sample of disadvantaged families who also had other problems such as maternal depression, marital conflict or low income. The evaluation demonstrated significant reductions in behaviour problems (including inattention), as well as significant improvements in parental competence in both the standard and enhanced behavioural family intervention compared to control group, with no benefit of EBFI over SBFI. These improvements in behaviour problems and parental competence were maintained at 12 month follow-up (Bor et al., 2002).

Incredible Years Parent Training Programme (IY; Webster-Stratton, 1982; Webster-Stratton & Hancock, 1998)

The IY is a group-based parenting intervention, available in both BASIC and ADVANCED format as well as the SCHOOL programme. Skills taught on the BASIC programme include i) how to establish a positive relationship with their child through play and child centred activities; ii) encouraging praise, reward, and incentives for appropriate behaviours, iii) guidance in the use of effective limit setting and clear instruction giving, and iv) strategies for managing non-compliance. Parents acquire these skills through facilitator-lead group discussion, brain storming, videotape modelling, role-play, shared problem solving, and rehearsal of taught intervention techniques through home assignments. Parents attend the group for 2.5

hours per week for 12 weeks. The ADVANCED version is a supplement to the BASIC version and lasts another 10 weeks, and covers interpersonal communication, anger management, and problem solving skills. The SCHOOL programme was developed to address risk factors associated with children's lack of academic readiness and poor home-school connections (Webster-Stratton & Hancock, 1998). The programmes have a strong evidence base for reducing conduct problems in both community and clinic settings, across different ethnic groups, as well as for children entering foster care (Webster-Stratton, 1990; Webster-Stratton, 1982; Linares et al., 2006; Reid et al., 2001; Hutchings et al 2007). There is a growing evidence-base for the efficacy of the BASIC intervention for children with conduct problems and ADHD symptoms (e.g. Hartman et al., 2003). The intervention has not been formally evaluated on children with a diagnosis of ADHD, although such a study is currently being undertaken by the programme developer. A recent evaluation examined the efficacy of the IY BASIC programme within a community-based sample of families with preschool children at risk of developing both conduct problems and ADHD (Jones et al., 2007). Following the delivery of the programme, the intervention group was associated with significantly lower levels of parent-reported inattention and hyperactive/impulsive difficulties, compared to the WL control group, even after controlling for post-intervention changes in child deviance. In addition 52% of those in the intervention condition, compared with 21% in the control condition, displayed clinically reliable improvements post-intervention (Jones et al, 2007). Further evaluation of the intervention group demonstrated that the post-intervention gains were maintained at 12- and 18-month follow-ups (Jones et al., in press)

To summarize so far, the evaluation of the NFPT provides strong evidence demonstrating its effectiveness on preschool children with ADHD (Sonuga-Barke et al., 2001), while the efficacy of the Triple - P and the IY programme have, to date, only been demonstrated on children with conduct problems and co-morbid ADHD (Bor et al., 2002; Jones et al 2007).

Theoretical Underpinnings of PT (the IY, Triple-P, and the NFPT)

As PT programmes were initially developed as interventions for families of children with conduct problems, the scientific underpinnings that drive many PT programmes are based on theoretical models of the development and maintenance of conduct problems (Webster-Stratton & Herbert, 1994). Typically, PT programmes are designed to help parents develop a positive relationship with their child by teaching them to use adaptive, non-violent discipline strategies to reduce or prevent behaviour problems, and by providing strategies to encourage the development of their child's social and emotional self-regulatory skills (Scott, 1999).

Many approaches to PT adopt a similar curriculum of intervention based on the principles of operant and classical conditioning, as well as social learning theory (Bandura, 1977). These theoretical models form the cornerstone of many PT programmes, including the IY and Triple-P programmes, and as a result, both programmes share some therapeutic content. It is to these models that we shall now turn.

Learning Theory

PT programmes are guided by operant conditioning principles, to enable parents to develop effective behaviour management skills (Webster-Stratton & Hancock, 1998; Sanders, 1999). Such interventions equip parents with behaviour modification techniques to increase the frequency of their child's pro-social behaviours through positive reinforcement, with attention, praise, and rewards. PT also provides strategies decrease the frequency of inappropriate behaviour through planned ignoring (parents can inadvertently reinforce their child's undesirable behaviours by attending to them – even if the attention is negative; Patterson, 1982). In addition, parents are encouraged to use non-violent discipline techniques (such as clear limit setting and use of time-out), as opposed to ineffective and violent forms of punishment, which not only elicits fear and hostility, but actually directly models aggressive behaviour for the child (Webster-Stratton & Herbert, 1994; Scott, 1999).

Not all behaviour is determined by its consequences (Scott, 1999). Some behaviour can be elicited by antecedent events (e.g. parent turns TV off, and the child has a tantrum). Within many PT programmes, parents are encouraged to closely monitor their child's behaviour, so that they can determine factors that trigger disruptive behaviour and make changes accordingly (Herbert, 1987). Setting up predictable and structured routines, and planning ahead to avoid confrontation is an essential component of effective parenting. For example, giving active children the opportunity to run around after school; avoiding demanding tasks when the child is tired / hungry; and taking books and toys to occupy the child when a long wait is likely, and so forth (Scott, 1999; Risley, Clark, & Cataldo, 1976).

Social Learning Theory

Processes other than stimulus-response psychology are involved in the integration of the child into the social world, such as imitation in early childhood and identification in middle childhood (Bandura, 1977), and such observational learning is important in the acquisition of moral and social behaviours. As a result, PT teaches parents to become good models for their child to imitate (Scott, 1999).

Patterson's Coercive Cycle

Perhaps one of the most influential model that describes the role of parent-child interaction in the development of child disruptive behaviour is Patterson's (1982) coercive cycle hypothesis. The model highlights the bi-directional nature of parent-child interaction, and identifies learning mechanisms which maintain coercive and dysfunctional patterns of family interactions, and predicts future antisocial behaviour in children (Patterson, Reid, & Dishion, 1992).

According to this model, parents are inadvertently training their children to become disruptive. To illustrate this point, a child's whining in response to a parental command is inadvertently negatively reinforced when the parent withdraws the command. Similarly, the parent's withdrawal of the command is also negatively reinforced because the child stops whining. Patterson refers to this as the negative reinforcement trap, which reflects the failure of the parent to control their child's behaviour effectively (Patterson, 1982).

The coercion hypothesis is also characterised by parents who escalate their own level of coercion by 'explosive' disciplining or chronic 'nagging' (which also models inappropriate behaviour for the child). Together these interactions lead to increased

coercive behaviour from the child and functions to establish extended chains of mutually aversive behaviour (Patterson, 1982).

Effective parenting inventions specifically teach parents positive child management skills as an alternative, and highlights the importance of positive attention and play, as well as effective limit setting, clear commands and follow-through.

Affective Nature of Parent child interaction

PT also stresses the importance of the affective nature of parent-child interaction, as a warm, positive bond promotes the child's emotional and social competence. A warm bond between parent and child also fosters resilience in the child to the extent that the association between harsh and ineffective parenting and externalising problems only occurs when such a bond is absent (Webster-Stratton & Herbert, 1994). This is why many parenting programmes place great emphasis on building a warm, positive relationship between parent and child, upon which limit setting and discipline can be built effectively.

Developmental Research

PT programmes are also informed by developmental research on parenting in everyday contexts, and early parent-child relationships (Hart & Risley, 1995). There is evidence to suggest that the risk of behaviour problems is reduced if parents are taught to use naturally occurring daily interactions to teach children language, social skills, use language to label and recognise emotions, developmental competencies, within an emotionally supportive context (Hart & Risley, 1975). Children are at greater risk of behaviour problems if they fail to acquire core language competencies

and impulse control in early childhood (Hart & Risley, 1995). As a result, PT encourages parents to help their children to develop language skills (by descriptive commenting and labelling), and to recognise emotions (both positive and negative) in themselves and in others. This also promotes the child's development social information processing skills. Children with conduct problems often misinterpret social cues – reading hostility and threat into what is actually a normal interaction (Dodge & Schwartz, 1997).

Both the IY and Triple-P are strongly grounded within these theoretical frameworks. One of the key differences between the programmes, however, is that the IY is a targeted intervention (for children diagnosed with conduct problems, or children at high risk of developing problems), whereas the Triple-P focuses on the prevention of social and emotional behaviour problems and strengthening parenting competencies at a population level. In this sense, the Triple-P targets *all* parents, and provides different levels of intervention depending upon the severity of family problems (Sanders, et al., 1999). The Triple-P adopts a public health perspective which involves the explicit recognition of the role of the broader ecological context for human development (Biglan, 1995; Mrazek & Haggerty, 1994). Triple-P's media and promotional strategy as a part of a larger system of intervention aims to change this broader context of parenting, and by doing so, reducing the stigma associated with parenting difficulties and attending parent interventions (Sanders, 1999).

In contrast to the IY and the Triple-P, the NFPT, is a psychosocial intervention that has been developed specifically to treat ADHD (Weeks, Laver-Bradbury, & Thompson, 1999). The programme is therefore directly informed by current patho-

physiological models of ADHD (such as the dual pathway model [Sonuga-Barke, 2002]). According to the dual pathway model, as previously mentioned, the core symptoms of ADHD are caused by underlying deficits in executive dysfunction or by a motivational delay aversion. Whilst the NFPT promotes the development of positive parent-child interaction, like the IY and the Triple-P, and provides parents with behaviour management techniques (based learning and social learning models) mentioned above, the strategies are more tailored for children with ADHD. For example, parents are provided with diaries so that they can record their child's behaviour on a daily basis to ascertain the antecedents that are eliciting, and the consequences that are maintaining certain behaviours (Weeks, Laver-Bradbury, & Thompson, 1999). The programme also highlights the importance of providing structured and predictable routines and clear boundaries, such as keeping commands short and simple, and asking children to repeat back any commands given, to facilitate their memory retention. Operant conditioning principles are also applied to reinforce skills such as concentration, listening, and waiting. Given the child's difficulties with concentration and memory, the programme promotes the use of shaping, which involves reinforcing each successive step that the child makes towards the desired behaviour. Specific games are also provided for parents to play with their children that encourage the development of skills such as listening and memory (such as Snap, I Spy, and Kim's game).

The programme also aims to help the children increase their delay tolerance. Sonuga-Barke (2004) suggested that delay fading could be a possible basis for reorganising the child's experience of delay, by altering the incentive value of delay, and ultimately increasing tolerance for delay. The NFPT uses the operant technique of

delay fading (Sonuga-Barke, 2004), whereby children are presented with repeated exposure to rewarded predictable delay periods of gradually increasing length. This is hypothesised to de-sensitise child to the aversive properties of delay through repeated exposure, and through classical conditioning principles of coupling signals for delay reward (for example, parents are encouraged to use timers facilitate the child's concept of waiting times and important transitions), Games that encourage the practice of turn taking and waiting are also suggested.

Another core component of the NFPT is Psycho education. For children with behaviour and emotional disorders and their families, education about their child's disorder is considered to be an essential component of a comprehensive approach to their care (Seltzer, Roncari, & Garfinker, 1980; Kemp, Hayward, Applewaite, Everett, & David, 1996). Not only can education encourage active participation in treatment, enhance adherence to treatment regimen, but can also provide parents with important coping skills. Psycho education also has the function of contributing to the de-stigmatisation of psychological disorders through improved knowledge about the nature and causes of the disorder (Schaffer, Fisher, Lucas, Dulca, & Schwab-Stone, 2000).

Why are these Interventions Successful at Targetting Preschool ADHD?

Whilst the NFPT contains some of the key elements of a CP intervention, it has the added advantage of being directly informed by key aetiological theories of ADHD, and therefore addresses the core symptoms of ADHD. The programme contains psychoeducation about ADHD, games aimed at tackling cognitive dysregulation and

inhibitory dysfunction and strategies aimed at reducing delay aversion (Weeks et al., 1999)

However despite the fact that Triple - P, and IY, are interventions developed to treat and prevent conduct problems, they appear to be effective for reducing ADHD in preschool children. This success may be attributed, at least in part, to the sound theoretical grounding of these interventions. Effective PT interventions draw from the principles of social learning theory, and emphasise the reciprocal nature of parent-child interaction (e.g. Hart & Risley, 1975; Patterson, 1982). Parents acquire behaviour management techniques, such as effective use of praise; using language to describe feelings; giving clear, concise instructions; effective limit setting; and the use of non-violent discipline techniques, all within the context of positive, sensitive, and responsive parenting. It is well documented that sensitive, responsive parenting in the early years provides the foundation for the development of child self-regulation skills (Hughes et al., 1998). Children with ADHD have particular difficulties with self-regulation skills such as listening, attending, and controlling their temper (Daley & Thompson, 2007). Therefore, providing parents with effective strategies, tailored to their child's individual needs, promotes child self-regulation, and can be instrumental in reducing symptoms of ADHD. The inclusion of strategies to promote more effective coping, problem-solving, and communication skills may also help parents to deal with the day to day stressors associated with parenting a child with ADHD.

Is the Evidence-Base which Supports ADHD Robust?

The evidence-base supporting the interventions reviewed above have several methodological issues that warrant further discussion. Firstly, in terms of the

measures used to assess the symptoms of preschool ADHD, the NFPT trial was particularly robust. The evaluation measured child ADHD symptoms using the Parental Account of Children's Symptoms (Taylor et al., 1991) - a well-validated structured clinical interview - as well as an objective observation measure of child attention and task switching (Sonuga-Barke et al 2001). The evaluation of the IY programme relied exclusively on parent report measures, and included the hyperactivity subscale of the Strengths and Difficulties Questionnaire (Goodman, 1997), and the Conners Parent Rating Scale (Conners, 1994). The SDQ and Conners have, however, been used extensively in treatment outcome studies, and are highly reliable and valid instruments (Goodman, 1997; Goodman & Scott, 1999; Conners, 1994). It should be noted, however, that the IY evaluation was conducted within the context of a larger trial – the North Wales Sure Start Trial. The trial evaluated the IY on a community sample of preschool children at risk of developing conduct problems (see Hutchings et al., 2007). Direct observations of parent-child interactions were included in the assessment battery of the main trial, but did not directly measure the core symptoms of ADHD. The trial evaluating Triple - P used a symptom checklist (based on the Diagnostic and Statistical Manual of Mental Health Disorders [4th edition; American Psychiatric Association 1994, 2000]) for screening purposes, and used only maternal reports on an Inattentive dimension of the Eyberg Child Behaviour Inventory (ECBI; Eyberg & Ross, 1978) as a measure of ADHD outcome (Burns & Patterson, 2000). The ECBI (Eyberg & Ross, 1978) was developed, and is predominantly used, as a measure of child conduct problems, assessed on an intensity and problem scale. The inattentive subscale of the ECBI was identified within a factor analytic study of the ECBI structure (Burns & Patterson, 2000). These analyses revealed a three-factor structure, with items resembling diagnostic criteria for

Oppositional Defiant Disorder (ODD), ADHD, and Conduct Disorder (CD). A recent study assessing the discriminant validity of these factors, however, found that, while the three-factor structure was successful in discriminating between children with and without externalizing problems, it was less effective in differentiating children within the externalizing spectrum. For example, the inattentive component discriminated children with significant attention problems from children without externalizing problems, but did not differentiate between children with ADHD and ODD (Weis et al., 2004). These results do question the utility of this measure within a treatment outcome study.

Secondly, the design of the NFPT study was particularly robust as it included a comparison intervention group (with no specific parenting strategies provided), in addition to a standard waiting list control group. With such a design one can be more confident in concluding that intervention outcomes are due to the components of the intervention as opposed to contact with therapists / services. Whilst the Triple - P evaluation did examine two intervention groups against a WL control group, one of these interventions was simply a more enhanced version of the other, and therefore both shared much of their therapeutic content. The IY trial only compared the intervention group with a standard control group. However, a recent examination of mediators of outcome for this particular sample, found that positive parenting (a key component of the PT) was a significant mediator of outcome, suggesting that improvements were due to therapeutic content, rather than group contact (Jones et al., submitted).

Thirdly, given the pervasiveness of impairment across situations, the use of multiple informants are strongly recommended in ADHD research. All evaluations, reviewed here, relied solely on the reports of one parent. However the NFPT study did include objective observation of child on-task behaviour, which is at least independent of parental report.

Finally, establishing the long-term stability of intervention outcome is of particular salience to PT research. There is some evidence to suggest that PT programmes are not entirely successful with every family, especially in the long term. Unfortunately, the positive effects of many prevention programmes decline rapidly after intervention (Serketich & Dumas, 1996). In this context, the IY evaluation was particularly robust, demonstrating 18-month stability of intervention effects (Jones et al., in press), whereas the Triple - P reported 12-month stability (Bor et al., 2002), while for NFPT outcome stability was only reported 15 weeks after programme completion (Sonuga-Barke et al., 2001).

Moderators of Outcome

The examination of moderators of outcome can help identify relevant sub groups of families with particularly good (or poor) treatment response (Brestan & Eyberg, 1998). From a clinical perspective, an understanding of patient characteristics that predict or moderate response to PT could help direct limited resources to those most likely to benefit, or to tailor specific interventions to meet patient needs (Hinshaw, 2002). The comprehensive investigation of putative moderators of outcome associated with psychosocial interventions for preschool ADHD is currently limited. A recent study of the NFPT, however, found that maternal ADHD symptoms was

associated with poorer outcome following parent training (Sonuga-Barke et al., 2003). Interestingly, another study recently suggested that mothers with elevated scores on a measure of ADHD were more positive about their ADHD children on measures of emotional relationships and interaction (Psychogiou et al., in press). This finding suggests that if parents with ADHD could be helped to manage their own ADHD symptoms, they might benefit more from PT (Daley & Thompson, 2007). Following a secondary analysis of the IY evaluation for families with co-morbid ADHD and conduct problems, no moderators of outcome were found, which indicates that the IY was successful for this population, regardless of initial level of risk. Predictor analysis found that severity of child ADHD symptoms at baseline was associated with better outcomes. Although maternal depression was not a barrier to initial outcome, it did impact negatively on the stability of intervention related effects in the long term (Jones et al., submitted) Finally no measures of parental ADHD symptoms were included in this study, so it was impossible to examine the impact of parental ADHD on outcome. McTaggart & Sanders (2007) examined moderators of intervention outcome for 177 parents who participated in Triple - P. Their results showed that parents' capacity to change dysfunctional parenting practices was not moderated by the child's gender, family income, family type, or pre-intervention level of parental stress, but was partially mediated by changes in parental satisfaction and efficacy. Irrespective of their socio-demographic background, parents who completed the Triple-P Positive Parenting Programme were equally likely to succeed in changing their parenting practices. These findings suggest the robustness of intervention effects across a diverse range of parents. No study has examined moderators of outcome for Triple - P with parents of children with ADHD.

Mode of Delivery

Mode of delivery is another important consideration for service providers. Both Triple - P and NFPT evaluations are individual based interventions although a group version of Triple - P has also been used (McTaggart & Sanders 2007), while IY is a group based intervention. Specific benefits have been associated with both modes of delivery. Individual therapist-led interventions have the advantage of increased flexibility, which is necessary with more complex cases (Daley & Thompson, 2007). Group based interventions, on the other hand, are more cost effective (Cunningham et al., 1995) and provides the opportunity for social support and contact with others in similar situations, which is especially important for disadvantaged families where social support is often lacking (Dumas & Wahler, 1983). Furthermore, group-based therapies such as IY can be applied flexibly to attend to individual family needs and address issues of co-morbidity (Reid & Webster-Stratton, 2001).

However, individual-based therapies may provide the optimal treatment mode for ADHD families, given the heterogeneity and complexity of the disorder.

The NFPT, Triple - P, as well as the IY are available in self-administered versions, and can all therefore be delivered on an individual level. Both the IY and Triple - P self-administered versions have been evaluated on families of children with conduct problems, and results suggested that while self-directed versions were not as effective as therapist led versions, child outcomes were superior to a no treatment, waiting-list control group (Markie-Dadds, & Sanders, 2006; Webster-Stratton 1988). An evaluation of the self-administered version of the NFPT programme is currently being conducted in the UK.

Barriers to Implementation

The field of PT currently places great emphasis in fostering therapeutic alliance and addressing barriers to attendance, in order to improve engagement and adherence with the programme. Therapeutic alliance is one of the most important determinants of positive outcome in children with oppositional, aggressive or anti-social behaviour. A collaborative approach to programme delivery is fundamental to promote therapeutic alliance. A reciprocal relationship between parent and therapist is essential, whereby therapists use their own knowledge and skills as well as the parent's unique strengths and perspectives. Respect for each parent's contribution is paramount in order to foster a non-blaming relationship built on trust and open communication. This way, parents acknowledge that they are jointly responsible in facilitating change (see Webster-Stratton & Herbert, 1994).

Research has been conducted to identify potential barriers to attendance. A common theme to emerge from these studies include work and family responsibilities, socio-economic disadvantage, and transport problems (Kazdin, 1997). IY offers a good model for therapeutic alliance by adopting a collaborative approach to programme delivery, and by overcoming barriers by routinely providing child care facilities on site, a meal, transport where needed, and holding groups in accessible locations (such as in the community) making intervention accessible to even the most disadvantaged families (Hutchings, Bywater & Daley 2007). Tangible benefits (such as prizes for completing homework) are also incorporated into weekly IY sessions.

Treatment Integrity and Implementation Fidelity

With the current emphasis on service providers to deliver evidence-based interventions, it is essential that interventions are implemented with fidelity. The IY programme is, again, a good example of an intervention that rigorously addresses fidelity issues. Within the IY evaluation, the groups were run by experienced and certified group leaders, who adhered to the programme delivery as specified in the programme manual. The evaluation addressed implementation fidelity by, providing all course materials, ensuring leaders had a three-day basic leader training and had previous experience in running a group; completion of a group leader Peer and Self Evaluation questionnaire; parent completed satisfaction questionnaires; Session Specific Checklists to monitor treatment integrity; access to mentor supervision, to evaluate progress and delivery method (see Hutchings et al., for more detail)

Within the Triple - P evaluation, all seven practitioners were trained prior to delivery of intervention, and supervision was provided. Detailed written protocols that specified the content of each session, in-session exercises to complete, and homework tasks were developed for both the standard and enhanced conditions. Practitioners completed the protocol adherence checklists and videotaped each intervention session. Analysis of checklists indicated 100% adherence with the specified protocol each week. Within the NFPT evaluation both therapists were trained prior to delivery of the intervention and they also received on-going supervision. Treatment delivery was manualised and weekly sessions were audio taped. Analysis of treatment sessions indicated high levels of treatment integrity.

To summarise, the three evaluations, reviewed above, suggest that psychosocial intervention is a valuable treatment alternative to stimulant medication during the

preschool years, especially when intervention is tailored to the problems that children with ADHD experience, delivered in a timely way (i.e. early) and when the interventions are informed by theories about the aetiology of ADHD.

Future Directions

While evidenced based interventions exist for preschool children, little evidence exists to inform clinicians about which intervention they should choose. There is a pressing need for a series of head-to-head trials to evaluate NFPT, Triple - P and IY together within the one study. Results of these head-to-head trials would be useful in informing clinicians about the relative efficacy of each intervention, as well as how sensitive each intervention was to moderators of outcome. Health economic evaluation of head-to-head trials would also allow clinicians and health care providers to compare and contrast interventions with different modes of delivery and number of sessions. This would facilitate an evaluation of the relationship between cost of delivery and short and long-term efficacy of intervention.

Despite the availability of effective evidence-based interventions, the prevalence of ADHD creates a need that far exceeds available personnel and resources. In many parts of the UK parents often have to travel long distances to access services provided at inconvenient times, leading to high levels of non-engagement or non-completion. A recent Cochrane review (Montgomery et al., 2006) concluded that self-administered interventions were worth considering in clinical practice targeting child behaviour problems. The implementation of self-administered interventions could reduce the amount of time therapists have to devote to each case, increase accessibility to intervention, and release clinician time to concentrate on more complex cases. For

families, self-administered interventions significantly reduce or eliminate costs, transport, as well as timing difficulties. Families can complete the intervention in their own home, in their own time, and at their own pace. They are also potentially cost effective and could be used to ease the financial burden of mental health problems on the community (Morawska & Sanders 2006).

While there is a some evidence to support the efficacy of self administered interventions for parents of children with conduct problems (Markie-Dadds & Sanders, 2006; Webster-Stratton et al., 1998), to date no studies have examined the efficacy of self administered intervention for young children with ADHD and possible comorbid conduct problems (Daley 2006). A greater emphasis should be placed on the evaluation of self-administered versions of the NFPT, Triple - P, and the IY programmes for parents of preschool children with ADHD.

Conclusions

Recent findings from the PATS study have highlighted the challenges of using medication with preschool children with ADHD. A number of evidence based parent training programmes do exist for preschoolers with ADHD. These interventions demonstrate good effect sizes, few moderators of outcome and offer ample opportunities for training for clinicians who wish to deliver them. It therefore seems inconceivable that any clinician working with preschool children with ADHD should not be able to offer some form of parent training intervention.

CHAPTER 3

STUDY 1

Efficacy of the Incredible Years BASIC Parent-training Programme as an early intervention for children with conduct problems and ADHD symptoms.²

² This study formed the basis of a paper published in *Child: Care, Health and Development*: Jones., K., Daley, D., Hutchings, J., Bywater, T., & Eames, C. (2007). Efficacy of the Incredible Years BASIC Parent-training Programme as an early intervention for children with conduct problems and ADHD.

Abstract

Background: The efficacy of the Incredible Years Basic parent-training programme for a community-based sample of families with preschool children at risk of developing both conduct problems (CP) and attention deficit hyperactivity disorder (ADHD) was examined.

Methods: Preschool children displaying signs of both early onset conduct problems and ADHD were randomly allocated to either Incredible Years (IY) parent-training (PT) intervention, or to a waiting list control group (WL). Child symptoms were assessed before and after the intervention.

Results: Post intervention, the intervention group was associated with significantly lower levels of parent-reported inattention and hyperactive/impulsive difficulties, even after controlling for post-intervention changes in child deviance. In addition 52 per cent of those in the intervention condition, compared with 21 per cent in the control condition, displayed clinically reliable improvements post-intervention, giving an absolute risk reduction of 31 per cent and a number needed to treat (NNT) of 3.23.

Conclusions: Findings from this study indicate that the IY PT programme is a valuable intervention for many preschool children displaying early signs of ADHD.

Attention Deficit Hyperactivity Disorder (ADHD; American Psychiatric Association [APA], 1994) is characterised by developmentally inappropriate levels of inattention, impulsivity, and over activity (APA, 1994; Barkley, 1997). These problems typically emerge in early childhood, are relatively persistent, and result in cross-situational impairment (e.g. at home and at school; APA, 1994). The current Diagnostic and Statistical Manual of Mental Disorders (4th ed; DSM-IV) specifies three subtypes of ADHD: predominantly inattentive subtype; predominantly hyperactive/impulsive subtype; or combined subtype. Problems must be evident in two or more settings (e.g. home and school), and the child must show significant impairment in social, school, or work functioning (APA, 1994; 2000). Prevalence estimates indicate that between 3-6% of school-aged children meet diagnostic criteria for ADHD (APA, 1994; 2000; Szatmari, 1992).

Left untreated, the long-term prognosis for these children is poor. Children with ADHD are at a much greater risk of experiencing problems in the educational, personal and social domains (Daley, 2006). Children with ADHD are also at a heightened risk of developing conduct problems, substance abuse, and interpersonal and occupational difficulties that can persist into adulthood (Manuzza et al., 1991; Taylor et al., 1996).

The disorder is also highly co-morbid (Szatmari et al., 1989a). Chief among these co-morbidities are conduct problems (including oppositional defiant disorder [ODD] and conduct disorder [CD]), occurring in an estimated 30-70% of children diagnosed with ADHD (Biederman et al., 1991; Szatmari et al., 1989a). These children typically experience more severe symptoms, more peer rejection, and their parents are more

likely to encounter higher levels of psychosocial adversity (Abikoff & Klein, 1992; Kuhne et al., 1997), which poses a significant clinical and public health problem (Szatmari et al., 1989b).

Intervention

Guidance from both the National Institute for Clinical Excellence in the UK and American Pediatric Association in the US indicates that a combination of psychostimulant medication (e.g. methylphenidate) and specific psychosocial therapies is the optimal intervention package for the management of ADHD symptoms. Despite evidence for the short-term benefit of this combination, no controlled evidence for the generalized long-term effectiveness has, as yet, been provided. There are also some ethical objections to the prescription of stimulant medication to young children, especially in light of the fact that ADHD is not typically diagnosed until the child reaches middle childhood (APA, 2000). Thus, behavioural-psychosocial treatment (BPT) is considered an appropriate first level treatment for preschoolers with symptoms of ADHD and conduct disorder (Conners et al., 2001).

Evidence for the efficacy of psychosocial intervention for parents of children with ADHD appears stronger for preschool children (Sonuga-Barke et al., 2001; Bor et al., 2002), weaker for school aged children, and non-existent for adolescents (Pelham et al., 1998). The success of psychosocial intervention in the preschool years is based on the premise that early intervention, before the transition to school and before the child's behaviour becomes associated with anti-social tendency and school failure, offers the best opportunity of altering the developmental course of the disorder (Daley 2006).

Given the importance assigned to family and parenting characteristics in the development of preschool children, parenting programmes are generally viewed as an essential component of early intervention. Some Parent-training (PT) programmes have a successful history as an effective intervention for treating children with ODD and CD (Brestan & Eyberg, 1998; Scott et al., 2001; Webster-Stratton, 1990; 1998). In essence, PT provides parents with child behaviour management techniques that are grounded in the principles of social learning theory. In spite of its origin as a treatment method for children with anti-social behaviour, recent studies have found that some PT programmes work equally well for children with co-morbid ADHD (Hartman et al., 2002; Pelham, 1998), and that conduct problems and ADHD symptoms may develop during a sensitive period in development through an interaction between the child's emotional dysregulation and parents' rejecting and coercive parenting (Morrell & Murray, 2003; Kochanska, 1993)

Evidence for Psychosocial Intervention for Preschool Children with ADHD

Pisterman et al., (1989) examined the efficacy of a group based parent-training programme on the compliance behaviour of preschool children with symptoms of ADHD. The treatment group showed significant improvements on observational measures of parent-child interactions and child compliance behaviour post-intervention. These gains were maintained at three-month follow up.

More recently, Sonuga-Barke and colleagues (2001) compared a PT intervention with a parent counselling and support treatment, and a wait-list control group WL. It was found that parent training significantly reduced ADHD symptoms and improved

mothers' sense of well-being. Fifty-three per cent of children in the PT group displayed clinically significant improvement following intervention. Similarly, Bor and colleagues (2002) evaluated intervention outcomes from standard and enhanced behavioural family intervention with WL control for preschool children with co morbid attentional/hyperactive difficulties and disruptive behaviour. Significant reductions in behaviour problems and increased parental competence were found in both family intervention groups compared with the control group, with 80 per cent of the children in the intervention group showing clinically significant improvements in observed negative behaviour, and in parent reported inattention.

Rationale for Examining the IY for ADHD

The Incredible Years (IY) BASIC parenting programme (Webster-Stratton & Hancock, 1998) has been identified as one of eleven 'Blueprint' interventions by the Center for Violence Prevention at the University of Colorado (Mihalic et al., 2002), having satisfied stringent scientific criteria (including use of long-term follow ups, randomised controlled trials, replication by independent researchers, and that they were published in sufficient detail to effective implementation by others). There is a strong evidence base for the effectiveness of this programme in enhancing parenting competencies and in reducing disruptive behaviours in children, and these gains have been maintained at long-term follow-up (Scott et al, 2001; Webster-Stratton, 1990; 1998). Many of these children with disruptive behaviours have co-occurring ADHD symptoms, and there is evidence that the IY programme is equally effective for these children (Scott et al., 2001; Hartman et al., 2002).

The IY parenting programme was selected as the intervention programme for this study due to the impressive evaluation data on the programme and the availability of training and supervision in Wales. Furthermore, a core component of the programme aims to help parents to develop skills to promote their child's emotional development. For children with ADHD symptoms in particular, this component may provide a valuable medium by which to break the negative interaction between coercive parenting and the child's emotional dysregulation (Morrel & Murray, 2003), thus improving the child's emotional regulation and ADHD symptoms in the long term. The programme was evaluated using a community sample of preschool children presenting signs of co-occurring disruptive behaviours and ADHD symptoms in 11 Sure Start centres in North and Mid-Wales (Hutchings et al., 2007; Hutchings et al., 2004).

Aims of the study:

Specifically the aims of the study were to:

1. Evaluate the effectiveness of the IY parenting programme for reducing ADHD symptoms in preschoolers with conduct problems and co-morbid ADHD symptoms
2. Examine whether post-intervention improvements for ADHD symptoms were independent of changes in conduct problem scores.

Methods

Participants

Participants in the research were drawn from an existing sample of 133 families, that had been previously randomised to one of two conditions on a two to one basis: intervention (PT) and wait-list control (WL) (Hutchings et al., 2007; Hutchings et al., 2004). The 133 families came from a sample of 255 families, who had been identified by their local health visitors, and who lived in designated Sure Start areas in North and Mid-Wales. Families were eligible for inclusion into the research if they had a child aged between 36 and 48 months, and if parents reported their child's behaviour to be above the clinical cut-off on either the problem or intensity subscale of the Eyberg Child Behaviour Inventory (ECBI; Intensity score ≥ 127 or problem score ≥ 11 ; Eyberg & Ross, 1978; Eyberg, 1980). To be eligible for this study, the parents must also have rated their child's behaviour to be above the clinical cut-off on the Hyperactivity subscale of the Strengths and Difficulties Questionnaire (SDQ; Hyperactivity score ≥ 7 ; Goodman, 1997). After these criteria were employed, 79 of the 133 families met inclusion criteria for this study, showing signs of both early onset externalising problems and hyperactivity. Fifty of these families were in the intervention group, and twenty-nine in the waiting list control group.

Demographic characteristics for the sample are presented in Table 1. All primary caregivers interviewed were mothers (mean age 27.71 [S.D. = 5.32]). Thirty nine per cent of families were single parents. The mean age of the index child was 46.28 months (SD = 6.16), and they were predominantly male (68%). There were no significant differences between the intervention and control groups on these socio-

demographic characteristics at baseline, indicating that the groups were well matched on these factors.

Table 1: Demographic Characteristics of Participants*

| Variable | Intervention (BPT) | | Control (WL) | | Total | |
|------------------------------|--------------------|------|--------------|------|----------|------|
| | (n = 50) | | (n = 29) | | (n = 79) | |
| | M | SD | M | SD | M | SD |
| Child's age (months) | 46.50 | 6.08 | 45.90 | 6.38 | 46.28 | 6.16 |
| Mother's age (years) | 27.54 | 5.80 | 28.00 | 4.48 | 27.71 | 5.32 |
| Number of children in family | 2.52 | 1.32 | 2.79 | 1.63 | 2.62 | 1.44 |

*Groups did not differ significantly on any characteristic (χ^2 and analysis of variance)

Measures

Child and family factors were assessed using a combination of interview, questionnaire, and direct behavioural observation. The measures were administered to primary care givers at baseline, and six months later, with the intervention being delivered during the intervening period.

Screening: Parent Report Measures

Eyberg Child Behaviour Inventory (ECBI; Eyberg & Ross, 1978;

Eyberg, 1980)

This is a 36-item parent report measure assesses the occurrence of problem behaviours in children aged from two to sixteen years. Each behaviour is rated on two scales: a seven-point Intensity scale, which measures the frequency of particular behaviours, and a *Yes-No* Problem scale that identifies whether the parent perceives

the behaviour to be a problem. The scale demonstrates good stability, with reliability coefficients ranging from .86 (test-retest) to .98 (internal consistency) (Robinson et al., 1980). The ECBI has shown good convergent validity, with ECBI scores being significantly correlated with scores on the Child Behaviour Checklist (CBCL; Achenbach & Edelbrock, 1986) and the Parenting Stress Index (PSI; Abidin, 1990). The ECBI has been shown to discriminate well between children with and without conduct problems (Eyberg & Ross, 1978; Baden & Howe, 1992).

Strengths and Difficulties Questionnaire (SDQ; Goodman, 1997)

This 25-item inventory was designed as a behavioural screening measure to assess the occurrence of particular behaviours that have been associated with conduct problems, hyperactivity, emotional symptoms, and peer problems in children. The scale has demonstrated good stability, whether judged by internal consistency (mean Cronbach's alpha: 0.73), cross-informant correlation (mean: 0.34), and test-retest stability after 4-6 months (mean: 0.62) (Goodman, 2001). In terms of discriminant validity, high SDQ scores have been associated with a strong increase in psychiatric risk (Goodman, 2001).

Parent Report measures (outcome)

Conners Abbreviated Parent/Teacher Rating Scale (Conners, 1994)

This 10-item scale assesses the incidence of ADHD symptoms observed by the parent in children aged 3-7 years. It comprises of the most highly loaded symptoms from the factor scales of the Conners Parent and Conners Teacher Rating Scale. The respondent (parent) is asked to rate the frequency of particular behaviours on a four-point scale ranging from 0 (not at all) to 3 (very much).

Observation of Mother and Child Behaviour: Dyadic Parent-child Interaction Coding System (DPICS; Eyberg & Robinson, 1981)

Mother and child behaviour was assessed using a 30-minute live home observation system (the Dyadic Parent-Child Interaction Coding System [DPICS; Eyberg & Robinson, 1981]). The DPICS comprises 37 behaviours relating to both parent and child, which are summarised into four 'parenting' composite variables: 1) positive parenting (including praise, positive affect, physical positive behaviour), 2) critical parenting (including negative commands and critical statements), 3) total commands, and parent non-verbal affect (valence); and three 'child' composite variables: 1) Child deviance (including negative and destructive behaviour and non-compliance), 2) pro-social behaviours (including physical warmth and positive statements), and 3) child non-verbal affect (valence).

Within the observational measure, coding is continuous and records the total frequency of each behaviour per specified interval. The observation is divided into six five-minute segments, which is recorded consecutively. The observations were carried out in a naturalistic, unstructured setting, whereby the families were instructed to continue with what they would normally do at that particular time of day. In order to obtain sufficient parent-child interaction data, families were instructed to stay in one room, and to have TVs and computers switched off.

Six trained observers coded the interactions. In order to maintain inter-rater reliability observers coded videotaped practice interactions on a weekly basis. Inter-rater agreement was assessed by having 20 per cent of observations coded by a second

rater. All coders were blind as to participant group status. An acceptable level of inter-rater agreement was achieved (75%).

Design

This study included children presenting signs of early onset co-occurring ADHD symptoms and disruptive behaviour from within a randomised controlled group design (stratified for sex and age of index child) with two conditions (IY and WL) and two time points (pre- and post-intervention).

Randomisation

The study utilised a pragmatic randomised controlled trial design. Participants were block-randomised by area. The unit of randomisation was the parent index-child pair. The fourth author blindly, and randomly, allocated participants on a 2:1 basis (intervention to control) after they were stratified by age and sex, using a random number generator. This design gives the opportunity to evaluate a larger intervention sample than a 1:1 ratio with only small loss of statistical power, and is a design favoured in this field of research. The benefits of this 2:1 design are mainly ethical in that more families receive the intervention, less have to wait for it, and additional places are available to be offered to non-research parents at each local service area in the subsequent (control) group.

Allocation was carried out after baseline assessment. Interviews and observations were carried out by researchers blind to participant allocation status at both time points to reduce bias.

Procedure

Pre- and post- intervention, participating families were visited in their home on two occasions within a three-day interval. At the first visit, interview and questionnaire measures were administered to the parent. This visit lasted approximately one hour. Live observations were carried out during the second visit. These visits took place between the hours of 4 and 7pm at the family home and lasted for approximately 40 minutes. During the 30-minute observation, the parent and index child were instructed to stay in one room, with the TV off, and to interact as they would normally do at that time of day.

Intervention and Treatment Integrity

Twelve intervention groups were delivered in 11 Sure Start areas across North and Mid Wales. The programme promotes positive parenting through the use of reinforcement, and there is a strong evidence base for the effectiveness of the programme in enhancing parenting skills, reducing child conduct problems, as well as improving parent-child relationships (Webster-Stratton, 1998; Scott et al., 2001). Skills taught on the programme include: i) how to establish a positive relationship with their child through play and child centred activities, ii) encouraging praise, reward, and incentives for appropriate child behaviours, iii) guidance in the use of effective limit setting and clear instruction giving, and iv) strategies for managing non-compliance. Parents acquire these skills through facilitator-lead group discussion, brain storming, videotape modelling, role-play, and rehearsal of taught intervention techniques, both within the group, and through home assignments. Parents attended the group for 2.5 hours per week for 12 weeks, and received weekly telephone calls from the group leader to encourage and monitor progress.

The groups were run by experienced and certified group leaders, who adhered to the programme delivery as specified in the programme manual. The programme addresses implementation fidelity by: providing all course materials, CDs, handouts, books, raffle prizes etc.; ensuring leaders had a three-day basic leader training and had previous experience in running a group; completion of a group leader Peer and Self Evaluation questionnaire to evaluate treatment exposure, adherence, treatment delivery; parent completed satisfaction questionnaires; completion of Session Specific Checklists to monitor treatment integrity, participant responsiveness, treatment delivery, and treatment differentiation; access to mentor supervision, to evaluate progress and delivery method, e.g. reviewing videotapes within a three-hour weekly supervision session with an IY trainer; and certification – evaluation of treatment fidelity based on observation of random videotapes by an independent IY trainer.

Results

Attrition

Attrition rates were generally low. Out of the 79 families assessed at baseline, 71 (90%) completed follow-up assessment. Of those who failed to complete post-assessment, six were in the intervention group, and two in the control group.

Attendance

Within the intervention condition, 44 out of 50 (88%) attended at least one session, and of those, 37 (84%) attended eight or more sessions. The overall mean attendance was 9.47 sessions (SD = 2.94).

Intention to Treat Strategy

Using an intention to treat strategy is a fundamental requirement of a randomised controlled trial. The strategy entails the inclusion of ALL participants who were randomly allocated to intervention and control groups, irrespective of whether they adhered to the intervention or not, or whether they dropped out of the research.

Intervention trials that do not analyse the data on an intention to treat basis are not, strictly speaking, randomised controlled trials, as such evaluations only include participants who have complied with the intervention and continued their participation in the research. Such trials are therefore unrealistic from a clinical perspective, as there is invariably some degree of treatment non-adherence and dropout in clinical practice.

In order to conduct proper intention to treat analysis, outcome data must be available for participants who have not adhered with treatment. However, if no outcome data are available due to participants being lost to follow-up, it is acceptable to carry forward their baseline scores to serve as their outcome.

Inclusion of cases in the current analyses was done on an intention to treat basis, in order to preserve randomisation. All participants who were randomly allocated to either intervention or control group were therefore included in the statistical analyses. As no post-intervention outcome data were available for the families who dropped out, it was therefore assumed that there had been no change, their baseline scores were carried forward to subsequent follow-ups.

Impact of Intervention on Conduct Problems:

The focus of this study is on the impact of intervention on ADHD symptoms. The intervention was very successful at reducing CD symptoms, but these results have been presented in a separate paper (Hutchings et al., 2007).

Preliminary Analyses (Equivalence):

Initial analyses examined the equivalence of groups at baseline on primary measures of outcome. Results of a Kolmogorov Smirnov test indicated that both the DPICS child deviance and the SDQ hyperactivity measures were significantly non-normal: $D(79) = 2.18, p = 0.00$; and $D(79) = 1.78, p = 0.04$, respectively. However, ANOVA is robust to the violation of the non-parametric assumption with more than 15 cases per cell (Green et al., 2000).

Using a series of one-way Analysis of Variance ANOVAs, no significant differences were found between the two groups at baseline, indicating that intervention and control families were well matched prior to receiving intervention. These findings are summarised in Table 2.

Table 2: Equivalence of Groups

| Measure | Intervention (n = 50) Mean (SD) | Control (n = 29) Mean (SD) | F | P |
|-------------------------|------------------------------------|-------------------------------|-------|------|
| Conners | 20.56 (5.86) | 19.34 (6.14) | .761 | .386 |
| Child Deviance (DPICS) | 17.48 (19.78) | 25.07 (37.78) | 1.406 | .239 |
| SDQ Hyperactivity Score | 8.34 (1.14) | 8.24 (1.15) | 0.137 | .713 |

Short-Term Intervention Effects

For the intervention group, the mean scores on the Conners decreased from 20.56 (SD = 5.86) at baseline to 14.60 (SD = 8.12) at follow-up, showing an average reduction in score of 5.96. Scores also decreased for the control group, although this decrease was considerably smaller, with a mean score of 19.50 (SD = 6.09) at baseline decreasing to 17.80 (SD = 6.53) at follow-up, a mean reduction of 1.7.

An ANCOVA was performed to statistically analyse the efficacy of intervention, with the follow-up Conners scores entered as the dependent variable; group (intervention and control) as the fixed factor, and baseline Conners score entered as the co-variate.

ADHD symptoms improved by an estimated 3.95 points more on average in the

treatment group than in the WLC group (95% Confidence Interval 0.87 – 7.03, $p = 0.013$). These improvements were found to be significant: $F [2, 76] = 6.53; p = 0.013$

Short-Term Intervention Effects (Controlling for Change in Child Deviance)

To establish whether improvements in ADHD symptoms were independent of improvements in child deviance, further analysis using ANCOVA was conducted, with changes in observed child deviance (DPICS score) from pre- to post-intervention added as an additional covariate. Results indicated that post-intervention improvements remained significant ($F [3, 65] = 8.77, p > 0.004$). These findings are summarised in Figure 2 and show an advantage of intervention over no intervention even when improvements in conduct problems were controlled for.

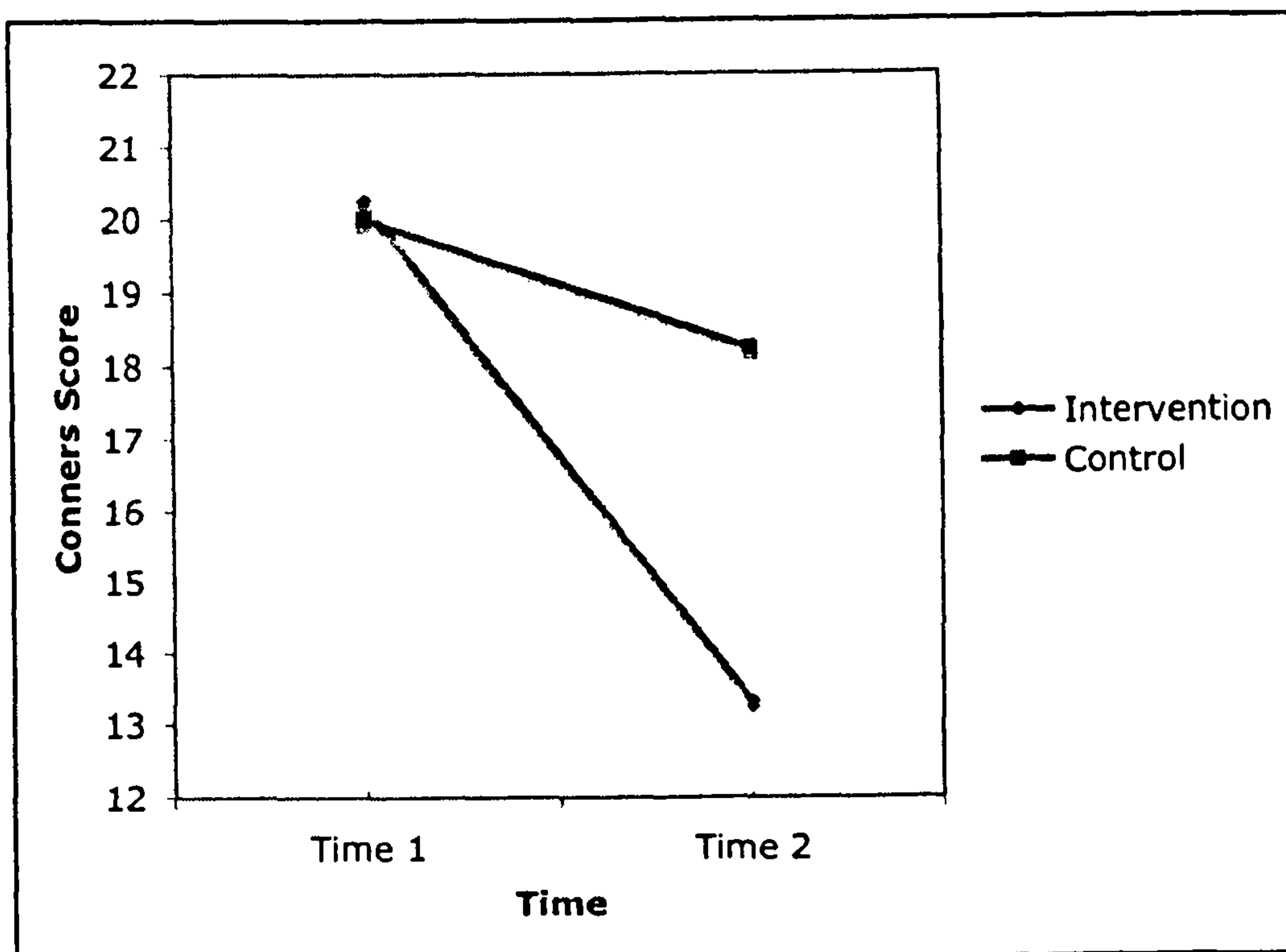


Figure 2: Short Term Intervention Effects for Intervention and Control Groups (Controlling for Change in Observed Child Deviance)

Clinical Significance of Change

To examine clinical significant change as opposed to statistical change, two criteria were used: The Reliable Change Index (RCI; Jacobson & Truax, 1991); and a reduction in scores to below clinical threshold on the Conners (Conners, 1994).

Analysis of clinical significance using RCI criteria indicated that intervention with a 12-week parent-training course is associated with improvement in 52 per cent of participants, compared with a 21 per cent improvement in the WL group, giving an Absolute Risk Reduction (ARR) of 31% (95% CI 11.4 – 50.6%), which yields a Number Needed to Treat (NNT) of 3.23 (95% CI 1.98 – 8.77).

Using the clinical cut-off criteria, fifty-eight per cent of the intervention group, compared with 33 per cent of the control group had follow-up scores that had fallen below the level of clinical concern (≤ 15 ; Conners, 1994), yielding an ARR of 24% (95% CI 20.1 – 45.99%), which gives an NNT of 4.17 (95% CI, 2.17 – 4.98).

Discussion

Overall, the results indicate that the intervention condition was associated with more positive outcomes for children. Using intention to treat analysis, improvements in parent-reported levels of child inattention and hyperactivity from baseline to follow-up were significantly greater in those families randomised to intervention compared to the control group. These findings suggest that the IY parent-training programme is a successful early intervention for preschool children presenting signs of co-morbid ADHD type symptoms and disruptive behaviour. The results contribute to the growing evidence in the literature for the effectiveness of PT programmes with families of preschool children with these types of difficulties. These improvements remained statistically significant even after controlling for changes in observed child deviance, suggesting that reductions in ADHD symptoms were independent of reductions in conduct problems. The IY PT programme may therefore provide an effective intervention treating early-onset ADHD symptoms alone.

Further investigation of the efficacy of the intervention demonstrated that over half of those in the intervention condition had shown clinically significant improvements in parent-reported negative behaviour. These findings are somewhat consistent with those of Sonuga-Barke et al. (2001), and with Bor et al., (2002), who reported that 53 per cent, and 80 per cent (respectively) of children in their PT groups demonstrated clinical significant improvements following intervention.

Limitations

These results must be interpreted with some degree of caution, as there are some methodological weaknesses that need to be addressed. Three key limitations are

salient. Firstly, the primary outcome measure used was parent-reported. In the context of intervention, parents' expectations of treatment outcome may bias their responses to self-reported outcome measures. The findings would be strengthened if supported by independent behavioural observations and by reports from independent sources (e.g. preschool teachers). Secondly, all children in this study scored high on measures of *both* hyperactivity and conduct problems, thus it was not possible to examine potential differential effects of treatment on subgroups of children. From a clinical perspective, however, this is typical of the presentation of ADHD and conduct problems at this particular age. Thirdly, in the absence of a long-term follow-up we cannot say that intervention gains were maintained beyond the 3 months post-intervention. Nevertheless, there is strong evidence that the effectiveness of the IY parent programme is relatively stable over time, with evidence from independent sources of long-term intervention effects (Scott et al., 2001; Webster-Stratton, 1990; 1998).

Clinical Implications

The IY basic parent-training programme appears to have a positive effect on ADHD type symptoms. The results of this study suggests that clinics who have already trained IY therapists, and currently do not have training on any other evidence-based intervention for ADHD, should consider using IY, particularly as a first-line early intervention.

Future Studies

The findings from this study leave two important unanswered questions, which need to be addressed. Firstly does the IY programme lead to changes in objective measures

of ADHD symptoms in addition to changes in parental reports of ADHD symptoms?

Secondly which early intervention programme is most effective at changing the developmental course of ADHD? Sonuga-Barke et al., (2001) have demonstrated impressive results with their New Forest Parent-training programme (NFPT).

Clinicians, and commissioners of health care interventions would obviously be interested to know whether IY or NFPT was better at altering the developmental course of ADHD. This complex question could only be answered with a head-to-head study of IY and NFPT.

CHAPTER 4

STUDY 2

Efficacy of the Incredible Years Programme as an early intervention for children with
conduct problems and ADHD: Long-term follow-up³

³ This study formed the basis of an empirical paper accepted for publication in *Child: Care, Health, and Development*: Jones, K., Daley, D., Hutchings, J., Bywater, T., & Eames, C. (in press). Efficacy of the Incredible Years Programme as an early intervention for children with conduct problems and ADHD: Long term follow-up.

Abstract

Background: This study examined the long-term efficacy of the Incredible Years (IY) BASIC Parenting Programme delivered as a preventive intervention with parents of preschool children who display signs of Attention Deficit Hyperactivity Disorder (ADHD) and conduct problems. Families were followed up after the completion of a controlled trial with 11 Sure Start areas in North and Mid-Wales and North West England.

Methods: Participants in the study were fifty preschool children whose parents had received the intervention. Child ADHD symptoms were assessed at baseline, at follow-up one (6 months after baseline); at follow-up two (twelve months after baseline); and at follow-up three (eighteen months after baseline). Families in the original waiting list control group were not assessed after follow-up one as they had subsequently received the same intervention.

Results: The significant post-intervention improvements in child ADHD symptoms evident at follow-up one were maintained over time, as demonstrated by statistical and clinical stability of measures. No significant differences were found for ADHD symptoms across each follow-up, indicating that the gains made post intervention were maintained for at least 12 months, with 57 per cent of the sample maintaining scores below the clinical cut-off on the Conners. Eighty-six, fifty-eight, and thirty per cent, respectively, had maintained at least a modest, large, or very large improvement in ADHD symptoms at follow-up three.

Conclusions: Findings from this study suggest that the IY PT programme is a valuable intervention in the longer term for many preschool children displaying early signs of ADHD.

Attention Deficit Hyperactivity Disorder (ADHD; American Psychiatric Association [APA], 1994; 2000) is currently one of the most common reasons for referral to child mental health services (Barkley 1997), with prevalence estimated to range between three to six percent in school aged children (APA 1994; 2000; Szatmari, 1992). The central feature of the disorder is a persistent pattern of inattention, impulsivity, and over activity. Symptoms typically emerge in early childhood, and are notably inappropriate for the child's age and developmental level (APA, 1994; 2000).

Course

The natural course of the disorder is discouraging for many individuals. Left untreated, children with high levels of ADHD symptoms are at risk of developing a host of difficulties within educational, personal, and social domains (Daley, 2006). Children with ADHD are also at increased risk of developing substance abuse, and interpersonal and occupational difficulties that can persist into adulthood (Manuzza et al., 1991; Taylor et al., 1996)

Co-Morbidity

The disorder also frequently co-occurs with conduct problems (including oppositional defiant disorder [ODD] and conduct disorder [CD]). An estimated 30-70 per cent of children diagnosed with ADHD also meet diagnostic criteria for conduct problems (Biederman et al., 1991; Szatmari et al., 1989a). Past research suggests that in many cases, this co-morbid condition is particularly intractable and resistant to treatment (Hinshaw & Melnick, 1995; Loeber, 1990; Lynham, 1996; Moffitt, 1993). These children tend to have poorer outcomes, experience more severe symptoms, more peer rejection, and their parents are more likely to encounter higher levels of psychosocial

adversity. These problems lead to increased utilisation of health and social services (Abikoff & Klein, 1992; Kuhne et al., 1997), which poses a major clinical and public health problem (Szatmari et al., 1989b).

Treatment

Based on guidance from the National Institute for Clinical Excellence in the UK, and the American Pediatric Association in the US, a combination of psychostimulant medication (e.g. methylphenidate; MPH) and behaviourally based intervention is considered to be the optimal intervention package for ADHD. Studies examining the efficacy of psychostimulant medication are limited to the short-term, and are not effective in all cases (Arnold et al, 1997; Pelham, 1999). There are also ethical objections to the prescription of psychostimulants, especially to preschool children and, until recently, no controlled trials had been conducted to examine the safety of psychostimulant medication with this young age group.

The Preschool ADHD Treatment Study (PATS; Greenhill et al., 2006; Wigal et al., 2006; Kollins et al., 2006) was the first controlled trial to assess the safety and efficacy of MPH in 183 children aged between three and five years. The trial was designed to evaluate the short-term efficacy (5 weeks) and long-term safety (40 weeks) in preschoolers with ADHD (Kollins et al., 2006). Throughout the medication period, the presence of treatment related adverse events (AE) were noted at each stage. Thirty per cent of parents reported moderate to severe AE's (including emotional problems, sleep disturbance, appetite decrease and irritability), and 11 per cent discontinued treatment due to these events (Wigal et al., 2006). This proportion is considerably higher than those reported in similar trials with school aged children

(e.g. the Multimodal Treatment Study of Children with ADHD [MTA Cooperative Group, 1999], reported a discontinuation rate due to adverse effects of <1%). In terms of efficacy, significant improvements in ADHD symptoms were found following MPH treatment compared with a placebo control group with some, but not all doses. However, effect sizes were notably smaller than those reported in the MTA study, suggesting that MPH is not as effective with preschool children as it is for their school-aged counterparts (Greenhill et al., 2006). Furthermore, the sample size was too small to effectively attest to the safety of MPH with preschool children (Wigal et al., 2006).

Alternatively, behavioural-psychosocial treatment (BPT) is considered a suitable first-level treatment for young children presenting signs of ADHD (Conners, et al, 2001), and there is growing evidence of the efficacy of BPT for parents of children with ADHD, especially if delivered in the preschool years (Daley & Thompson, 2007).

The success of BPT for preschool children is based on the principle that early intervention, before the child's transition to school, and before the child has experienced secondary risk factors such as school failure, peer rejection, and anti-social tendency, offers the best opportunity of changing the developmental course of the disorder (Daley, 2006).

Parent-Training

As parents are the child's primary agents of socialisation during the preschool years, parent-training programmes are viewed as an important element of early BPT.

Behaviourally based parent-training programmes have been developed to enhance parenting skills, and have been demonstrated to be the most effective interventions for

reducing childhood conduct problems, both in clinical and community settings (see Hutchings & Lane, 2005)

Over the last two decades studies have found that some PT programmes are equally efficacious for young children with ADHD. Following PT intervention, improvements have been found in parent-child interaction (Pisterman, et al., 1989), in compliance and on-task behaviour (Sonuga-Barke et al., 2001), and in parent-reported ADHD symptoms and child behaviour problems (Bor et al, 2002). Sonuga-Barke and colleagues (2001) found that intervention with PT significantly reduced ADHD symptoms both clinically and statistically, when compared with a parent counselling and support group (PC&S) and with a waiting list control group (WL). The effects of intervention were maintained for 15 weeks after treatment. More recently, Bor and colleagues (Bor et al, 2002), in an evaluation comparing intervention outcomes from standard and enhanced PT with WL control, found significant reductions in behaviour problems for both intervention conditions when compared with the control group, with sustained improvements at 1-year follow-up.

The Incredible Years Basic Parent-Training Programme

Given the pressing demand for evidence-based practice, it is essential that service providers deliver well-researched, empirically validated programmes. While there are numerous parent-training programmes available, few have as much empirical support as the Incredible Years (IY) BASIC parenting programme (Webster-Stratton & Hancock, 1998; see Mihalic et al., 2002, & Brestan & Eyberg, 1998, for reviews). The programme has been shown to be effective at one-month (Webster-Stratton et al.,

1998), to three year follow-ups (Webster-Stratton, 1990). There is also evidence to suggest that this process is cost-effective (Edwards et al., 2007).

There is now growing evidence to suggest that the IY parent-training programme may be as effective for children with ADHD as they are for children with conduct problems (Hartman et al., 2003; Scott et al., 2001). In a recent study of preschool children displaying signs of early emerging ADHD symptoms and conduct problems, Jones et al. (2007), found that the IY was successful in reducing ADHD symptoms. Following the delivery of the IY programme, the intervention group demonstrated significantly lower levels of parent-reported ADHD symptoms, compared with the waiting-list control group. These improvements remained significant even after controlling for the confounding effects of improvements in observed child deviance, indicating that the programme's efficacy in reducing ADHD symptoms was independent of any improvements in child conduct problems. Fifty-two per cent of children in the intervention condition, compared with twenty-one per cent in the WL control condition, showed clinically reliable improvements following intervention.

Despite increasing evidence in the literature supporting the short-term efficacy of the IY in reducing ADHD symptoms in preschool children, there is insufficient research investigating the stability of these short-term gains over time. Establishing long-term efficacy is of particular importance here for two key reasons. Firstly, there is some research to suggest that parenting programmes are not entirely successful with every family, especially in the long term (Webster-Stratton & Hooven, 1998).

Unfortunately, the positive effects of many prevention programmes decline rapidly shortly after intervention (Serketich & Dumas, 1996). Secondly, in light of the

particular intractability of symptoms associated with this group of children, it is critical to assess outcome stability. The findings from long-term evaluations could point to the need to deliver booster sessions, or to offer additional support at specified time-points following the initial intervention (Serketich & Dumas, 1996).

Present Study

The long-term efficacy of the IY programme was evaluated by following up a community sample of preschool children that had presented signs of co-occurring ADHD and conduct problems. Follow ups were carried out six, twelve, and eighteen months after baseline, and following the delivery of the intervention in 11 Sure Start Centres in North and Mid-Wales and North West England (Hutchings et al., 2007; Jones et al., 2007). Specifically, the aim of the study was to evaluate the long-term stability of improvements in ADHD symptoms following intervention with IY reported by Jones et al., (2007).

Methods

Participants

Participants in the research were drawn from an existing sample of 133 families, that had been previously randomised to one of two conditions on a two to one basis:

intervention (PT) and wait-list control (WL) (the original trial protocol is described in Hutchings et al. 2004, and the main findings are reported in Hutchings et al., 2007).

To be eligible for the present trial, families were eligible for inclusion if they had a child aged between 36 and 48 months, lived in designated Sure Start areas, and if the child scored above the clinical cut-off on either the problem or intensity subscale of the Eyberg Child Behaviour Inventory (ECBI; Intensity score ≥ 127 , or problem score ≥ 11 ; Eyberg & Ross, 1978; Eyberg, 1980), and on the Hyperactivity subscale of the Strengths and Difficulties Questionnaire (SDQ; ≥ 7 ; Goodman, 1997).

As Figure 3 demonstrates, 79 of the 133 families were eligible, with children displaying signs of *both* early onset ADHD and conduct problems. Fifty of these families were in the intervention group, and twenty-nine in the waiting list control group. Findings from the controlled trial, which compared intervention and control families pre- and post-intervention, are reported in a separate paper (see Jones et al., 2007). The present paper represents the longer-term evaluation of the intervention families from the previously reported trial. Intervention families were followed up at twelve months (follow-up two) and eighteen months (follow-up three) after baseline. The six intervention families lost to follow-up were included in an intention to treat analysis.

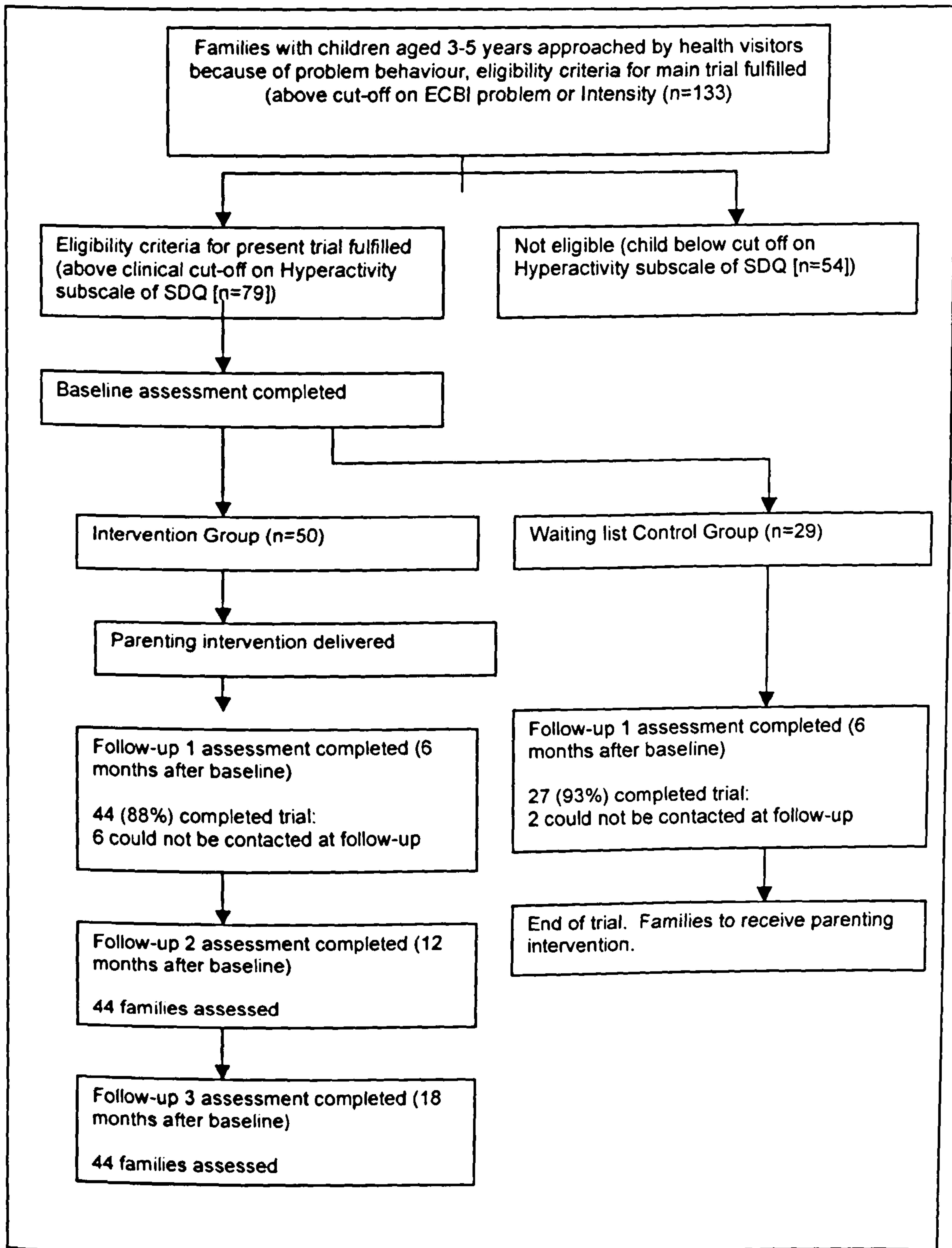


Figure 3: Flow of participants through the trial

All primary caregivers interviewed were mothers (mean age at baseline 27.54 [S.D. = 5.80]). Almost half of the mothers (46%) were lone parents. The mean age of the index child at baseline was 46.50 months (SD = 6.08), and they were predominantly male (64%). The mean number of children per family was 2.52 (S.D. = 1.32).

Measures

Child and family factors were assessed using a combination of interview, questionnaire, and direct behavioural observation at two separate home visits at each data collection point. The measures were administered to primary care givers on entry to the trial (baseline), and at follow-ups one, two, and three (6, 12, and 18 months later). The intervention was delivered within the six-month period between baseline and follow-up one.

Screening: Parent Report Measures

Eyberg Child Behaviour Inventory (ECBI; Eyberg & Ross, 1978; Eyberg, 1980)

This inventory was used as a baseline screening measure to assess child conduct problems. The ECBI is a 36-item parent report measure that assesses the occurrence of problem behaviours in children aged from 2-16 years. Each behaviour is rated on two sub-scales: a seven-point Intensity scale, which measures the frequency of particular behaviours, and a *Yes-No* Problem scale that identifies whether the parent perceives the behaviour to be a problem. The scale demonstrates good stability, with reliability coefficients ranging from .86 (test-retest) to .98 (internal consistency) (Robinson et al., 1980). The ECBI has shown good convergent validity, with ECBI scores being significantly correlated with scores on the Child Behaviour Checklist

(CBCL; Achenbach & Edelbrock, 1986) and the Parenting Stress Index (PSI; Abidin, 1990). The ECBI has been shown to discriminate well between children with and without conduct problems (Eyberg & Ross, 1978; Baden & Howe, 1992).

Strengths and Difficulties Questionnaire (SDQ; Goodman, 1997)

This 25-item inventory was designed as a behavioural screening measure to assess the occurrence of particular behaviours that have been associated with conduct problems, hyperactivity, emotional symptoms, and peer problems in children. The scale has demonstrated good stability, whether judged by internal consistency (mean Cronbach's alpha: 0.73), cross-informant correlation (mean: 0.34), and test-retest stability after 4-6 months (mean: 0.62) (Goodman, 2001). In terms of discriminant validity, high SDQ scores have been associated with a strong increase in psychiatric risk (Goodman, 2001). In the present study, the Hyperactivity subscale of the SDQ was used as a baseline screening measure to identify children within the sample who displayed signs of ADHD.

Primary Outcome Measure:

Conners Abbreviated Parent/Teacher Rating Scale (Conners, 1994)

This 10-item scale assesses the incidence of ADHD symptoms observed by the parent in children aged 3-7 years. It comprises the most highly loaded symptoms from the factor scales of the Conners Parent and Conners Teacher Rating Scale. The respondent (parent) is asked to rate the frequency of particular behaviours on a four-point scale ranging from 0 (not at all) to 3 (very much). In the context of the present study, the Conners was used to assess child ADHD symptoms at baseline and at all subsequent follow-ups.

Observation of Mother and Child Behaviour: Dyadic Parent-child Interaction Coding System (DPICS; Eyberg & Robinson, 1981)

Mother and child behaviour was assessed using a 30-minute live home observation system (the Dyadic Parent-Child Interaction Coding System [DPICS; Eyberg & Robinson, 1981]). The DPICS comprises 37 behaviours relating to both parent and child, which are summarised into four 'parenting' composite variables: 1) positive parenting (including praise, positive affect, physical positive behaviour), 2) critical parenting (including negative commands and critical statements), 3) total commands, and parent non-verbal affect (valence); and three 'child' composite variables: 1) Child deviance (including negative and destructive behaviour and non-compliance); 2) pro-social behaviours (including physical warmth and positive statements); and 3) child non-verbal affect (valence).

Observational coding is continuous and records the total frequency of each behaviour per specified interval. The observations were carried out in a naturalistic, unstructured setting, whereby the families were instructed to engage in their normal daily activities for that particular time of day. In order to obtain sufficient parent-child interaction data, families were instructed to stay in one room, and to have TVs and computers switched off.

Families were observed at baseline and at each follow-up. Six trained observers coded the interactions. In order to maintain inter-rater reliability observers coded videotaped practice interactions on a weekly basis. Inter-rater agreement was assessed by having 20 per cent of observations coded by a second rater. All coders

were blind as to participant group status. An acceptable level of inter-rater agreement was achieved (75%).

Procedure

At each data collection point, participating families were visited at their home on two occasions within a three-day interval. At the first visit, interview and questionnaire measures were administered to the parent. This visit lasted approximately one hour. Observational assessments were carried out during the second visit, and lasted about forty minutes.

Intervention and Treatment Integrity

Twelve intervention groups were delivered in 11 Sure Start areas across North and Mid Wales and English borders. The programme runs for one 2-hour session per week for 12 weeks, and is based on a collaborative approach with two trained leaders introducing a structured sequence of topics over the course of the programme (see Hutchings et al., 2007; Webster-Stratton & Hancock, 1998, for a more detailed description of course content). All leaders had run at least one group before the study commenced, received 3 hours of weekly supervision from the third author, and achieved leader certification during, or shortly after, completion of the trial. The programme addresses implementation fidelity by: providing all course materials, CDs, handouts, books, raffle prizes etc.; ensuring leaders had a three-day basic leader training and had previous experience in running a group; completion of a group leader Peer and Self Evaluation questionnaire to evaluate treatment exposure, adherence, treatment delivery; parent completed satisfaction questionnaires; completion of Session Specific Checklists to monitor treatment integrity, participant responsiveness,

treatment delivery, and treatment differentiation; access to mentor supervision, to evaluate progress and delivery method, e.g. reviewing videotapes within a three-hour weekly supervision session with an IY trainer; and certification – evaluation of treatment fidelity based on observation of random videotapes by an independent IY trainer.

Results

Attrition

Inclusion of cases in the analyses was based on an intention to treat strategy. Out of the 50 intervention families who completed baseline assessment, six were lost to follow-up (18 months after baseline).

Attendance

Forty-four out of 50 (88%) attended at least one session, and 37 (74%) attended eight or more sessions. The overall mean attendance rate was 9.47 sessions (SD = 2.94).

Impact of Intervention on Conduct Problems

The focus of this study is on the impact of the intervention on ADHD symptoms. The intervention was very successful at reducing CD symptoms, both in the short-term and longer term, and these results have been presented elsewhere (see Hutchings et al., 2007; Hutchings et al., 2007; Bywater et al., submitted).

Short-Term Findings: Impact of Intervention on ADHD Symptoms

In the short-term, the intervention was successful in reducing ADHD symptoms for the intervention group, as compared to the wait-list control group (Jones et al, 2007). Following intervention, the intervention group was associated with lower levels of parent-reported inattention and hyperactive/impulsive difficulties, even after controlling for post-intervention changes in observed child deviance. Fifty two per cent of those in the intervention condition, compared with 21 per cent in the control

condition showed clinically reliable improvements, yielding a number needed to treat (NNT) of 3.23 (95% CI 1.98 – 8.77). These findings are presented in more detail in a separate paper (Jones et al, 2007). Further follow-ups of the intervention group were conducted to examine whether these improvements in child behaviour were maintained over time.

Preliminary Analyses

Results of Kolmogorov Smirnov tests for all variables were statistically non-significant for all three time-points, indicating that the assumption of normality had not been violated.

Long-Term Findings

From pre- to post-intervention, mean scores on the Conners decreased from 20.56 (SD = 5.86) to 14.6 (SD = 8.12), showing an average reduction in score of 5.96.

These mean scores remained relatively stable at subsequent follow-ups, with a mean score of 13.44 (SD = 7.69) on the Conners at follow-up one, and 13.53 (SD = 8.01) at follow-up two.

A series of repeated measures Analysis of Variance ANOVAs, with time as the repeated measure was used to examine the data. As previously reported, a significant difference in Conners scores was found from baseline to follow-up one (post-intervention): $F(1, 78) = 7.28, p = 0.009$. At subsequent follow-ups of the intervention group, no significant differences were found from follow-up one to follow up two, $F(1, 48) = 0.70, p = 0.41$; and from follow-up two to follow up three,

$F(1, 49) = 0.72, p = 0.40$. These findings are summarised in Figure 4, which show mean scores on the Conners for the intervention group at each time point.

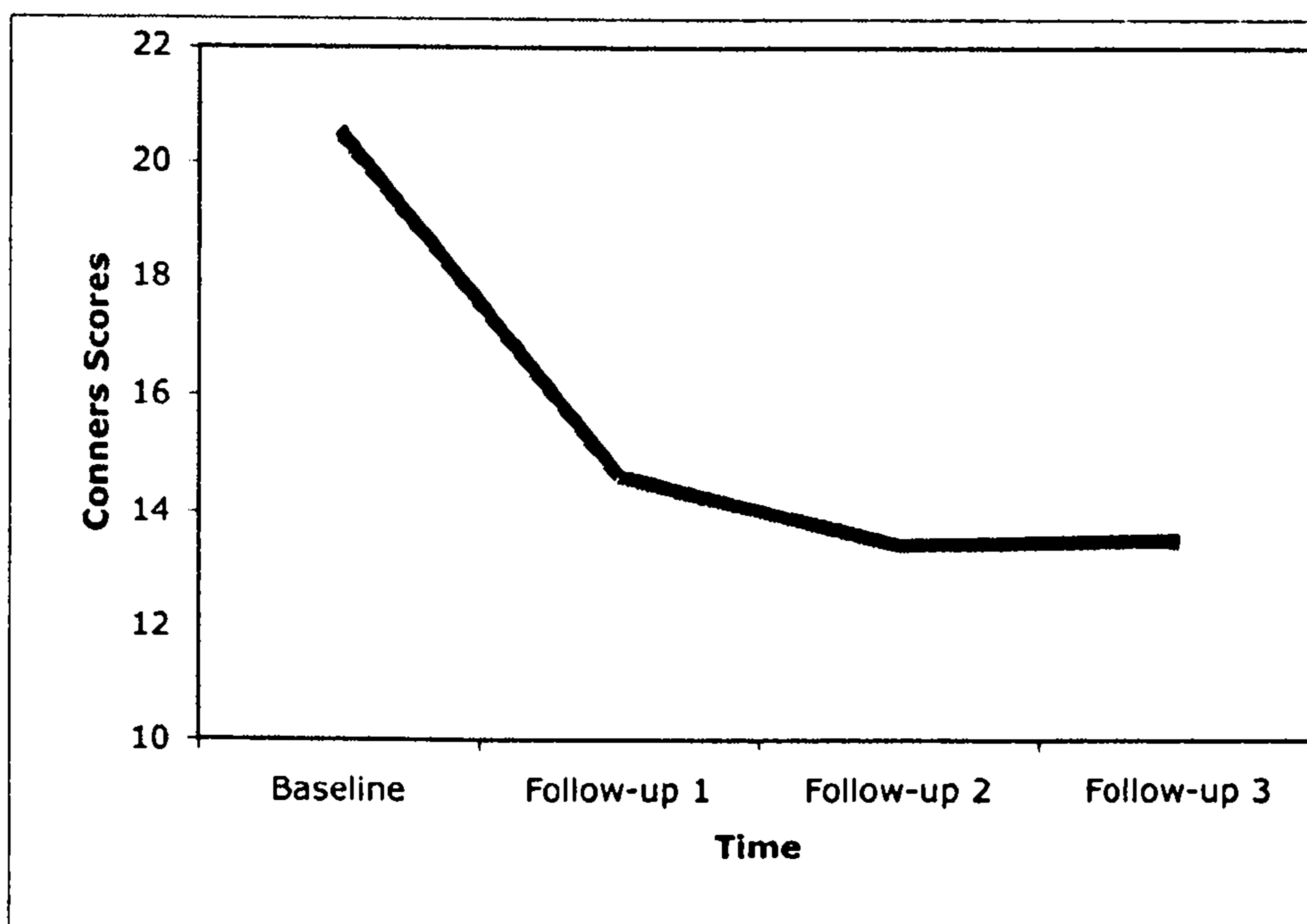


Figure 4: Long-Term Intervention Effects For Intervention Group from Baseline to Follow-up Three.

Long-Term Findings: Controlling for Observed Child Deviance Scores

In order to determine whether the sustained improvements in ADHD symptoms were independent of improvements in observed child deviance, further analyses using repeated measures analysis of co-variance ANCOVA was carried out, with observed child deviance scores for each follow up entered as a time-varying co-variate. Results indicated that the maintained gains in ADHD symptoms were not related to sustained improvements in child deviance. Comparing follow-up 1 to follow-ups 2 and 3, $F(1, 47) = 0.047, p = .83$, and comparing follow-up 2 to follow-up 3, $F(1, 47) = 0.011, p = .92$.

Clinical Significance of Change in Children's Disruptive behaviour

Two criteria were employed to investigate clinical significant change: The Reliable Change Index (RCI; Jacobson & Truax, 1991); and a reduction in scores to below clinical threshold on the Conners. Using the RCI criteria, 53 per cent of the group met recovery criteria at follow-up one, 47 per cent at follow-up two, and 46 per cent at follow-up three. Using the clinical cut-off criteria, 58 per cent of families had scores that had fallen below the level of clinical concern on the Conners at follow-up one (≤ 15 ; Conners, 1994), 60 per cent at follow-up two, and 57 per cent at follow-up three.

Magnitude of Improvement

Further analyses were conducted to determine the magnitude of maintained improvements made by the sample at each follow-up. This analysis was conducted using Cohen's (1988) criteria for magnitude of change (0.3 SD = modest change; 0.8 SD = large change, and 1.5 SD = very large change) and are presented in Table 3. An examination of Table 3 demonstrates that the majority of the sample maintained at least a modest improvement, over half maintained at least a large change, and almost a third maintained a very large change across each follow-up. Furthermore, Table 3 shows that the more severe cases (as indexed as being above the clinical cut-off on the Conners as well as the SDQ at baseline) benefited more from the intervention, as evidenced by demonstrating a greater magnitude of change across each follow-up, compared to the sample as a whole. Similarly, boys in the sample maintained slightly larger changes over time than the girls.

Table 3: Indices of clinically significant change

| Size of change | Proportion of children | | | | | | | |
|----------------|---|--|-----------------------------|---|-----------------------------|---|---------------------|--|
| | Follow-up 1 | | | | Follow-up 2 | | | |
| | In whole sample (n = 50) | In those starting above clinical cut- off* (n = 40) | In whole sample (n = 50) | In those starting above clinical cut-off* (n = 40) | In whole sample (n = 50) | In those starting above clinical cut-off* (n = 40) | | |
| ADHD Symptoms | Modest improvement or more (≥ 0.3 SD) | 88% | 88% | 92% | 95% | 86% | 88% | |
| | Large improvement (≥ 0.8 SD) | 56% | 65% | 57% | 69% | 58% | 63% | |
| | Very large improvement (≥ 1.5 SD) | 42% | 50% | 35% | 43% | 30% | 31% | |
| | | Males (n = 32) | Females (n = 18) | Males (n = 32) | Females (n = 18) | Males (n = 32) | Females (n = 18) | |
| ADHD Symptoms | Modest improvement or more (≥ 0.3 SD) | 91% | 83% | 99% | 78% | 88% | 83% | |
| | Large improvement (≥ 0.8 SD) | 66% | 42% | 61% | 51% | 58% | 50% | |
| | Very large improvement (≥ 1.5 SD) | 50% | 37% | 34% | 44% | 33% | 30% | |

Discussion

The results demonstrate that the positive effect of IY parenting intervention on children's ADHD symptoms remained stable over time. Using intention to treat analysis, no significant differences were found in parent reported levels of child inattention and hyperactivity between post-intervention scores and both subsequent follow-ups. At follow-ups two and three, families had sustained the significant reduction in ADHD symptoms that was evident at post-intervention assessment, indicating that intervention gains were maintained for at least 12 months after the delivery of the programme, even after controlling for gains maintained in observed child deviance.

Using the RCI criteria, further analysis of intervention efficacy over time demonstrated that around half of the sample showed clinically reliable improvements at post-intervention and follow-ups, in parent-reported child ADHD symptoms. Similarly, using clinical cut-off as an indicator of clinical improvement, over half of the sample had scores that had fallen below the level of clinical concern on the Conners at each time point.

Using Cohen's (1988) guidelines for magnitude of clinical change, at eighteen months after baseline, a large majority of the sample had sustained at least a modest clinically significant improvement, over half maintained at least a large improvement, and almost a third retained a very large reduction in ADHD symptoms. The results indicate that the greatest magnitude of recovery was observed in those who were in

most need, as indexed by having more severe symptoms at baseline. This finding is encouraging given the poor prognosis associated with the condition (e.g. Lynham, 1996; Moffitt, 1993).

Collectively, therefore, the findings support the long-term efficacy of the evidence-based IY parent-training programme for preschool children presenting signs of conduct problems and co-occurring ADHD (Hartman et al, 2003; Scott et al, 2001).

Not only was the programme found to be effective in the long-term reduction of conduct problems (Bywater et al., submitted), the intervention was also successful in the long-term reduction of ADHD symptoms in this co-morbid group of children.

The results contribute to previous findings supporting the efficacy of PT for ADHD in preschool children (e.g. Sonuga-Barke et al, 2001; Bor et al., 2002), and more specifically supports the efficacy and utility of the IY programme as a first-line intervention for preschool children with ADHD symptoms (Jones et al, in press). The fact that the gains were maintained over time, and that greater effects were seen for the more severe cases at follow-ups, suggests that the symptoms are not as refractory as initially thought (e.g. Loeber, 1990; Lynham, 1996; Moffitt, 1993), at least during the preschool years. In this light, the early identification and intervention with young children with ADHD could, potentially, prevent or reduce the risk of more serious problems later in development.

Limitations

The study is not without its limitations. Firstly, the primary outcome measure used was parent-reported. It is widely acknowledged that in the context of intervention, parents' expectations of treatment outcome may bias their responses to self-reported outcome measures. A convergence of self-report and independent observations would have increased the confidence of the findings. Secondly, the children in the study had elevated scores on measures of both conduct problems and ADHD. As a result, it was not possible to examine the differential effects of treatment on subgroups of children. Nonetheless, from a clinical perspective, this is typical of the presentation of ADHD and conduct problems at the preschool age. Thirdly, the children in the sample displayed *symptoms* of ADHD, as measured by the SDQ Hyperactivity subscale, which does not necessarily indicate that they will develop the disorder in the future. However, as the sample of children in this study were preschoolers, a measure of ADHD symptoms was considered to be adequate here, given that the disorder is typically not diagnosed until the child reaches the age of six. Finally, although it can be concluded that the intervention effects at post-intervention remain stable for at least 12 months, long term comparison with a control group was not possible, thus it cannot be concluded that the sustained improvements were attributable to the intervention. However, intervention families demonstrated maintenance of improvements in hyperactivity that was evident at post-intervention a year previously. No significant improvements were found in the control group at post-intervention assessment, so there is little evidence to suggest that the intervention group improved and maintained gains as a result of spontaneous remission or regression towards the mean of the general population.

Clinical Implications

The IY BASIC parent-training programme appears to have a lasting positive effect on ADHD symptoms in preschool children, and should at least be considered as a first line intervention for young children with ADHD. The stability of ADHD scores post intervention in this study, highlight the utility of early intervention for ADHD symptoms using an evidenced based intervention, delivered with fidelity (Hutchings et al., in press). The fact that the positive influences of intervention were maintained 18 months after the end of intervention, and in the absence of booster sessions, highlights the need for and possible cost effectiveness of further investment in early preventative intervention services in the UK.

CHAPTER 5

STUDY 3

The Incredible Years Programme as an early intervention for children with conduct problems and ADHD: Moderators and mediators of outcome.⁴

⁴ This evaluation formed the basis of a paper submitted to British Journal of Clinical Psychology for review. (Jones, K., Daley, D., Hutchings, J., Bywater, T., Whitaker, C., and Eames, C. The Incredible Years Programme as an early intervention for children with conduct problems and ADHD: Moderators and mediators of outcome.

Abstract

Objectives: The present study explored predictors, moderators, and mediators of intervention outcome, with a sub-sample of families from within a randomised controlled evaluation of the Incredible Years (IY) parenting programme (Hutchings, Bywater, Daley, et al., 2007; Bywater, Hutchings, Daley, et al., submitted), delivered to families of preschool children displaying symptoms of ADHD and conduct problems (Jones, Daley, Hutchings, et al., 2007; Jones, Daley, Hutchings, et al., in press).

Methods: Participants in the study were 79 preschool children, who had been randomised to either intervention (IY) or wait-list (WL) control conditions. Fifty families were in the intervention group, and 29 in the control group. Child and family risk factors, as well as parenting skill were assessed using a combination of parent-report and direct observational measures.

Results: Predictor analyses demonstrated that children with more severe baseline ADHD symptoms benefited most from intervention. Children whose mothers were depressed at baseline demonstrated poorer outcomes at 18-month follow-up. All other candidate variables, including parenting skill, single parenthood, teen parenthood, income, and severity of conduct problems, failed to show predictive or moderating effects, suggesting that the intervention was successful for families, irrespective of initial risk status. Mediator analysis indicated that change in observed positive parenting was a significant partial mediator of change in child ADHD symptoms, suggesting improvement in positive parenting is a key ingredient of intervention success.

Conclusions: Children with more severe levels of ADHD symptoms at baseline benefited the most from intervention. Maternal depression predicted poorer long-term outcome at 18-month follow-up. The failure to uncover moderators of outcome suggests that the intervention was successful even for the most disadvantaged families within the sample.

Interventions for preschool ADHD

Guidance from both the National Institute for Clinical Excellence in the UK and American Paediatric Association in the US indicates that a combination of psychostimulant medication (e.g. methylphenidate) and specific psychosocial therapies provide the optimal intervention package for the management of ADHD symptoms for school-aged children. However, the use of psychostimulant medication to treat ADHD during the preschool period is a subject of controversy due to limited evidence of short- and long-term efficacy (Greenhill, Kollins, Abikoff et al., 2006), concerns about potential side effects (Wigal, Greenhill, & Chuang et al., 2006), as well as ethical objections, among some practitioners and parents, to the use of medication at such an early stage in development (Perring, 1997). Consequently, psychosocial intervention is considered a suitable alternative intervention for treating preschool ADHD (Conners, 2001).

Parent-training (PT) programmes have been identified as the most successful interventions for conduct problems, both in clinical and preventive settings (Beauchaine, Webster-Stratton, & Reid, 2005; Brestan & Eyberg, 1998; Kazdin, 1997). Although evidence to support the efficacy of PT programmes with ADHD is, by comparison, limited, there is growing evidence from randomised controlled trials to support the efficacy of PT programmes in reducing ADHD symptoms, especially when delivered during the preschool period (Daley & Thompson, 2007). Following PT intervention, improvements have been found in parent-child interaction (Pisterman, McGrath, Firestone et al., 1989), in compliance and on-task behaviour (Sonuga-Barke, Daley, Thompson et al., 2001), and in parent-reported ADHD

symptoms and child behaviour problems (Bor, Sanders, & Markie-Dadds, 2002; Jones et al., 2007).

Whilst controlled outcome trials are essential for establishing the overall efficacy of interventions, and are important for informing policy, exploring potential moderators and mediators of outcome within such trials have been assigned high priority in the field of PT (Kraemer, Wilson, Fairburn et al., 2002). The identification of these variables is important in advancing current understanding of treatment effects, to improve research methodology, and ultimately to develop more effective and targeted interventions (March & Curry, 1998).

Moderators and Predictors of outcome

Not all interventions are universally efficacious, and the investigation of predictors and moderators of outcome can help identify relevant subgroups with particularly good (or poor) treatment response (Brestan & Eyberg, 1998; Nock, 2003). Predictors may be associated with outcome within the treatment group only, or across treatment and control groups. Moderators, on the other hand, examine whether a predictor variable is differentially associated with outcome in the treatment versus control groups (Baron & Kenny, 1986). From a clinical perspective, an understanding of patient characteristics that predict or moderate response to PT could help direct limited resources to those most likely to benefit, or to tailor specific interventions to meet the individual needs of families (Hinshaw, Owens, Wells et al., 2000).

Child-Specific Moderators

Candidate child-specific predictors of treatment response that have emerged from the PT literature include sex, age, and symptom severity (Gardner, Hutchings, Bywater et al., submitted; Reyno & McGrath, 2006). In the few studies that have examined sex differences, PT interventions appear to be equally effective for both sexes (e.g. Beauchaine et al., 2005; Gardner et al., submitted). In terms of child age, it is well documented that PT is most effective when offered at an early age, before the child encounters secondary risk factors such as school failure and peer rejection (Ruma, Burke, & Thompson, 1996; Daley, 2006). Studies that have examined the association between symptom severity and outcome have produced more mixed findings. For example, in a number of evaluations that have examined predictors of outcome in children with conduct problems, those with more severe co-occurring problems (such as aggression, impulsivity, and hyperactivity) benefited more from PT than children with less severe problems (e.g. August, Realmuto, Hektner & Bloomquist, 2001; Reid, Webster-Stratton, & Hammond, 2003). Similarly, several evaluations have found baseline by programme interactions, in which children with higher levels of adjustment problems benefit the most from PT (Allen & Philliber, 2001; Stoolmiller, Eddy, & Reid 2000). In contrast, findings from the MTA study (MTA cooperative group, 1999), examining moderators among school-aged children with ADHD, found that children with more severe ADHD symptoms at baseline displayed poorer treatment response, to both medication and behavioural interventions, whereas the severity of co-occurring conduct problems did not moderate outcome (Owens, Hinshaw, Kraemer et al., 2003).

Parent / Psychosocial Factors

Parent and family-specific factors, such as parental psychopathology and socioeconomic status, also emerge as candidate moderators or predictors of outcomes. Studies that have examined maternal distress (including maternal depression and low income, and single parenthood), have traditionally reported poorer treatment response to PT intervention (Dumas & Wahler, 1983; Knapp & Deluty, 1989; Webster-Stratton & Hammond, 1990), which is not surprising given that maternal distress affects many aspects of child adjustment (Downey & Coyne, 1990). In a recent meta-analytic review (Reyno & McGrath, 2006), distressed parents, including those with depression and low income, demonstrated poorer response to PT intervention. Similarly, within the MTA study, maternal depression was associated with worse outcomes to both behavioural and medication management, although SES did not predict outcome (Owens et al., 2003). Songua-Barke et al 2002 reported that maternal ADHD symptoms were associated with poorer outcome following PT intervention for preschool children with ADHD. In contrast, Beauchaine et al (2005) pooled the data of 6 Incredible Years PT randomised controlled trials, and found that younger mothers, and mothers with higher levels of depression demonstrated better treatment response following PT, compared with older and non-depressed parents. Consistent with these findings, Baydar, Reid, & Webster-Stratton (2003), evaluating the same parenting programme, found that mothers who were depressed were just as likely to benefit from the programme as were non-depressed mothers.

Mediators of outcome

A mediator is a variable that changes during treatment, is associated with outcome, and can explain the active ingredient of treatment (Baron & Kenny, 1986; MTA cooperative group, 1999). Examining the mechanisms that contribute towards the success of an intervention is important for refining implementation, and for testing causal hypotheses about the relationship between specific components of an intervention with outcome (Rutter, 2005).

Parenting practices have consistently accounted for the variance in children's behavioural changes following intervention with PT (e.g. Hinshaw et al, 2000; Reid, Webster-Stratton, & Baydar, 2004). Within the field of PT, there is growing evidence, based on secondary analyses of randomised controlled trials (Forgatch & DeGarmo, 1999; Gardner, Burton, & Klimes, 2006; Gardner et al., submitted; Reid et al., 2004) to suggest that change in parenting skill may be the most significant ingredient of effective parenting programmes (Hutchings et al., 2004), and that change in parenting skill may play a causal role in the child's behaviour change (Gardner et al., 1999; 2003).

Background to study

The present study explored moderators and mediators of outcome with a sub-group of families from within the North Wales Sure Start Trial. The main Sure Start trial evaluated the efficacy of the Incredible Years parenting programme for families of children at risk of developing conduct problems. Main evaluation results reported by Hutchings et al. (2007) found robust improvements in child conduct problems and

parenting skill, that remained stable at 12- and 18-month follow-ups (Bywater, Hutchings, Daley et al., submitted). An examination of moderators and mediators of outcome found that male children who were younger and who had mothers with higher levels of stress and depression at baseline demonstrated better outcomes (Gardner et al., submitted). Other candidate moderators, including teen or lone parenthood, and low income showed no predictive effects, suggesting that the intervention was successful even for the most disadvantaged families. Mediator analysis demonstrated that improvement in positive parenting skill predicted change in child conduct problems, suggesting that positive parenting is a key ingredient of intervention success.

Present study

Given that over half of the children within the trial displayed high levels of ADHD, the existing data set provided a unique opportunity to evaluate the Incredible Years programme with a sub-group of families whose children also displayed signs of ADHD. An evaluation of the efficacy of intervention with this sub-group of families found significant improvements in ADHD symptoms (Jones et al., 2007), that were maintained at 18-month follow-up (Jones et al., in press).

The present study explores moderators and mediators of outcome from within this co-morbid sample. Specifically, the aims are to:

1. Examine candidate moderators and predictors of outcome. Predictors were selected based on findings reported in the PT literature, and from ADHD treatment literature. Child specific moderators included age, sex, severity of ADHD symptoms, and severity of conduct problems. Parent variables included maternal depression, parent age, single parenthood, teen parenthood, and income.
2. Explore putative intervention mechanisms, by examining change in observed positive parenting and observed critical parenting as mediators of child outcomes.

Methods

Participants

Participants in the research were a subgroup of the 133 families who took part in the North Wales Sure Start trial, a multi-site, community-based study examining the efficacy of the IY with parents of children at risk of developing conduct problems (see Hutchings et al., 2007). Families had been randomised to one of two conditions on a two to one basis: intervention (PT) and wait-list control (WL). The subgroup consisted of 79 of the 133 families, with children displaying signs of co-morbid conduct problems and ADHD symptoms, having met eligibility criteria for the main trial: i) child aged between 36 to 48 months; ii) living in designated Sure Start areas; iii) child scored above cut-off on the problem or intensity subscale of the Eyberg Child Behaviour Inventory (ECBI; Intensity score ≥ 127 , or problem score ≥ 11 ; Eyberg, 1980; Eyberg & Ross, 1978), as well as scoring above the level of clinical concern on the Hyperactivity subscale of the Strengths and Difficulties Questionnaire (SDQ; Hyperactivity score ≥ 7 ; Goodman, 1997). Fifty of these families were in the intervention group, and twenty-nine in the waiting list control group.

All primary caregivers were mothers (mean age at 27.71 [S.D.= 5.32]). Thirty nine per cent of families were lone parents, and the mean number of children per family was 2.52 (S.D. = 1.32). The mean age of the index child was 46.28 months (S.D. = 6.16), and they were predominantly male (68%). No significant group differences existed between intervention and control families on these socio-demographic variables at baseline, indicating that the groups were well matched on these characteristics.

Measures

Child and family factors were assessed using a combination of interview, questionnaire, and direct behavioural observation at each data collection point. All families were assessed on entry to trial (baseline), and at follow-up (6 months later), with the programme being delivered in the interim. Intervention families were also followed-up at 12 and 18 months after baseline.

Demographic information: Personal Data and Health Questionnaire (PDHQ; Hutchings, 1996).

The PDHQ is a semi-structured interview based on the work of Herbert (1993), administered to the primary caregiver, aimed at obtaining basic socio-demographic and general health information on family members, as well as the child's developmental history.

Maternal Depression: The Beck Depression Inventory (BDI; Beck, Mendelson, Mock & Erbaugh, 1961).

The BDI is a thoroughly researched 21-item questionnaire that assesses symptoms of depression in adults. It has been extensively used and shown to have good internal consistency ($\alpha = .81$), moderate to high test-retest reliability (ranging from $r = .60$ to $r = .90$), as well as satisfactory discriminant validity between clinic and non-clinic populations (Beck, Streer, & Garbin, 1988).

Eyberg Child Behaviour Inventory (ECBI; Eyberg & Ross, 1978; Eyberg, 1980)

This inventory was used as a baseline screening measure to assess child conduct problems. This is a 36-item parent report measure that assesses the occurrence of problem behaviours in children aged between two-sixteen years. Each behaviour is rated on two sub-scales: a seven-point Intensity scale, which measures the frequency of particular behaviours, and a *Yes-No* Problem scale that identifies whether the parent perceives the behaviour to be a problem. The scale demonstrates good stability, with reliability coefficients ranging from .86 (test-retest) to .98 (internal consistency) (Robinson et al., 1980).

Conners Abbreviated Parent/Teacher Rating Scale (Conners, 1994)

This 10-item scale assesses the incidence of ADHD symptoms observed by the parent in children aged 3-7 years. It comprises of the most highly loaded symptoms from the factor scales of the Conners Parent and Conners Teacher Rating Scale.

Strengths and Difficulties Questionnaire (SDQ; Goodman, 1997)

This 25-item inventory was designed as a behavioural screening measure to assess the occurrence of particular behaviours that have been associated with conduct problems, hyperactivity, emotional symptoms, and peer problems in children. The scale has demonstrated good stability, whether judged by internal consistency (mean Cronbach's alpha: 0.73), cross-informant correlation (mean: 0.34), and test-retest stability after 4-6 months (mean: 0.62) (Goodman, 2001). In terms of discriminant

validity, high SDQ scores have been associated with a strong increase in psychiatric risk (Goodman, 2001). In the present study, the Hyperactivity subscale of the SDQ was used as a baseline screening measure to identify children within the sample who displayed signs of ADHD.

Observation of Mother and Child Behaviour: Dyadic Parent-child Interaction Coding System (DPICS; Eyberg & Robinson, 1981)

Mother and child behaviour was assessed using a 30-minute live home observation system (the Dyadic Parent-Child Interaction Coding System [DPICS; Eyberg & Robinson, 1981]). The DPICS comprises 37 behaviours relating to both parent and child, which are summarised into four 'parenting' composite variables: 1) positive parenting (including praise, positive affect, physical positive behaviour), 2) critical parenting (including negative commands and critical statements), 3) total commands, and parent non-verbal affect (valence); and three 'child' composite variables: 1) Child deviance (including negative and destructive behaviour and non-compliance); 2) pro-social behaviours (including physical warmth and positive statements); and 3) child non-verbal affect (valence).

Randomisation

The study adopted a pragmatic randomised controlled trial design (RCT). After baseline assessment was completed in each Sure Start centre, participants were block-randomised by area on a 2:1 basis (intervention to control) after they were stratified

by age and sex, using a random number generator (see Hutchings et al, 2007, for further details of the randomisation process).

Procedure

At each data collection point, home visits were conducted with participating families on two occasions within a three-day interval. At the first visit, interview and questionnaire measures were administered to the mother. The assessment battery took approximately one hour to administer. Direct observations of parent-child interaction were conducted during the second visit, which lasted about forty minutes. In order to obtain a naturalistic observation, families were instructed prior to the visit to stay in one room, with the TV off, and interact as they normally would do at that time of day.

Intervention and Treatment Integrity

Twelve intervention groups were delivered in eleven Sure Start areas across North and Mid Wales and the borders. The intervention promotes positive parenting through the use of reinforcement, and is based on a collaborative approach with two trained leaders introducing the following structured sequence of topics over the course of the programme: i) how to establish a positive relationship with their child through play and child centred activities; ii) using praise, rewards, and incentives for pro-social behaviour; iii) guidance in the use of effective limit setting and clear instruction giving; and iv) strategies for managing non-compliance (Webster-Stratton &

Hancock, 1998). Parents attended the group for two to two and a half hour weekly sessions over a 12-week period.

All leaders had run at least one previous group, received three hours of weekly supervision from the third author throughout the 12-week programme, achieving leader certification during, or shortly after completion of the trial. Implementation fidelity was addressed by: providing all course materials; ensuring leaders had received a three-day basic leader training; completion of a group leader Peer and Self-Evaluation questionnaire to evaluate treatment exposure, adherence, and treatment delivery; parent completed satisfaction questionnaires; completion of Session Specific Checklists to monitor integrity, participant responsiveness, treatment delivery, and treatment differentiation; access to mentor supervision, to evaluate progress and delivery method (e.g. reviewing videotapes within a three-hour weekly supervision session with an IY mentor); and certification – evaluation of treatment fidelity based on observation of random videotapes by an independent IY trainer.

Results

Attrition

Inclusion of cases in the analyses was done on an intention to treat basis. Attrition rates were generally low. Out of the 79 families assessed at baseline, 71 (90%) completed follow-up assessment. Of those who failed to complete post-assessment, six were in the intervention group, and two in the control group.

Attendance

Within the intervention condition, 44 out of 50 (88%) attended at least one session, and of those, 37 (84%) attended eight or more sessions. The overall mean attendance was 9.47 sessions (SD = 2.94).

Equivalence

Using a series of one way ANOVAs, no significant differences were found at baseline between intervention and control groups on all measures of outcome at baseline, indicating that the groups were well matched on behavioural and demographic characteristics prior to receiving intervention (see Hutchings et al, 2007; Jones et al, 2007).

Predictor Analyses

Predictors of Short-Term Outcome (Baseline – Follow-Up 1)

Intervention Group

Of the nine variables examined as potential predictors of outcome, only one emerged as a significant predictor within the intervention group. As Table 4 shows, the severity of ADHD symptoms at baseline, as measured by the Conners, significantly predicted treatment response at follow-up 1. Children with higher Conners scores at baseline, showed a better response to treatment. Other child factors including sex, age, and severity of conduct problems (parent-reported and observed child deviance) did not predict outcome. Family characteristics, including maternal depression, lone parent status, teen parent status, and weekly income were not associated with treatment response.

Control Group

Within the control group, child age and ADHD severity emerged as significant predictors of outcome at follow-up one, and maternal depression was a marginal predictor. Older children, and children with higher baseline Conners scores, demonstrated better improvements at follow-up one. However, improvements in ADHD symptoms for the control group from baseline to follow-up one were very small and statistically non-significant (see Jones et al., 2007). Children whose mothers displayed high baseline depression scores demonstrated worse outcomes, although the predictive effect was only marginally significant (Table 4).

Table 4: Standardised Regression Coefficients in the Simultaneous Regression of Treatment Outcomes on Candidate Predictors (intervention and control group)

| Predictor | Measure | Intervention | | Control | |
|---------------------------|-------------------------|--------------|---------|---------|---------|
| | | β | P= | β | p= |
| Sex of child | PDHQ | -0.043 | 0.803 | 0.201 | 0.280 |
| Teen parent status | PDHQ | -0.024 | 0.878 | 0.162 | 0.392 |
| Lone parent status | PDHQ | 0.061 | 0.735 | -0.350 | 0.103 |
| Child age | PDHQ | 0.040 | 0.824 | 0.536 | 0.017** |
| Weekly income | PDHQ | -0.089 | 0.645 | 0.147 | 0.479 |
| Maternal depression | BDI | 0.228 | 0.159 | -0.379 | 0.088* |
| Severity ADHD symptoms | Conners | 0.459 | 0.006** | 0.733 | 0.009** |
| Severity conduct problems | ECBI Intensity Subscale | -0.127 | 0.473 | -0.254 | 0.301 |
| Observed child deviance | DPICS | -0.077 | 0.604 | 0.167 | 0.415 |

Predictors of Long-Term Outcome (Intervention Group: Follow-ups 2 and 3)

For the intervention group only, candidate predictors were also examined at follow-ups 2 and 3 (12 and 18 months after baseline, respectively). As Table 5 shows, only one significant predictor was found. The level of maternal depression at baseline significantly predicted outcome at follow-up 3, showing that those with higher initial depression score demonstrated poorer outcomes than non-depressed families.

Table 5: Standardised Regression Coefficients in the Simultaneous Regression of treatment outcomes on candidate predictors: Intervention group follow-up two and follow-up three.

| Predictor | Measure | Follow-up 2 | | Follow-up 3 | |
|---------------------------|-------------------------|-------------|-------|-------------|---------|
| | | β | P= | β | p= |
| Sex of child | PDHQ | 0.057 | 0.783 | 0.281 | 0.130 |
| Teen parent status | PDHQ | -0.022 | 0.908 | 0.126 | 0.450 |
| Lone parent status | PDHQ | 0.045 | 0.837 | 0.199 | 0.303 |
| Child age | PDHQ | 0.002 | 0.993 | 0.028 | 0.883 |
| Weekly income | PDHQ | 0.049 | 0.830 | -0.178 | 0.384 |
| Maternal depression | BDI | 0.093 | 0.624 | -0.448 | 0.011** |
| Severity ADHD symptoms | Conners | -0.065 | 0.734 | 0.011 | 0.949 |
| Severity conduct problems | ECBI Intensity Subscale | 0.015 | 0.945 | 0.141 | 0.449 |
| Observed child deviance | DPICS | 0.042 | 0.812 | -0.144 | 0.362 |

Moderators

An examination of Table 6 indicates that there were no moderating effects of baseline predictor variables on outcome.

Table 6: Moderator analyses: association between improvements in ADHD symptoms and risk factors

| Correlation between baseline risk factor and change in Conners score | | | |
|--|------------------------|-----------------------------|-----------------------|
| | Intervention n=50 | | Control n=29 |
| Child age (PDHQ) | r= 0.122 p= 0.399 | $\beta = -0.294, p = 0.719$ | R=0.219 P=0.254 |
| Weekly income (PDHQ) | r= -0.097 p= 0.504 | | R= -0.342 p= 0.070 |
| Maternal depression (Beck depression inventory) | r= 0.260 p= 0.069 | $\beta = 0.126, p = 0.592$ | R= -0.148 p= 0.444 |
| Severity ADHD (Conners) | r= 0.456 p= 0.001** | $\beta = 0.486, p = 0.64$ | R= 0.393 p= 0.035* |
| Severity conduct problems (ECBI intensity) | r= 0.910 p= 0.531 | $\beta = 0.331, p = 0.348$ | R= -0.205 p= 0.286 |
| Severity conduct problems (Observed – DPICS) | r= -0.109 p= 0.452 | $\beta = 0.714, p = 0.256$ | r= 0.181 p= 0.348 |
| | | $\beta = -0.137, p = 0.389$ | |

Mediator Analyses

Positive Parenting

Firstly, results of correlation analyses demonstrated that all three variables were correlated, including intervention status, potential mediator, and outcome, thus

conforming to current definitions of mediation within RCTs (Kraemer, et al., 2002). Positive change in observed positive parenting correlated with positive change in parent-reported child ADHD symptoms (Conners $r=.292$, $p=.01$); change in positive parenting correlated with intervention status ($r=.346$, $p=.01$); and intervention status correlated with change in parent-reported child ADHD symptoms ($r=.339$, $p=.01$). Secondly, hierarchical multiple regression was used with change in ADHD symptoms (Conners) as the dependent variable. In step 1, the effect of intervention on child ADHD symptoms was entered as the independent variable, and in step 2, the mediator variable (positive parenting) was entered as an independent variable. As Figure 5 demonstrates, the effect of intervention on child ADHD symptoms is reduced when positive parenting is introduced as a potential mediator. A Sobel test confirmed that partial mediation effect was significant ($z=3.23$, $p=.001$).

Direct: .224

Indirect: .154

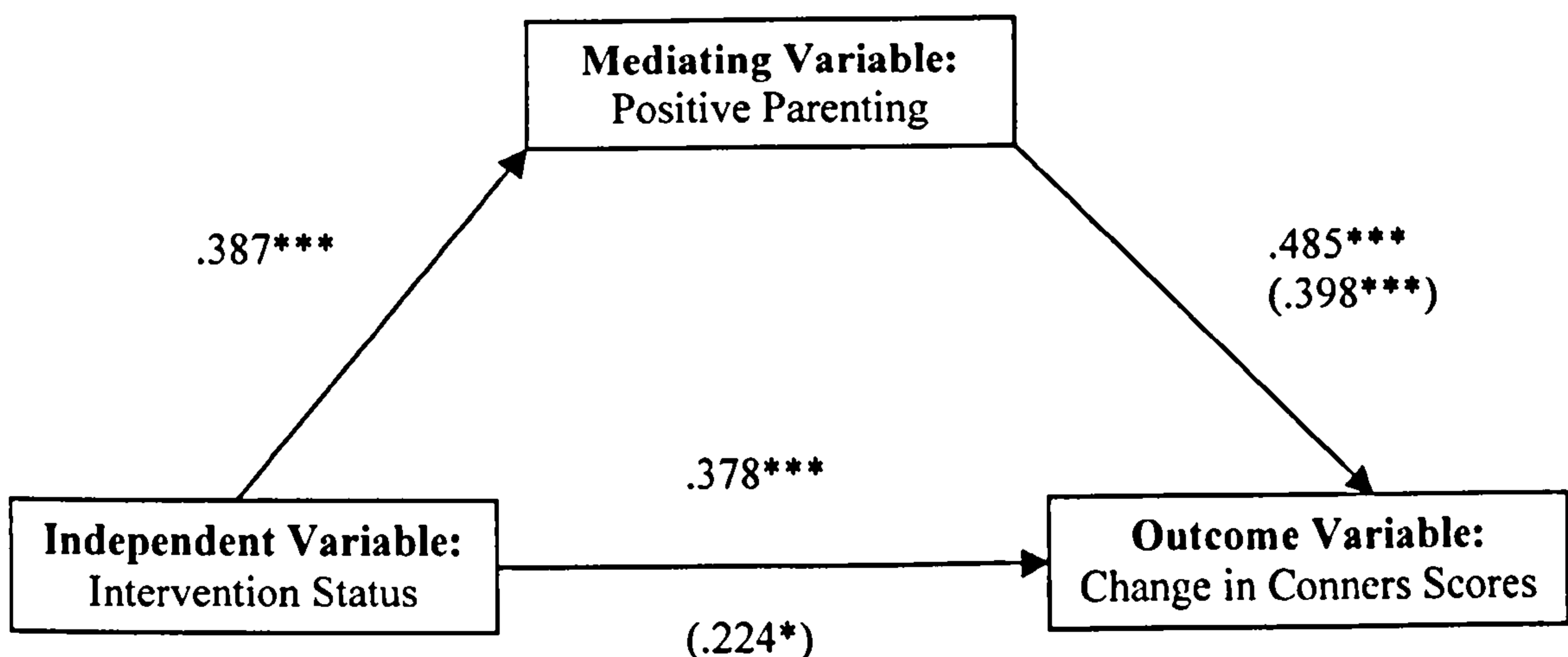


Figure 5: Standardised Coefficient of Intervention Status on Outcome:

Critical Parenting

Change in critical parenting was not associated with change in Conners scores, and was therefore not further investigated as a mediator.

Discussion

The current study addressed two primary objectives. The first was to explore predictive and moderating effects of child and family risk factors on intervention outcome. The second was to identify potential mediators of outcome. These were examined within the context of an RCT evaluating the efficacy of the IY PT programme with families of preschool children who displayed signs of conduct problems and ADHD (Hutchings et al., 2007; Jones et al., 2007).

Predictors (Baseline – Follow-up)

Within the intervention group, only one significant predictive relationship was found from baseline to post-intervention. Children with more severe levels of ADHD symptoms at baseline responded better to PT intervention, when compared with children with less severe baseline levels of ADHD. This finding is inconsistent with the traditional pattern of findings within the ADHD treatment literature. For example, in the MTA study, the severity of ADHD symptoms at baseline predicted poorer treatment response to both medication and parent-training intervention (Owens et al., 2003). This inconsistency, however, could be due to the younger age of children in this study, which highlights the importance of early intervention. The association between severity and more successful outcomes is particularly noteworthy with this particular sample, given that the co-morbid condition is often considered hard to treat (Lynham, 1996; Moffitt, 1993). These results are, on the other hand, consistent with studies that have evaluated the IY programme with families of children with conduct problems (Beauchaine et al., 2005; Gardner, et al., submitted).

The other eight risk factors examined (including severity of conduct problems, sex, age, family income, maternal depression, teen and single parenthood) were not associated with outcome, suggesting that the intervention is effective, irrespective of initial level of risk.

Within the control group, severity of ADHD symptoms also predicted better outcomes from baseline to follow-up. However, this finding should be interpreted with some degree of caution. Although severity of ADHD symptoms predicted positive change in ADHD symptoms at follow-up, for the control group, these changes were small, and non-significant when compared to the large, significant, improvements associated with the intervention group (see Jones et al., 2007). Older child age predicted better outcomes, which does not correspond with the typical findings in the literature (e.g. Daley, 2006; Ruma et al., 1996; Webster-Stratton & Herbert, 1994). However, this may be due to the small age range of the children within this sample (i.e. all preschool). Higher maternal depression at baseline was marginally associated with poorer outcome, although the prediction was not significant. This trend, is however, consistent with the literature on the negative influence of maternal depression on child adjustment (e.g. Downey & Coyne, 1990)

Predictors of Long-Term Outcomes (Intervention Group)

For the intervention group, predictors were also examined at follow-ups two and three (twelve and eighteen months after baseline, respectively). The only significant predictor to emerge was that maternal depression at baseline was associated with

poorer outcomes at follow-up three. This suggests that mothers who display high levels of depression at baseline may benefit from extra therapeutic effort following the delivery of intervention to ensure the long-term stability of programme effectiveness. This finding partially supports the traditional pattern of findings in the literature, which highlight the influence of depression on treatment response (e.g. Dumas & Wahler, 1983; Knapp & Deluty, 1989; Owens et al., 2003; Reyno & McGrath, 2006). Although maternal depression was not a barrier to the implementation of the intervention in this study, but it did impact on the stability of intervention related effects in the longer term. This finding is inconsistent with studies that have examined maternal depression as a potential predictor of outcome with the IY programme. These studies typically report that depressed parents respond equally well to treatment, or even better, when compared to their non-depressed counterparts (Beauchaine et al., 2005; Gardner, et al., submitted). However the children in this study with conduct problems and co-morbid ADHD reflect an even more 'at risk' sample, where intervention effects may be more sensitive to the influence of maternal depression.

Other candidate predictors, including age, sex, teen parenthood, single parenthood, and income predictors were not associated with long-term outcome, suggesting that the stability of intervention-related improvements was not affected by these important and well recognised risk factors.

Moderators of Outcome

The examination of moderators of outcome within the intervention and control group failed to uncover any effects. The lack of moderating effects suggest that families benefited equally from the intervention, which does not support the typical pattern of findings in the PT literature, where risk factors such as severity, maternal depression, as well as income have been associated with poor treatment response (e.g. Dumas & Wahler, 1983; Reyno & McGrath, 2006). However these findings do support studies that have examined moderators of outcome within evaluations of the IY programme (e.g. Baydar, et al., 2003; Beauchaine, et al., 2005; Gardner et al., submitted). It is likely that the IY programme achieves this level of success with ‘hard to reach’ disadvantaged families through its strong emphasis on therapeutic alliance and by addressing barriers to attendance in its delivery.

Mediators

Based on current literature, parenting skill, including critical parenting and positive parenting were examined as potential intervention mechanisms. Positive parenting skill, as measured by direct observation of parent-child interaction, was a significant partial mediator of outcome, suggesting that a change in positive parenting is a key component contributing to the efficacy of the intervention. This finding is consistent with previous literature on PT (Hinshaw et al., 2000; Reid et al., 2004), and replicate those reported by Gardner et al., (submitted), who reported similar results with the whole sample of families who took part in the North Wales Sure Start Trial (Hutchings et al., 2007). The fact that the similar results were achieved with the co-

morbid sub-group suggests that the same intervention mechanism (i.e. positive parenting) mediates improvements in child ADHD symptoms as well as conduct problems. This important finding highlights the need to continue to address the role of parenting with the multi-modal treatment of ADHD.

Limitations

There are a number of limitations that are worthy of consideration. Firstly, the sample size was relatively small for moderator analysis, although results provide useful exploratory findings of moderators of outcome within a sample of children with ADHD and conduct problems. Secondly, the primary outcome measure (the Conners) was parent-reported. In the context of intervention research, parents' expectations of treatment outcome may bias their responses to self-report measures. The findings from the study would be strengthened if a convergence of self-report and direct observation methods were used. However, observational measures of ADHD symptoms were not collected. Thirdly, all children in the sample displayed high levels of ADHD and conduct problems, and consequently it was not possible to explore potential differential moderator and mediator effects within sub-groups of children with different symptomatology. However, this is typical of the presentation of ADHD during the preschool years. Finally, it was not possible to explore whether the presence of maternal ADHD symptoms predicted or moderated outcome as previously identified by Sonuga-Barke et al (2002), as a measure of parental ADHD was not included in the assessment battery of the Sure Start trial.

Clinical implications

Prospective identification of treatment non-responders is the first step towards developing new interventions that are effective for children who do not respond well to current approaches. Both predictor and moderator analyses suggest that the IY may provide a valuable first-line intervention for preschool children with symptoms of ADHD, even with families of children with more severe symptoms, and families with high levels of socio-economic disadvantage. These findings are particularly salient given the current concerns about medicating this young age-group (e.g. Perring, 1997).

CHAPTER 6

GENERAL DISCUSSION

Summary of main thesis findings

Overview of main objectives

This study was developed to evaluate the IY BASIC PT programme (Webster-Stratton, 1989) with families of children who displayed signs of early emerging ADHD and conduct problems. The first objective was to examine the short-term efficacy of the IY PT programme in reducing the behavioural symptoms of ADHD. The second was to determine the long-term stability of treatment related effects, and the third was to explore potential predictors, moderators, and mediators of outcome. These objectives were addressed by conducting a secondary re-analysis with a sub-group of families from an existing database of preschool children at risk of developing conduct problems (Hutchings et al., 2007). The sub-group of families were based on a community sample of disadvantaged families, living in designated Sure Start areas across North and Mid Wales, and whose children displayed signs of early emerging conduct problems *and* ADHD (Hutchings et al., 2007).

Study one

The short-term efficacy of the IY programme was examined using an intention-to-treat, randomised controlled group design. Using Analysis of Covariance, results demonstrated that the intervention condition was associated with more positive outcomes for children. Significantly greater improvements in levels of child inattention, hyperactivity, and impulsivity, were reported by parents in the intervention group as compared to those in the control group. The positive outcomes associated with the intervention group remained significant even after controlling for

change in child conduct problems, demonstrating improvements in ADHD symptoms as independent of improvements in conduct problems. The independence of improvements in ADHD symptoms from improvements in conduct problems suggests that the IY programme may provide a useful PT intervention for preschool children presenting with ADHD-only symptoms. Correlation analyses were conducted to examine the association between ADHD change scores and child deviance change scores (see Appendix 8). Results demonstrated that they were not significantly correlated at follow-ups one, two, or three, which further supports the independence of ADHD and child deviance.

The investigation of clinical significance, using the Reliable Change Index (RCI) criteria (Jacobson & Truax, 1991), demonstrated that over half of the children in the intervention group displayed clinically significant improvements post-intervention, and over half had scores that had fallen below the clinical threshold on the Conners (Conners 1994).

Overall, these findings contribute to the growing evidence-base in the literature of the efficacy of parenting interventions for preschoolers with symptoms of ADHD (e.g. Pisterman et al., 1989; Sonuga-Barke et al., Bor et al., 2002).

Study Two

Given that the positive effects of PT intervention can decline over time (e.g. Serketich & Dumas, 1996), study two examined the longitudinal stability of intervention gains

within the same sample of families. Long-term follow-ups were conducted with the intervention families at 12- and 18- months after baseline.

The stability of intervention-related effects were examined using a series of repeated measures Analysis of Variance for each follow-up. Results indicated that there were no significant differences between Conners change scores at each follow-up, even after the confounding effects of co-morbid child conduct problems had been controlled, indicating that the improvement evident at post-intervention were stable over subsequent follow-ups, and continued to remain independent of conduct problems. These findings support the long-term efficacy of the IY programme (e.g. Webster-Stratton, 1990; Scott et al., 2001; Bywater et al., submitted), and are consistent with the findings of Bor et al., (2002) who reported 12-month stability with the Triple - P intervention for children with co-occurring ADHD and conduct problems.

The examination of clinically reliable improvements over time, using the Reliable Change Index (Jacobson & Truax, 1991), demonstrated that almost half showed clinically significant improvements at 12 and 18-month follow-ups. Using clinical cut-off criteria, over half of the sample maintained scores that were below the level of clinical concern on the Conners at each follow-up.

Magnitude of change was examined using Cohen's (1988) guidelines. At follow-up three, a large proportion of families had maintained at least a modest significant

improvement, over half at least a large improvement, and almost a third had maintained a very large improvement. In addition, children with more severe ADHD scores at baseline benefited more from intervention, as indexed by showing a greater magnitude of change at each follow-up compared to the sample as a whole.

Evidence for the long-term stability of the IY provides further support for the efficacy and utility of the IY as a first line intervention for this preschool population. This finding is particularly encouraging given that the co-morbid condition is often considered to be recalcitrant and resistant to treatment (Hinshaw & Melnick, 1995; Loeber, 1990; Lynham, 1996; Moffitt, 1993).

Study 3

In light of the considerable variability in treatment outcomes among families, it is important to identify potential subgroups of families with particularly good (or poor) treatment response (Nock, 2003). From a clinical perspective, an understanding of patient characteristics that predict or moderate outcome could help direct limited resources to those most likely to benefit (Hinshaw et al., 2000). It is also important to explore mechanisms that contribute towards the success of intervention (Barron & Kenny, 1986; Hinshaw et al., 2001) in order to develop more effective interventions and for refining implementation (Kazdin, 2001; March & Curry, 1998).

The third and final study therefore explored mediators and moderators of outcome within the sample. Firstly, candidate predictors of outcome were examined using

multiple linear regression with change in Conners scores (Conners, 1994) as the dependent variable, and baseline scores for each predictor variable as the independent variables. Results of these analyses demonstrated that for the intervention group at post-intervention, only one significant predictor was found. The severity of AD/HD symptoms at baseline, as measured by the Conners, was associated with a more positive treatment response compared to those with less severe levels. This finding is inconsistent with some traditional patterns of findings. For example, in the psychosocial treatment arm of the MTA study (MTA Cooperative Group, 1999), those with greater severity demonstrated poorer outcomes at follow-up than those with lower severity of ADHD symptoms (Owens et al., 2003). On the other hand, studies that have examined predictors in relation to the IY intervention for children with conduct problems, report better outcomes for children with more severe symptoms (August et al 2001; Barrera et al., 2002; Reid et al., 1999). Again, this finding is particularly noteworthy with this co-morbid sample, given that this condition is considered to be resistant to treatment, and their families are more likely to meet higher levels of psychosocial adversity (Moffitt, 1993; Lynham, 1996). All other candidate predictors examined, including severity of conduct problems; sex; age; family income; maternal depression; teen; and single parenthood; were not associated with outcome, suggesting that the intervention is effective, irrespective of initial level of risk.

Within the control group, severity of ADHD symptoms also predicted better outcomes from baseline to follow-up. However, improvements in AD/HD symptoms

for the control group from baseline to follow-up one were very small and statistically non-significant (see Jones et al., 2007). Older child age predicted better outcomes, which does not correspond with the typical findings in the literature (e.g. Daley, 2006; Ruma et al., 1996; Webster-Stratton & Herbert, 1994). However, this may be due to the small age range of the children within this sample (i.e. all preschool). Higher levels of maternal depression at baseline were marginally associated with poorer outcome, although the prediction was not significant. This trend, is however, consistent with the literature on the negative influence of maternal depression on child adjustment (e.g. Downey & Coyne, 1990).

Predictors of outcome were also examined at follow-ups two and three for the intervention group (12 and 18 months after baseline, respectively). The only significant predictor identified was that elevated baseline scores of maternal depression were associated with poorer outcomes at follow-up 3. Although maternal depression was not a barrier to the implementation of the intervention in this study, it did impact on the stability of intervention related effects in the longer term. This finding is partially consistent with the traditional pattern of findings in the literature, which highlight the negative influence of depression on treatment response (e.g. Dumas & Wahler, 1983; Knapp & Deluty, 1989; Owens et al., 2003; Reyno & McGrath, 2006). The association between maternal depression and poorer long-term outcome is, however, inconsistent with studies that have examined maternal depression as a potential predictor of outcome with the IY programme. These studies

typically report that depressed parents respond equally well to treatment, or even better, when compared to their non-depressed counterparts (Beauchaine et al., 2005; Gardner, et al., submitted). However the children in this study displayed symptoms of conduct problems and co-morbid ADHD and reflect an even more 'at risk' sample (e.g. Cunningham, Benness, & Siegel, 1988; Cunningham & Boyle, 2002; Lahey, Piacentini, McBurnett et al., 1988), where intervention effects may be more sensitive to the influence of maternal depression. This finding suggests that mothers who display high levels of depression at baseline may benefit from extra therapeutic effort following the delivery of intervention to ensure the long-term stability of programme effectiveness.

Consistent with the findings of short-term predictor analyses, the other eight candidate predictors, including age, sex, teen parenthood, single parenthood, and income predictors were not associated with long-term outcome, suggesting that the stability of intervention-related improvements was not affected by these important and well recognised risk factors.

Putative moderators of outcome were examined by conducting separate multiple regressions for each risk factor. No significant moderating effects were found for any of the candidate variables, including child age, income, maternal depression, severity of ADHD, and severity of conduct problems. These findings are somewhat inconsistent with studies that have examined moderators of outcome for other PT programmes for ADHD (e.g. Owens et al., 2003). For example, in the MTA study

(MTA cooperative group, 1999; Owens, 2003), maternal depression and severity of child ADHD symptoms predicted poorer treatment response. These findings are, on the other hand, consistent with studies that have examined moderators of outcome for the IY programme, which demonstrate that IY is effective regardless of initial risk status (e.g. Gardner et al., submitted). Failure to uncover moderation effects provides further support for the efficacy of the programme, even for the most disadvantaged families. The success of the intervention in engaging hard to reach families may be attributable to the IY programme philosophy of fostering therapeutic alliance, which is one of the main determinants of positive outcomes with PT interventions (Kazdin, 1997), and by the strong emphasis placed on addressing barriers to attendance (such as the provision of free childcare, transport, and meals).

The second objective of study three was to explore mediators of outcome. Based on the current literature (Forgatch & DeGarmo, 1999; Gardner et al., submitted), change in observed parenting skill, including critical and positive parenting were examined as potential mediators. Within Barron & Kenny's (1986) model of mediation analysis, condition, putative mediator, and outcome must be correlated with each other in order to further assess mediation. Critical parenting was not associated with outcome, and therefore did not qualify for mediation analysis (Barron & Kenny, 1986). Using multiple regression, positive parenting was found to be a significant partial mediator of outcome, which replicate earlier studies within the PT literature (e.g. Forgatch & DeGarmo, 1999; Gardner et al., 2006). This finding also suggests that the successful intervention mechanisms for reducing ADHD symptoms is the same as for conduct

problems. The results also support studies that have demonstrated the influence of early negative parenting on the development, maintenance and escalation of ADHD. For example, longitudinal studies indicate that ineffective, coercive, and over-stimulating parenting contributes to early delays in executive functioning and to later hyperactivity (Jacobvitz & Sroufe, 1987; Morrell & Murray, 2003).

Collectively, these studies have provided evidence of short- and long-term efficacy of the IY for reducing symptoms of ADHD in preschool children, and with few predictors of outcome. The IY may therefore provide a promising alternative intervention for this population, lending itself as a successful first-line intervention for early emerging symptoms of ADHD.

Methodological Considerations

In interpreting the present findings, a number of methodological limitations inherent in this study justify further discussion. First, the primary outcome measure (the Conners [Conners, 1994]) used as the dependent variable in all three studies is based on parent report. Whilst the Conners has well established validity and reliability (Conners, Sitarenios, Parker, & Epstein, 1998), and is widely used in both research and practice, in the context of intervention research parents expectations of treatment outcome may bias their responses to self-report measures. For example, there is some evidence that parents might overestimate change following intervention (e.g. Patterson, 1982). A convergence of parent report and independent behavioural observations would have increased confidence in the findings. Independent

observations were conducted to examine parent-child interaction, although it did not measure ADHD related behaviours. However, the child deviance scores used as covariates in studies one and two, were based on this observational system.

Furthermore the Conners rating scale (Conners, 1994) has been found to correlate strongly with observational measures of ADHD, such as the Classroom Observation Code (Abikoff, Gittleman-Klein, & Klein, 1977; Schachar, Sandberg, & Rutter, 1986). It may also be worthy of noting here, that the outcome measures included in the original Ph.D. proposal (Appendix 1) included an observational measure of ADHD behaviour, based on an adapted version of the Classroom Observation Code (Abikoff, et al., 1977).

Second, as all children in these studies scored above the clinical threshold on measures of both conduct problems and ADHD, it was not possible to examine the possible differential effectiveness of treatment on sub-groups of children with different symptoms. A separate examination of children with inattentive and hyperactive subtypes of ADHD could have been conducted in this study, but this would have been complicated by the co-occurrence of conduct problems. The co-morbid ADHD and conduct problem condition is more often associated with the hyperactive/impulsive subtype of ADHD (Barkley, 1997).

Third, the children were eligible for inclusion to the study if they scored above the threshold on the Hyperactivity Subscale of the SDQ (Goodman, 1997). It may be argued that the Hyperactivity subscale of the SDQ is not the best measure of ADHD symptoms, in a sense that elevated scores at baseline might not necessarily indicate that children will go on to receive a diagnosis of ADHD in the future. As the children in the sample were preschool age, a measure of ADHD symptoms, as opposed to diagnostic criteria, was considered appropriate given that ADHD is not typically diagnosed until the child reaches middle childhood.

Fourth, long-term comparison with a control group was not possible, as the control group had been offered the intervention after completion of initial follow-up assessment. Given the evidence of the stability of these disruptive behaviours in preschool children (Campbell, 1995), and consequently the importance assigned to early intervention (Daley, 2006), it was considered unethical to allow preschool children who displayed signs of early onset conduct problems and ADHD to remain untreated through to 12 or 18-month follow-ups.

Consequently, although it can be concluded that the improvements in child ADHD symptoms were stable across long term follow-ups, in the absence of a comparison control group, it cannot be concluded that these gains were attributable to the intervention. Nevertheless, intervention families maintained improvements in ADHD symptoms that were evident at post-intervention more than a year previously. As there were no significant improvements found in the control group at initial follow-

up, there is little evidence to suggest that the intervention group improved and maintained these gains as a result of spontaneous recovery or regression towards the mean of the general population.

Fifth, because the study did not include a comparison intervention (e.g. a support group with no therapeutic content), it cannot be concluded with confidence that the long-term stability of improvements were due to therapeutic content and process, as opposed to contact with group leaders and parents in similar situations. However, the examination of mediators of outcome demonstrated that positive parenting, a core component of the IY intervention, was a significant mediator of outcome, suggesting that improvements were due to the therapeutic process of the IY. Furthermore, few studies have been able to control for contact, with the exception of Sonuga-Barke et al., 2002.

Sixth, it was not possible to examine maternal ADHD as a moderator or predictor of outcome. As this study was a secondary re-analysis of an existing database, measures of maternal ADHD were not included in the initial assessment battery, as the main aim of the trial was to use outcome measures related to children with conduct problems and their families. Such a measure was, however, included in the assessment battery of the original proposed Ph.D. study (Appendix 1).

Finally, with regards to the use of change scores in the regression analyses in study three, the problems with using change scores are worthy of discussion here. The use of change scores have been widely criticised for their purported unreliability and for

their sensitivity to regression towards the mean (Cronbach & Furby, 1970).

Change scores tend to be much less reliable than their component variable (Kessler, 1977). For instance, if pretest and posttest scores on a measure (in this particular case, the Conners at baseline and follow-ups) are equally reliable and have the same variance, the reliability of the *change score* can be greatly compromised if the baseline and follow-up scores are correlated (which one would expect on the same measure). This reduction in reliability depends upon the strength of the relationship between the scores at the two time points. Appendix 9 includes tables that display the correlations between the Conners scores (which entered into the computation of difference scores for the predictor and moderator analyses), for the intervention group, the control group, and all cases. An examination of these tables demonstrate that the Conners scores are positively correlated at each time-point, ranging from moderate relationship (.351) to strong (.749). As a result, despite the fact that the reliability of the Conners is relatively high (coefficient alphas of .74-.94), this would have been significantly reduced (especially in the cases where the correlations were high). Consequently, caution should be applied in interpreting the findings.

However, some psychometricians, have shown that there are common circumstances in which change scores can be highly reliable (Simmernan & Williams, 1982), and Woodward (1975) demonstrated the paradoxical result that change scores can yield powerful tests of causal hypotheses even when they are extremely unreliable.

Bearing in mind these methodological considerations, the present study contributed to the growing evidence of the efficacy of PT interventions for families of preschool

children with ADHD symptoms. Further research will lead to a better understanding of this important clinical area.

Clinical Implications

The short-term efficacy of the IY demonstrated in this study suggests that the IY may provide a valuable first-line intervention for preschool ADHD symptoms. The positive effects of intervention were maintained at follow-ups, 12- and 18-months after baseline. In the absence of booster sessions, this finding further supports the utility and effectiveness of the IY programme for preschool children with ADHD symptoms. As predictor and moderator analyses demonstrated that both efficacy and stability were largely independent of initial risk status, the IY may provide a successful intervention at targeting families traditionally considered 'hard to treat'. As maternal depression emerged as a predictor of poor outcome at follow-up three (18 months after baseline), families with this risk may benefit from additional monitoring following the delivery of intervention, as further therapeutic input may be required in order to maintain improvements in child ADHD symptoms in the longer term.

The overall findings are encouraging for this specific sample, as symptoms associated with the co-morbid condition are considered to be particularly intractable and resistant to treatment. The results are also particularly salient, given the current concerns regarding the use of drug therapy with preschool children (Greenhill et al. 2006;

Kollins et al., 2006; Perring, 1997). The IY PT may therefore provide the alternative first-choice treatment for preschool children presenting signs of ADHD, and medication introduced only for those children where PT is not effective.

It is important to note that clinics wishing to deliver the IY intervention should ensure that the programme is adhered to faithfully, and barriers to attendance addressed accordingly.

Future Directions

A large prospective follow-up study, evaluating the efficacy of the IY with families of children with preschool ADHD, would facilitate a greater understanding of efficacy, stability, as well as moderators of outcome. Inclusion of an independent behavioural observation measure of ADHD symptoms, as well as a measure of maternal ADHD would provide a more robust design. A larger sample size would enable the examination of the relationship between potential moderators and mediators of outcome as some risk factors may be differentially associated with the mechanisms of intervention. For instance, positive parenting might mediate outcome for disadvantaged families, whereas other components of intervention might mediate outcomes for other sub-groups of families. A prospective follow-up study with an ADHD specific sample is currently being undertaken by the programme developer in the US.

Other evidence-based PT interventions have been demonstrated to be effective in improving the symptoms of ADHD in preschool children, including the NFPT (Weeks et al., 1999), and the Triple-P (Sanders et al., 1998; 2000). A series of head-to-head trials to evaluate the relative efficacy of the NFPT, the Triple-P, and the IY, interventions together within the one study, would be useful for service providers and clinicians. Such a study would also facilitate an understanding of the sensitivity of each intervention to predictors and moderators of outcome. Health economic evaluation of head-to-head trials would also enable clinicians and health care providers to compare and contrast interventions with different modes of delivery (e.g. group vs individual therapy), and number of sessions. This would enable an evaluation of the relationship between cost of delivery and short and long-term efficacy of intervention.

How would a head-to-head study be set up

Design

A head to head trial could be designed as a prospective follow-up randomised controlled trial with three intervention groups – the Triple-P, the IY, and the NFPT, compared with a no-intervention, waiting list control group (WLC). Such a design would facilitate the evaluation of the relative efficacy of each intervention compared with the WLC. The inclusion of a control intervention group – an intervention that involves contact with therapist or group – without any therapeutic content, would effectively control for potential placebo and Hawthorne effects. The control intervention group should be as similar as possible to the active intervention groups in

all respects other than content (i.e. similar duration, and mode of delivery).

However, with the three interventions comprising different numbers of sessions and different modes of delivery, this would be difficult to achieve, unless three control intervention groups were set up to complement each programme. This would be extremely costly and labour intensive, and would increase the number of participants required to ensure the trial be sufficiently powered to detect intervention related change.

Participants

Firstly, it would be necessary to select the population from which the sample would be drawn (e.g. children meeting diagnostic criteria for ADHD with or without co-morbid conduct problems, or children with elevated scores on measures of ADHD). Secondly, after deciding on the population to be investigated, power calculations should be carried out in order to estimate the number of participants required in each group to sufficiently power the trial.

As a relatively large sample would be required with three intervention groups and a control group, a multi-site design would increase recruitment potential, with each site running each intervention and a control group, so that the randomisation process would be comparable across each site.

Measures

Primary outcome measures should be well validated and reliable measures of child ADHD symptoms and co-morbid symptoms such as ODD, CD, and anxiety.

Symptomatology should be multiply determined through a combination of interview,

questionnaire, and direct behavioural observational techniques. There are a number of interview schedules that have been designed to administer to parents to assess children's symptoms, such as the PACS (Taylor, Schachar, Thorley, & Wieselberg, 1986), or the Diagnostic Interview Schedule for Children (DISC IV; Schaffer, Fisher, Lucas, Dulcan, & Schwab-Stone, 2000). Parent-report questionnaires that assess symptoms of ADHD include measures such as the Conners (Conners, 1994), the Hyperactivity subscale of the SDQ (Goodman, 2001), the Kendal Self Control Rating Scale (SCRS; Kendal & Wilcox, 1979), and more general questionnaire measures of children's internalising and externalising symptoms such as the Child Behaviour Checklist (CBCL; Achenbach & Edlebrock 1986). A version of the Classroom Observation Code (COC: Abikoff, Gittelman-Klein, & Klein, 1977), adapted for use in the home could be utilised as a direct measure of the core symptoms of ADHD.

In accordance with the dual pathway model of ADHD (Sonuga-Barke, 2002), neuropsychological tests could be administered to measure inhibitory control (such as the Stop Signal Task [Logan, Cowan, & Davis, 1984]), and to assess delay aversion (such as the choice delay task [Sonuga-Barke, Taylor, Sembi, & Smith, 1992]).

Associated behaviour problems could be determined using measures of disruptive behaviour (ECBI and social competence scale and child behaviour checklist), and a measure of child intelligence, such as the Wechsler Intelligence Scale for Children (WISC; Wechsler, 2003).

Demographic information (such as age, sex, number of children, marital status, educational level, and income) as well as child developmental history (e.g. problems during pregnancy and birth / language development / major illnesses etc) could be ascertained using a semi structured interview such as the Personal Data and Health Questionnaire (PDHQ; Hutchings, 1996), as well as parental health information (e.g. history of depression / substance abuse, etc.).

Given the situational pervasiveness of ADHD, it would be useful to have an informant other than the child's parents, such as school-teachers, to report on the child's behaviour. With pre-school children, however, this would be slightly problematic. While most children from the age of 2 years receive some form of nursery care, there are inconsistencies in the level and amount of nursery care that young children receive, as well as inconsistencies in contact with the same member of staff.

In order to examine risk factors that could potentially moderate treatment outcome, or improve as a result of parent training, it would be necessary to include in the assessment battery, assessment of the quality of parent-child interaction (e.g. the Dyadic Parent Child Interaction Coding System; DPICS; Robinson & Eyberg, 1981), measures of parental competencies and style (e.g. the Parental Sense of Competence [PSOC; Johnston & Mash, 1983], the Parenting Stress Index [PSI; Abidin, 1990], or the Parenting Scale [Arnold, O'Leary, Wolff, & Acker, 1993]), and an assessment of parental mental health, including depression (e.g. BDI; [Beck, Ward, Mendelson, Mock, & Erbaugh, 1961]; the Hamilton Rating Scale for Depression [Hamilton, 1967]; or the Major Depression Inventory [MDI; Bech, Rasmussen, Raabek Olsen,

Noerholm, & Abildgaard, 2001), and maternal ADHD symptoms (Adult ADIID Rating Scale (Barkley & Murphy, 1998).

Once consensus reached on the battery of measures, a detailed protocol should be written, explaining the process of the data collection process and the administration of the measures. Researchers should also be trained to use the measures reliably, to ensure that the data collection process be carried out the same at each site. The measures should also be piloted. Such piloting would help establish reliability and validity of any new measures developed for the purpose of the research, or amendments made to existing measures. This piloting process would also help to gauge the recruitment process (e.g. highlight any difficulties in finding the relevant sample and their willingness to participate in the study), and address any practical issues in the administration of the measures that may arise once data collection is underway (by which time it would be too late to change).

Data Collection

The assessment battery would be administered to all families at baseline, and again at 6-month after baseline, with the programmes running in the intervening period. The intervention groups would also be followed-up at later time-points in order to determine the relative stability of each programme over time.

Randomisation

Upon completion of baseline data collection, groups would be randomised to one of four groups: three interventions and a control group. In a multi-site trial, block

randomisation by site would ensure equivalence of the number of families allocated to each group across each site. Stratification by factors known to influence the severity of symptoms, such as sex and co-morbidity, would balance (where chance alone might not) the groups in the distribution of these potential confounding variables.

Health Economic Evaluation

Conducting a cost-effectiveness evaluation of the interventions, in collaboration with a health economist, would provide valuable information to policy makers and practitioners as to the relative cost and efficacy of each of the intervention programmes.

Typically, such a costing would take into account the cost the initial training (in terms of training fees and therapist time), purchase of the package, weekly supervision, and venue rental for the duration of the intervention. In order to assess running costs, therapists involved with the trial would complete weekly cost diaries to measure costs including travel, course materials (such as handouts and homework sheets), telephone calls to families, provision of crèche facilities, and refreshments). The cost of each intervention could then be compared with the effectiveness of each programme in improving child symptoms (e.g. the reduction in scores on primary outcome measure of ADHD symptoms).

Furthermore, costs could be examined from a multi-agency public sector perspective, including participants' utilisation of health, social, and special educational services. This would enable the evaluation of whether the intervention has added economic

benefits in reducing families' use of these services. Such information could be gathered using client service receipt inventories such as the Service Utilisation Questionnaire, administered to parents at each time point, which assesses the child (and parent's) use of these services over the preceding 6 months.

Finally, sensitivity analysis with the training cost of group leaders removed would produce an estimate of the incremental cost effectiveness ratio for rollout of the programme. Further subgroup sensitivity analysis, with children categorised into risk groups for ADHD (e.g. relatively mild, moderate, or severe) could establish whether cost effectiveness varied with the intensity of risk at baseline.

Self-administered programmes

Despite the availability of effective evidence-based interventions, the growing prevalence of preschool ADHD creates a need that far exceeds available personnel and resources. In many parts of the UK families often have to travel long distances to access services provided at inconvenient times, leading to high levels of non-engagement or non-completion. A recent Cochrane review (Montgomery et al., 2006) concluded that self-administered interventions were worth considering in clinical practice targeting child behaviour problems. The implementation of self-administered interventions could provide benefits to both families and clinicians. Families can complete the intervention in their own home, and at their own pace. For clinicians, they can reduce the amount of time therapists have to devote to each case, increase

accessibility to intervention, and release clinician time to concentrate on more complex cases. They are also potentially cost effective and could be used to ease the financial burden of mental health problems on the community (Morawska & Sanders 2006).

While there is some evidence to support the efficacy of self administered interventions for parents of children with conduct problems (Markie-Dadds & Sanders, 2006; Webster-Stratton et al., 1998), to date no studies have examined the efficacy of self administered intervention for preschool children with ADHD and possible comorbid conduct problems (Daley 2006). A greater emphasis should be placed on the evaluation of self-administered versions of the NFPT, Triple - P, and the IY programmes for parents of preschool children with ADHD.

Conclusions

Recent findings from the PATS study have highlighted the challenges of using medication with preschool children with ADHD. This study has demonstrated the short- and long-term efficacy of the IY programme with families of preschool children with ADHD and conduct problems. With the exception of maternal depression, no moderators of outcomes were found, suggesting that the intervention is effective even for the most disadvantaged, hard to treat families. The IY therefore

may provide a valuable alternative intervention for preschool ADHD, provided the programme is delivered faithfully, and barriers to attendance addressed accordingly.

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APPENDICES

Appendix 1: Initial Study Protocol

Version II (22/04/05)

Project Protocol

Project Title: Evaluation of the efficacy of the Webster-Stratton Incredible Years Parent-training Programme for families of children referred to CAMHS with symptoms of ADHD.

Background

Attention Deficit Hyperactivity Disorder (ADHD; American Psychiatric Association, [APA] 1994) is one of the terms used to describe a childhood psychiatric disorder that is characterised by developmentally inappropriate problems in sustaining attention, impulsivity, and over activity (Barkley, 1997; APA, 1994). These problems typically arise in early childhood, are relatively persistent, and result in cross-situational impairment (e.g. at home and at school; APA, 1994). The disorder is one of the most common reasons for referral into specialist mental health services (Barkley, 1997), representing between one third and one half of all referrals (Popper, 1988). Prevalence estimates indicate that between 3-5% of school-aged children meet diagnostic criteria for ADHD (APA, 1994; Szatmari, 1992). Children diagnosed with the disorder form a heterogeneous group in that the degree to which the pattern and severity of different symptoms displayed varies significantly between individuals. This heterogeneity is further complicated by the fact that ADHD symptoms commonly co-occur with various medical, psychiatric, or developmental disorders (APA, 1994). Chief among these co-morbidities are conduct problems (occurring in an estimated 30-60% of children diagnosed with ADHD), anxiety disorders (25-40%), and specific learning disability (10-26%) (Barkley, 1998; Biederman, Faraone, & Lapey, 1992; Conners & Erhdart, 1998).

Left untreated, the long-term outcome for these children is poor. Their pattern of deficits can disrupt academic efforts as well as social relationships during the school years, and is a major predictor of subsequent academic underachievement, as well as adolescent conduct disorder, substance abuse, and persistent family, attentional, interpersonal and occupational difficulties that can pervade into adulthood (Manuzza & Klein, 1991; Taylor, Chadwick, Heptinstall, & Danckaerts, 1996).

Despite the evidence for a neurostructural (Dunn & Kronenberger, 2003) and genetic basis for ADHD (Thapar, Holmes, Poulton & Harrington, 1999) it is becoming increasingly evident that psychosocial factors make an important contribution to the development, persistence and prognosis of children with ADHD. Woodward, Taylor, & Dowdney (1998), found that the quality of parenting provided for ADHD children

may contribute to their behavioural difficulties. Poor parental coping, as well as the use of harsh discipline methods continued to be significantly associated with ADHD even after the confounding effects of child conduct problems and parental psychopathology health had been controlled.

The nature of ADHD symptoms, by definition, makes the child with ADHD difficult to parent, which may contribute to parental lack of coping and use of harsh discipline methods. For younger ADHD children the focus of interaction is primarily on discipline and control. Boys with ADHD were found to be negative and non-compliant during play episode and unresponsive to their mothers' directions and interactions (Taver-Behring, Barkley, & Karlsson, 1985). In an observational study, Gardner, Sonuga-Barke, & Sayal (1999) demonstrated that mothers of children with behaviour problems used fewer positive and pre-emptive strategies to resolve conflict.

Guidance from both the National Institute for Clinical Excellence in the UK and American Pediatric Association in the US indicates that a combination of psychostimulant medication (e.g. methylphenidate) and specific psychosocial therapies is the optimal intervention package for the management of ADHD symptoms. Despite evidence for the short-term benefit of this combination, no controlled evidence for the generalized long-term effectiveness has, as yet, been provided.

Evidence for the efficacy of psychosocial intervention for parents of children with ADHD appears strongest for preschool children (Sonuga-Barke, Daley, Thompson, Weeks, & Lever-Bradbury, 2001; Bor et al., 2002), weaker for school aged children, and non-existent for adolescents (Pelham, Wheeler, & Chronis, 1998). The success of psychosocial intervention in the preschool years is based on the premise that early intervention, before the child's behaviour becomes associated with anti-social tendency and school failure offers the best opportunity of altering the developmental course of the disorder.

In school aged children with ADHD, whose behaviour is characterized by high levels of aggression and non-compliance, and alternative intervention, aimed at helping parents to reduce their child's anti-social behaviour may also help reduce their ADHD behaviours. Recent evidence suggests that parent-training may be equally effective for children with conduct disorder and attentional problems (Hartman, Stage, & Webster-Stratton, 2003) and that conduct disorder and ADHD symptoms may develop during a sensitive period in boys development through an interaction between the child's emotional dysregulation and parents rejecting and coercive parenting (Morrell & Murray, 2003).

Rationale for study

The proposed research aims to examine the efficacy of Webster-Stratton's Incredible Years Parenting Intervention in reducing childhood ADHD symptoms. It is a hypothesis generating study, aimed at parents of children referred to CAMHS with symptoms of ADHD (non-diagnosed). There is a strong evidence base for the effectiveness of this intervention in enhancing parental competencies and in reducing child conduct problems (Webster-Stratton, 1998, Webster-Stratton & Hammond, 1998). The effectiveness of this intervention in enhancing parent-child relationships

and reducing conflict may also reduce ADHD symptoms. Specifically the aims are to:

- i) Explore the impact of ADHD on children's function
- ii) Explore the efficacy of the Incredible Years Parent-training Programme for children with ADHD
- iii) Examine specific moderators of intervention outcome

Overview of Evaluation Method

Participants

Forty eight families who have been referred to CAMHS for ADHD assessment will be recruited to take part in the research. To be eligible to participate, families must meet following criteria:

Inclusion Criteria

- Referred to CAMHS for ADHD assessment
- Score above clinical cut-off on the PACS ADHD subscale
- Child aged between 5-11 years
- One parent must be able to attend the parent group sessions that will be run during school hours.

Exclusion Criteria:

- Not having already received any treatment for the child's ADHD symptoms
- Families not to have been on an IY parenting programme in the past (e.g. for a sibling)

Assessment Battery

In terms of the effectiveness of the programme for enhancing parenting competencies and in reducing symptoms of ADHD; and in order to explore potential moderators of treatment outcome, the following outcome domains are examined: Parenting competencies; parental mental health; child symptoms; child IQ; parent-child interaction. Demographic information will also be collected. Participant characteristics will be assessed using a combination of assessment techniques, including direct behavioural observation, semi-structured interview, and ratings scales, which are listed below.

Demographics

- Personal Data and Health Questionnaire (PDHQ; Hutchings, 1996)
- Index of Major Life Events.

Parenting Competencies

- Parental Sense of Competence (PSoC; Gibaud-Wallston & Wandersman, 1978; Johnston & Mash 1983)
- Parenting Stress Index/short form (PSI/SF; Abidin, 1990; 1995)

Parental Mental Health

Adult ADHD Rating Scale (AARS; Barkley & Murphy, 1998)

Beck Depression Inventory (BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961)

Child Symptoms

- Parental Account of Children's Symptoms (PACS; Taylor, Schachar, Thorley, & Wieselberg, M., 1986; Taylor, Sandberg, Thorley, & Giles, 1991)
- Self Control Rating Scale (SCRS; Kendall & Wilcox, 1979; Kendall, Zupan, & Brasswell, 1981)
- Conners Abbreviated Parent/Teacher Rating Scale (Conners, 1994)
- Strengths and Difficulties Questionnaire (SDQ; Goodman, 1997)
- Adapted Classroom Observation Code for use in home setting (COC; Abikoff, Gittelman-Klein, & Klein 1977)

Child IQ / Neuropsychological tests

- Subset of Weschler Intelligence Scale for Children (WISC; Wechsler, 2003; Kaufman, Kaufman, Balgopal, & McLean, 1996).
- Choice Delay Task (Mischel, Shoda, & Rodriguez, 1989; Sonuga-Barke, Taylor, Sembi, & Smith, 1992)

Parent-child Interaction

- Dyadic Parent-child Interaction Coding System (DPICS; Robinson & Eyberg, 1981)

Intervention and Programme Integrity

The Incredible Years BASIC parent-training programme was developed by Webster Stratton (1981) for parents of oppositional defiant / conduct disordered children.

Many of these children have a co-morbid diagnosis of ADHD and there is evidence that the programme is equally effective for these children (Scott, Spender, Doolan,

Jacobs, & Aspland, 2001; Hartman, Stage, & Webster-Stratton, 2003). The proposed intervention is an extended, 16-week, version of the Incredible Years BASIC Parent-training Programme (Webster-Stratton, 1981) that has been adapted specifically for use with families whose children have ADHD. In addition to the BASIC 12-week curriculum, additional sessions will include elements of the ADVANCE programme and components of the SCHOOL programme (for an overview of these programmes, see Webster-Stratton, Reid, & Hammond, 2001). In the present study, only children with ADHD will be offered the intervention. Groups of 12 parents will meet weekly, in the Child and Adolescent Mental Health Services (CAMHS) clinic in Bangor, with group facilitators, for two hour sessions that introduce them to a parenting tool kit. Skills taught on the programme include i) how to establish a positive relationship with their child through play and child centred activities, ii) encouraging praise, reward, and incentives for appropriate child behaviours, iii) guidance in the use of effective limit setting and clear instruction giving, and iv) strategies for managing non-compliance. Parents acquire these skills through facilitator-lead group discussion, brain storming, videotape modelling, and rehearsal of taught intervention techniques,

both within the group, and through home assignments, discussion of video clips, practice within the group setting, and homework assignments.

The groups are run by experienced and certified group leaders, who adhere to the programme delivery as specified in the programme manual. All parent group sessions are videotaped for the purpose of randomly examining implementation fidelity. The integrity of the intervention might be compromised if the programme is not adhered to in entirety with all components applied. Such adherence is necessary in order to preserve the behaviour change mechanisms that made the original model effective (Mihalic, Fargan, Irwin, Diane, & Elliot, 2002).

Design

The study will employ random allocation of families (stratified for the child's age) to either intervention or to waiting list control groups. The randomisation process is completed by the supervisor, in order to ensure that the research team are naive as to the group status of participants.

Power calculations, based on large effect size and an alpha level of 0.05, stipulated that 26 participants in each group will yield more than adequate power (above 0.8) to detect differences between the groups.

Family assessment will occur at baseline and four months after baseline (during which period the intervention takes place). Control participants will be given the opportunity to take part in the parent-training programme after their four-month follow-up assessment.

Forty-eight eligible families will be recruited at two recruitment phases. Due to limited time available to complete all data collection within the research time frame, a crossover design will be used for the first set of 24 participants recruited. That is, they will initially be allocated at random to either treatment or control groups. After the treatment group have completed the parent-training intervention, follow-up assessments will be completed for both groups. The control group will then receive intervention, and, subject to them still meeting criteria for inclusion, their follow-up will also serve as a baseline assessment, and they will be followed up again in four months, after their training is complete. For the next set of 24 recruitments, participants will be allocated to either treatment or control groups, baseline measures will be administered prior to intervention, with follow ups conducted at four months.

Repeated measures analysis of variance, change scores, and clinically significant change indices would be used to investigate the efficacy of intervention. Potential moderators of successful outcome would be examined using multiple linear regression. Key baseline measures, including severity of child ADHD symptoms, parental psychopathology (e.g. depression, ADHD), parenting stress, treatment adherence etc., would be used to predict child ADHD symptom scores at follow-up.

Procedure

There will be two recruitment phases, with the first being in July/August 2005, and the second in February/March 2006. Twenty-four families will be recruited at each phase. Families whose child's names have been referred to CAMHS for ADHD assessment will be visited in their homes by CAMHS professionals for PACS

assessment. Families who score above the clinical cut-off on the ADHD subscale of the PACS and who meet criteria for inclusion will be invited to take part in the research. Families will be given an information sheet, and both the research and the parenting programme will be explained to them. Subject to their interest in taking part, and their consent to have their details forwarded to the research team, CAMHS will then pass their names on to the research team.

Families will then be contacted by the research team to arrange a home visit to collect baseline data. During this visit, the research and the parenting programme is explained again, and the interviews, questionnaires, and tests are administered, and the observational measures completed. After baseline is completed, the 24 families are randomly assigned to either treatment group or control group. The treatment group will attend a parenting course within a month. When treatment group have completed the intervention, all families are visited again to collect follow-up data. Once this process is completed, the control group receive their intervention.

Ethical Considerations

At the assessment phase, a bilingual form providing an overview of the research and the Incredible Years Parenting Programme will be given to the parent prior to requesting informed consent to have their details forwarded to the research team. The leaflet explains the purpose of the study, why the participating families were chosen, and what will happen should they decide to take part. The participant will be reassured that all information provided by the family will remain strictly confidential, and be available to members of the research team only. The leaflet also explicitly states that participants, having given their consent, are free to withdraw from the study at any time without this affecting their quality of care, or access to other services or future parenting programmes.

In order to ensure that the patients GP is made aware of the patients participation in the trial, a feed-back form, reporting the patients involvement in the study, will be forwarded to the GP who referred the patients initially.

A potential issue for ethical concern is the fact that psycho-stimulant treatment for children who may go on to receive a formal diagnosis of ADHD will be delayed until the parents have completed the parenting course. However, the maximum period participants would have to wait for intervention is 4 months. The standard waiting list in CAMHS from referral to assessment and diagnosis is, at present, estimated at approximately six months.

In order to ensure that all information remains confidential, participants are assigned an identification number that is used on all measures and schedules instead of names. The database relating participants to their identification number is stored on protected computer files, encrypted with a password that is known only by the chief investigator and supervisor. Note that the research team and the implementation team are entirely separate groups of individuals.

Timescale

The first nine months (October 2004-June 2005) of the three-year Ph.D. study will be spent developing a literature review, and training in administering the assessment battery. July and August 2005 will be spent recruiting, and collecting baseline

measures from the first set of 24 participants. The first intervention group for treatment families will run from September 2005-January 2006. Following which both treatment and control groups will be visited again to collect follow-up measures. The control group will then receive their intervention in February or March 2006. Also in January 2006, the second set of 24 participants will be recruited, visited to collect baseline measures, and allocated to treatment or control group. The treatment group will receive intervention in February/March 2006, thus, there will be two groups running in CAMHS at the same time from February-June 2006. At the end of treatment, families will be visited to collect follow-up data, and the control group will be offered a place on the parenting course in September 2006. The final year of the study (October 2006-2007) will be spent analysing the data and writing up the final thesis.

Dissemination

Journal and conference papers would be the main outlets for reporting the results of the main experiments. The assessment methodology and the results of the intervention studies would also be reported during training days for practitioners in the field of child mental health.

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Appendix 2a: Ethics application cover letter (North West Wales NHS Research Ethics Committee)

1st April, 2005

Dr Rossela Stoicescu-Jones
North West Wales Local Research Ethics Committee.
Directorate of Quality and Clinical Assurance
North West Wales NHS Trust
Ysbyty Gwynedd
Bangor
Gwynedd
LL57 2PW

Dear Dr Stoicescu-Jones

Re: Application for NHS Research Ethics Ref: 05/WNo01/15

I enclose an application for approval by North West Wales NHS REC, regarding a Ph.D. research project: "Evaluation of Parent-training Intervention for Children with ADHD". Approval is being sought for the identification of families by Child and Adolescent Mental Health Service (CAMHS) staff for possible recruitment to the programme, and also to provide pre- and post- intervention data. The Webster Stratton Incredible Years Parenting Programme, which is already being run as a core part of the service, is provided by Child and Adolescent Mental Health Services in Bangor, for families whose children have been referred for ADHD assessment.

The study involves the identification of 5-9 year old children referred to CAMHS with query ADHD. Parents are then invited to participate in the research programme. The research involves random allocation of children to one of two parenting group (all participants get the same intervention, but the second group is a waiting list control group who receive the intervention four months later).

One of these parenting groups is due to start in September 2005, which would mean obtaining baseline measures during July and August.

I trust that the enclosed information is adequate but am happy to provide further information if required.

Yours sincerely

Karen Jones (Ph.D. Student, School of Psychology, University of Wales, Bangor)

**Appendix 2b: Ethics Application Cover Letter (School of Psychology,
Bangor University: CAMHS Study)**

January 31, 2005

Dr Michaela Swales
Chair: School of Psychology Research Ethics Committee
School of Psychology
Brigantia Building
University of Wales, Bangor

Dear Dr Swales

Re: Ph.D. Ethics Proposal - Evaluation of the efficacy of the Webster-Stratton Incredible Years Parent-training Programme for families of children who have symptoms of ADHD.

I enclose an application for approval by School of Psychology, regarding a Ph.D. research project: "Evaluation of Parent-training Intervention for Children with ADHD". Approval is being sought for the identification of families by Child and Adolescent Mental Health Service (CAMHS) staff for possible recruitment to the programme, and also to provide pre- and post- intervention data. The Webster Stratton Incredible Years Parenting Programme, which is already being run as a core part of the service, is provided by Child and Adolescent Mental Health Services in Bangor, for families whose children have been referred for ADHD assessment.

The study involves the identification of 5-9 year old children referred to CAMHS with query ADHD. Parents are then invited to participate in the research programme. The research involves random allocation of children to one of two parenting group (all participants get the same intervention, but the second group is a waiting list control group who receive the intervention four months later).

One of these parenting groups is due to start in September 2005, which would mean obtaining baseline measures during July and August.

I trust that the enclosed information is adequate but am happy to provide further information if required.

Yours sincerely

Karen Jones
Ph.D. Student, School of Psychology, University of Wales, Bangor

**Appendix 2c: Ethics Application Cover Letter (School of Psychology,
Bangor University: School/Community Study)**

November 7, 2005

Dr Michaela Swales
Chair: School of Psychology Research Ethics Committee
School of Psychology
Brigantia Building
University of Wales, Bangor

Dear Dr Swales

Re: Proposed amendment to proposal number 638: Ph.D. Study - Evaluation of the efficacy of the Webster-Stratton Incredible Years Parent-training Programme for families of children who have symptoms of ADHD.

Due to major difficulties with recruitment (in terms of low numbers), I write to propose a slight amendment to the original recruitment procedure, outlined in the above-mentioned proposal, which received favourable ethical approval by both the School of Psychology REC, and COREC earlier this year.

Following a recent meeting with my supervisors, Dr David Daley, and Dr Judy Hutchings, it was proposed that, *in addition* to recruiting through Child and Adolescent Mental Health Service (CAMHS), we identify and recruit families of children who display high levels of ADHD type symptoms in the general population. It was suggested that we contact head teachers of local primary schools, asking whether they are willing to help by distributing letters to parents of all children in the school (aged between 5-11 inclusive). The letter asks parents whether they have any concerns regarding their child's behaviour and development – in terms of inattention and/or hyperactivity – and if so, whether they would be interested in finding out more about the research project. The schools' only involvement with the research would be to distribute these letters to the parents.

From this point forward, the research protocol remains effectively the same as the original proposal. Thus, as soon as consent is received from parents for the research team to make initial contact, an appointment for a home visit will be arranged to administer the PACS interview. Families who then meet criteria on this measure, and who consent to take part in the parenting group and the research project, will be visited again in order to collect the full assessment battery.

The groups will be run by Dr Judy Hutchings and her colleagues as part of the Trust's primary care work, which will run parallel with the groups held for referred families in CAMHS. At the end of the study, Judy will help parents to access additional services, should they feel that this is necessary.

As a result of the difficulties with recruitment, the first groups will now be starting in February 2006, as opposed to September 2005 as was originally proposed.

I have attached a copies of the following documents:

1. The original research protocol (Version II)
2. Letter to head teachers
3. Consent forms for school to distribute letters
4. Letters to parents
5. Consent for initial contact
6. Information sheet
7. Consent form to take part in the study

I am in the process of translating the letters and consent forms into Welsh. I trust that the enclosed information is adequate but I am more than happy to provide further information if required.

Yours sincerely

Karen Jones

Ph.D. Student, School of Psychology, University of Wales, Bangor

**Appendix 3a: Letter of Invitation for Screening (CAMHS Study Parent
Invitation Letter)**

GWASANAETH IECHYD MEDDWL
ADOLESCENT
PLANT A PHOBL IFANC
HEALTH SERVICE
(Cynorthwyo Plant)
Guidance)
Talarfon, Ffordd Caergybi,
Holyhead Road,
Bangor, Gwynedd. LL57 2EE
Gwynedd. LL57 2EE

CHILD AND
MENTAL

(Child
Talarfon,
Bangor,

Ffon/Telephone : (01248) 355825
Ffacs/Fax : (01248) 371109
Cyf./Your Ref.:

Cyf./Ref. :
Eich

Dyddiad/Date:

Annwyl

Dear

Yr ydych yn derbyn y llythyr hwn oherwydd i'ch plentyn gael ei gyfeirio at ein gwasanaeth ac, o ganlyniad, ar y rhestr aros am asesiad o'i problemau diffyg sylw a gorfywiogrwydd.

You are receiving this letter because has been referred to our waiting list for assessment for problems with attention and over activity.

Hoffem adael i chi wybod y bod ein gwasanaeth yn cymryd rhan mewn prosiect ymchwil mewn cyd-weithrediad â Phrifysgol Cymru, Bangor i archwilio'r dulliau gorau o helpu plant sydd gydag anhawsterau o'r un math a'r rhai mae eich plentyn, o bosib, yn ei ddangos.

We are writing to let you know that we are taking part in a research project in collaboration with the University of Wales, Bangor exploring the best ways to help children with the type of difficulties that your child has.

Os yr ydych yn fodlon ystyried cymryd rhan, bydd aelod o'n staff yn cysylltu â chi i drefnu ymweliad yn eich cartref i ofyn ychydig o gwestiynnau am ymddygiad eich plentyn er mwyn gweld os yw'ch plentyn yn addas i'w gynnwys yn yr ymchwil. Dylai'r ymweliad hwn gymryd rhwng 20-30 o funudau.

If you are willing to consider taking part, our staff will arrange to visit you at your home to discuss questions about your child's behaviour to see if they are suitable for inclusion in the research. This will take 20-30 minutes.

Os yr ydych yn fodlon, byddwn yn gofyn am eich cydsyniad yn ystod yr ymweliad yma. Hoffem eich sicrhau na fydd eich penderfyniad i gymryd rhan ai peidio yn cael unrhyw effaith ar y gwasanaethau a dderbyniwch.

If you are agreeable, your consent to the research will be obtained at this time. We want to reassure you that whether you decide to take part or not, your decision would not affect the services you receive.

Gwerthfawrogir eich help yn fawr iawn, oherwydd bwriad yr ymchwil yw i helpu plant fel eich plentyn chi i gael yr help orau bosibl yn y dyfodol.

Your help would be greatly appreciated. Your participation in the research is to help children like your child in the future.

Os yr ydych yn fodlon ystyried cymryd rhan yn yr astudiaeth, wnewch chi plis arwyddo'r ffurflen amgaeedig, a'i ddychwelyd cyn gynted a phosibl yn yr amlen wedi ei stampio.

If you are willing to consider taking part in the study, would you please sign the enclosed form as soon as possible in the stamped address provided.

Edrychwn ymlaen i glywed ganddoch yn fuan.

We look forward to hearing from you soon.

Yr eiddoch yn gywir

Yours sincerely

Dr Kieran Lynch,
Seiciatrydd Ymgynghorol Plant

*Dr Kieran Lynch
Consultant Child Psychiatrist*

Appendix 3b: Letter of Invitation for Screening (School Study Parent Invitation Letter)

Dear parent / guardian

The University is conducting a research project with the North West Wales NHS Trust, to find the best ways to help children who have difficulties with attention, impulsivity, and/or show signs of hyperactivity.

We are writing to parents of all children (aged between 5-11 years) in your child's school. We are looking for parents who have concerns about their child's behaviour, in terms of the difficulties mentioned above.

If you would like to learn more about the study please sign the enclosed consent form and a researcher from the University will contact you to ask a few questions about your child to see if the research would be suitable for you and your child. The researcher will also provide you with more detailed information about the study.

If you would like to learn more please return the form as soon as possible in the stamped addressed envelope provided and a member of the research team will contact you.

We look forward to hearing from you soon. Your help would be greatly appreciated. The aim of the research is to help parents of children with these types of difficulties to be in a good position to help their children manage their difficulties.

Yours faithfully

Dr Judy Hutchings
University of Wales, Bangor.

Appendix 4: Letter to School Headteachers

Evaluation of the Webster-Stratton Incredible Years Parenting Programme for families of children who display signs of inattention, impulsivity, and hyperactivity.

Dear.....

The University of Wales Bangor is currently conducting a research project in collaboration with the North West Wales NHS Trust, to evaluate the effectiveness of the Webster-Stratton Incredible Years Parenting programme for families of children who have difficulties with attention, impulsivity, and / or overactivity. The Incredible Years Parenting Programme is one in a series of programmes aimed at parents, teachers, and children to prevent or reduce conduct problems and anti-social behaviour. Many of you will already be familiar with the Incredible Years Teacher Classroom Management Programme and the Dinosaur School programme. The parenting programme provides a ‘parenting toolkit’ to help parents to establish a positive relationship with their child through play, encouragement, and reward. The programme also helps parents to use effective limit setting techniques as well as strategies for managing non-compliance. There is a strong evidence base for the effectiveness of this intervention in enhancing parental competencies and in reducing child conduct problems. The research is being jointly funded by the University and North West Wales NHS Trust as a PhD studentship, being undertaken by Karen Jones. The PhD is supervised by Dr David Daley and myself.

At present we are in the process of trying to recruit families of children who have difficulties with inattention, concentration, impulsivity, and/or hyperactivity, and who may be interested in taking part in a research project. We are writing to a number of local primary schools in Gwynedd asking for their help with the recruitment process. If you decide to help us, a researcher from the University will visit you to explain the study in more detail, and to leave letters to be distributed to all children in the school who are aged between 5-11 (year 1 to year 6). The letter to parents (copy attached) asks whether they have any concerns about their child’s behaviour (in terms of inattention, concentration, and/or hyperactivity), and whether they would be interested in finding out more about the research study, which may help them to manage their child’s difficulties effectively.

If you decide that you would like to help us with the recruitment, all this would involve for you as the school, would be to distribute the letters to children (years 1-6).

From that point forward, the families would contact the research team directly, should they be interested in taking part.

If you decide to take part, would you please complete the attached consent forms, and return them in the stamped addressed envelope provided, as soon as possible.

Your identity, the school's identity, and the identity of any children participating in this study, will remain strictly confidential.

If you need to know any more about the study, you can call Karen on either 01248 382651 (day) or 01286 675501 (eves); email her at karen.jones@bangor.ac.uk, or write to her at The Brigantia Building, University of Wales Bangor, Penrallt Road, Bangor, Gwynedd, LL57 2AS.

Complaints about the conduct of this research should be addressed to Professor Richard Hastings, acting Head of School of Psychology, University of Wales, Bangor, Adeilad Brigantia, Penrallt Road, Bangor, Gwynedd, LL57 2AS, or to Mr Keith Thomson, Chief Executive, North West Wales NHS Trust, Ysbyty Gwynedd, Penrhosgarnedd, Bangor, LL57 2PW.

Thank you for taking the time to read this.

I look forward to hearing from you.

Yours sincerely,

Dr. Judy Hutchings.
Director, Incredible Years Wales

Name of School:

.....

Address:

.....

.....

Post Code:

.....

Telephone Number:

.....

E-mail:

.....

Fax:

.....

Head teacher Name:

.....

Number of children in school:

.....

Number of children in Year 1-6.....

Any further information about school that could be of use to us:

.....

.....

.....

.....

I confirm that I am willing to help the research project by distributing letters to parents of all children in years 2-6. I understand that a member of the research team will be contacting me to give me further information about the project.

Signature of Head teacher

Complaints about the conduct of this research should be addressed to Professor Richard Hastings, acting Head of School of Psychology, University of Wales, Bangor, Adeilad Brigantia, Penrallt Road, Bangor, Gwynedd, LL57 2AS, or to Mr Keith Thomson, Chief Executive, North West Wales NHS Trust, Ysbyty Gwynedd, Penrhosgarnedd, Bangor, LL57 2PW.

Appendix 5a: Consent Forms (Screening). Screening Consent (CAMHS Study)***Cydsyniad i Ymweliad gan Aelod o'n Staff***

Yr wyf i (enw mewn llythrenau bras) _____ yn hapus i' aelod o staff gysylltu a mi I drefnu cyfweiliad er mwyn I mi ddysgu mwy am y prosiect ymchwil ac I weld os yw fy mhlentyn yn addas i'w gynnwys yn yr ymchwil, sydd yn archwilio'r dulliau gorau I helpu plant sydd yn dangos problemau diffyg sylw a gorfywiogrwydd.

Eich enw llawn:.....

Enw llawn y plentyn:.....

Dyddiad Geni:.....

Rhif Ffon:.....

Rhif Ffon symudol:.....

Llofnod y Cyfranogwr _____

Dyddiad _____

Llofnod y Cynrychiolydd o CAMHS

Dyddiad _____

Consent to a Visit by a Member of our Staff

I (name in print) _____ agree to being contacted by a member of staff to arrange an interview to learn about the research project and to see whether my child is suitable for inclusion in the research, which is investigating the best ways to help children who have difficulties with inattention and hyperactivity

Your name in full:

Your child's name in full:

Date of birth:

Telephone number:

Mobile number:.....

Signature of participant _____

Date _____

Signature of CAMHS

Representative _____

Date _____

Appendix 5a: Consent Forms (Screening). Screening Consent (School Study)***Cydsyniad i Ymweliad gan Aelod o'r Tim Ymchwil***

Yr wyf i (enw mewn llythrenau bras) _____ yn hapus i' aelod o'r tim ymchwil I gysylltu a mi I drefnu cyfweiliad er mwyn I mi ddysgu mwy am y prosiect ymchwil ac I weld os yw fy mhlentyn yn addas i'w gynnwys yn yr ymchwil, sydd yn archwilio'r dulliau gorau I helpu plant sydd yn dangos problemau diffyg sylw a gorfywiogrwydd.

Eich enw llawn:.....

Enw llawn y plentyn:.....

Dyddiad Geni:.....

Rhif Ffon:.....

Rhif Ffon symudol:.....

Llofnod y Cyfranogwr _____

Dyddiad _____

Consent to a Visit by a Member of our Staff

I (name in print) _____ agree to being contacted by a member of the research team to arrange an interview to learn about the research project and to see whether my child is suitable for inclusion in the research, which is investigating the best ways to help children who have difficulties with inattention and hyperactivity

Your name in full:

Your child's name in full:

Date of birth:

Telephone number:

Mobile number:

Signature of participant _____

Date _____

Appendix 6 a: CAMHS Study Consent Form

Consent Form

Child study for parents attending the parenting group

I (name) _____ have read and understood the information sheet dated 22.04.05 (Version II) for the above study and have had the opportunity to ask questions.

I agree to take part in this study and to provide information to the researcher for use in the study.

I understand that I can withdraw from the study at any time and that my withdrawal will not affect my access to any current or future health or public services.

Consent to take part in study:

Signature of Participant _____

Date _____

Signature of researcher _____

Date _____

Consent for use of videotape during observations:

Signature of Participant _____

Date _____

Signature of researcher _____

Date _____

Appendix 6 b: School Study Consent Form**Consent Form****Child study for parents attending the parenting group**

I (name) _____ have read and understood the information sheet dated 22.04.05 (Version II) for the above study and have had the opportunity to ask questions.

I agree to take part in this study and to provide information to the researcher for use in the study.

I understand that I can withdraw from the study at any time and that my withdrawal will not affect my access to any current or future health or public services.

Consent to take part in study:

Signature of Participant _____

Date _____

Signature of researcher _____

Date _____

Consent for use of videotape during observations:

Signature of Participant _____

Date _____

Signature of researcher _____

Date _____

Appendix 7a: Information Sheet: CAMHS Study

Information Sheet 22/04/05 (Version II)

Child Study for Parents Attending the Parenting Group

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your family and any health professional if you wish. Please ask us if there is anything that is not clear or if you would like more information.

What is the purpose of this study?

The Incredible Years Wales Centre, based at the University of Wales, Bangor, has been conducting research for several years with parents of young children with the aim of developing ways of supporting parents in the difficult task of child rearing. At the same time, CAMHS in Bangor have been delivering parent-support group programmes for families whose children are experiencing difficulties with attention, impulsiveness, and hyperactivity.

We are now beginning a three-year study of children who have been referred to CAMHS, and whose parent/s have attended, or are about to attend, a parenting group. Parenting groups are being held at your local CAMHS clinic in Bangor. These groups are being run as part routine clinical care to support families with children who have problems with attention and hyperactivity. Each parent-support group will consist of a small group of parents like yourselves who will attend 16 weekly sessions. The group will be lead by a trained and experienced professional who will talk with the parents about ways they can help with their child's development. In the group parents will explore ways that they can use at home to manage their child's behaviour without getting too stressed. Videos of typical family situations will be shown which illustrate common childhood behaviours and ways of dealing with them. Parents will have the opportunity to discuss the videos and also to practice the techniques they learn both in the group and at home.

Why have I been chosen?

We are asking all parents in your area who have a child, aged between five to nine years, who have been showing symptoms of hyperactivity and inattention, and who have been referred to CAMHS.

Your CAMHS worker has forwarded your name to the project, with your agreement, because you have said that you would like the opportunity to attend a parenting group and perhaps help us with our study.

What will happen to me if I take part?

If you take part in this study you will be given a place on one of these two parenting groups. A researcher will visit you at home sometime during the next month or so months and again five months later. Some of the parents taking part will be visited a third time, five months after the second visit. At each visit, the researcher will ask you to complete a total of nine questionnaires about your child and yourself. She will also ask you and your child to take part in some activity such as playing a game and then tidying up so that she can watch and record (write down) what the child does during these activities. During these activities, and with your permission, the researcher will also videotape the activities. The purpose of videotaping these activities is to make sure that the researcher is recording the information accurately, should someone need to check this during the course of the study. The researcher will also complete a short assessment with your child. Each visit will last about two hours. You will receive an expenses payment of £10 for each of these visits to reimburse you for your time and to thank you for co-operation with the study.

Two groups will be run, one beginning soon, and the other in about five months time. It is important to make sure that deciding who attends which group is done at random, which means that everyone taking part has an equal chance of being in either parenting group. To be fair to everyone taking part, the group that you will attend will be decided by chance (a bit like choosing out of a hat). You will be told which of

the two groups you will be attending after the researcher has completed the first visit and collected the information provided by you.

All the information you provide will be kept at the University of Wales, Bangor, in such a way that it will not be possible to identify you or your child. The videotapes

will be stored securely for the duration of the study, and will be securely destroyed at the end of the project. When the findings of this study are reported, information from the families taking part will be reported as a group not as individuals.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form.

If you decide not to take part, you will still be able to access the parenting group and other services offered at CAMHS.

You may withdraw from the study at any time. If you withdraw from the research part of the study you can still carry on with the parenting group.

If you are unable to complete the parenting course we would still like you to remain part of the study, even if you move from the area, and to continue to assist the researcher during her scheduled visits.

Your withdrawal from any part of this study will not affect your access to the parenting group or any other services that are currently offered by CAMHS, and will not affect the quality of care that you receive.

22/04/05 Version II

Any queries about this research should be addressed to Karen Jones, School of Psychology, University of Wales, Bangor, Adeilad Brigantia, Penrallt Road, Bangor, Gwynedd LL57 2AS.

Complaints about the conduct of this research should be addressed to Professor Richard Hastings, acting Head of School of Psychology, University of Wales, Bangor, Adeilad Brigantia, Penrallt Road, Bangor, Gwynedd, LL57 2AS, or to Mr Keith Thomson, Chief Executive, North West Wales NHS Trust, Ysbyty Gwynedd, Penrhosgarnedd, Bangor, LL57 2PW.

Appendix 7b. Information Sheet: School Study

Child Study for Parents Attending the Parenting Group

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your family and any health professional if you wish. Please ask us if there is anything that is not clear or if you would like more information.

What is the purpose of this study?

The Incredible Years Wales Centre, based at the University of Wales, Bangor, has been conducting research for several years with parents of young children with the aim of developing ways of supporting parents in the difficult task of child rearing.

We are now beginning a three-year study of children who have are experiencing difficulties with inattention, impulsivity, and hyperactivity, and whose parent/s have attended, or are about to attend, a parenting group. Parenting groups are being held in Bangor. These groups are being run as part routine community care to support families with children who have problems with attention and hyperactivity. Each parent-support group will consist of a small group of parents like yourselves who will attend 16 weekly sessions. The group will be lead by a trained and experienced professional who will talk with the parents about ways they can help with their child's development. In the group parents will explore ways that they can use at home to manage their child's behaviour without getting too stressed. Videos of typical family situations will be shown which illustrate common childhood behaviours and ways of dealing with them. Parents will have the opportunity to discuss the videos and also to practice the techniques they learn both in the group and at home.

Why have I been chosen?

We are asking all parents in your child's school, whose children are experiencing difficulties with inattention and/ or hyperactivity/impulsivity.

What will happen to me if I take part?

If you take part in this study you will be given a place on one of these two parenting groups. A researcher will visit you at home sometime during the next month or so months and again five months later. Some of the parents taking part will be visited a third time, five months after the second visit. At each visit, the researcher will ask you to complete a total of nine questionnaires about your child and yourself. She will also ask you and your child to take part in some activity such as playing a game and then tidying up so that she can watch and record (write down) what the child does during these activities. During these activities, and with your permission, the researcher will also videotape the activities. The purpose of videotaping these activities is to make sure that the researcher is recording the information accurately, should someone need to check this during the course of the study. The researcher will also complete a short assessment with your child. Each visit will last about two hours. You will receive an expenses payment of £10 for each of these visits to reimburse you for your time and to thank you for co-operation with the study.

Two groups will be run, one beginning soon, and the other in about five months time. It is important to make sure that deciding who attends which group is done at random, which means that everyone taking part has an equal chance of being in either parenting group. To be fair to everyone taking part, the group that you will attend will be decided by chance (a bit like choosing out of a hat). You will be told which of the two groups you will be attending after the researcher has completed the first visit and collected the information provided by you.

All the information you provide will be kept at the University of Wales, Bangor, in such a way that it will not be possible to identify you or your child. The videotapes will be stored securely for the duration of the study, and will be securely destroyed at the end of the project. When the findings of this study are reported, information from the families taking part will be reported as a group not as individuals.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form.

If you decide not to take part, you will still be able to access the parenting group and other community-based services.

You may withdraw from the study at any time. If you withdraw from the research part of the study you can still carry on with the parenting group.

If you are unable to complete the parenting course we would still like you to remain part of the study, even if you move from the area, and to continue to assist the researcher during her scheduled visits.

Your withdrawal from any part of this study will not affect your access to the parenting group or any other services.

26/04/06 Version I

Any queries about this research should be addressed to Karen Jones, School of Psychology, University of Wales, Bangor, Adeilad Brigantia, Penrallt Road, Bangor, Gwynedd LL57 2AS.

Complaints about the conduct of this research should be addressed to Professor Richard Hastings, acting Head of School of Psychology, University of Wales, Bangor, Adeilad Brigantia, Penrallt Road, Bangor, Gwynedd, LL57 2AS, or to Mr Keith Thomson, Chief Executive, North West Wales NHS Trust, Ysbyty Gwynedd, Penrhosgarnedd, Bangor, LL57 2PW.

Appendix 8: Correlation Table (Relationship between Child Deviance Change Scores and Conners Change Scores at Follow-ups One, Two, and Three.

As Table 7 demonstrates, change in ADHD symptoms (measured by the Conners; Conners, 1994) and change in observed child deviance (measured by the Dyadic Parent Child Interaction Coding System; DPICS, Eyberg & Robinson, 1981) within the sample were not correlated at all time-points, indicating that ADHD symptoms and Child deviance are independent.

Table 7: Correlations between Conners change scores and child deviance change scores at follow-ups one, two, and three

| | Conners change Baseline – follow-up 1 | Conners change Follow-up 1 to follow- up 2 | Conners change Follow-up 2 to follow- up three |
|---|--|--|--|
| Child deviance change: Baseline – follow-up 1 | 0.095 | | |
| Child deviance change: Follow-up 2 – follow- up 3 | | -0.163 | |
| Child deviance change: Follow-up 3 – follow- up 4 | | | 0.038 |

Appendix 9: Tables of correlations between all measures that entered into the calculation of change scores in the findings of study 3

Table 8: Correlations between Conners scores at baseline and follow-up 1 for intervention and control group

| | Intervention | Control |
|-------------|--------------|---------|
| | Baseline | |
| Follow-up 1 | .366** | .574** |

* = This table corresponds with the findings reported in Table 4

** = significant at 0.01 level (2 tailed)

Table 9: Correlations between Conners scores at follow-up 1 and follow-up 2, and follow-up 2 to follow-up 3 (intervention group only)*.

| | Follow-up 1 | Follow-up 2 |
|-------------|-------------|-------------|
| Follow-up 2 | .749** | |
| Follow-up 3 | | .612** |

* = This table corresponds with the findings reported in Table 5

** = Significant at 0.01 level (2-tailed)

* = This table corresponds with the findings reported in Table 5

** = Significant at 0.01 level (2-tailed)

Table 10: Correlations between Conners scores at baseline and follow-up 1, and observed positive parenting at baseline and follow-up 1 for all cases (intervention and control)*

| | Conners baseline | Positive parenting baseline |
|---------------------|------------------|-----------------------------|
| Conners follow-up 1 | .574** | |

| | |
|---------------------------------------|---------------|
| <i>Positive parenting follow-up 1</i> | <i>.351**</i> |
|---------------------------------------|---------------|

** = This table corresponds with the findings reported in Figure 5*

*** = Significant at 0.01 level (2-tailed)*

