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PROFESSIONAL DOCTORATES

Parent training for young people with hyperactivity : efficacy of a self-directed intervention

Kelly, Joanne; Kelly, Joanne

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Parent training for young children with hyperactivity: Efficacy of a self-directed intervention.

Joanne Kelly

University of Wales, Bangor

Thesis submitted in Partial Fulfilment of the Requirement of the Degree of Doctorate in Clinical Psychology (D.Clin.Psy)

June 2007

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Summary

Attention Deficit Hyperactivity Disorder (ADHD) is a condition characterised by severe and pervasive symptoms of inattention, hyperactivity and impulsivity. Current research has suggested that without effective intervention children with a diagnosis of ADHD can experience significant functional impairment in a number of areas including social functioning and academic achievement, and are at increased risk of the development of future substance abuse, criminality, and psychopathology.

The following paper firstly presents a review of the current literature on the development, maintenance, and ways of intervening with ADHD in childhood. The relative benefits of medication management versus psychosocial interventions are examined, and a number of parent training interventions are reviewed. The main study then focuses on an evaluation of the efficacy of a self-directed intervention for ADHD. Change in measures of child behaviour, and parental well-being were investigated and the findings supported those previously found for the efficacy of parent training approaches for ADHD, and added to the emerging literature on self-directed interventions with this population. Identified limitations of this study and directions for future research are discussed.

Finally, contributions made to theory, research and practice are explored; wherein the strengths and weaknesses of this study are further discussed, and implications for clinical practice and future directions are considered. Additionally, personal reflections and process issues are documented.

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1.g: Information Sheet 2 (English & Welsh versions)

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1.i: Consent Form 2 (English & Welsh versions)

1.j: COREC - Ethics Approval Letter

1.k: NHS Ethical Approval Letter

2.a: Notes for contributors to 'Journal of Child Psychology and Psychiatry'

3.a: Notes for contributors to 'British Journal of Clinical Psychology'

Acknowledgements

Firstly, I would like to thank the parents who gave up their time to speak to me on the phone, at varying hours of the day and night, and who gave me an understanding of the real life impact that ADHD can have on families.

A thank you goes to my supervisor, Dr Dave Daley for his endless patience in explaining what needs to be done and how, and optimism in the face of rapidly approaching deadlines.

A special mention has to go to both Louise Cunliffe and Rob Jones, for making me believe that I can do this and then telling me to stop moaning and just get on with it!

Thanks go to all my fellow 2004 cohort for seeing out this journey together, especially the usual suspects; Prav, Jess & Kaz for unfailing emotional, practical and occasionally alcohol-based support.

Personal thanks go to Sheila, for believing from the beginning, and to Scott for making me see the humour in almost every situation and not complaining when my work covered every possible surface in the house! Finally special thanks are reserved for my mother for alternately assuming the roles of chief cook, washer-uper and housekeeper when deadlines loomed near. Thanks Mam!

This work is dedicated to Mama, who has always kept me looking at the stars even if it has occasionally felt like I was sitting in the gutter!

SECTION 1

ETHICS PROPOSAL

APPLICANT'S CHECKLIST Ethics Proposal 1 - 1

All studies except clinical trials of investigational medicinal products

REC Ref:	06/Q1505/74
Short Title of Study:	Self directed intervention for ADHD
CI Name:	Dr David Daley
Sponsor:	

Please complete this checklist and send it with your application

- Send ONE copy of each document (except where stated)
- ALL accompanying documents must bear version numbers and dates (except where stated)
- When collating please do NOT staple documents as they will need to be photocopied.

Document	Enclosed?	Date	Version	Office use
Covering letter on headed paper	◉ Yes ○ No			
NHS REC Application Form, Parts A&B	Mandatory	26/07/2006	version 1	
NHS REC Application Form, Part C (SSA)	◉ Yes ○ No	26/07/2006	version 1	
Research protocol or project proposal (6 copies)	Mandatory	26/07/2006	version 4	
Summary C.V. for Chief Investigator (CI)	Mandatory	26/07/2006		
Summary C.V. for supervisor (student research)	◉ Yes ○ No	26/07/2006		
Research participant information sheet (PIS) – letter 1	◉ Yes ○ No	26/07/2006	version 5	
Research participant information sheet (PIS) – letter 2	◉ Yes ○ No	26/07/2006	version 5	
Research participant consent form – consent 1	◉ Yes ○ No	26/07/2006	version 3	
Research participant consent form – consent 2	◉ Yes ○ No	26/07/2006	version 3	
Letters of invitation to participants	◉ Yes ○ No	26/07/2006		
GP/Consultant information sheets or letters	○ Yes ◉ No			
Statement of indemnity arrangements	◉ Yes ○ No			
Letter from sponsor	○ Yes ◉ No			
Letter from statistician	○ Yes ◉ No			
Letter from funder	◉ Yes ○ No	08/03/2006		version 1
Referees' or other scientific critique report	○ Yes ◉ No			
Summary, synopsis or diagram (flowchart) of protocol in non–technical language	○ Yes ◉ No			
Interview schedules or topic guides for participants	◉ Yes ○ No	26/07/2006		version 1
Validated questionnaire	◉ Yes ○ No			version 1
Non–validated questionnaire	○ Yes ○ No			
Copies of advertisement material for research participants, e.g. posters, newspaper adverts, website. For video or audio cassettes, please also provide the printed script.	◉ Yes ○ No			

WELCOME TO THE NHS RESEARCH ETHICS COMMITTEE AP Ethics Proposal 1 - 2

An application form specific to your project will be created from the answers you give to the following questions. Please read this guidance carefully before selecting your answers.

1. Is your project an audit or service evaluation?

○ Yes ◉ No

2. Select one research category from the list below:

○ Clinical trials of investigational medicinal products (including phase 1 drug development)
○ Clinical investigations or other studies of medical devices
◉ Other clinical trial or clinical investigation
○ Research administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
○ Research involving qualitative methods only
○ Research limited to working with human tissue samples and/or data

If your work does not fit any of these categories, select the option below:

○ Other research

2a . Please answer the following questions:

a) Does the study involve the use of any ionising radiation? ○ Yes ◉ No
b) Will you be taking new human tissue samples? ○ Yes ◉ No
c) Will you be using existing human tissue samples? ○ Yes ◉ No

3. Is your research confined to one site?

○ Yes ◉ No

4. Does your research involve work with prisoners?

○ Yes ◉ No

5. Does your research involve adults unable to consent for themselves through physical or mental incapacity?

○ Yes ◉ No

6. Is the study, or any part of the study, being undertaken as an educational project?

◉ Yes ○ No

NHS Research Ethics Committee NHS
Application form

Ethics Proposal 1 - 3

This form should be completed by the Chief Investigator, after reading the guidance notes. See glossary for clarification of different terms in the application form.

Short title and version number: (maximum 70 characters – this will be inserted as header on all forms)
Self directed intervention for ADHD

Name of NHS Research Ethics Committee to which application for ethical review is being made:
Liverpool Adult

Project reference number from above REC: 06/Q1505/74
Submission date: 25/07/2006

PART A: Introduction

A1. Title of the research

Full title: Parent Training for Children with hyperactivity. Efficacy of an augmented Self Administered Parent Training Intervention.

Key words: Self directed, Parent Training, hyperactivity, children

A2. Chief Investigator

Title: Dr
Forename/Initials: David
Surname: Daley
Post: Lecturer and Senior Research Tutor
Qualifications: B.A, M.Phil, PhD, C.Psychol
Organisation: North Wales Clinical Psychology Programme, School of Psychology
Address: University of Wales, Bangor
Gwynedd
Post Code: LL57 2AS
E–mail: d.daley@bangor.ac.uk
Telephone: 01248 388067
Fax: 01248 383718

A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application

A3. Proposed study dates and duration

Start date: 01/10/2006
End date: 30/09/2007
Duration: Years: 1 ; Months:

A4. Primary purpose of the research: *(Tick as appropriate)*

Ethics Proposal 1 - 4

- [ ] Commercial product development and/or licensing
- [x] Publicly funded trial or scientific investigation
- [ ] Educational qualification
- [ ] Establishing a database/data storage facility
- [ ] Other

A6. Does this research require site-specific assessment (SSA)? (Advice can be found in the guidance notes on this topic.)

(•) Yes ( ) No

If No, please justify:

If Yes, Part C of the form will need to be completed for each research site and submitted for SSA to the relevant Local Research Ethics Committee. Do not submit Part Cs for other sites until the application has been booked for review and validated by the main Research Ethics Committee.

Management approval to proceed with the research will be required from the R&D Department for each NHS care organisation in which research procedures are undertaken. This applies whether or not the research is exempt from SSA.

A7. What is the principal research question/objective? *(Must be in language comprehensible to a lay person.)*

What is the efficacy of an augmented self administered manual based parent training intervention for children with hyperactivity

A8. What are the secondary research questions/objectives? *(If applicable, must be in language comprehensible to a lay person.)*

Can augmented self directed intervention lead to changes in both parent–child interaction style and parent–chid emotional relationships

A9. What is the scientific justification for the research? What is the background? Why is this an area of importance? *(Must be in language comprehensible to a lay person.)*

Parent training PT based interventions have demonstrated efficacy for reducing hyperactivity and Attention Deficit Hyperactivity Disorder ADHD symptoms, however PT approaches are usually therapist led individual based treatment formats. Consequently such approaches are costly, time consuming and given that there has been a dramatic increase in the number of children diagnosed with ADHD, service provision is unlikely to meet the clinical needs of this population.

Self directed interventions may offer a cost effective approach to parent training in terms of resources, therapist training, availability and time. They overcome a major limitation of many PT programmes in that they do not require the participants to attend clinic based sessions and are therefore more accessible and practical for a large number of parents. The aim of this research will be to establish the efficacy of a self administered, manual based parent training intervention for children with hyperactivity and ADHD.

A10. Give a full summary of the purpose, design and methodology of the planned research, including a brief explanation of the theoretical framework that informs it. It should be clear exactly what will happen to the research participant, how many times and in what order. Describe any involvement of research participants, patient groups or communities in the design of the research.

This section must be completed in language comprehensible to the lay person. It must also be self–standing as it will be replicated in any applications for site–specific assessment on Part C. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.

For this research study parents and children will be selected using a 2 stage screening process. Stage 1– Child and Adolescent mental health services who intend to run self directed intervention training for clients on their waiting list will be asked to send letters inviting parent to join the research study.

Parents will be asked to provide written consent to:
i) Complete a brief screening questionnaire (Strength and Difficulties Questionnaire).
ii) Be contacted for further details about the study.
iii) To take part in a short telephone based interview about their child's behaviour.
iv) Complete four short questionnaires about their child's behaviour and their own wellbeing.
v) Allow the researcher to observe 10 minutes of their child's solo play and 15 minutes of parent–child interaction.

Parents of children who score above the level of clinical concern on the SDQ and over 17 points on the PACS interview will be invited to join the study. All consenting parents will be randomised to either immediate augmented interention, or delayed augmented intervention. Parents in the immediate intervention group will be invited to one of two augmentation days, then given the manual to follow, telephone weekly and tested again on all measures at week 7. Parents in the delayed intervention group, will receive nothing for 6 weeks, be tested again, and then invited to attend an augmentation day and given the manual to follow.

A11. Will any intervention or procedure, which would normally be considered a part of routine care, be withheld from the research participants?

○ Yes ◉ No

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A12. Give details of any clinical intervention(s) or procedure(s) to be received by research participants over and above those which would normally be considered a part of routine clinical care. *(These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material.)*

Additional Intervention	Average number per participant		Average time taken (mins/hours/days)	Details of additional intervention or procedure, who will undertake it, and what training they have received.
	Routine Care	Research		
Psychological therapies	0	1		During the life of the study, the intervention group will receive self directed intervention.

A13. Give details of any non-clinical research-related intervention(s) or procedure(s). *(These include interviews, non-clinical observations and use of questionnaires.)*

Additional Intervention	Average number per participant	Average time taken (mins/hours/days)	Details of additional intervention or procedure, who will undertake it, and what training they have received.
Telephone Interview	2	30	
Video Recording	2	30	

A14. Will individual or group interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could take place during the study (e.g. during interviews/group discussions, or use of screening tests for drugs)?

○ Yes ◉ No

The Information Sheet should make it clear under what circumstances action may be taken

A15. What is the expected total duration of participation in the study for each participant?

Pre-and post intervention assessment will involve two hours of assessment. The augmentation day will take 6 hours and the study will run for 6 weeks. Parents can put as much or as little effort into the self directed intervention, but is is expected that on average 30 - 60 minutes a day will be spent on interacting and playing with the child as suggested by the manual

A16. What are the potential adverse effects, risks or hazards for research participants either from giving or withholding medications, devices, ionising radiation, or from other interventions (including non-clinical)?

There are no risks to the participants from the intervention, it has previously been trialed in two pilot studies. The only risk is that their children's behaviour will deteriorate initially when they begin to change the way they parent their child. This issue is covered in the self directed manual and will be dealt with at the augmentation day.

A17. What is the potential for pain, discomfort, distress, inconvenience or changes to lifestyle for research participants?

None

A18. What is the potential for benefit to research participants?

Ethics Proposal 1 - 7

It is possible that they may teach themselves new ways to deal with their child's behaviour, and that their child's symptoms of ADHD may decrease.

A19. What is the potential for adverse effects, risks or hazards, pain, discomfort, distress, or inconvenience to the researchers themselves? *(if any)*

No risks over and above the risk or lone workers. The Lone worker policy of both the University and North East Wales Trust will be stricly adheered to.

A20. How will potential participants in the study be (i) identified, (ii) approached and (iii) recruited?
Give details for cases and controls separately if appropriate:

For this research study parents and children will be selected using a 2 stage screening process. Stage 1– Child and Adolescent mental health services who intend to run self directed intervention training for clients on their waiting list will be asked to send letters inviting parent to join the research study. Consenting parents would return consent forms identifying themsleves and giving contact details to the research team. Parents who rate their child as scoring above the point of clincial concern on the Strength and Difficulties Questionnaire, and who report a symptom score greater then 17 on the PACS interview would be invited to participate.

Parents who consent to join the study, but who do not meet study criteria would be advised to remain on the clinic waiting list for a full assessment.

A21. Where research participants will be recruited via advertisement, give specific details.

☑ Not Applicable

If applicable, enclose a copy of the advertisement/radio script/website/video for television (with a version number and date).

A22. What are the principal inclusion criteria? *(Please justify)*

Children who score above the point of clinical concern on the SDQ and PACS interview
Parents fluent in either Welsh or English

A23. What are the principal exclusion criteria? *(Please justify)*

Children older than 9 years of age
Children whose parents have attended clinic sesions for ADHD with a previous child

A24. Will the participants be from any of the following groups? *(Tick as appropriate)*

- ☑ Children under 16
- ☐ Adults with learning disabilities
- ☐ Adults who are unconscious or very severely ill
- ☐ Adults who have a terminal illness
- ☐ Adults in emergency situations
- ☐ Adults with mental illness (particularly if detained under Mental Health Legislation)

- ☐ Adults with dementia
- ☐ Prisoners
- ☐ Young Offenders
- ☐ Adults in Scotland who are unable to consent for themselves
- ☐ Healthy Volunteers
- ☐ Those who could be considered to have a particularly dependent relationship with the investigator, e.g. those in care homes, medical students
- ☐ Other vulnerable groups

Justify their inclusion.

A25. Will any research participants be recruited who are involved in existing research or have recently been involved in any research prior to recruitment?

○ Yes ○ No ◉ Not Known

If Yes, give details and justify their inclusion. If Not Known, what steps will you take to find out?

A26. Will informed consent be obtained from the research participants?

◉ Yes ○ No

If Yes, give details of who will take consent and how it will be done. Give details of any particular steps to provide information (in addition to a written information sheet) e.g. videos, interactive material.

If participants are to be recruited from any of the potentially vulnerable groups listed in A24, give details of extra steps taken to assure their protection. Describe any arrangements to be made for obtaining consent from a legal representative.

If consent is not to be obtained, please explain why not.
Parents will be asked to give specific written consent for aspect of the study. children will be asked to give verbal consent to particpate in the parent–child observation

Copies of the written information and all other explanatory material should accompany this application.

A27. Will a signed record of consent be obtained?

◉ Yes ○ No

If Yes, attach a copy of the information sheet to be used, with a version number and date.

A28. How long will the participant have to decide whether to take part in the research?

7 – 14 days

A29. What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters etc.)*

Members of the research team are bi–lingual, and would be able to conduct telephone interviews, and give instructions and help with questionnaires in both English and Welsh. Due to copyright restrictions it is not possible to reproduce all questionnaires in other languages, and the reliability of the assessments in languages othe than Welsh and English is

unproven. Threfore participants who were not fluent in either Welsh or English would have to be excluded from the study

A30. What arrangements are in place to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?

This is a very short trial, none of the data will be examined until after data collection is complete, so new information about the study is unlikely to become available

A31. Does this study have or require approval of the Patient Information Advisory Group (PIAG) or other bodies with a similar remit? *(see the guidance notes)*

○ Yes ◉ No

A32a. Will the research participants' General Practitioner be informed that they are taking part in the study?

○ Yes ◉ No

If Yes, enclose a copy of the information sheet/letter for the GP with a version number and date.

A32b. Will permission be sought from the research participants to inform their GP before this is done?

○ Yes ◉ No

If No to either question, explain why not
No G.P information sheet as the Child and Adolesent Mental Health Service will be contacting the G.P

It should be made clear in the patient information sheet if the research participant's GP will be informed.

A33. Will individual research participants receive any payments for taking part in this research?

○ Yes ◉ No

A34. Will individual research participants receive *reimbursement of expenses* or any other *incentives or benefits* for taking part in this research?

○ Yes ◉ No

A35. What arrangements have been made to provide indemnity and/or compensation in the event of a claim by, or on behalf of, participants for *negligent* harm?

Negligent harm cover has been selected for this study, the policy cover note is appended

Please forward copies of the relevant documents.

A36. What arrangements have been made to provide indemnity and/or compensation in the event of a claim by, or on behalf of, participants for *non-negligent* harm?

Negligent harm cover has been selected for this study

Please forward copies of the relevant documents. Ethics Proposal 1 - 10

A37. How is it intended the results of the study will be reported and disseminated? *(Tick as appropriate)*

- [x] Peer reviewed scientific journals
- [ ] Internal report
- [x] Conference presentation
- [ ] Other publication
- [ ] Submission to regulatory authorities
- [ ] Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- [x] Written feedback to research participants
- [x] Presentation to participants or relevant community groups
- [ ] Other/none e.g. Cochrane Review, University Library

A38. How will the results of research be made available to research participants and communities from which they are drawn?

A short summary sheet will be sent to all participants at the end of the study. The resutls will also be presented at local ADHD support group meetings.

A39. Will the research involve any of the following activities at any stage (including identification of potential research participants)? *(Tick as appropriate)*

- [ ] Examination of medical records by those outside the NHS, or within the NHS by those who would not normally have access
- [ ] Electronic transfer by magnetic or optical media, e–mail or computer networks
- [ ] Sharing of data with other organisations
- [ ] Export of data outside the European Union
- [ ] Use of personal addresses, postcodes, faxes, e–mails or telephone numbers
- [ ] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [x] Use of audio/visual recording devices
- [ ] Storage of personal data on any of the following:
  - [ ] Manual files including X–rays
  - [ ] NHS computers
  - [ ] Home or other personal computers
  - [x] University computers
  - [ ] Private company computers
  - [x] Laptop computers

Further details:

A40. What measures have been put in place to ensure confidentiality of personal data? Give details of whether any encryption or other anonymisation procedures have been used and at what stage:

All data will be anonymised. EAch participant will be allocated a unique participant number and that number will be used on all the data. A seperate list that of names and participants will be generated and stored seperately from the main data set.

All paper data, and tapes will be stored in locked filing cabinets. All electronic copies of the data will be stores on password controlled computers.

A41. Where will the analysis of the data from the study take place and by whom will it be undertaken?

Analysis of the data will take place in Dr Daley's office at the University in Bangor, and will be undertaken by the reserach team with supervision by Dr Daley

A42. Who will have control of and act as the custodian for the data generated by the study?

Dr Daley will act as custodian

A43. Who will have access to the data generated by the study?

Only the Research Team

A44. For how long will data from the study be stored?

5 Years Months

Give details of where they will be stored, who will have access and the custodial arrangements for the data:
At the end of the study the paper data will be destroyed, tapes will be stores in a secure locked filing cabinet in Dr Daley's office. An electronic copy of the data will be kept on Dr Daley's space on the university server which is password controlled.

A45–1. How has the scientific quality of the research been assessed? *(Tick as appropriate)*

- ☐ Independent external review
- ☐ Review within a company
- ☐ Review within a multi–centre research group
- ☑ Internal review (e.g. involving colleagues, academic supervisor)
- ☐ None external to the investigator
- ☐ Other, e.g. methodological guidelines *(give details below)*

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
A Colleague Dr Elizabeth Burnside had reviewed the application for me. usually the approval of the School of Psycholgoy ethics committee is taken as independent external review, however in this case due to time constraints I have had to submit to the school of psychology and COREC in parallel.

If you are in possession of any referees' comments or other scientific critique reports relevant to the proposed research, these must be enclosed with the application.

A45–2. Has the protocol submitted with this application been the subject of review by a statistician independent of the research team? *(Select one of the following)*

- ○ Yes – copy of review enclosed
- ○ Yes – details of review available from the following individual or organisation (give contact details below)
- ◉ No – justify below

No but while I am not a qualified statistician, I do teach statistics and feel confident with the power calculation and analysis which is requried

A48. What is the primary outcome measure for the study?

Parental account of childhood symptoms interview scores are the primary outcome measure

A49. What are the secondary outcome measures? *(if any)*

Parent–child interaction style
Parent–child emotional relationship
parental well–being

A50. How many participants will be recruited?
If there is more than one group, state how many participants will be recruited in each group. For international studies, say how many participants will be recruited in the UK and in total.

60

A51. How was the number of participants decided upon?

Using Cohen's a power primer to estimate sample size, and the large effect sizes generated for this intervention when delivered by therpists (Sonuga–Barke, Daley, Thompson, Laver–Bradbury & Weeks 2001),an alpha of 0.05 and Two group analysis of Variance as the method of analysis 60 participants should yield more than adequate power great than 0.8 to test for differences

If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.

A52. Will participants be allocated to groups at random?

(•) Yes ( ) No

If yes, give details of the intended method of randomisation:
Participants will be allocated to condition by Dr Daley using a random number generator, even numbers will be intervention and odd numbers control.

A53. Describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

One way analysis of variance will be used to examine differences between conditions at baseline, if no differences exist then repeated measures analysis of variance will be used to examine change in scores from T1 to T2. If baseline differences exist then one way analysis of co–variance will be used to examine differences at T2 controlling for any difference at T1

A54. Where will the research take place? *(Tick as appropriate)*

- [x] UK
- [ ] Other states in European Union
- [ ] Other countries in European Economic Area

☐ Other

If Other, give details:

A55. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK, the European Union or the European Economic Area?

◉ Yes ○ No

If Yes give details of each rejected application including:

Name of Research Ethics Committee or regulatory authority:	North East Wales
Decision and date taken:	sustantial amendment 13/06/2006
Research ethics committee reference number:	04/WN/N0o3/26

A56. In how many and what type of host organisations (NHS or other) in the UK is it intended the proposed study will take place?

Indicate the type of organisation by ticking the box and give approximate numbers if known:

	Number of organisations
☐ Acute teaching NHS Trusts	
☐ Acute NHS Trusts	
☑ NHS Primary Care Trusts or Local Health Boards in Wales	3
☐ NHS Trusts providing mental healthcare	
☐ NHS Health Boards in Scotland	
☐ HPSS Trusts in Northern Ireland	
☐ GP Practices	
☐ NHS Care Trusts	
☐ Social care organisations	
☐ Prisons	
☐ Independent hospitals	
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	

Other:

A57. What arrangements are in place for monitoring and auditing the conduct of the research?

Dr Daley will personally supervise the reserach team. Monthly research team meetings will be held, but additional meetings will be arranged should the need arise. Dr Daley will also shadow members of the reserach team at various times during data collection to ensure the quality of data collection and conduct of the research.

Will a data monitoring committee be convened?

◉ Yes ○ No

If Yes, details of membership of the data monitoring committee (DMC), its standard operating procedures and summaries of reports of interim analyses to the DMC must be forwarded to the NHS Research Ethics Committee which gives a favourable opinion of the study.

Ethics Proposal P - 14

What are the criteria for electively stopping the trial or other research prematurely?

We intend to make weekly telephone calls to participants in the intervention group, this is so that we can remind them to move onto the next weekly section of the manual. We also ask one generic safety question during this call " How have things been for you and your child this week". Should evidence emerge from these weekly calls that suggested the interention was causing any undue harm or distress then we would electively halt the trial. The intervention has been piloted without any problems, and it is a self directed version of a widely used, and effective intervention so no problems with safety or tolerability are expected.

A58. Has external funding for the research been secured?

(•) Yes ( ) No

If Yes, give details of funding organisation(s) and amount secured and duration:

Organisation:	Economic and Social Research Council CASE Phd studentship
Address:	Polaris House
	North Star Ave
	Swindon
Post Code:	SN21UJ
UK contact:	Zoe Grimwood
Telephone:	Fax:
E-mail:	Zoe.Grimwood@esrc.ac.uk
Amount (£):	53000 Duration: 36 Months

A59. Has the funder of the research agreed to act as sponsor as set out in the Research Governance Framework?

(•) Yes ( ) No

Has the employer of the Chief Investigator agreed to act as sponsor of the research?

( ) Yes (•) No

Sponsor *(must be completed in all cases)*

Name of organisation which will act as sponsor for the research:

Status:

(•) NHS or HPSS care organisation ( ) Academic ( ) Pharmaceutical industry ( ) Medical device industry ( ) Other

If Other, please specify:

The University of Wales, Bangor will only act as sponsor to the project when the study has been approved by the School of Psycholgoy ethics committee. Approval should be in place by 01/09/2006

Address:

Post Code:

Telephone: Fax:

E-mail:

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The responsibilities of the sponsor may be shared between co-sponsors. If this applies, name the lead sponsor for the REC application in this box and enclose a letter giving further details of co-sponsors and their responsibilities.

Sponsor's UK contact point for correspondence with the main REC

Title: Forename/Initials: Surname:

Address:

Post Code:

Telephone: Fax:

E-mail:

A60. Has any responsibility for the research been delegated to a subcontractor?

○ Yes ◉ No

A61. Will individual *researchers* receive any personal payment over and above normal salary for undertaking this research?

○ Yes ◉ No

A62. Will individual *researchers* receive any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A63. Will the host organisation or the researcher's department(s) or institution(s) receive any payment or benefits in excess of the costs of undertaking the research?

○ Yes ◉ No

A64. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share-holding, personal relationship etc.) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

A65. Other relevant reference numbers if known *(give details and version numbers as appropriate)*: Ethics Proposal 1 - 16

Applicant's/organisation's own reference number, e.g. R&D (if available):

Sponsor's/protocol number:

Funder's reference number:

International Standard Randomised Controlled Trial Number (ISRCTN):

European Clinical Trials Database (EudraCT) number:

Project website:

A66. Other key investigators/collaborators *(all grant co-applicants should be listed)*

Title:	Miss		
	Forename/Initials: J	Surname: Kelly	
Post:	Trainee Clinical Psychologist		
Qualifications:	B.Sc		
Organisation:	North Wales Clinical Psychology Programme, University of Wales, Bangor		
Address:	Brigantia Building		
	Bangor	Telephone:	01248 382205
	Gwynedd	Fax:	01248 383718
Postcode:	LL57 2AS		
E-mail:	caritas11@hotmail.com		

Title:	Miss		
	Forename/Initials: M	Surname: O'Brien	
Post:	PhD student		
Qualifications:	B.Sc, M.Sc		
Organisation:	School of Psychology		
Address:	Brigantia building		
	Bangor	Telephone:	01248 382205
		Fax:	01248 383718
Postcode:	LL57 2AS		
E-mail:	Michelle.OBrien@nww-tr.wales.nhs.uk		

Title:	Miss		
	Forename/Initials: V	Surname: Hawker	
Post:	MSc student		
Qualifications:	B.Sc		
Organisation:	School of Psychology		
Address:	Brigantia building		
	Bangor	Telephone:	01248 382205
		Fax:	01248 383718
Postcode:	LL57 2AS		
E-mail:	v.hawker@bangor.ac.uk		

Title:	Mrs	
	Forename/Initials: S	Surname: Parsonage
Post:	ADHD Therapist	
Qualifications:		
Organisation:	North East Wales Child and Adolescent Mental Health Service	
Address:	Catherine Gladstone House,	

Hawarden Way, Mancott

Telephone: 01244 538883
Fax: 01244 538883

Postcode: CH6 1EP
E-mail: SUE PARSONAGE
<SUE.PARSONAGE@new-tr.wales.nhs.uk>

A67. If the research involves a specific intervention, (e.g. a drug, medical device, dietary manipulation, lifestyle change etc.), what arrangements are being made for continued provision of this for the participant (if appropriate) once the research has finished?

☐ Not Applicable

The research team are not making any charges for the intervention materials. Dr Daley is running the augmentation day in collaboration with at least one member of staff from each clinic involved in the study. If the results of the study demonstrate that the intervention is effective then it would be up to the individual clinics to continue to offer the service. A decision has already been made by each clinic to offer the interention to those randomised to the delayed intervention (control) group.

PART A: Summary of Ethical Issues

A68. What do you consider to be the main ethical issues which may arise with the proposed study and what steps will be taken to address these?

It is possible that the child's behaviour may deteriorate during the course of the study, as a reaction to changes in the way that their parents treat them. This may result in distress in the parents. We intend to deal with this possibility in two ways

1) Through weekly telphone calls to the parents in the intervention group

2) By addressing this posibility and discussing methods of coping during the one say augmentation

A70. Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/degree:
Joanne Kelly – D.Clin.Psy
Michelle O'Brien PhD
Victoria Hawker M.Sc in Clinical Foundations

Name of educational establishment:
School of Psycholgoy
University of Wales, Bangor

Name and contact details of educational supervisor:
Dr David Daley
North Wales Clinical Psycholgoy Programme
School of Psychology
University of Wales, Bangor
LL57 2AS

A71. Declaration of supervisor

I have read and approved both the research proposal and this application for the ethical review. I undertake to fulfil the responsibilities of a supervisor as set out in the Research Governance Framework for Health and Social Care.

Signature: .....

Print Name: Dr David Daley

Date: 28/07/2006 (dd/mm/yyyy)

A one–page summary of the supervisor's CV should be submitted with the application

PART B: Section 1 – List of proposed research sites

List below all research sites you plan to include in this study. The name of the site is normally the name of the acute NHS Trust, GP practice or other organisation responsible for the care of research participants. In some cases it may be an individual unit, private practice or a consortium – see the guidance notes.

Principal Investigators at other sites should apply to the relevant local Research Ethics Committee for site–specific assessment (SSA) using Part C of the application form. Applications for SSA may be made in parallel with the main application for ethical review (once the main REC has validated the application), or following issue of a favourable ethical opinion. Approval for each site will be issued to you by the main REC following SSA.

1. Name of the research site:

North East Wales Child and Adolescent Mental Health Service, Catherine Gladstone House, Hawarden Way, Mancott, Flintshire, CH6 1EP

Principal Investigator for the study at this site:

Title: Mrs Forename/Initials: Sue Surname: Parsonage

Post: Senior Therapist
Address: North East Wales Child and Adolescent Mental Health Service, Catherine

Postcode: CH6 1EP

2. Name of the research site:

Denbighshire Child and Adolescent Mental Health Service, Lawnside, Rhy LI18 3EP

Principal Investigator for the study at this site:

Title: Dr Forename/Initials: Patrick Surname: Loughran

Post: Clinical Psychologist
Address: Denbighshire Child and Adolescent Mental Health Service, Lawnside, Rhy LI18 3EP

Postcode: LL18 3EP

3. Name of the research site:

Conwy Child and Adolescent Mental Health Service, Argyle Rd, Llandudno LL30 1DF

Principal Investigator for the study at this site:

Title: Dr Forename/Initials: Carolyn Surname: Hinds

Post: Clinical Psychologist
Address: Conwy Child and Adolescent Mental Health Service, Argyle Rd, Llandudno LL30 1DF

Postcode: LL30 1DF

– The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

– I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

– If the research is approved I undertake to adhere to the study protocol, the terms of the full application of which the main REC has given a favourable opinion and any conditions set out by the main REC in giving its favourable opinion.

– I undertake to seek an ethical opinion from the main REC before implementing substantial amendments to the protocol or to the terms of the full application of which the main REC has given a favourable opinion.

– I undertake to submit annual progress reports setting out the progress of the research.

– I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer.

– I understand that research records/data may be subject to inspection for audit purposes if required in future.

– I understand that personal data about me as a researcher in this application will be held by the relevant RECs and their operational managers and that this will be managed according to the principles established in the Data Protection Act.

– I understand that the information contained in this application, any supporting documentation and all correspondence with NHS Research Ethics Committees or their operational managers relating to the application, will be subject to the provisions of the Freedom of Information Acts. The information may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

Signature: .....

Date: 28/07/2006 (dd/mm/yyyy)

Print Name: Dr David Daley

Part C Site Specific Assessment (SSA)

This form should be completed by the Principal Investigator for each site (see glossary)

Part C should be completed and sent with the relevant enclosures to each NHS Research Ethics Committee, which needs to consider site-specific issues. See guidance notes at the COREC website for further information about the application procedure.

The data in this box is populated from Part A.

Short title and version number:

Self directed intervention for ADHD

Name of NHS Research Ethics Committee to which application for ethical review is being made:

Liverpool Adult

Project reference number from above REC: 06/Q1505/74

Name of NHS REC responsible for SSA:

North East Wales

SSA reference (for REC office use only):

Questions C1, C4, C5, C6, C7, C8 and C13a correspond to questions A1, A2, A65, A10, A12, A13 and A29 on main application form respectively and will populate automatically:

C1. Title of the research*(Populated from A1)*

Full title: Parent Training for Children with hyperactivity. Efficacy of an augmented Self Administered Parent Training Intervention.

Key words: Self directed, Parent Training, hyperactivity, children

C2. Who is the Principal Investigator for this study at this site?

Title: Mrs Forename/Initials: Sue Surname: Parsonage

Post: Senior Therapist

Qualifications:

Organisation:

Address: North East Wales Child and Adolescent Mental Health Service, Catherine

Post Code: CH6 1EP

E-mail: SUE PARSONAGE <SUE.PARSONAGE@new-tr.wales.nhs.uk>

Telephone: 01244 538883

Fax: 01244 538883

A copy of a current CV (maximum 2 pages of A4) for the Principal Investigator(s) must be submitted with the application

C2-1. Give the names and posts of other investigators or members of the research team responsible to the local Principal Investigator for this site.

Include all staff with a significant research role. If the site is a network or consortium, list all participating investigators below.

Title:

Ethics Proposal 1 - 22

Forename/Initials:

Surname:

Position:

Qualifications:

Role in the research team:

C3. Indicate the number of trials/projects within the organisation that the local Principal Investigator has been involved with in the previous 12 months:

How many are still current (active or recruiting)?

C4. Chief Investigator *(Populated from A2)*

Title: Dr Forename/Initials: David Surname: Daley

Post: Lecturer and Senior Research Tutor

Qualifications: B.A, M.Phil, PhD, C.Psychol

Organisation: North Wales Clinical Psychology Programme, School of Psychology

Address: University of Wales, Bangor
Gwynedd

Post Code: LL57 2AS

E-mail: d.daley@bangor.ac.uk

Telephone: 01248 388067

Fax: 01248 383718

C5. Other relevant reference numbers if known *(Populated from A65)*

Applicants/organisation's own reference number, e.g. R&D (if available):

Sponsor's/protocol number:

Funder's reference number:

International Standard Randomized Controlled Trial Number (ISRCTN):

European Clinical Trials Database (EudraCT) Number:

Project website:

C6. Give a full summary of the purpose, design and methodology of the planned research, including a brief explanation of the theoretical framework that informs it. It should be clear exactly what will happen to the research participant, how many times and in what order. Describe any involvement of research participants, patient groups or communities in the design of the research.
(Populated from A10)

For this research study parents and children will be selected using a 2 stage screening process. Stage 1– Child and Adolescent mental health services who intend to run self directed intervention training for clients on their waiting list will be asked to send letters inviting parent to join the research study.

Parents will be asked to provide written consent to:

i) Complete a brief screening questionnaire (Strength and Difficulties Questionnaire). Ethics Proposal 1 - 23
ii) Be contacted for further details about the study.
iii) To take part in a short telephone based interview about their child's behaviour.
iv) Complete four short questionnaires about their child's behaviour and their own wellbeing.
v) Allow the researcher to observe 10 minutes of their child's solo play and 15 minutes of parent–child interaction.

Parents of children who score above the level of clinical concern on the SDQ and over 17 points on the PACS interview will be invited to join the study. All consenting parents will be randomised to either immediate augmented interention, or delayed augmented intervention. Parents in the immediate intervention group will be invited to one of two augmentation days, then given the manual to follow, telephone weekly and tested again on all measures at week 7. Parents in the delayed intervention group, will receive nothing for 6 weeks, be tested again, and then invited to attend an augmentation day and given the manual to follow.

C7. Give details of any clinical intervention(s) or procedure(s) to be received by research participants over and above those which would normally be considered a part of routine clinical care. *(These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material.)*
(Populated from A12)

Additional Intervention	**Average number per participant**		**Average time taken** (mins/hours/days)	**Details of additional intervention or procedure, who will undertake it, and what training they have received.**
	Routine Care	Research		
Psychological therapies	0	1		During the life of the study, the intervention group will receive self directed intervention.

C8. Give details of any non–clinical research–related intervention(s) or procedure(s). *(These include interviews, non–clinical observations and use of questionnaires.)*
(Populated from A13)

Additional Intervention	**Average number per participant**	**Average time taken** (mins/hours/days)	**Details of additional intervention or procedure, who will undertake it, and what training they have received.**
Telephone Interview	2	30	
Video Recording	2	30	

C9a. Give the name of the research site for which the PI is responsible: *(Please give the name only. Further details of locations should be given in C10. The name of the site is normally the name of the acute NHS Trust, GP practice or other organisation responsible for the care of research participants. In some cases it may be an individual unit, private practice or consortium – see the guidance notes. Each GP practice is a separate site unless a formal consortium/network is in place.)*

North East Wales Child and Adolescent Mental Health Service, Catherine
Gladstone House, Hawarden Way, Mancott, Flintshire, CH6 1EP

If you wish to add further information about the definition of the site, please do so below:

C9b. Give the name of the NHS or other organisation with which the PI holds the necessary contract (substantive or honorary) to undertake the research at this site:

North East Wales NHS Trust

C9c. For NHS sites, give the name and contact details of the Research Governance contact for the research site at the

care organisation or consortium:

Title: Miss
Forename/Initials: J
Surname: Howells
Address: Clinical Audit / Research Effectiveness Dept
Wrexham Medical Institut
Telephone: 01978 291100
Fax: 01978 291100
Postcode: LL13 7YP
E-mail: jenny.howells@new-tr.wales.nhs.uk

C9d. For non-NHS sites, give details of the arrangements for the management and monitoring of the research at this site:

NHS site

C10. Specify all locations or departments at which research procedures will be conducted at this site.
Include details of any centres at other NHS care organisations where potential participants may be seen and referred for inclusion in the research at this site. Give details of any research procedures to be carried out off site, for example in participants' homes.

North East Wales Child and Adolescent Mental Health Service

C11. How many research participants/samples is it anticipated will be recruited/obtained from this organisation in total?

30

C12a. Give details of who will be responsible for obtaining informed consent locally, their qualifications and relevant expertise and training in obtaining consent for research purposes:

Dr Daley will be responsible not the local PI

C13a. What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters etc.) (Populated from A29)*

Members of the research team are bi-lingual, and would be able to conduct telephone interviews, and give instructions and help with questionnaires in both English and Welsh. Due to copyright restrictions it is not possible to reproduce all questionnaires in other languages, and the reliability of the assessments in languages othe than Welsh and English is unproven. Threfore participants who were not fluent in either Welsh or English would have to be excluded from the study

C13b. What local arrangements have been made to meet these requirements (where applicable)?

☐ Not Applicable

No local arrangments, the reserach team are bi-lingual

C14. In addition to informing the GP (if required), what arrangements have been made to inform those responsible for the care of the research participants in the host care organisation of their involvement in the research?

none

C15. Are the facilities and staffing available locally adequate to perform any necessary procedures or interventions required for the study, and to deal with any unforeseen consequences of these? *(This should include consideration of procedures and interventions in both control and intervention arms of a study.)*

◉ Yes ○ No

If Yes, give the information necessary to justify your answer. If No, indicate what arrangements are being made to deal with the situation:
All assessment is telphone bases or home based, all intervention is self directed.

C16a. Give brief details of a contact point where participants may obtain further information about the study.

From Dr Daley

C16b. What is the contact point for potential complaints by research participants?

Local REC or Prof Hastings head of the School of Psychology

C16c. Is there a local source where potential participants can obtain independent information about being involved in a research study? *See guidance notes.*

no

C16d. Please specify the headed paper to be used for the participant information sheet.

North Wales Clinical Psychology Programme, School of Psychology

C17. If any extra support might be required by research participants as a result of their participation, what local arrangements are being made to provide this?

Participants will be encouraged to contact the research team, if they feel they need extra support but they will also remain on the waiting list to access the CAMHS service

– The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

– I undertake to abide by the ethical principles underpinning the Declaration of Helsinki and good practice guidelines on proper conduct of research.

– If the research is approved I undertake to adhere to the study protocol, the terms of the full application of which the main REC has given a favourable opinion and any conditions set out by the main REC in giving its favourable opinion.

– I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Controller.

– I understand that research records/data may be subject to inspection for audit purposes if required in future.

– I understand that personal data about me as a researcher in this application will be held by the relevant RECs and their operational managers and that this will be managed according to the principles established in the Data Protection Act.

– I understand that the information contained in this application, any supporting documentation and all correspondence with Research Ethics Committees relating to the application will be subject to the provisions of the Freedom of Information Acts. The information may be disclosed in response to a request under the Acts except where statutory exemptions apply.

Signature of the local Principal Investigator * .....

Date: (dd/mm/yyyy)

Print Name:

** The Chief Investigator should sign where s/he is also the local Principal Investigator for this research site.*

***PART C IS NOW COMPLETE AND SHOULD BE SUBMITTED** to the NHS Research Ethics Committee responsible for the site–specific assessment.*

Ethics protocol

Title

Parent Training for Children with Hyperactivity. Efficacy of a Self-Directed Parent Training Intervention.

Background

Attention deficit hyperactivity disorder (ADHD) is a condition characterised by severe and pervasive symptoms of inattention, over activity and impulsivity (DSM-IV; American Psychiatric Association, 1994). ADHD is a relatively common developmental disorder with an estimated prevalence rate ranging from 3% to 5% of the population (APA, 1994). Traditionally ADHD has been conceptualised as a condition of school aged children (Sonuga-Barke, Daley, Thompson & Swanson, 2003; Lahey et al., 1998). More recently ADHD has been understood as a chronic, debilitating condition that may persist into adolescents and adulthood (Barkley, 1998; Stevenson, Stevenson & Whitmont, 2003). Children with ADHD have higher risk of significant social and academic impairment (Bierderman, Farone & Milberg, 1996), engage in more socially aggressive behaviours, and experience higher degrees of parental conflict, peer rejection and future psychopathology (Shelton, Barkley & Crosswait, 1998; Pierce, Ewing & Cambell, 1999). While ADHD is the disorder, many research studies examine a sub-clinical variant of the disorder call hyperactivity, children with hyperactivity score high on symptom counts of ADHD, but may not meet the strict impairment criteria for ADHD.

ADHD is a clinically heterogeneous condition and it is likely that there is more than one developmental pathway in its aetiology. Sonuga-Barke (2002) proposed a dual pathway model that postulates that the development of ADHD is underpinned by two coexisting pathways. One pathway is mediated by executive dysfunction, based on deficient inhibitory control. The other pathway implicates disturbances in motivational processes based on delay aversion in the development of ADHD.

However the condition is considered highly heritable (Todd et al., 2001 Gjone, Stephenson and Sundet (1996) reported on twin and familial studies that provide strong evidence for the influence of genetic factors on attention and activity levels and Levy, Hay, McStephen, Wood & Waldman (1997) reported concordance rates of 51% to 82% for monozygotic twins. However the environmental context of a child's development must also be taken into account when evaluating the contribution genetic factors play in the development of ADHD and the process by which any genetic predisposition towards ADHD is expressed. The evidence for environmental factors exerting a causal influence in the aetiology of ADHD is limited. However psychosocial factors have been associated with increased risk of externalising disorders including ADHD in young children. Parenting style, maternal mental health, chaotic family environments and social deprivation are among the psychosocial risk factors related to externalizing behaviour problems in early childhood (Campbell, 1995; Podolski and Nigg, 2001).

Substantial research attention has been administered towards studying children with ADHD and to date pharmacological approaches are the preferred treatment for school aged children with the condition. The National Institute of Mental Health (NIMH)

Multimodal Treatment study of children with ADHD (Richters et al 1995) reported psychostimulants (e.g. methylphenidate, dextroamphetamine) were more effective than psychosocial interventions for treating school aged children with ADHD. Reports indicate that psychostimultant medication effectively controls symptoms of ADHD in 75-80% of school aged children (Barkley, DuPaul & McMurray, 1991). The superiority of psychostimulant medication over psychosocial interventions for treating ADHD in school aged children is not altogether unexpected. Developmental research has shown that psychosocial interventions are effective treatment approaches for externalising disorders in children when applied before behaviour patterns have become entrenched and resistant to change, typically this occurs by 8 years of age (Eron, 1990; Brestan & Eyberg, 1998).

There has been a paucity of research into young children with ADHD type symptoms. However for some time ADHD has been recognised as a condition of early onset. Indeed epidemiological data indicates that 2% of 3 to 5 year olds have ADHD symptoms (Lavigne et al., 1996). In recent times there has been significant increase in preschool children receiving a diagnosis of ADHD. It has also become more likely that those children will go on to be treated with psychotropic medication (Zito et al., 2000).

There have been few studies regarding the use of psychostimulant medication for preschool children with ADHD. Generally these studies have provided empirical support for the short term efficacy of stimulant medication for this age group. Musten, Firestone, Bennet and Mercer (1997) found that stimulant medications improved attention, impulsivity and behaviour in preschoolers with ADHD.

However a number of concerns have been raised regarding the use of psychostimulant medication for young children. These range from ethical objections to utilising medication to modify children's behaviour (Perring, 1997) to concerns about the lack of evidence for the long term effectiveness stimulant medication (Pelham 1998). Side effects of stimulant medication have also been a cause of concern. Research has indicated that preschool children seem to be at increased risk of developing short term side effects (Ghuman et al., 2001). There is also a lack of research evidence regarding the long term effects of stimulant medication on preschool children's physical and neurological development(Sonuga-Barke et al., 2003).

There is a substantial evidence base for the efficacy of psychosocial interventions for young children exhibiting behaviour disorders and ADHD. In an extensive review of non-pharmacological interventions for ADHD, parent training (PT) was found to have positive outcomes for young children (Pelham, Wheeler & Chronis, 1998). Two recent studies evaluating parent-based interventions for young children with ADHD have highlighted the value of early intervention parent training. Sonuga-Barke, Daley, Thompson, Laver-Bradbury and Weeks (2001) evaluated treatment outcomes of PT and parent counselling and support (PC&S) compared with a waiting list (WL) control group. Results indicated that in comparison to PCS and WL, PT reduced ADHD symptoms and increased mother's sense of well being. Bor, Sanders and Markie-Dadds (2002) compared standard and enhanced behavioural family intervention with waiting list control for preschool children with ADHD and behavioural problems. Lower levels of behaviour problems and increased parental competence were found in both behavioural family intervention groups compared to

the WL. These studies suggest that PT is a valuable treatment alternative to stimulant medication for young children with ADHD.

PT psychosocial interventions have demonstrated efficacy however, PT approaches are usually therapist led individual based treatment formats. Consequently such approaches are costly, time consuming and given that there has been a dramatic increase in the number of preschool children diagnosed with ADHD, service provision is unlikely to meet the clinical needs of this population.

Self-directed interventions may offer a cost effective approach to parent training in terms of resources, therapist training, availability and time. Self-directed interventions overcome a major limitation of many PT programmes in that they do not require the participants to attend clinic based sessions and are therefore more accessible and practical for a large number of parents. In general self directed based therapies have been delivered in written form (Bibliotherapy) although a range of media have been used e.g. manuals, videos audiotape, to provide information and advice to parents without the need for therapist contact. In a recent review Montgomery (2004) found media based interventions were moderately effective compared to no treatment for a range of child behaviour problems (Webster-Stratton, Kolpakoff & Hollingsworth, 1988; Seymour, Brock, During & Poole, 1989).

The aim of this research will be to establish the efficacy of a self-directed, manual based parent training intervention for young children with ADHD.

Research question

What is the efficacy of an augmented self-directed manual based parent training intervention for young children with hyperactivity?

Design and procedure

For this research study parents and children will be selected using a 2 stage screening process. Stage 1- Child and Adolescent mental health services who intend to run self directed intervention training for clients on their waiting list will be asked to send letters inviting parent to join the research study.

Parents will be asked to provide written consent to:

i) Complete a brief screening questionnaire (Strength and Difficulties Questionnaire).

ii) Be contacted for further details about the study.

iii) To take part in a short telephone based interview about their child's behaviour.

iv) Complete four short questionnaires about their child's behaviour and their own wellbeing.

v) Allow the researcher to observe 10 minutes of their child's solo play and 15 minutes of parent-child interaction.

Prior to acceptance into the study parents will be sent four short questionnaire measures regarding their child's behaviour and parental well being; The Strengths and Difficulties Questionnaire (Goodman, 1997, 1999), The General Health Questionnaire, (Goldberg, 1992); The Parenting Sense of Competence Scale (Johnston & Mash, 1989); and the The ADHD Rating Scale (DuPaul, Power, Anastopoulos & Reid, 1998). In stage 2 of the screening process, parents will be

interviewed using the Parental Account of Childhood Symptoms (PACS; Taylor, Sanberg, Thorley & Giles, 1991).

Parents will provide written

i) Consent to joining a research intervention trial.

ii) Consent to being randomised into the intervention or delayed intervention group.

iii) Consent to being videotaped.

Once baseline data has been collected, the study supervisors, using a random number generator will randomly assign children to the intervention or delayed intervention group. Parents in the intervention group will receive a self-directed parent training manual (Thompson & Daley, 2006). The self-directed parent-training manual has been specifically designed for this research. Parents will follow the manual for 6 weeks. In addition parents in the intervention group receive a weekly telephone call from their local CAHMS service. The purpose of this intervention related telephone call is to ask about the child's behaviour, their use of the manual and to remind them to move on to the next section of the manual. Seven weeks after entering the trial all participants will complete the same assessment measures again (all questionnaire measures, PACS and observation measures).

Parents will experience minimal inconvenience, in that the questionnaires are relatively brief and all postage costs will be covered by the University of Wales, Bangor. Parents will not be required to attend any clinic appointments and the researcher will contact the parent in order to conduct clinical interviews and record

the child's play, at a date and time convenient for the parent. At the end of the study, participants can request a summary of the main research findings.

Measures

a) Parental Account of Childhood Symptoms (PACS). (Taylor, Sanberg, Thorley, & Giles, 1991).

The PACS is a structured clinical interview for parent's that assesses the frequency and severity of core ADHD symptoms in children the PACS has been used in previous research to measure child behaviour before and after psychosocial interventions. The PACS has high inter-rater reliability, good construct validity and has been well validated against clinical judgement (Taylor et al., 1991).

b) Strengths and Difficulties Questionnaire (SDQ). (Goodman, 1997, 1999)

The SDQ is a 25 item informant-rated behavioural inventory of both positive and negative attributes in children aged 3 to 16 years old. Scoring results in five subscales; hyperactivity, conduct problems, emotional symptoms, peer problems and prosocial behaviour. The first four of which contribute to a total difficulties score. It has high discriminant validity, and there is an association between high SDQ scores and an increase in psychiatric risk (Goodman, 2001).

c) The General Health Questionnaire (GHQ 12). (Goldberg, 1992)

The GHQ-12 is a widely used, reliable, well-validated 12 item questionnaire designed to assess disturbed mood and is often used as a screening measure for depression. The scale assess functioning in four areas; depression, anxiety, social dysfunction and

somatic disturbance. This measure has good discriminant validity, and is a reliable and convergent measure (Hardy, Shapiro, Haynes, & Rick, 1999).

d) Parental Sense of Competence Scale (PSOC; Johnston and Mash, 1989).

This questionnaire is used to measure two dimensions of parenting self esteem: parenting satisfaction and parenting efficacy. The PSOC has been used across numerous studies to measure self esteem of parents in both clinical and nonclinical samples. The 17 item questionnaire is considered a valid and reliable measure (Johnston & Mash, 1989).

g) Observation of engagement

In addition a ten minute observation of the child's solo play will be recorded using an observation measure developed by Sonuga-Barke et al. (2001). The observation measure uses a set of standard toys, lego, play dough etc. Two measures are taken, total observed time on task and total number of switches of attention between activity zones. Dividing the time on task by total number of switches yields a measure of observed engagement.

Data management and analysis

Analysis of Co-Variance (ANCOVA) will examine differences between immediate and delayed intervention groups at post-intervention, controlling for differences at baseline.

Risk Assessment

Lone worker policies – conducting observations in the community at peoples homes (Trust Policies).

Possible disclosures/child protection issues (Trust Policies)

Data Storage

Videotapes, audiotapes, and all paper-based measures will be stored securely.

Financial information

- Photocopying = £10
- Stationary = £10
- Telephone charges (approx 50mins @ 3p x 25) = £37.25
- Toys for observations = £40
- Video tapes x 25 = £25
- Audiotapes x 25 = £15
- £10 per book x 25 for intervention = £250
- Room hire in Wrexham = £50
- Room hire in Rhyl = £50
- Total = £487.25

Timetable

May 2006 – Obtain approval from School of Psychology ethics

June 2006 - Training on PACS

November 2006 – begin collecting baseline data

Feb 2007 – finish data collection

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Appendix 1.a

Strengths and Difficulties Questionnaire

(Goodman, 1997, 1999)

Strengths and Difficulties Questionnaire

For each item, please mark the box for Not True, Somewhat True or Certainly True. It would help us if you answered all items as best you can even if you are not absolutely certain or the item seems daft! Please give your answers on the basis of the child's behaviour over the last six months.

Child's Name ..... Male/Female

Date of Birth.....

	Not True	Somewhat True	Certanly True
Considerate of other people's feelings	☐	☐	☐
Restless, overactive, cannot stay still for long	☐	☐	☐
Often complains of headaches, stomach-aches or sickness	☐	☐	☐
Shares readily with other children (treats, toys, pencils etc.)	☐	☐	☐
Often has temper tantrums or hot tempers	☐	☐	☐
Rather solitary, tends to play alone	☐	☐	☐
Generally obedient, usually does what adults request	☐	☐	☐
Many worries, often seems worried	☐	☐	☐
Helpful if someone is hurt, upset or feeling ill	☐	☐	☐
Constantly fidgeting or squirming	☐	☐	☐
Has at least one good friend	☐	☐	☐
Often fights with other children or bullies them	☐	☐	☐
Often unhappy, down-hearted or tearful	☐	☐	☐
Generally liked by other children	☐	☐	☐
Easily distracted, concentration wanders	☐	☐	☐
Nervous or clingy in new situations, easily loses confidence	☐	☐	☐
Kind to younger children	☐	☐	☐
Often lies or cheats	☐	☐	☐
Picked on or bullied by other children	☐	☐	☐
Often volunteers to help others (parents, teachers, other children)	☐	☐	☐
Thinks things out before acting	☐	☐	☐
Steals from home, school or elsewhere	☐	☐	☐
Gets on better with adults than with other children	☐	☐	☐
Many fears, easily scared	☐	☐	☐
Sees tasks through to the end, good attention span	☐	☐	☐

Do you have any other comments or concerns?

Please turn over - there are a few more questions on the other side

Overall, do you think that your child has difficulties in one or more of the following areas: emotions, concentration, behaviour or being able to get on with other people?

No	Yes- minor difficulties	Yes- definite difficulties	Yes- severe difficulties
☐	☐	☐	☐

If you have answered "Yes", please answer the following questions about these difficulties:

- How long have these difficulties been present?

Less than a month	1-5 months	6-12 months	Over a year
☐	☐	☐	☐

- Do the difficulties upset or distress your child?

Not at all	Only a little	Quite a lot	A great deal
☐	☐	☐	☐

- Do the difficulties interfere with your child's everyday life in the following areas?

	Not at all	Only a little	Quite a lot	A great deal
HOME LIFE	☐	☐	☐	☐
FRIENDSHIPS	☐	☐	☐	☐
CLASSROOM LEARNING	☐	☐	☐	☐
LEISURE ACTIVITIES	☐	☐	☐	☐

- Do the difficulties put a burden on you or the family as a whole?

Not at all	Only a little	Quite a lot	A great deal
☐	☐	☐	☐

Signature ..... Date .....

Mother/Father/Other (please specify:)

Thank you very much for your help

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Appendix 1.b

ADHD Rating Scale-IV

(DuPaul, Power, Anastopoulos & Reid, 1998)

AD/HD Diagnostic Rating Scale (Du Paul)

Name:_____

Date of Birth:_____

Each rating should be considered in the context of what is appropriate for the age of the children you are rating.

Frequency Code: 0=never 1=occasionally 2=often 3=very often

1.Fails to give attention to details or makes careless mistakes in schoolwork	0	1	2	3
2.Has difficulty sustaining attention to tasks or activities.	0	1	2	3
3.Does not seem to listen when spoken to directly.	0	1	2	3
4.Does not follow through on instructions and fails to finish schoolwork (not due to oppositional behavior or failure to understand).	0	1	2	3
5.Has difficulty organizing tasks and activities.	0	1	2	3
6.Avoids, dislikes or is reluctant to engage in tasks that require sustained mental effort.	0	1	2	3
7.Loses things necessary for tasks or activities (school assignments, pencils or books).	0	1	2	3
8.Is easily distracted by extraneous stimuli.	0	1	2	3
9.Is forgetful in daily activities.	0	1	2	3
10.Fidgets with hands and feet or squirms in seat.	0	1	2	3
11.Leaves seat in classroom or in other situations in which remaining seated is expected.	0	1	2	3
12.Runs about or climbs excessively in situations in which remaining seated is expected.	0	1	2	3
13.Has difficulty playing or engaging in leisure activities quietly.	0	1	2	3
14.Is "on the go" or often acts as if "driven by a motor".	0	1	2	3
15.Talks excessively.	0	1	2	3
16.Blurts out answer before questions have been completed.	0	1	2	3
17.Has difficulty waiting in line.	0	1	2	3
18.Interupts or intrudes on others (e.g., butts into conversations or games).	0	1	2	3

Appendix 1.c

General Health Questionnaire-12

(Goldberg, 1992)

General Health Questionnaire

We should like to know if you have had any medical complaints and how your health has been in general over the past few weeks. Please answer all the questions on the following page simply by underlining the answer which you think most nearly applies to you. Remember that we want to know present and recent complaints, not those you had in the past.
It is important that you try to answer all the questions.

Have you recently:

1.been able to concentrate on whatever you are doing?	Better than usual	Same as usual	Less than usual	Much less than usual
2. Lost much sleep over worry?	Not at all	No more than usual	Rather more than usual	Much more than usual
3. Felt you are a useful part in things?	More so than usual	Same as usual	Less useful than usual	Much less useful
4.Felt capable of making decisions about things?	More so than usual	Same as usual	Less so than usual	Much less than usual
5) Felt constantly under strain?	Not at all	No more than usual	Rather more than usual	Much more than usual
6)Felt you couldn't overcome your difficulties?	Not at all	No more than usual	Rather more than usual	Much more than usual
7. Been able to enjoy your normal day to day activities?	More so than usual	Same as usual	Less so than usual	Much less than usual
8. Been able to face up to your problems?	More so than usual	Same as usual	Less able than usual	Much less than usual
9.Been feeling unhappy and depressed?	Not at all	No more than usual	Rather more than usual	Much more than usual
10.Been losing confidence in yourself?	Not at all	No more than usual	Rather more than usual	Much more than usual
11.Been thinking of yourself as a worthless person?	Not at all	No more than usual	Rather more than usual	Much more than usual
12.Been feeling reasonably happy, all things considered?	More so than usual	About the same as usual	Less so than usual	Much less than usual

Appendix 1.d

Parental Sense of Competence scale

(Johnston and Mash, 1989).

Parenting Sense of Competence Scale

This is a questionnaire about your attitudes and feelings that relate to parenting. Please circle the answer that most closely resembles how you feel. *There are no right or wrong answers.*

	Strongly agree	**agree**	**unsure**	**disagree**	**strongly disagree**
The problems of taking care of a child are easy to solve once you know how your actions affect your child - an understanding I have acquired.	5	4	3	2	1
Even though being a parent can be rewarding, I am frustrated now while my child is at his/her present age.	5	4	3	2	1
I do not know why it is, but sometimes when I'm supposed to be in control, I feel more like the one being manipulated.	5	4	3	2	1
Being a parent is manageable, and any problems are easily solved.	5	4	3	2	1
Being a parent makes me tense and anxious.	5	4	3	2	1
I would make a fine model for a new mother/father to follow in order to learn what s/he would need to know in order to be a good parent.	5	4	3	2	1
I go to bed the same way that I wake up in the morning: feeling like I have not achieved very much.	5	4	3	2	1
My mother/father was better prepared to be a good mother/father than I am.	5	4	3	2	1
A difficult problem in being a parent is not knowing whether you're doing a good job or a bad one.	5	4	3	2	1
I meet my own personal expectations for expertise in caring for my child.	5	4	3	2	1
If anyone can find the answer to what is troubling my child, I am the one.	5	4	3	2	1
Sometimes I feel like I'm not getting anything done.	5	4	3	2	1
Considering how long I've been a mother/father, I feel thoroughly familiar with this role.	5	4	3	2	1
My talents and interests are in other areas - not being a parent.	5	4	3	2	1
If being a mother/father of a child were only more interesting, I would be better motivated to do a better job as a parent.	5	4	3	2	1
I honestly believe I have all the skills necessary to be a good mother/father to my child.	5	4	3	2	1
Being a good mother/father is a reward in itself.	5	4	3	2	1

Appendix 1.e

Parental Account of Child Symptoms

(Taylor, Sanberg, Thorley, & Giles, 1991).

SPA 0 = No 1 = Yes ( )

Subject No: ( )( )( )
Date: ( )( )( )( )( )( )

Parent Account of Child Symptoms (PACS):
systematic, semi-structured interview to be given to parents

The following questions are about your child and how things have been going in general. All of the questions start off by focusing on the last week, but we are also interested to find out how typical this last week has been of the past six months. Before we start it might be a good idea to think back to six months ago (when ..... would have been .....yrs. mos.) as this will help in remembering any changes which may have taken place since then.

Some of the questions may not apply to your child but it is important that we ask the same questions of everybody. As we will be asking about a number of different behaviours and situations I am afraid that the questions may become rather repetitive so please bear with me.

The following questions are about behaviour patterns most children show to some extent.

ADHD Scale

A. I would now like to ask you a few questions about your daughter's behaviour.

1. I will start with sleeping.
Was s/he a good sleeper in the last week?
Or did she tend to wake up at night; and if she woke up did she easily get back to sleep?
Did she have a nightmare? or wake up screaming?
Sleepwalking?
Tired during the day?

Problems might include insomnia, nightmares, night terrors, sleepwalking, etc.

(Notes: Do not include tiredness during the day due to an unusually late night; problems about going to bed or bed wetting; or waking up at night unless it is clearly linked to distress, caused by worries or fear of the dark.)

No difficulty	0	
Slight or dubious difficulty (little distress and no interference with daytime activities)	1	
Definite difficulty (child either distressed or suffers moderate interference with daytime activities, e.g. late rising because of sleep loss)	2	
Serious difficulty (child severely distressed or marked interference with daytime activities)	3	
Situation not arisen, unrateable or missing	9	____h1

Has she had problems with her sleep in the last six months?
How bad have they been? ____h2

On how many nights has she had such difficulties in the last week?
If the answer is vague: **Would it be more or less than 3 days a week?**

No difficulty	0	
On one or two nights/week	1	
On three to four nights/week	2	
On >5 nights/week	3	
Situation not arisen,, unrateable or missing	9	____h3

Would this be usual for her in the last 6 months?
(Rate 0 if has happened but less than once a week) ____h

2. Now I would like to ask about some of the things s/he enjoys doing.
Has she watched <u>television</u> this week?
When was the last time you saw her doing this?

<u>How long did she watch for</u>?
If the answer is vague: **Would it be more or less than half an hour?**

More than 20 mins	0	
More than 15 mins but less than 20 mins	1	
From 6 to 15 mins	2	
No more than 5 mins	3	
Situation not arisen, unrateable or missing	9	____ h1

What that be a typical time for him when s/he likes the programme? ____ h2

Those particular times she was watching TV, was she <u>up and down out of her seat</u> at all?
How many times during that particular period?
If answer is vague: **Would it be every 15 minutes or less?**

Not at all/sits still	0	
About once every 15 mins	1	
Once every 5 mins	2	
More than once a minute but less than 5 times a minute	3	
More than 5 times a minute	4	
Situation not arisen, unrateable or missing	9	____ h3

What would be her typical rate of getting up and down out of her seat during a programme she enjoys watching? ____ h4

That particular time of watching that we were talking about, was she <u>fidgeting</u> at all?
(Like swinging legs, tapping fingers or fiddling with an object?)

How much?
If the answer is vague: **Would it be all the time, more than half the time or less than half the time?**

Not at all	0	
Less than half of the time	1	
More than half of the time but not throughout	2	
Continuous, never stopped	3	
Situation not arisen, unrateable or missing	9	____ h3

What would be her particular pattern during watching a Television programme she enjoys? ____ h4

3. Has she done anything which she enjoys doing on her own recently?
Such as painting, drawing, modelling, jigsaws etc.
When was the last time you saw her doing that?
Was this typical of her playing on her own?
(If not), what would be a more typical situation?
When did you last see her doing that?

That particular time, how long was she playing for?
If the answer is vague: **Could he play on his own for 30 minutes, or would it usually be less than that?**

More than 30 mins	0	
16 to 30 mins	1	
6 to 15 mins	2	
No more than 5 mins	3	
Situation not arisen, unrateable or missing	9	____ h1

How long would be typical for her to play on her own like this? ____ h2

(Notes: If the attention span differs according to activity, rate the longest duration. Do not include activities shared with a parent or another child.)

The time that you have just described of her playing on her own, was she up and down out of her seat at all?

How many times during that period?

Not at all	0	
About once in every 15 mins	1	
More than once per 15 mins but less than once per 5 mins	2	
Every 5 mins or more	3	
Situation not arisen, unrateable or missing	9	____ h3

What would be the typical rate of her getting up and down while playing on her own? ____ h4

The time that we have just talked about of her playing on her own, was she fidgeting about at all?
If the answer is vague: **Would it be all the time, or more/less than half?**

How much?

Not at all	0	
Less than half of the time	1	
More than half of the time but not throughout	2	
Continuous, never stopped	3	
Situation not arisen, unrateable or missing	9	____ h3

What would be her typical pattern of fidgeting during that kind of activity on her own? ____ h4

4. Has she played indoors with other children like her brothers and sisters or friends recently?
When was the last time you saw her?
What did they play with/ what sort of game was it?

That time she was playing with other children/someone else, how long did she stick to one activity for?

More than 30 mins	0	
16 to 30 mins	1	
6 to 15 mins	2	
No more than 5 mins	3	
Situation not arisen, unrateable or missing	9	____ h1

Was this typical of her playing with other children?
How long would she usually spend on one activity? ____h2

That particular time you have just described of her playing with another child/other children, was s/he running around unneccessarily in and out of rooms during the time they played; or was she staying in one place?
How often did s/he do that?

Not at all	0	
About once in every 15 mins	1	
More than once per 15 mins but less than once per 5 mins	2	
Every 5 mins or more	3	
Situation not arisen, unrateable or missing	9	____ h3

Would that be her typical pattern during a similar activity? ____ h4

5. Have you seen her at a mealtime during the last week?
When was the last time?
Was that a meal that she was supposed to sit down at the table with you?

(Note: If not, choose a meal time during which the child was supposed to sit down at the table and which is also well remembered.)

That particular time, did she get up and leave the table at all?
(Note: Do not rate getting up to fetch a glass of water etc., unless parent states these are excuses to get up.)

How often did she do that?

Not at all	0	
Once	1	
2x to 5x	2	
more than 5 times	3	
Situation not arisen, unrateable or missing	9	____ h1

Would that be usual for her during mealtimes over the past 6 months? ____ h2

6. Has she been with you to the shops in the last week?
When was the last time?

That particular time, did she run away from you at all?

If so, how much of the time was she with you between running away?

Not running away at all	0	
Running away every 5 mins or less	1	
Running away every 2 to 5 mins	2	
More than every 2 mins	3	
Situation not arisen, unrateable or missing	9	____ h1

What would be her usual pattern when she is in a shop with you? ____ h2

(Notes: Include disturbing other shoppers by pushing the trolley in an uncontrolled way. If parent keeps child restrained in trolley due to past experience of repeated running off, or has stopped taking the child shopping for the same reason, rate severity the last time in shops if within the last month.)

7. You have told me about ..... (behaviours stated e.g. not sticking to activities, or fidgeting, or rushing around - refer to any above)

Do you regard this as a problem?

No problem	__
Minor problem	__
Serious problem	__

Appendix 1.f

Information Sheet 1

(English & Welsh versions)

Rhaglen Seicoleg Clinigol
Gogledd Cymru

Ysgol Seicoleg
Prifysgol Cymru, Bangor
Bangor, Gwynedd LL57 2DG

Ffacs: (01248) 383718

North Wales Clinical
Psychology Programme

School of Psychology
University of Wales, Bangor
Gwynedd LL57 2DG

Fax: (01248) 383718

Parent Training for Children with hyperactivity . Efficacy of a Self Administered Parent Training Intervention.

PARTICIPANT INFORMATION SHEET ONE

Researchers: Dr Dave Daley, Joanne Kelly , Michelle O'Brien and Victoria Hawker
North Wales Clinical Psychology Programme.

Invitation paragraph
You are being invited to take part in a research study. Before you decide to take part 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 others if you wish. Please contact me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?
Wrexham ADHD service have recently decided to run a self directed intervention service for people who are currently on their waiting list for assessment. The aim of this service would be to introduce parents of children who probably have ADHD to a wider range of skills which they can use to help their child. This service will be in addition to the traditional services which you are currently waiting for. I would like to invite you to help us to evaluate whether this new service is helpful of not.

Why have I been chosen?
You have been chosen because you are currently on the waiting list for an assessment at the ADHD service.

Do I have to take part?
It is up to you whether or not you decide to take part. If you decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the service you receive from the ADHD service

What does it involve?
At this stage you are only being asked to consent to be contacted with further details about the study. This would involve a telephone call from Dr Daley or Joanne Kelly who will explain the study to you, and check that you understand what is involved. If you are still happy to take part we will then post you more detailed information and consent letters.

What are the possible benefits of taking part?
If you decide to take part you may be selected to receive an intervention that could reduce your child's difficult behaviours and increases you own sense of well being. In addition you will be helping researchers evaluate the effectiveness of a self administered parent training manual for children with ADHD

Further information
If you require any further information please contact Dr Dave Daley, Department of Clinical Psychology, 43 College Road, Bangor, Gwynedd, LL57 2DG, telephone 01248 388067 or via e mail d.daley@bangor.ac.uk
If you decide to take part, please keep this information sheet so that you can refer to it in the future. You will also be given a signed copy of the consent form to keep for your information.
If you have any complaints about the conduct of the study, these should be addressed to:
i) Hilary Pepler,Chief Executive, North East Wales N.H.S. Trust, Maelor hospital, Croesnewydd Road, Wrexham.
ii). Professor Richard Hastings, Head of the School Psychology, University of Wales Bangor, Bangor, Gwynedd, LL57 2DG.

Thank you for taking the time to read this information sheet.

Hyfforddiant i Rieni Plant gyda Gorfywiogrwydd. Effeithlonrwydd Ymyriad a Weithredir gan Rieni eu Hunain.

TAFLEN WYBODAETH UN I RAI SY'N CYMRYD RHAN

Ymchwilwyr: Dr Dave Daley, Joanne Kelly, Michelle O'Brien a Victoria Hawker
Rhaglen Seicoleg Glinigol Gogledd Cymru.

Paragraff gwahoddiad
Rydym yn eich gwahodd i gymryd rhan mewn astudiaeth ymchwil. Cyn i chi benderfynu cymryd rhan, mae'n bwysig eich bod yn deall y rheswm dros wneud yr ymchwil a'r hyn y bydd yn ei olygu. Cymerwch amser i ddarllen y wybodaeth ganlynol yn ofalus a'i thrafod gydag eraill os ydych yn dymuno. Cysylltwch â mi os nad oes rhywbeth yn glir, neu os hoffech ragor o wybodaeth. Cymerwch eich amser i benderfynu a ydych am gymryd rhan ai peidio.

Beth yw pwrpas yr astudiaeth?
Mae Gwasanaeth ADHD Wrecsam wedi penderfynu cynnal gwasanaeth ymyriad hunan-gyfeiriedig i bobl sydd ar eu rhestr aros ar hyn o bryd ar gyfer asesiad. Nod y gwasanaeth hwn fyddai cyflwyno i rieni plant sydd ag ADHD i amrywiaeth ehangach o sgiliau y gallent eu defnyddio i helpu eu plentyn. Bydd y gwasanaeth hwn yn ychwanegol i'r gwasanaethau traddodiadol yr ydych yn disgwyl amdanynt ar hyn o bryd. Hoffwn eich gwahodd i'n helpu i werthuso a yw'r gwasanaeth newydd hwn yn fuddiol ai peidio.

Pam ydw i wedi cael fy newis?
Rydych wedi cael eich dewis oherwydd eich bod ar restr barod ar hyn o bryd am asesiad yn y gwasanaeth ADHD.

Oes rhaid i mi gymryd rhan?
Chi sydd i benderfynu a ydych am gymryd rhan ai peidio. Os penderfynwch gymryd rhan, cewch y daflen wybodaeth hon i'w chadw, a bydd gofyn i chi lofnodi ffurflen gydsynio. Os byddwch yn penderfynu cymryd rhan, mae gennych hawl i dynnu allan unrhyw bryd heb roi rheswm. Os penderfynwch dynnu'n ôl ar unrhyw adeg, neu beidio â chymryd rhan, ni fydd hynny'n effeithio ar safon y gwasanaeth yr ydych yn ei dderbyn gan y gwasanaeth ADHD.

Beth mae'n ei olygu?
Ar y cam hwn, dim ond cydsynio i ni gysylltu â chi gyda rhagor o fanylion am yr astudiaeth yr ydych. Bydd yn cynnwys galwad ffôn gan Dr Daley neu Joanne Kelly a fydd yn egluro'r astudiaeth i chi, ac yn cadarnhau eich bod yn deall yr hyn mae'n ei olygu. Os ydych chi'n dal yn hapus cymryd rhan, byddwn wedyn yn postio rhagor o wybodaeth fanylach a llythyrau cydsynio atoch.

Beth yw manteision posibl cymryd rhan?
Os penderfynwch gymryd rhan efallai y cewch eich dewis i dderbyn ymyriad a allai leihau ymddygiad anodd eich plentyn a gwneud i chi eich hun deimlo'n well. Yn ogystal, byddwch yn helpu ymchwilwyr i werthuso effeithiolrwydd llawlyfr hyfforddiant a weithredir gan rieni eu hunain i blant gydag ADHD.

Gwybodaeth bellach
Os oes arnoch angen rhagor o wybodaeth, cysylltwch â Dr Dave Daley, Adran Seicoleg Glinigol, 43 Ffordd y Coleg, Bangor, Gwynedd LL57 2DG, ffôn 01248 388067 neu drwy e-bost: d.daley@bangor.ac.uk
Os penderfynwch gymryd rhan, cadwch y daflen wybodaeth hon fel y gellwch gyfeirio ati yn y dyfodol. Byddwch yn derbyn copi wedi'i lofnodi o'r ffurflen gydsynio hefyd, er gwybodaeth i chi.
Dylech gyfeirio unrhyw gwynion sydd gennych am y modd y gwneir yr astudiaeth at:
i) Hilary Pepler, Prif Weithredwr, Ymddiriedolaeth GIG Gogledd Ddwyrain Cymru, Ysbyty Maelor,
Ffordd Croesnewydd, Wrecsam.
ii). Yr Athro Richard Hastings, Pennaeth yr Ysgol Seicoleg, Prifysgol Cymru, Bangor, Gwynedd, LL57 2DG.

Diolch i chi am gymryd amser i ddarllen y wybodaeth hon.

Appendix 1.g

Information Sheet 2

(English & Welsh versions)

Parent Training for Children with hyperactivity: Efficacy of a Self Administered Parent Training Intervention.

PARTICIPANT INFORMATION SHEET TWO

Researchers: Dr Dave Daley, Joanne Kelly and Michelle O'Brien & Victoria Hawker
North Wales Clinical Psychology Programme.

Invitation
Thank you for agreeing to take part in this research study so far, your help has been greatly appreciated. Now that you have spoken to Dr Daley or Joanne Kelly over the phone you have been invited to join the next part of the research study and it is hoped that you will wish to continue to take part. We would like to remind you about the study.

What is the purpose of the study?
The aim of the study is to evaluate the effectiveness of a parent training intervention which you can teach yourself.

Do I have to take part?
It is up to you whether or not you decide to take part. If you decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the service you receive from your health visitor or nursery nurse.

What does it involve?
You will be asked to complete a number of questionnaires about yourself and your child. You will then be asked to take part in a telephone based interview with one of our researchers (Joanne or Victoria) and visited at home by another researcher (Michelle) who will observe your child at play for 10 minutes, and you and your child at play for 15 minutes with toys which we will provide. On the basis of all of this information we will be able to determine whether you are able to join the study. Dr Daley will telephone you to tell you whether or not you are able to join the study. If you are able to join the study you would then be allocated to one of two groups. One group will be invited to join a one day training programme run by Wrexahm ADHD service and receive a parent training manual to follow for 6 weeks, which outlines strategies to help manage children with high levels of hyperactivity. This group will also receive a weekly telephone call lasting 3-4 minutes from Wrexham ADHD service which is part of the intervention. The purpose of this telephone call is to ask you some questions about your child's behaviour, your use of the manual and to remind you to move on to the next section of the manual. After 6 weeks this group would be asked to repeat all our measures again. The second group would be asked to wait for 6 weeks, and then complete all of our measures again. If you are allocated to the goup which has to wait. For 6 weeks, you will receive all the same information and training once the study has finished

What if I am not invited to join the study?
If you are not invited to join the study but are still concerned about your child's behaviour. Don't worry you will still remain on the waiting list for a full assessment from the Child and Adolescent Mental Health Service

What are the possible benefits of taking part?
Parent based therapies for young children with difficult behaviours have proven effectiveness. You have been selected to receive a parent training intervention that could reduce your child's difficult behaviours and increases you own sense of well being. In addition you will be helping researchers evaluate the effectiveness of a parent training intervention that you can teach yourself.

What are the possible side effects of any treatment received when taking part?
No side effects have been identified for this intervention.

What are the possible disadvantages or risks of taking part?
You will be asked to give some of your time to completing questionnaires (10-15 minutes having an interview (40-50 minutes), and a home based observation of your child at play (25 – 30 minutes).

What if something goes wrong?
The risks involved in taking part in this study are very small; however the study does have full insurance cover in the unlikely event you think you have been harmed in some way.

Will my taking part in the study be kept confidential?
All information collected during the course of the research will be kept strictly confidential unless you tell the researcher something which makes them concerned that there might be serious risk to you or another person. If this was the case the researcher would try to discuss the matter with you first. All the information collected, will be destroyed when the study has finished.

What will happen to the results of the research study?
The results of the study will be published in a scientific journal and shared with health care professionals who work with young children and their families.
It is important to be reassured that you will not be identified in any report or publication.

Further information
If you require any further information please contact Dr Dave Daley North Wales Clinical Psychology Programme, University of Wales Bangor, 43 College Road, Bangor, Gwynedd, LL57 2DG, telephone 01248 388067 or via e mail:

If you decide to take part, please keep this information sheet so that you can refer to it in the future. You will also be given a signed copy of the consent form to keep for your information.
If you have any complaints about the conduct of the study, these should be addressed to:
i) Hilary Pepler,Chief Executive, North East Wales N.H.S. Trust, Maelor hospital, Croesnewydd Road, Wrexham.
ii)Professor F. Lowe, Head of School Psychology, University of Wales Bangor, Bangor, Gwynedd, LL57 2DG.

Thank you for taking the time to read this information sheet.

Hyfforddiant i Rieni Plant gyda gorfywiogrwydd: Effeithlonrwydd Ymyriad a Weithredir gan Rieni eu Hunain.

TAFLEN WYBODAETH DAU I RAI SY'N CYMRYD RHAN

Ymchwilwyr: Dr Dave Daley, Joanne Kelly, Michelle O'Brien a Victoria Hawker
Rhaglen Seicoleg Glinigol Gogledd Cymru.

Gwahoddiad
Diolch yn fawr am gytuno i gymryd rhan yn yr astudiaeth ymchwil hyd yma - gwerthfawrogir eich cymorth yn fawr. Nawr eich bod wedi siarad â Dr Daley neu Joanne Kelly ar y ffôn, gwahoddir chi i ymuno â rhan nesaf yr astudiaeth ymchwil a gobeithir y byddwch yn dymuno parhau i gymryd rhan. Hoffem eich atgoffa am yr astudiaeth.

Beth yw pwrpas yr astudiaeth?
Nod yr astudiaeth yw gwerthuso effeithiolrwydd ymyriad hyfforddiant rhieni y gellwch ei ddysgu i chi'ch hun.

Oes rhaid i mi gymryd rhan?
Chi sydd i benderfynu a ydych am gymryd rhan ai peidio. Os penderfynwch gymryd rhan, cewch y daflen wybodaeth hon i'w chadw, a bydd gofyn i chi lofnodi ffurflen gydsynio. Os byddwch yn penderfynu cymryd rhan, mae gennych hawl i dynnu allan unrhyw bryd heb roi rheswm. Os penderfynwch dynnu'n ôl ar unrhyw adeg, neu beidio â chymryd rhan, ni fydd hynny'n effeithio ar y gwasanaeth yr ydych yn ei dderbyn gan eich ymwelydd iechyd neu nyrs feithrin.

Beth mae'n ei olygu?
Gofynnir i chi lenwi nifer o holiaduron amdanoch chi eich hun a'ch plentyn. Gofynnir i chi wedyn gymryd rhan mewn cyfweliad ar y ffôn gydag un o'n hymchwilwyr (Joanne neu Victoria) a bydd ymchwiliwr arall yn ymweld â chi adref (Michelle) a fydd yn arsylwi'ch plentyn yn chwarae am 10 munud, a chi a'ch plentyn yn chwarae am 15 munud gyda theganau y byddwn ni'n eu darparu. Ar sail y wybodaeth hon, byddwn yn gallu pennu a ellwch ymuno â'r astudiaeth ai peidio. Bydd Dr Daley yn eich ffonio i ddweud wrthych a fyddwch yn gallu ymuno â'r astudiaeth ai peidio. Os gellwch ymuno â'r astudiaeth, byddwch yn cael eich rhoi mewn un o ddau grŵp wedyn. Gwahoddir un grŵp i ymuno â rhaglen hyfforddiant undydd a gynhelir gan wasanaeth ADHD Wrecsam a derbyn llawlyfr hyfforddiant rhieni i'w ddilyn am 6 wythnos, sy'n nodi strategaethau i helpu i reoli plant â lefelau uchel o orfywiogrwydd. Bydd y grŵp hwn hefyd yn derbyn galwad ffôn wythnosol a fydd yn para 3-4 munud gan wasanaeth ADHD Wrecsam, sy'n rhan o'r ymyriad. Pwrpas yr alwad ffôn hon yw gofyn ychydig o gwestiynau i chi am ymddygiad eich plentyn, eich defnydd o'r llawlyfr ac i'ch atgoffa i symud ymlaen i adran nesaf y llawlyfr. Ar ôl 6 wythnos, gofynnir i'r grŵp hwn ailadrodd ein holl fesurau eto. Gofynnir i'r ail grŵp aros 6 wythnos, ac wedyn gwneud ein holl fesurau eto. Os cewch eich rhoi yn y grŵp sy'n gorfod aros am 6 wythnos, byddwch yn derbyn yn union yr un wybodaeth a hyfforddiant ar ôl i'r astudiaeth ddod i ben.

Beth os na chaf i wahoddiad i ymuno â'r astudiaeth?
Os na wahoddir chi i ymuno â'r astudiaeth, ond rydych yn dal yn bryderus am ymddygiad eich plentyn, peidiwch â phoeni, byddwch yn parhau ar y rhestr aros am asesiad llawn gan y Gwasanaeth Iechyd Meddwl Plant a Phobl Ifainc.

Beth yw manteision posibl cymryd rhan?
Mae effeithiolrwydd therapïau wedi eu seilio ar rieni i blant ifainc gydag ymddygiad anodd wedi cael ei brofi. Rydych wedi cael eich dewis i dderbyn ymyriad hyfforddiant rhieni a allai leihau ymddygiad anodd eich plentyn a gwneud i chi eich hun deimlo'n well. Yn ogystal, byddwch yn helpu ymchwilwyr i werthuso effeithiolrwydd ymyriad hyfforddiant rhieni y gellwch ei ddysgu i chi'ch hun.

Beth yw sgil-effeithiau posibl unrhyw driniaeth a dderbynnir wrth gymryd rhan?
Nid oes unrhyw sgil-effeithiau wedi cael eu nodi ar gyfer yr ymyriad hwn.

Beth yw'r anfanteision neu'r risgiau posibl wrth gymryd rhan?
Gofynnir i chi roi ychydig o'ch amser i lenwi holiaduron (10-15 munud yn cael cyfweliad (40-50 munud), arsylwir eich plentyn yn chwarae yn eich cartref (25 – 30 munud).

Beth os aiff rhywbeth o'i le?
Mae'r risgiau sy'n ymwneud â chymryd rhan yn yr astudiaeth hon yn fychan iawn; fodd bynnag, mae'r astudiaeth wedi ei hyswirio'n llawn yn yr achos annhebygol eich bod yn meddwl i chi gael eich niweidio mewn rhyw ffordd.

Fydd y ffaith fy mod wedi cymryd rhan yn yr astudiaeth yn cael ei chadw'n gyfrinachol?
Bydd yr holl wybodaeth a gesglir yn ystod yr ymchwil yn cael ei chadw'n hollol gyfrinachol, oni bai eich bod yn dweud rhywbeth wrth yr ymchwilwyr sy'n gwneud iddynt boeni bod risg ddifrifol i chi neu berson arall o bosib. Pe bai hyn yn wir, byddai'r ymchwiliwr yn ceisio trafod y mater gyda chi'n gyntaf. Caiff yr holl wybodaeth a gesglir ei dinistrio ar ôl i'r astudiaeth ddod i ben.

Beth fydd yn digwydd i ganlyniadau'r astudiaeth ymchwil?
Caiff canlyniadau'r astudiaeth eu cyhoeddi mewn cylchgrawn gwyddonol, a'u rhannu â gweithwyr proffesiynol ym maes gofal iechyd sy'n gweithio â phlant ifainc a'u teuluoedd. Mae'n bwysig i chi fod yn dawel eich meddwl na fydd modd eich adnabod mewn unrhyw adroddiad na chyhoeddiad.

Gwybodaeth bellach
Os oes arnoch angen rhagor o wybodaeth, cysylltwch â Dr Dave Daley, Rhaglen Seicoleg Glinigol Gogledd Cymru, Prifysgol Cymru Bangor, 43 Ffordd y Coleg, Bangor, Gwynedd LL57 2DG, ffôn 01248 388067 neu drwy e-bost: d.daley@bangor.ac.uk

Os penderfynwch gymryd rhan, cadwch y daflen wybodaeth hon fel y gellwch gyfeirio ati yn y dyfodol. Byddwch yn derbyn copi wedi'i lofnodi o'r ffurflen gydsynio hefyd, er gwybodaeth i chi.
Dylech gyfeirio unrhyw gwynion sydd gennych am y modd y gwneir yr astudiaeth at:
i) Hilary Pepler, Prif Weithredwr, Ymddiriedolaeth GIG Gogledd Ddwyrain Cymru Ysbyty Maelor,
Ffordd Croesnewydd, Wrecsam.
ii) Yr Athro F. Lowe, Pennaeth yr Ysgol Seicoleg, Prifysgol Cymru, Bangor, Gwynedd, LL57 2DG.

Diolch i chi am gymryd amser i ddarllen y wybodaeth hon.

Appendix 1.h

Consent Form 1

(English & Welsh versions)

Rhaglen Seicoleg Clinigol
Gogledd Cymru

Ysgol Seicoleg
Prifysgol Cymru, Bangor
Bangor, Gwynedd LL57 2DG

Ffacs: (01248) 383718

North Wales Clinical
Psychology Programme

School of Psychology
University of Wales, Bangor
Gwynedd LL57 2DG

Fax: (01248) 383718

CONSENT FORM ONE

Study Title. Parent Training for Pre-schoolers with hyperactivity: Efficacy of a Self Administered Parent Training Intervention.

Name of Researcher: Dr Dave Daley, Joanne Kelly, Michelle O'Brien & Victoria Hawker.

Please tick each corresponding box

1. I confirm that I have read and understand the information sheet for the above study ☐

2. I understand that my participation is voluntary and that I can withdraw at any time without giving reason. ☐

3. I agree to be contacted with further information about the above study ☐

_____ _____ _____

Name of person giving consent Date Signature

Contact Details:

Address_____

_____

Postcode_____

Telephone number_____ Mob _____

When is a good time to contact you _____

Date Signature

Consent form 1 Version 2 15/02/2005

FFURFLEN GYDSYNIO UN

Teitl yr Astudiaeth. Hyfforddiant i Rieni Plant Cyn Oedran Ysgol gyda Gorfywiogrwydd: Effeithlonrwydd Ymyriad Hyfforddiant Rhieni a Ddysgant i'w Hunain.

Enw'r Ymchwiliwr: Dr Dave Daley, Joanne Kelly, Michelle O'Brien a Victoria Hawker.

Ticiwch bob bocs perthnasol

1. Rwy'n cadarnhau fy mod i wedi darllen a deall y daflen wybodaeth ar gyfer yr astudiaeth uchod ☐

2. Rwy'n deall fy mod yn cymryd rhan o'm gwirfodd, a bod gennyf hawl i dynnu'n ôl ar unrhyw adeg heb roi rheswm. ☐

3. Rwy'n cytuno i chi gysylltu â mi gyda rhagor o wybodaeth am yr astudiaeth uchod ☐

_____ _____ _____

Enw'r sawl sy'n rhoi cydsyniad Dyddiad Llofnod

Manylion Cyswllt:

Cyfeiriad _____

_____

Cod post _____

Rhif ffôn_____ Ffôn symudol _____

Yr amser gorau o'r diwmod i gysylltu â chi _____

Dyddiad Llofnod

Appendix 1.i

Consent Form 2

(English & Welsh versions)

CONSENT FORM TWO

Study Title. Parent Training for children with hyperactivity. Efficacy of a Self Administered Parent Training Intervention.

Name of Researcher: Dr Dave Daley, Joanne Kelly Michelle O'Brien & Victoria Hawker North Wales Clinical Psychology Programme

Please tick each corresponding box

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I can withdraw at any time without giving reason. ☐

3. If selected I agree to complete some short questionnaires about my child's behaviour and my own wellbeing ☐

4. If selected I agree to take part in a telephone interview about my child's behaviour ☐

5. If selected I agree for 10 minutes of my child's play with a toy provided by the researcher to be videotaped on two occasions. ☐

6 If selected I agree for 15 minutes of play and tidy up between myself and my child to be videotaped on two occasions ☐

7. If selected I agree to receive the intervention manual and answer a few minutes of questions over the phone each week about my child's behaviour and my use of the manual. ☐

8. If selected I agree to take part in the above study. ☐

_____ _____ _____

FFURFLEN GYDSYNIO DAU

Teitl yr Astudiaeth. Hyfforddiant rhieni ar gyfer plant gyda gorfywiogrwydd. Effeithlonrwydd Ymyriad Hyfforddiant a Weithredir gan Rieni eu Hunain.

Enwau'r Ymchwilwyr: Dr Dave Daley, Joanne Kelly, Michelle O'Brien a Victoria Hawker

Rhaglen Seicoleg Glinigol Gogledd Cymru.

Ticiwch bob bocs perthnasol

1. Rwy'n cadarnhau fy mod wedi darllen a deall y daflen wybodaeth ar gyfer yr astudiaeth uchod ac wedi cael cyfle i ofyn cwestiynau. ☐

2. Rwy'n deall fy mod yn cymryd rhan o'm gwirfodd, a bod gennyf hawl i dynnu'n ôl ar unrhyw adeg heb roi rheswm. ☐

3. Os caf fy newis, rwy'n cytuno i lenwi ychydig o holiaduron byr am ymddygiad fy mhlentyn, a'm lles fy hun. ☐

4. Os caf fy newis, rwy'n cytuno i gymryd rhan mewn cyfweliad ar y ffôn am ymddygiad fy mhlentyn ☐

5. Os caf fy newis, rwy'n cytuno i chi recordio 10 munud o'm plentyn yn chwarae gyda thegan a ddarperir gan yr ymchwiliwr ar dâp fideo, ar ddau achlysur. ☐

6. Os caf fy newis, rwy'n cytuno i 15 munud o chwarae a thacluso rhyngof fi fy hun a'm plentyn, gael ei recordio ar dâp fideo, ar ddau achlysur. ☐

7. Os caf fy newis, rwy'n cytuno i dderbyn llawlyfr yr ymyriad ac ateb ychydig funudau o gwestiynau ar y ffôn bob wythnos am ymddygiad fy mhlentyn, a'm defnydd o'r llawlyfr. ☐

8. Os caf fy newid, rwy'n cytuno i gymryd rhan yn yr astudiaeth uchod. ☐

_____ _____ _____

Enw'r sawl sy'n rhoi cydsyniad Dyddiad Llofnod

Manylion Cyswllt:

Cyfeiriad _____

Cod post _____ Rhif Ffôn _____

Appendix 1.j

COREC - Ethics Approval Letter

Liverpool (Adult) Local Research Ethics Committee
1 Arthouse Square
61-69 Seel Street
Liverpool
L1 4AZ

Telephone: 0151 296 7541
Facsimile: 0151 296 7536

17 October 2006

Dr David Daley
Lecturer and Senior Research Tutor
North Wales Clinical Psychology Programme, School of Psychology
University of Wales, Bangor
Gwynedd
LL57 2AS

Dear Dr Daley

Full title of study: **Parent Training for Children with hyperactivity. Efficacy of an augmented Self Administered Parent Training Intervention.**
REC reference number: **06/Q1505/74**

Thank you for your letter of 11 October 2006, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the research site(s) taking part in this study. The favourable opinion does not therefore apply to any site at present. I will write to you again as soon as one Local Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at sites requiring SSA.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Application	5.1	28 July 2006
Investigator CV		
Protocol	2	15 February 2005

Covering Letter		26 July 2006
Interview Schedules/Topic Guides		
Questionnaire	validated	
Advertisement		
Letter of invitation to participant		
Participant Information Sheet	sheet 2 v5	
Participant Information Sheet	sheet 1 v5	26 July 2006
Participant Consent Form	form 2 - 3	26 July 2006
Participant Consent Form	form 1 -3	
Response to Request for Further Information : - Covering Letter Participant Information Sheet(2) ADHD Scale	 2	11 October 2006 11 October 2006 11 October 2006 11 October 2006
researchers C V's		
Letter from funder		

Research governance approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final research governance approval from the R&D Department for the relevant NHS care organisation.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q1505/74	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Dr T Purewal
Chair

Email: Ronald.Wall@centralliverpoolpct.nhs.uk

Enclosures: *Standard approval conditions*

E-mail copy to: Miss J Howells, R&D, Wrexham Medical Institute

Central Office for Research Ethics Committees

RESEARCH IN HUMAN SUBJECTS OTHER THAN CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1. Standard conditions of approval by Research Ethics Committees

1. **Further communications with the Research Ethics Committee**

1.1 Further communications during the research with the Research Ethics Committee that gave the favourable ethical opinion (hereafter referred to in this document as "the Committee") are the personal responsibility of the Chief Investigator.

2. **Commencement of the research**

2.1 It is assumed that the research will commence within 12 months of the date of the favourable ethical opinion.

2.2 In the case of research requiring site-specific assessment (SSA) the research may not commence at any site until the Committee has notified the Chief Investigator that the favourable ethical opinion is extended to the site.

2.3 The research may not commence at any NHS site until the local Principal Investigator (PI) or research collaborator has obtained research governance approval from the relevant NHS care organisation.

2.4 Should the research not commence within 12 months, the Chief Investigator should give a written explanation for the delay. It is open to the Committee to allow a further period of 12 months within which the research must commence.

2.5 Should the research not commence within 24 months, the favourable opinion will be suspended and the application would need to be re-submitted for ethical review.

3. **Duration of ethical approval**

3.1 The favourable opinion for the research generally applies for the duration of the research. If it is proposed to extend the duration of the study as specified in the application form, the Committee should be notified.

4. **Progress reports**

4.1 Research Ethics Committees are required to keep a favourable opinion under review in the light of progress reports and any developments in the study. The Chief Investigator should submit a progress report to the Committee 12 months after the date on which the favourable opinion was given. Annual progress reports should be submitted thereafter.

4.2 Progress reports should be in the format prescribed by COREC and published on the website (see).

4.3 The Chief Investigator may be requested to attend a meeting of the Committee or Sub-Committee to discuss the progress of the research.

1.1. 5. Amendments

5.1 If it is proposed to make a substantial amendment to the research, the Chief Investigator should submit a notice of amendment to the Committee.

5.2 A substantial amendment is any amendment to the terms of the application for ethical review, or to the protocol or other supporting documentation approved by the Committee, that is likely to affect to a significant degree:

(a) the safety or physical or mental integrity of the trial participants

(b) the scientific value of the trial

(c) the conduct or management of the trial.

5.3 Notices of amendment should be in the format prescribed by COREC and published on the website, and should be personally signed by the Chief Investigator.

5.4 A substantial amendment should not be implemented until a favourable ethical opinion has been given by the Committee, unless the changes to the research are urgent safety measures (see section 7). The Committee is required to give an opinion within 35 days of the date of receiving a valid notice of amendment.

5.5 Amendments that are not substantial amendments ("minor amendments") may be made at any time and do not need to be notified to the Committee.

6. Changes to sites *(studies requiring site-specific assessment only)*

6.1 Where it is proposed to include a new site in the research, there is no requirement to submit a notice of amendment form to the Committee. Part C of the application form together with the local Principal Investigator's CV should be submitted to the relevant LREC for site-specific assessment (SSA).

6.2 Similarly, where it is proposed to make important changes in the management of a site (in particular, the appointment of a new PI), a notice of amendment form is not required. A revised Part C for the site (together with the CV for the new PI if applicable) should be submitted to the relevant LREC for SSA.

6.3 The relevant LREC will notify the Committee whether there is any objection to the new site or Principal Investigator. The Committee will notify the Chief Investigator of its opinion within 35 days of receipt of the valid application for SSA.

6.4 For studies designated by the Committee as exempt from SSA, there is no requirement to notify the Committee of the inclusion of new sites.

7. Urgent safety measures

7.1 The sponsor or the Chief Investigator, or the local Principal Investigator at a trial site, may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety.

7.2 The Committee must be notified within three days that such measures have been taken, the reasons why and the plan for further action.

8. Serious Adverse Events

8.1 A Serious Adverse Event (SAE) is an untoward occurrence that:

(a) results in death
(b) is life-threatening
(c) requires hospitalisation or prolongation of existing hospitalisation
(d) results in persistent or significant disability or incapacity
(e) consists of a congenital anomaly or birth defect
(f) is otherwise considered medically significant by the investigator.

8.2 A SAE occurring to a research participant should be reported to the Committee where in the opinion of the Chief Investigator the event was related to administration of any of the research procedures, and was an unexpected occurrence.

8.3 Reports of SAEs should be provided to the Committee within 15 days of the Chief Investigator becoming aware of the event, in the format prescribed by COREC and published on the website.

8.4 The Chief Investigator may be requested to attend a meeting of the Committee or Sub-Committee to discuss any concerns about the health or safety of research subjects.

8.5 Reports should not be sent to other RECs in the case of multi-site studies.

9. **Conclusion or early termination of the research**

9.1 The Chief Investigator should notify the Committee in writing that the research has ended within 90 days of its conclusion. The conclusion of the research is defined as the final date or event specified in the protocol, not the completion of data analysis or publication of the results.

9.2 If the research is terminated early, the Chief Investigator should notify the Committee within 15 days of the date of termination. An explanation of the reasons for early termination should be given.

9.3 Reports of conclusion or early termination should be submitted in the form prescribed by COREC and published on the website.

10. **Final report**

10.1 A summary of the final report on the research should be provided to the Committee within 12 months of the conclusion of the study. This should include information on whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research including any feedback to participants.

11. **Review of ethical opinion**

11.1 The Committee may review its opinion at any time in the light of any relevant information it receives.

11.2 The Chief Investigator may at any time request that the Committee reviews its opinion, or seek advice from the Committee on any ethical issue relating to the research.

12. **Breach of approval conditions**

12.1 Failure to comply with these conditions may lead to suspension or termination of the favourable ethical opinion by the Committee.

Appendix 1.k

NHS Ethics Approval Letter

Ymddiriedolaeth GIG Siroedd Conwy a Dinbych
Conwy & Denbighshire NHS Trust

TO:
Dr Dave Daley
Lecturer and senior research tutor
North Wales Clinical Psychology Programme,
School of Psychology,
University of Wales Bangor
Gwynedd LL57

Ein cyf/Our ref: LTJ January 2007
Eich cyf/Your ref:
Dyddiad/Date 12 January 2007
Wrth ffonio gofynnwch am/if telephoning ask for
Lona Tudor Jones
Llinell Uniongyrchol/Direct Line:
01745 – 589624
E-Mail Address
Lona.TudorJones@cd-tr.wales.nhs.uk

Dear Dr Daley

Re : Trust Approval to Proceed

Project Title: Parent Training for children with hyperactivity. Efficacy of an augmented self administered parent training intervention.
Project Ref: 2006/psych/337

I am pleased to inform you that the above project has obtained approval to proceed at the Conwy and Denbighshire NHS Trust subject to ethical approval and that the power calculation and analysis plan being revisited before the data collection is completed to ensure the scientific integrity of the project.

As part of regular monitoring undertaken by the Trust R&D Committee, you will be required to complete a short progress report. This will be requested on a six monthly basis. However, please contact me sooner should you need to report any particular successes or problems concerning your research. Whilst the Trust is keen to reduce the burden of paperwork for Researchers failure to produce a progress report may result in withdrawal of approval and any allocated funding.

To confirm the details of the amount of funding , if any, allocated to your project please contact Shelagh Evans, Management Accounts in the Finance Department, H M Stanley Hospital. Ext 3771.

All research conducted at Conwy and Denbighshire NHS Trust must comply with the Research Governance Framework for Health and Social Care in Wales (November 2001). An electronic link to this document is provided on the Trust's R&D webpages. Alternatively you may obtain a paper copy of this document via the Trust R&D Office.

Please note the following as Principal investigator ie. the person designated as taking overall responsibility within the team of researchers for the design, conduct and reporting of the study.

- Controlled trials are registered.
- The research proposal has ethical approval.
- The study complies with ethical and legal requirements.
-

- The research follows the protocol approved by the relevant ethics committee and the research sponsor.
- Any proposed changes or amendment to or deviations from the protocol and submitted for approval to the ethics committee, the research sponsor and any other appropriate body.
- The research proposal is worthwhile, of high scientific quality and value for money
- The arrangements, resources proposed and procedures are in place to ensure the collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage.
- The research team are suitably qualified and have the necessary skills and experience. Students and new researchers have adequate supervision, support and training.
- Care staff are suitably informed about their patients taking part in research.
- Assistance will be provided to any potential enquiry audit or investigation related to the funded work. All data associated with the study are available for audit.
- The principal investigator plays a key role in detecting and preventing scientific misconduct by adopting the role of guarantor on published outputs.
- Unless participants or the relevant ethics committee request otherwise, participants' care professionals are given information specifically relevant to their care which arises in the research.
- The findings from the work are open to critical review.

I trust this is in order. If you would like further information on any of the points covered by this letter, please do not hesitate to contact me. On behalf of the R&D Committee, may I wish you every success with your research.

Yours sincerely

Lona Tudor Jones.

Lona Tudor Jones
R&D Manager

Cc
Julie Whitmore, Ethics Office, Glan Clwyd Hospital
Shelagh Evans, Management Accounts, Finance, H M Stanley Hospital

The following amendments were made to the study proposal:

As this study was conducted within the remit of a larger study, led by Dr Dave Daley, the proposed observation of child solo play and parent-child interaction was not collected or analysed in the current study.

Children reported by their parents to be above the level of clinical concern (≥6) on the Strengths and Difficulties Questionnaire Hyperactivity scale (SDQ; Goodman, 1997, 1999) were invited to join the study.

SECTION 2

LITERATURE REVIEW

Running Head: PSYCHOSOCIAL INTERVENTIONS FOR ADHD

Psychosocial interventions for ADHD: Current findings and recommended interventions.

Joanne Kelly

NWCPP, School of Psychology, University of Wales, Bangor, Gwynedd LL57 2DG

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Abstract

Attention Deficit Hyperactivity Disorder (ADHD) is a condition characterised by severe and pervasive symptoms of inattention, hyperactivity and impulsivity. Without effective intervention children with a diagnosis of ADHD can experience significant functional impairment in a number of areas including social functioning and academic achievement, and are at increased risk of the development of future substance abuse, criminality, and psychopathology. This article endeavours to provide a broad overview of what is currently known about the development, aetiology, and maintenance of ADHD in childhood, before examining intervention for ADHD in greater detail. The relative benefits of medication management and psychosocial intervention are examined, and a number of parent training interventions are reviewed. Identified gaps in the current literature are highlighted, and areas of clinical interest are discussed.

Introduction

Attention Deficit Hyperactivity Disorder (ADHD) is a condition characterised by severe and pervasive symptoms of inattention, hyperactivity and impulsivity, over and above that expected for the child's age or stage of development (Goldman, Genel, Bezman, & Slanetz, 1998) and seen across multiple settings. The DSM-IV distinguishes between three separate subtypes of ADHD: predominantly hyperactive type, predominantly inattentive type, and combined type; which features aspects of both inattention and hyperactivity. In order for diagnostic criteria to be met symptoms must have persisted for over six months, have begun before the age of seven and have resulted in significant functional impairment in more than one setting, that isn't better accounted for by differential diagnosis (Barkley, Fisher, Newby, & Breen, 1988; American Psychiatric Association, 1994).

This review will endeavour to provide a broad overview of what is currently known about the development, aetiology, and maintenance of ADHD in childhood before going on to examine intervention for ADHD in greater detail. The relative benefits of medication management and psychosocial intervention will be examined, and a number of parent training (PT) interventions that have been evaluated for use with ADHD will be reviewed.

Prevalence

ADHD is a relatively common developmental disorder with an estimated prevalence rate in the general population ranging from 2% to 5% of school-aged children, and up to 2% of preschool children, meeting the criteria for diagnosis (McArdle, O'Brien & Kolvin, 1995; Scahill et al., 1999). Traditionally, ADHD has been more readily

identified in males than in females, with estimates of a male to female ratio of four to one (Gaub & Carlson, 1997), although females are now increasingly being diagnosed (Rappley, 2005). However, caution should be used in extrapolating from these figures as prevalence rates reported in the literature tend to show some variance dependant on the population studied, the assessment protocol applied and the diagnostic criteria utilised (Guevara & Stein, 2001).

Developmental Trajectory

Although traditionally conceptualised as a condition primarily effecting young children (Sonuga-Barke, Daley, Thompson, & Swanson, 2003), evidence now suggests that ADHD may have a more chronic course persisting through adolescence into adulthood (Barkeley, 1998; Stevenson, Stevenson & Whitmont, 2003). Children with ADHD have a higher risk of significant social and academic impairment (Biederman et al., 1996; Merrell & Tymms, 2001), engage in more socially aggressive behaviours, (Shelton, Barkeley, & Crosswait, 1998) and experience higher degrees of parental conflict, peer rejection and risk of future psychopathology (Pierce, Ewing, & Campbell, 1999). Barkley (1998) found that ADHD related difficulties were the main reason for referral of school-aged children to mental health services for assessment and intervention.

Comorbidity

Children with ADHD are more likely to be diagnosed with a coexisting psychiatric disorder than those without (August, Realmuto, MacDonald, Nugent, & Crosby, 1996). Studies looking at differences between community samples of ADHD and non-ADHD control children found a higher incidence of oppositional defiant disorder

(ODD), conduct disorders (CD) and affective problems in children who had received a diagnosis of ADHD (Biederman et al., 1992; Scahill et al., 1999). This is a worrying trend as the co-occurrence of ADHD and ODD has been found to be predictive of the persistence of both disorders into middle childhood (DuPaul, McGoey, Eckert & VanBrackle, 2001). Jensen, Martin and Cantwell (1997) estimated rates of co-morbidity for children diagnosed with ADHD to be 25-50% for ODD or CD, 25% for anxiety, 20% for affective disorders, and they postulated that specific developmental disorders may be present in 20% of cases.

Long-Term Prognosis

Elia, Ambrosini and Rapopart (1999) undertook a systematic review of prospective studies that looked at an ADHD diagnosed cohort from school-age to adolescence and found that between 22-71% still met the diagnostic criteria for ADHD or continued to exhibit significant symptoms. This is broadly reflective of the wide ranging estimates found by other researchers of 4% to 75% of children continuing to meet diagnostic criteria into adulthood (Biederman, Mick & Faraone, 2000; Wilens, Biederman, & Spencer, 2002). Although again, the degree in variation between these estimates may be attributable to methodological factors such as the system of classification used, the method of measurement employed and the follow-up period, from childhood to adulthood, utilised by each study (Barkley, Fischer, Smallish, & Fletcher, 2002).

Substance abuse, criminality and conduct disorders are higher amongst this group in late adolescence and adulthood than their non-ADHD peers (Mannuzza, Klein, Bessler, Malloy, & LaPadula, 1993; Weiss, Hechtman, Milroy, & Perlman, 1985), with even poorer outcomes found for those diagnosed with co-morbid CD/ODD in

childhood (Biederman et al., 1996; Barkley, Fischer, Edelbrock, & Smallish, 1991). Additionally, parental psychopathology, marital discord, negative parent-child interaction (Barkeley et al., 1991), and low socioeconomic status (SES) (Biederman et al., 1996), appear to be correlated with the relative persistence of ADHD when identified as co-morbid with CD/ODD.

Socio-environmental Factors

Biological, environmental, family and social system factors have all been implicated in the development and maintenance of ADHD. Pre-natal factors associated with the development of ADHD include premature delivery, and maternal cigarette, drug and alcohol abuse (Botting, Powls, Cooke, & Marlow, 1997; Hartsough & Lambert, 1985; Milberger, Biederman, Faraone, Chen, & Jones, 1996). Evidence for an association between psychosocial factors and ADHD in early childhood include; parenting style, coercive parent-child interactions, maternal mental health, parental substance abuse, chaotic family environments, social deprivation/low SES and externalising behaviour problems (Campbell, 1995; Podolski & Nigg, 2001; Taylor, 1994). However, Kessler et al. (2005) reported that the only significant predictors of the persistence of the disorder into adulthood were the severity of childhood ADHD and efficacy of treatment, and that controlling for these factors negated the predictive value of other factors such as co-morbidity and SES (Clarke, Heussler, & Kohn, 2005).

Aetiology

The precise aetiology of ADHD is not currently known (Durson, 2003), and there is as yet no proven medical tests that can be specifically used to diagnose ADHD e.g. neurophysiological or neurochemical indicators (Tannock, 1998). However, the

theoretical knowledge base has gained pace in recent years partly in tandem with developments in medical technologies such as neuro-imaging techniques (Voeller, 2004). The current theoretical consensus postulates that the development and maintenance of ADHD is dependant upon an interaction between environmental and genetic factors (Larsson, Larsson, & Lichtenstein, 2004).

Genetics

ADHD is considered to be highly heritable, (Todd et al., 2001), with estimates of up to 84% of adults with ADHD subsequently parenting at least one child warranting the same diagnosis (Faraone, Biederman, Mennin, Gershon, & Tsuang, 1996). A genetic predisposition for hyperactivity has been muted as a factor in the development of ADHD (Biederman et al. 1992). Gjone, Stephenson and Sundet (1996) reported on twin and familial studies that provide strong evidence for the influence of genetic factors on attention and activity levels, with estimates of heritability ranging from 60%-90% (Waldman & Gizer, 2006).

However, when evaluating the contribution genetic factors can play in the development of ADHD it is also important to consider the way in which genetic predisposition is expressed, and to account for the relative influence of environmental factors (Hinshaw, 1994). Sonuga-Barke, Thompson, Abikoff, Klein, & Brotman (2006) posited that ADHD resulted from the interaction between a genetic predisposition towards poor impulse control and affect regulation, and the social environment. Therefore children with an identified genetic predisposition towards ADHD may not develop the disorder unless this necessary gene x environmental interaction occurred. This concept is analogous to the way in which, despite being a

highly heritable trait, as a nation our average height has steadily increased over the past few centuries due to the mediatory influence of an improved lifestyle, and in this respect genetics may play a contributory rather than determinant role in the development of the disorder (Rutter, 2007).

Neurochemical Theories

Biologically driven theories postulate that ADHD symptoms result from the dysregulation of neurotransmitter systems concerning dopamine, adrenalin/ noradrenaline and serotonin (McCracken, 1991; Waldman & Gizer, 2006). These systems have been successfully targeted by psycho-stimulant medication, resulting in positive effects on observable behaviour, which in turn added further weight to the argument for a biological underpinning to ADHD (Taylor, 1994; Taylor, 1999). Frank, Santamaria, O'Reilly and Willcult (2006) found that adults with ADHD were more susceptible to the influence of distractor stimuli, were less sensitive to working memory contextual information, and were impaired in positive reinforcement learning. However, these deficits were reversed by the administration of stimulant medication, and they presented this to be evidence of the role of dopamine function in ADHD.

When considering the impact that ADHD can have on myriad areas of functioning, and the poor long-term prognosis, it is evident that the evaluation and development of timely, efficacious, interventions is sorely needed. Such interventions should attempt to sufficiently account for the child's cognitive, emotional and environmental needs and be targeted at the identified multiple areas of dysfunction, whilst minimising the potential for negative side effects (Chronis, Jones, & Raggi, 2006).

Intervention

Stimulant Medication

Substantial research attention has been administered towards studying pharmacological approaches to intervention in ADHD (Swanson, McBurnett, & Wigal, 1993; Vitiello, 2001), and medication is widely offered as a first-line treatment with an estimated 85% of school-aged children diagnosed with ADHD receiving psycho-stimulants (Olfson, Gameroff, Marcus, & Jensen, 2003). The main psycho-stimulant medications prescribed in the UK are methylphenidate (MPH), licensed for use in children six years and over, and dexamphetamine (DEX) licensed for use in children aged three years upwards.

Short-term studies of the efficacy psycho-stimulants versus placebo controls for reducing the core symptoms of ADHD in school-aged children have found effect sizes of between 0.8 and 1 for medication. Stimulant medication has also been found to improve the core symptoms of attention, impulsivity and behaviour in preschoolers (Elia, Borcherding, Rapoport, & Keysor, 1991; Spencer et al., 1996; Musten, Firestone, Pitserman, Bennett, & Mercer, 1997).

However, limitations identified with studies in this area include a lack of long-term monitoring of effects, relatively small sample sizes and a restricted range of outcome measures for both efficacy and safety (Vitiello, 2001). A number of concerns have also been raised in response to psycho-stimulant use, ranging from the ethical implications implicit in using medication to modify children's behaviour (Perring, 1997) to the potential for negative side-effects (Musten et al., 1997; Pelham, 1999), especially in preschoolers (Firestone, Musten, Pisterman, Mercer, & Bennett, 1998).

In an attempt to examine the efficacy of medication for use in preschool children with ADHD, Kollins et al. (2006) undertook a rigorously controlled large-scale multi-site study comprising several phases (PATS; The Preschool ADHD Treatment Study). Kollins et al. (2006) reported that ADHD symptoms were reduced in the short term by administration of methylphenidate; the effect sizes for medication in this trial were 0.54 as reported by parents and 0.66 for teachers. However, of those families initially screened, 12% of parents refused to allow their child to participate in the medication trial, and 11% subsequently dropped out due to medication side effects, including appetite suppression and emotional difficulties (Wigal et al., 2006).

Ghurman et al. (2001) reported that preschool children seem to be at increased risk of developing short-term side effects from stimulant medication and the potential for negative long-term effects, on children's physical and neurological development, has not been fully examined (Sonuga-Barke et al., 2003; Smith, Waschbush, Willoghby, & Evans, 2000; Swanson, McBurnett, Christian, & Wigal, 1995). Identified side effects of medication can include sleep disturbance, appetite suppression, dizziness, and occasionally increased likelihood of affective difficulties such as anxiety and irritability (Barkley, McMurray, Edelbrock, & Robbins, 1990; DuPaul, Barkley, & Connor, 1998). In addition to this up to a third of children medicated with stimulants show no positive response (DuPaul et al., 1998), and on a typical stimulant medication regimen continuous dosing is not advocated, meaning that effects tend to wear off by the evening (Garland, 1998).

Although the short-term efficacy of medication has been established in relation to core symptom reduction, it fails to address all the areas of identified need. Intervention at an environmental level is required to effectively alter the developmental trajectory of ADHD (Sonuga-Barke, Auerbach, Campbell, Daley, & Thompson, 2005). For this reason it is may be necessary to consider a multimodal approach to intervention in ADHD, whereby both environmental and biological factors are addressed.

Combined Intervention

In their multi-modal treatment study of ADHD, Jensen et al. (1999) compared the efficacy of medication management alone against three other treatment groups; psychosocial intervention, a combined medication and psychosocial intervention, and routine community care in a sample of 579 children diagnosed with ADHD, aged 7-9.9 years. In the medication management group 85% of the children were prescribed stimulant medication, with anti-depressant medication additionally administered in some cases. Results revealed that medical management alone appeared to be more effective in reducing the core symptoms of ADHD, as compared with psychosocial intervention in isolation or routine community care, with 38% of the children who received medication achieving scores within the normal range one year post-intervention.

Jensen et al. (1999) failed to find any significant difference in the improvement of ADHD core symptoms as a result of combining a psychosocial element with medication. However, in this combined condition an equivalent improvement, to that found for medication management alone, was achieved with lower dosages of

medication. This is an important finding as the negative side-effects of psycho-stimulant medication appear to be positively correlated with dosage (Elia et al., 1991; Greenhill et al., 1996), meaning that combined treatments may offer an avenue for reducing the potential of such side-effects.

The findings of the MTA study influenced the National Institute of Clinical Excellence (NICE, 2000) report on ADHD interventions wherein medical management was recommended as the frontline intervention of choice, followed by psychosocial interventions. However, this study has also come in for criticism for a number of reasons including the fact the treatment offered in the medication management condition was individually tailored to each of the children involved, with doses individually titrated and monitored via blood tests, whereas no such bespoke psychosocial intervention was offered (Pelham, 1999; Swanson et al., 2002). In addition to this the psychosocial element of the treatment programme was not clinically replicable as it contained a number of disparate elements including: summer camps, additional classroom help, individual sessions for each child, teacher support, parental individual and group sessions, and psychological advice with no singular theoretical origin (Morell & Murray, 2003). Although the gains found in the MTA study were maintained up to fourteen months post-intervention, the longer-term picture on the efficacy of stimulant medication remains unclear partly due to a lack of longitudinal research and methodological irregularities between studies (Ingram, Hechtman, & Morgenstern, 1999).

It is also worth noting that the improvements found by the MTA study tended to focus on the reduction of core symptoms in isolation and tended not to address the

psychosocial issues found to be related to ADHD, such as family functioning and parental mental health needs (Chronis, Pelham, Gnagy, Roberts, & Aronoff, 2003). In a subsequent analysis of the MTA study data, Swanson et al. (2002) found large effect sizes for psychosocial intervention when subgroups were examined separately. Further analysis using different outcome measures to assess ADHD symptoms indicated that combined medication and psychosocial intervention showed more efficacious long-term improvements (Green & Ablon, 2001) and additional positive outcomes were found for the combined treatment in terms of improvements in child social skills, parent-child relations and parenting behaviours (Hinshaw et al., 2000). Parents also expressed higher satisfaction with the treatment condition that included a behavioural component (Pelham, Fabiano, Gnagy, Greiner, & Hoza, 2004).

Children with ADHD experience chronic impairment in functioning across multiple domains, therefore a multi-modal approach to treatment may be required to address this (Chronis et al., 2006). As research has shown that ADHD often occurs within systems that are not functioning correctly (Campbell, 1995; Podolski & Nigg, 2001), treating the child in isolation offers little help or support to the rest of the system. Medication is limited at best in its application for the heterogeneous psychosocial and environmental factors associated in the development and maintenance of ADHD, such as peer relationships, family functioning and parental management styles (Offord et al., 1992). This review will now focus on alternative ways of intervening with ADHD and the theoretical, clinical and research evidence that underpins these approaches.

Neuropsychological Explanations

ADHD is a clinically heterogeneous condition and it is likely that its aetiology is determined by more than one developmental pathway. In an effort to account for this, two predominant theoretical models have been developed. One account postulates that ADHD is mediated by executive dysfunction, based on deficient inhibitory control (Barkley, 1997), whilst the other model implicates disturbances in motivational processes based on delay aversion in the development of ADHD (Sonuga-Barke, Williams, Hall, & Saxton, 1996).

The former pathway relates to how deficits in inhibitory control mechanisms can lead to executive dysfunction thus resulting in impaired ability to reason, plan, execute and control actions (Barkley, 1997). Executive functioning has been implicated in working memory, aspects of attention and the ability to accurately monitor and self-regulate behaviour which have also been found to be deficient in children with ADHD (Mariani & Barkley, 1997; Biederman et al., 1993). This model has received empirical support from a number of studies that have shown executive functioning deficits in children with ADHD relative to controls (Houghton et al., 1999; Sonuga-Barke et al., 2003). The second model postulates a delay aversion hypothesis related to motivational processes that constitute a functional response to environmental demands on the part of the child (Sonuga-Barke et al., 1996; Sagvolden, Aase, Zeiner, & Berger, 1998; Sonuga-Barke, Houlberg, & Hall, 1994). When environmental control is possible this can result in impulsive behaviour designed to minimise any delay e.g. not waiting their turn during a board game. When the child is unable to manipulate their environment in such way, or when prevented from carrying out such actions due to situational or parental constraints, then this may result in inattentive or

hyperactive behaviours that serve a similar function. More recently the dual pathway model proposed by Sonuga-Barke (2002) took an inclusive stance that posited that the development of ADHD may in fact be underpinned by both theoretical explanations: independently functioning as coexisting pathways, and represent the two distinct subtypes of the disorder.

Parenting and ADHD

Recent research has demonstrated a link between parenting practices and the development of the neuropsychological deficits found in ADHD (Johnson & Mash, 2001). Inconsistent parenting in terms of setting consequences for maladaptive behaviours have been found to result in the non-development of response inhibition in the child (Bor, Sanders & Markie-Dadds, 2002). Aase and Sagvolden (2006) found that children with ADHD exhibited deficits in sustained attention when environmental reinforcers were infrequent, and such children also showed a preference for tangible reinforcers. Aase and Sagvolden (2006) posit that clear environmental contingencies are needed to deal with these altered reinforcement mechanisms, and that frequent reinforcers of this nature can have an effect on child behaviour analogous to that of low dose medication, as they also result in dopamine release. Support comes from Pelham et al. (2000) who found no observable differences in behaviour between medicated and non-medicated children with ADHD when the environment was structured to provide predictable consequences for misbehaviour, and clear guidelines for acceptable behaviour, with tangible, timely, and frequent reinforcers. These findings directly implicate the role of parenting practices in the development of adaptive of maladaptive attentional processes in the child (Johnson & Mash, 2001).

A direct relationship between parenting practices and child behaviour has been found (Patterson, 1982), and it has been shown that early parenting difficulties in accommodating to the child's needs can lead to long-term difficulties in the child's ability to actively listen, attend and negotiate their needs (Chronis et al., 2006). Children with ADHD can be difficult to parent; eliciting negative parenting practises that form a self-perpetuating negative cycle of coercive interactions between child and parent (Barkley, Guevremont, Anastopoulos, & Fletcher. 1992; Patterson, 1982). Encouragingly research suggests that this situation is not irreversible. Parents can continue to exert positive influence in this area through interactions attenuated to the needs of the child with clear, consistent limit setting by all care givers, the modelling of pro-social behaviour, and the effective use of praise for acceptable behaviour in order to scaffold attention and develop delay tolerance in the child (Daley & Thompson, in press).

Interventions designed to aid parents in developing and utilising such parenting skills have been found to be efficacious in the treatment of ADHD (Sonuga-Barke, Daley, Thompson, Laver-Bradbury, & Weeks, 2001; Bor et al., 2002). In view of the high co-morbidity of this disorder, and the fact that behavioural difficulties not only occur in the home but can also extend into the community, then the provision of effective psychosocial management strategies has intrinsic appeal.

Psychosocial Interventions

King and Ollendick (2006) presented a framework comprising six key areas by which the efficacy of psychosocial interventions could be evaluated: (1) clear theoretical rationale, (2) clear identification of the problem and of the targeted client group, (3)

include salient program features such as realistic goal setting, flexibility, and time limited interventions, (4) manual-based treatments, (5) research support for its efficacy including clinically significant outcomes, and (6) they should be acceptable to both clients and society at large. The remainder of this review will attempt to examine parent training approaches to psychosocial intervention with ADHD, whilst remaining mindful of these key areas of evaluation.

The majority of currently validated psychosocial treatment programmes for ADHD have been based upon behaviour management principles and have been directed at school-aged children, although an emerging number of studies are now looking at these programmes with preschoolers (Sonuga-Barke et al., 2001). Psychosocial approaches targeted at ADHD have also been shown to be effective with co-morbid difficulties such as oppositional and defiant behaviours (Sonuga-Barke et al., 2003).

Parent Training (PT)

Negative long-term outcomes have been found for children with behavioural problems, exposed to ineffectual parenting (Chamberlain & Patterson, 1995). PT programmes have traditionally been designed to target established risk factors for disruptive/anti-social behaviours and have consistently been shown to be the most efficacious psychosocial intervention within this area (Kazdin, 1987; Webster-Stratton & Hammond, 1990). Parents are assisted in developing effective parenting practices with the shared aim of improving outcomes for their child and in enhancing the quality of the parent-child relationship (Pelham, Wheeler, & Chronis, 1998). Such programmes centre on the premise that effective parenting practices are not innate behaviours but rather acquirable skills that can be learnt and practiced. Antecedent

patterns of maladaptive child behaviours are identified and addressed through the use of behavioural consequences such as time out, and parents are equipped with techniques to aid positive reciprocal communication thus promoting emotional literacy in the child (Patterson, Reid, Jones, & Conger, 1975). In general such programmes, when specifically targeted at ADHD populations, aim to enhance parental understanding of ADHD, in addition to providing the skills necessary to deal with associated behavioural difficulties.

Structured PT programmes are the most researched form of psychological intervention in child and adolescent mental health (Pelham et al., 1998). Based on well established models of parent-child interaction, PT programmes originated in North America in the 1960's and built upon behavioural learning theory, (Wahler, Winkel, Peterson & Morrison, 1965; Patterson, 1969), and play therapy, (Hanf, 1969). The influence of which can be seen in many of the current parent training programmes despite their continued evolution over the subsequent years (e.g. Webster-Stratton, 1981, 1984).

Originally clinic-based and individually delivered to families by a qualified therapist, PT has undergone significant changes in format and mode of delivery over the past few decades (see Chronis, Chacko, Fabiano, Wymbs, & Pelham, 2004). Such programmes have been implemented in a number of different formats and can be delivered to both groups or on an individual basis, by a therapist or suitably trained clinician. More recently emerging PT approaches include the use of self-directed interventions, with minimal therapist involvement, and the utilisation of varying

media (Markie-Dadds & Sanders, 2006; Sanders, Montgomery, & Brechman-Toussaint, 2000a).

Regardless of the mode of delivery, PT should include information on the importance of consistently delivered, tangible consequences for inappropriate behaviour, and rewards for positive behaviours, so that the child can appreciate the link between the behaviour and the subsequent consequence (Chronis et al., 2006). Techniques employed that are common to most PT approaches include modelling, psycho-education, role-play, and the transfer of learnt skills to home via practice. Parents are instructed on how to develop positive relationships with their children, whilst managing problem behaviours, through techniques such as the development of mutually rewarding play skills and the appropriate use of reward and consequences. An intrinsic goal of PT is to ensure maintenance of gains through parental adoption of the techniques introduced (Pelham et al., 1998).

The use of manual-based PT has been fairly extensively evaluated over the past three decades with children exhibiting behavioural difficulties such as conduct disorder (CD) ranging in age from pre-schoolers to adolescents, with fairly consistent results in the successful reduction of non-compliant or oppositional behaviours (Patterson et al., 1975; Webster-Stratton & Hammond, 1990; Forehand & McMahon, 1981). Evidence has been found not only for short-term improvements in child behaviour but also in parenting practices, and in parental perceptions of child adjustment (Webster-Stratton, Kolpacoff & Hollingsworth, 1989; Webster-Stratton, 1984, 1981; McMahon & Forehand, 1984), additionally improvements in child behaviour have been found to be successfully generalised to the home and other settings (Patterson, 1982; Sanders &

Plant, 1989). PT attendance has also been demonstrated to correlate with a decrease in the risk of continued neglect and/or physical abuse (Wekerle & Wolf, 1993). When examined, such programmes tend to have high consumer satisfaction (Webster-Stratton, 1989; McMahon & Forehand, 1984), and the inclusion of a PT component to existing treatment packages has also resulted in higher reported rates of acceptability from parents (Anastopoulos, Shelton, DuPaul, & Guevremont, 1993) and increased parental well-being (Pelham et al., 1998).

A substantial evidence base for the efficacy of PT with children exhibiting behaviour disorders with co-occurring ADHD exist. In an extensive review of non-pharmacological interventions for ADHD, PT was found to have positive outcomes (Pelham et al., 1998). Chronis et al. (2004) comprehensively evaluated a number of studies that were heterogeneous in design, and that utilised a variety of manual-based PT approaches with children ranging in age from pre-school to adolescent. They discovered that PT resulted in positive gains in both parent and child behaviours (average effect size found was .87), and also in subjective reports of parent-child interactions. However they also highlighted the fact that knowledge about the possible moderators and mediators of success in PT with children with ADHD was currently limited.

ADHD has high co-morbidity with other disorders therefore it is not entirely suprising that interventions targeted primarily at CD/ODD have also been found to be of benefit in reducing problematic child behaviours in children with ADHD (August et al., 1996). However, Chronis and colleagues (2004) reported that although there was a number of studies that had demonstrated the efficacy of PT with children with

ODD/CD and co-occurring ADHD, there was a relative scarcity of studies that examined children primarily diagnosed with ADHD, and the high rate of co-morbidity meant that it was difficult to separate the individual effects on these disorders in the published literature. This potentially makes extrapolation of results problematic, as it has been proposed that ADHD and ODD as isolated disorders may be qualitatively distinct from the comorbid subgroup (Hinshaw, 1994). Therefore further research is needed to partial out the intervention elements that may be responsible for treatment effects specific to the separate disorders.

This review will now focus on some of the predominant manual-based PT approaches of recent years, their utility in addressing the difficulties presented by ADHD and the outcome of evaluations with this population.

Community Parent Education Programme (COPE; Cunningham, Bremner & Secord, 1997)

Cunningham et al. (1995) conducted a time-limited community based PT programme primarily focussed upon oppositional/defiant behaviours with 'at risk' children. They compared a 12-week individual clinic based PT (C/I), and a 12-week community-based large group PT (C/G) against a waiting list control (WLC). The intention was to examine the efficacy of PT groups when placed within the local community as opposed to being based within a clinic setting. This was done in an attempt to make PT more accessible, economically efficacious and socially acceptable. A collaborative, solution focussed approach was facilitated within the groups using video based examples of child management errors (Cunningham et al., 1997).

Questionnaire and observational measures were used to examine a number of areas including parental depression and sense of competence, child behaviour and parent-child interactions. Post-intervention reductions in child behaviour problems were found and treatment gains were maintained more favourably for the C/G condition than those found for families in either the I/C or WLC groups. Additionally the community-based programme resulted in enhanced adherence and participation in the intervention; which the authors attributed to a reduction in the practical and psychological barriers to seeking help. This approach has been used clinically with children with identified attention/hyperactivity difficulties and co-ocurring disruptive behaviours (Pelham et al., 2004) however no formal systemic evaluation specifically with an ADHD population has been undertaken to date (Chronis et al., 2004).

The Incredible Years programme (IY; Webster-Stratton & Hancock, 1998)

The Incredible Years (IY) programmes developed by Webster-Stratton and colleagues, have been adapted and expanded over time to include programmes directly targeted at both children and teachers, in addition to those aimed at parents. IY PT programmes have been subjected to over a decade of research evaluation in relation to children exhibiting disruptive behaviour, many of whom also possessed co-morbid ADHD symptoms, with promising results (Webster-Stratton & Hammond, 1997). The IY program focuses on the development of practices and skills that promote emotional development in children, and address the muted link between coercive parenting and emotional dysregulation in the child, and this is of particular value in addressing the difficulties found in ADHD (Morrell & Murray, 2003).

The BASIC IY PT programme aims to increase social competence and reduce problem behaviour in children through the introduction of effective parenting skills. Usually run over the course of twelve weekly group based session, lasting up to 120 minutes each, strategies are introduced for managing unwanted behaviours without resorting to physical punishment. Techniques utilised include effective ways of using praise and incentives, limit setting and the withdrawal of parental attention when faced with unwanted behaviours. Spaccarelli, Cotler and Penman (1992) suggested that some families do not respond well to parent training when it is provided in isolation, and require other problems to be addressed in tandem. Webster-Stratton (1991) attempted to address this area by expanding upon the BASIC PT programme to create the ADVANCE programme, which included issues pertaining to broader family concerns over the course of an additional ten weeks. Topics covered included: anger management and problem-solving strategies, (both for the parents themselves and for them to impart to their children), marital communication and ways of coping with depression,

Webster-Stratton and Hammond (1997) looked at a series of randomised controlled trials (RCT) in their review of programme effectiveness and discovered that the BASIC programme successfully reduced childhood conduct problems and promoted positive parent-child interactions, as well as effecting positive change in parental attitudes towards their children. Treatment gains were maintained at a four-year follow up. The ADVANCE PT programme was also found to be efficacious in reducing maternal depression, developing parental communication and problem-solving skills, and improving the social skills of the children involved (Webster-Stratton, 1994). The evidence for long-term maintenance of these gains is fairly

limited but there is some research that suggests that gains have been maintained up to fourteen years post-intervention (Webster-Stratton, 1996; Long, Forehand, Wierson, & Morgan, 1994).

The IY programs have not yet been evaluated with a population with a primary diagnosis of ADHD, but a recent study (Jones, Daley, Hutchings, Bywater, & Eames, in press) examined the efficacy of the IY BASIC PT versus Waiting list control (WLC), in a community-based population of pre-school children, deemed to be at risk of developing both ADHD and conduct problems, with promising results. Post-intervention measures revealed decreased levels of inattention and improvements in hyperactive/impulsive difficulties for those children in the PT condition. Additionally clinically significant changes were found for 52% for those in the PT condition, as compared to 21% of those in the WL condition.

Triple P (TP; Sanders, 1999)

The Triple P positive parenting program is a time-limited PT intervention, originally developed to the target behavioural difficulties found in children up to the age of twelve. TP has been successfully evaluated with children with conduct disorders and/or oppositional behaviours with efficacious reductions in problematic child behaviour, dysfunctional parenting practices, and increased parental competence (Connell, Sanders & Markie-Dadds, 1997; Sanders, Markie-Dadds, Tully, & Bor, 2000). It has recently been examined in relation to its potential efficacy in intervening with children with attention/hyperactivity difficulties and with children having received a clinical diagnosis of ADHD (Bor et al., 2002). TP has been developed into two versions; standard (SFBI) and enhanced (EBFI) behavioural family interventions.

SFBI involves ten one-to-one sessions with parents focussing upon seventeen core child management strategies, thought to promote children's development and competence, and on developing parental problem solving skills. Emphasis is placed upon not only the acquisition, but also on the maintenance and generalisability of these skills and parents are encouraged to set and monitor their own goals through a six step planned activities routine. EBFI included sessions on coping skills (CST) and partner support training (PST), which were targeted at the identified family-risk factors of parental adjustment and marital conflict.

Bor and colleagues (2002) compared SFBI and EFBI behavioural against a waiting list control (WLC) for pre-school children with co-occurring attention/hyperactivity difficulties and behavioural problems, drawn from a community sample of disadvantaged families. Self-report measures, a semi-structured interview and a home-based observation were conducted pre-, and post-intervention, and also at one year follow-up. Results indicated that lower levels of behavioural problems and increased parental competence resulted from both versions of TP as compared to WLC at post-intervention. These gains were also maintained at one-year post-intervention, with a reported 80% of children exhibited a clinically significant improvement in observable child behaviour at follow-up. However, no advantage was found for EBFI over SBFI.

In addition to this Hoath and Sanders (2002) conducted a RCT of an ADHD specific version of the TP (Enhanced Group Triple P; EGTP) as compared to WL with a population of children aged 5-9, with clinically diagnosed ADHD. In addition to the standard TP parent group resources, parents in the EGTP condition were provided

with an information leaflet on ADHD (Sanders & Hoath, 2001). Parents attended five group sessions and were consulted on four occasions by telephone. ADHD specific modifications to the standard TP program included: psycho-education on ADHD, with an additional emphasis placed on the impulsivity, limited attention and concentration problems found in children with ADHD, and the need for predictability and consistency in the application of parenting strategies. The final fifth group session was devoted to coping skills and partner support. Outcome measures included parental reports of child behaviour, parenting practices and family functioning, and additional teacher rated reports of child behaviour in the classroom. Hoath and Sanders (2002) found that compared to WL, EGTP resulted in a reduction in the intensity of problematic child behaviours and maladaptive parenting strategies, and increased reports of self-efficacy for the parents. These findings were also maintained at three months post-intervention.

These findings suggest that TP interventions have some utility in promoting positive parenting practices and in reducing the problematic child behaviours found in ADHD, although further research into the specificity of these programmes in their application with ADHD is required.

New Forest Parent Training (NFPT; Weeks, Laver-Bradbury, & Thompson, 1999)

The New Forest Parent Training package (NFPT) is a specialist psychosocial intervention for childhood ADHD that combines parent management training with an additional component targeted at fostering the positive reciprocal parent-child interactions, flagged up as playing a possible mediatory role in the development of attention and impulse control (Johnson & Mash, 2001). The NFPT programme

attempts to encourage the parent to take on the task of being the child's trainer in guiding them to become less aversive to delay and in scaffolding their attentional abilities (Dalen, Sonuga-Barke, Hall & Remington, 2004). It consists of four main components: psycho-education, focus on parent-child relationships (positive parenting, praise, play, and an emphasis on language in its ability to foster self-regulation), behaviour management training, and attention training.

Sonuga-Barke and colleagues (2001) examined the efficacy of NFPT with pre-school children exhibiting ADHD symptoms who were randomly allocated to either parent training (PT), parent counselling and support (PC&S) or a waiting list control group (WL). The PT element involved eight one hour weekly sessions within a tier-two specialist service with the aim of providing a repertoire of behavioural strategies to decrease negative child behaviours, and increase attention. PC&S involved supporting the parents but with no specific advice offered. Sonuga-Barke et al. (2001) analysed outcomes for both children and their mothers, the results of which indicated that in comparison to PC&S and WL, PT not only reduced ADHD symptoms but also increased the mothers' sense of well being. Additionally, the reduction in maternally reported ADHD symptoms was maintained at 15 weeks post-intervention. Most promisingly, treatment effect sizes comparable to those found in trials of stimulant medication with older children with ADHD (.87) were found, and clinically significant change was achieved in 53% of the PT group. Therefore, although further research evaluation is needed to confirm the maintenance of effects in the longer-term and to replicate intervention effects, NFPT appears to be efficacious in reducing both the core symptoms of ADHD and in improving maternal mental health.

Behavior Management Flow Chart (BMFC; Danforth, 1998b)

The Behaviour Management Flow Chart (BMFC) is a PT programme aimed at intervening with childhood non-compliance and disruptive behaviours, but it has also been evaluated in both individual and group based formats with clinical ADHD populations. BMFC programme content that is specific to ADHD includes psycho-education on the nature and aetiology of ADHD, (based upon Barkley, 1997), with particular focus on typical child-parent interactions in ADHD and the role of coercive processes in maintaining problematic child behaviour (Danforth, Barkley, & Stokes, 1991; Patterson, 1982).

Danforth (1998; 1999; 2001a) reported on an initial series of small sample studies (total n=13) using BMFC on an individual basis with the families of thirteen children in total with comorbid ODD and ADHD. Results indicated that intervention resulted in a reduction in oppositional/aggressive behaviour, and improvements in parenting practices and parental mental health, however it is difficult to generalise these results due to the small sample sizes used. In an attempt to rectify this limitation Danforth, Harvey, Ulaszek, and Eberhard McKee (2006) examined the efficacy of the BMFC in a group format with 45 children presenting with ADHD and defiant, aggressive behaviours. Each group lasted up to 90 minutes in length, with up to ten families in each group, over the course of eight weeks. Pre-, and post-intervention questionnaire measures, assessing parental report of child behaviour, parenting behaviour and stress, were administered. Telephone based interviews of parental reports of child behaviour were also conducted and an audiotape recording of parent-child interactions was used to monitor utilisation of parenting strategies. A reduction in problematic child behaviour, including hyperactive and defiant behaviours, with positive gains in

parental reports of stress and effective parenting behaviours were found in the short-term. Therefore this intervention may have utility in mediating parental mental health and in improving child behaviour, including the core symptoms of ADHD, however there continues to be a lack of long-term evaluation of the BMFC, which makes extrapolation of these results problematic.

Moderators of PT Efficacy

Much of the investigation into the moderators of PT have been conducted with programmes targeted primarily at children with behavioural difficulties, however many of these factors still apply to PT used with an ADHD population (Chronis et al., 2004).

Parental Psychopathology

A review of the current literature by Chronis et al. (2006) found that the main factor preventing optimal response to PT in children with behavioural difficulties (ODD and CD) was parental psychopathology, especially maternal depression (see Chronis et al., 2003; Webster-Stratton, 1992a). Parenting a child with behavioural difficulties has been demonstrated to exert considerable demands on parents and can lead to increased stress (Chronis et al., 2003). Additionally, as maternal depression has been highlighted as a risk factor for the development of conduct problems in children with ADHD (Chronis et al., 2006), it is highly likely that a number of parents entering such interventions will have, or will have experienced, mental health difficulties. This may mean that these parents have limited resources in terms of the time, energy and mental effort required to engage in PT, and this is an important area in which to direct both future research and clinical input.

Maternal ADHD

Sonuga-Barke, Daley, and Thompson (2002) found that poorer outcomes for parent training were associated with maternal ADHD symptoms. A possible explanation for this may be that in order participate in PT and to implement behavioural strategies at home this requires the parents to first sufficiently engage, attend and organise themselves: exactly the abilities that require fostering in ADHD. In order to compensate for these potential deficits parents may benefit from additional support, or adjunctive elements to PT (Sonuga-Barke, Thompson, Daley, & Laver-Bradbury, 2004; Chronis et al., 2004). Conversely, mothers scoring high on ADHD symptoms expressed more positive attitudes in relation to their emotional relationships and interaction with their children with ADHD, suggesting an empathic function of having shared difficulties (Psychogiou, Daley, Thompson, Goodson, & Sonuga-Barke, in press). This may mean that there is scope for assisting these parents in managing their own symptoms to in turn aid their management and relationship with their child (Daley & Thompson, in press).

Treatment Dropout

Treatment dropout appears to be a particular problem in working with families within a PT framework. Pekarik and Stephenson (1988) found dropout rates of between 45-65% and similarly Kazdin and Wassell (2000) experienced a dropout rate of 37% in PT groups for behavioural problems. Pre-intervention child variables that appear to be predictive of subsequent dropout include poor quality peer relations, a higher degree of antisocial behaviours and lower IQ score (McMahon, Forehand, Griest, & Wells, 1981; Pelham et al., 1998). Demographic variables included families of low SES, ethnic minorities, younger mothers and single parent families (Cunningham et al.,

1995; Chronis et al., 2004). In addition to this parental experience of negative life-events, heightened perception of stress, and a maternal history of antisocial behaviour were also associated with treatment dropout (Prinz & Miller, 1994). However it is often difficult to easily isolate these factors, due to their complex inter-related nature and multi-agency assistance may be required to address these difficulties (Scott, Knapp, Henderson, & Maughan, 2001).

Parental Expectations of Treatment

When attempting to intervene psychosocially, it is important to consider parental beliefs and attitudes towards the cause of their child's behaviour and the perceived potential efficacy of any treatment offered. A challenge of engaging parents in PT is in enabling them to acknowledge and accept responsibility for the management of their child's difficulties (Daley & Thompson, in Press). Johnson and Freeman (1997) found that parents tend to attribute the behaviours of children with ADHD to internal stable factors that are not easily amenable to change, and this may also be related to ineffective parenting strategies (Chronis et al., 2006). An adjunctive psycho-educative component on the nature of ADHD may be useful in addressing this.

Parental cognitions around expectations of treatment are important to consider in terms of treatment compliance and dropout, as it has been demonstrated that these factors may have a more influential effect than other stressors, including parental psychopathology, on the likelihood that treatment is adhered to (Nock & Kazdin, 2001).

Conclusions

ADHD in childhood is associated with myriad impairments in social, educational and functional domains (Bierderman et al., 1996; Merrell & Tymms, 2001). Prospective studies suggest that its course is chronic, persisting into adulthood and associated with an increased risk of subsequent anti-social behaviour and substance abuse (Stevenson et al., 2003; Pierce et al., 1999; Mannuzza et al., 1993). Sonuga-Barke et al. (2006) posited that ADHD resulted from the interaction between the social environment and a genetic predisposition towards poor impulse control and affect regulation. This suggests that there is more than one avenue for intervening with this disorder.

Although medication has shown some efficacy in the short-term with school-aged children (The MTA Cooperative Group, 1999), the PATS study (Kollins et al., 2006) revealed that side-effects were exhibited by a number of the preschool children examined and that medication was not the preferred treatment of choice for a number of parents. In addition to this, results from the MTA study appear to suggest that combined psychosocial treatment and medication may offer the best compromise in terms of both outcome and minimisation of potential harm (Jensen et al., 1999; Elia et al, 1991).

Add to this the lack of long-term follow-up, little evidence of holistic improvement beyond symptom reduction and the fact that continuous dosing of stimulant medication is not recommended (Garland, 1998), and the necessity of empirically-validated bespoke psychosocial approaches, towards intervening with the specific aetiology and difficulties found in ADHD, is clear (Pelham et al., 1998). Such

approaches have begun to be evaluated and show promising outcomes in terms of improvements in child behaviours, clinically significant change and gains in parental competence (Danforth et al., 2006; Sonuga-Barke et al., 2001).

With reference to the framework proposed by King and Ollendick (2006), all of the approaches reviewed herein fulfil the criteria of being manual-based, time limited approaches, based upon clear theoretical rationale. Where they differ most is in the identification of ADHD as the primary focus of intervention. Although standard PT programmes targeted at addressing disruptive behaviours have shown efficacy with children with ADHD (Cunningham et al., 1995), a number of emerging approaches have used ADHD specific materials with promising results (Hoath & Sanders, 2002; Sonuga-Barke et al., 2001). In terms of research evaluation there is an identified lack of long-term follow-up, and head to head trials of PT programs (Daley & Thompson, in press).

The acceptability of treatment is important as adherence to, and acceptance of, the techniques presented therein involves a substantial commitment on the part of the parent that extends beyond the treatment phase (Markie-Dadds & Sanders, 2006). Chronis et al. (2006) found that, to date, no ADHD intervention study had included components addressing parental expectations of treatment, and this may be a useful focus of future clinical research. Practical considerations for parents such as outside responsibilities and childcare requirements need to be taken into consideration, i.e. the time and financial implications involved in attending clinical appointments, and the effort involved in learning new information and techniques (Daley & Thompson, in press). There is a need to balance the potential gains with a consideration of the

practicalities involved in undertaking PT, and how these can interact with the additional stressors placed upon families with a child with ADHD.

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Appendix 2.a

Notes for contributors to 'Journal of Child Psychology and Psychiatry'

The Journal of Child Psychology and Psychiatry

Published on behalf of the Association for Child and Adolescent Mental Health

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Tony Charman

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Author Guidelines

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Kiernan, C. (1981). Sign language in autistic children. *Journal of Child Psychology and Psychiatry*, *22*, 215-220.

Thompson, A. (1981). *Early experience: The new evidence*. Oxford: Pergamon Press.

Jones, C.C., & Brown, A. (1981). Disorders of perception. In K. Thompson (Ed.), *Problems in early childhood* (pp. 23-84). Oxford: Pergamon Press.

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SECTION 3

EMPIRICAL PAPER

Running Head: SELF-DIRECTED INTERVENTION FOR ADHD

Parent training for young children with hyperactivity: Efficacy of a self-directed intervention.

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Abstract

Objectives: The aim of this study was to examine the efficacy of a self-directed intervention for ADHD.

Design: A randomised controlled repeated measures design was employed.

Methods: School-aged children exhibiting symptoms of hyperactivity were randomly allocated to either a self-directed version of the New Forest Parent Training (NFPT), or to a waiting list control (WLC). Parental reports of child behaviour and parental well-being were examined.

Results: Results revealed that intervention was efficacious in reducing ADHD symptoms, particularly hyperactivity, and an improvement parental well-being was also found. 30% of those in the NFPT condition, as compared to 0% of in the WLC, exhibited clinically significant change in post-intervention scores.

Conclusions: These findings suggest that self-directed NFPT may be of benefit for use with children presenting with symptoms of ADHD.

Introduction

Attention Deficit Hyperactivity Disorder (ADHD) is one of the most common developmental disorders with an estimated prevalence ranging from 2% to 5% of school-aged children, and up to 2% of preschool children, in the general population (McArdle, O'Brien & Kolvin, 1995; Lavigne et al., 1996). Traditionally thought of as a condition primarily effecting young children (Sonuga-Barke, Daley, Thompson, & Swanson, 2003), evidence now suggests, that without effective intervention, ADHD may have a more chronic, pervasive trajectory persisting through adolescence into adulthood (Stevenson, Stevenson & Whitmont, 2003).

Research reveals that children with a diagnosis of ADHD appear to be at increased risk of significant functional impairment in a number of areas including academic achievement and social interactions (Merrell & Tymms, 2001; Campbell, 2002). Worryingly, ADHD is also associated with an increased risk of the development of future substance abuse, criminality, and psychopathology (Mannuzza, Klein, Bessler, Malloy, & LaPadula, 1993; Pierce, Ewing, & Campbell, 1999).

However, the trajectory of ADHD is not predetermined. Kessler et al. (2005) reported that the only significant predictors of the persistence of the disorder into adulthood were the severity of childhood ADHD and the efficacy of treatment. Controlling for these factors negated the predictive value of other factors such as co-morbidity and socio-economic status (Clarke, Heussler, & Kohn, 2005). Therefore, it is evident that the evaluation and development of evidence-based efficacious treatments for ADHD is an issue of priority in terms of health and social care.

As it has been posited that ADHD may result from the interaction between the social environment and a genetic predisposition towards poor impulse control and affect regulation, (Sonuga-Barke, Thompson, Abikoff, Klein, & Brotman, 2006), there may be several possible avenues for intervening with this disorder, including pharmacotherapy and psychosocial intervention.

Psychosocial interventions are designed to aid parents in developing and utilising parenting skills targeted at identified areas of dysfunction. Those specifically developed for use with an ADHD population aim to enhance parental understanding of the disorder, whilst simultaneously facilitating the skills necessary to deal with associated behavioural difficulties. Such psychosocial interventions have generally been found to be efficacious in the treatment of ADHD (Sonuga-Barke, Daley, Thompson, Laver-Bradbury, & Weeks, 2001; Bor, Sanders, & Markie-Dadds, 2002).

Once such intervention is the New Forest Parent Training package (NFPT; Weeks, Laver-Bradbury, & Thompson, 1999). This is a specialist psychosocial intervention for childhood ADHD that combines parent management training with an additional component targeted at fostering the positive reciprocal parent-child interactions, flagged up as playing a possible mediatory role in the development of attention and impulse control (Johnson & Mash, 2001). Sonuga-Barke and colleagues (2001) examined families of pre-school children exhibiting ADHD symptoms who were randomly allocated to either parent training (PT), parent counselling and support (PC&S) or a waiting list control group (WL), the results of which indicated that in comparison to both PC&S and WL, PT not only reduced ADHD symptoms but also increased the maternal well-being. Additionally, the reduction in parent reported

ADHD symptoms were maintained at 15 weeks post-intervention. In this study 53% of the PT group showed clinically significant change post-intervention and significant treatment effect sizes were found (.87), which are comparable to those typically found in trials of stimulant medication with older children with ADHD.

Despite demonstrated efficacy, traditionally delivered parent training interventions can represent a substantial service investment, both financially and in terms of resources implications, and also require a significant commitment on the part of the client (Scott, Knapp, Henderson, & Maughan, 2001). It has been revealed that low-income families, and those from rural areas, are significantly less likely to access psychosocial interventions than more affluent families living in urban areas (Hunsley, Aubry, & Lee, 1997). Identified barriers to engagement with such interventions include the associated stigma, time and expense involved in attending appointments (Elgar & McGrath 2003). When coupled with the fact that there has been a dramatic increase in the number of school-aged children being referred to mental health services for ADHD assessment and intervention (Barkley, 1998), then current service provision is unlikely to meet the future clinical need. In view of the long-term trajectory of the disorder, it is important that service provision is timely enough to prevent problems before they become exacerbated.

Self-directed media-based psychosocial interventions (SDI) show potential in circumventing traditional barriers to engagement by offering viable opportunities to provide intervention to a greater number of those families who need it, therefore increasing both accessibility and acceptability. An additional benefit to such a mode

of delivery is that it may aid families in assuming greater responsibility as agents of change (Scogin, Bynum, Stephens, & Calhoon, 1990; Elgar & McGrath, 2003).

Delivery of such interventions can range from being completely self-administered to those that require therapist involvement, and may form part of standard health care service delivery. In general, SDI's have been delivered primarily in written form (bibliotherapy), although a range of media have been used to provide information and advice to parents without the need for therapist contact e.g. manuals, videos, and audiotapes. When targeted at behavioural difficulties in childhood, such interventions aim to provide instruction in child-management skills to families, psycho-education about the disorders at hand and augmentation of social support networks (Elgar & McGrath, 2003).

The efficacy of self-directed parent training has been most extensively researched with child behaviour problems. Sanders, Markie-Dadds, Tully and Bor (2000b) reported on the efficacy of three levels of the Triple P behavioural family intervention; Standard behavioural family intervention (SFBI), Enhanced behavioural family intervention (EFBI), and self-directed intervention (SDI), as compared to waiting list control (WLC), for 305 families with children aged 36-48 months old. As expected from the results of previous studies, greater post-intervention improvements were found for the families in the EFBI and SFBI conditions as compared to WLC. However, SDI also showed significantly greater improvements than WLC. These gains were maintained at one-year post-intervention for all treatment groups, although interestingly additional improvements in child behaviour were only found in the

families who had participated in the SDI. This suggested that this mode of delivery resulted in ongoing impact for these families.

In examining SDI with school-aged children with ADHD, Long, Rickert and Ashcraft (1993) compared the efficacy of medication alone against a condition combining stimulant mediation with an adjunctive behaviourally based information booklet for parents. Parental reports suggested that significantly greater improvements in the intensity of child behaviour problems, and in parental knowledge of behavioural principles, existed for those who had received the additional information booklet, and the gains noted in child behaviour were also reflected in teacher ratings. However, no reduction was found for the frequency of child behaviour problems, and the relatively small sample size meant that definite conclusions are difficult to draw.

In a recent review Mongomery, Bjornstad and Dennis (2006) found media-based interventions were moderately effective, as compared to no treatment, for a range of child behaviour problems. They found evidence to suggest that presenting information in a media-based format increased access, and lowered cost, whilst effecting clinically significant changes in child behaviour. They concluded that if incorporated into standard service delivery, such interventions have the potential to reduce the necessity for professional involvement, thus freeing up scarce resources that could be allocated to other more complex cases, increasing the potential for a greater number of families to be seen within a shorter time frame. Despite these findings there is currently a paucity of empirical evaluation of SDI, especially with an ADHD population, and obvious advantages in increasing acceptability and accessibility, whilst reducing cost

mean that rigorous evaluation in real-life health care settings is essential (Elgar and McGrath, 2003).

The aim of this current research will be to establish the efficacy of a self-directed, manual-based version of the NFPT, for young children, (aged 5-9 years), exhibiting symptoms of ADHD. It is predicted that parentally reported levels of hyperactive and inattentive child behaviours, and measures of parental mental health and well-being, may improve as a result of participating in the intervention. Additionally it is hoped that any gains found have clinical, as well as statistically relevant significance.

Method

Participants

Twenty-one primary care givers and their children were recruited from the waiting lists of three Child and Adolescent Mental Health Service (CAMHS) teams in North Wales and were invited to take part in the research intervention trial. All were awaiting assessment for ADHD, but only children scoring above the borderline clinical cut-off on the Strengths and Difficulties Questionnaire hyperactivity score were invited to enter the study (SDQ; Hyperactivity score ≥ 6; Goodman, 1997, 1999). A total of thirty-six parents were contacted; three did not meet inclusion criteria and the remaining twelve were subsequently un-contactable by telephone or declined to take part. Of the parents entering the study nineteen were female and two male, and 52.6% of these met the clinical cut off on the General Health Questionnaire (GHQ-12 ≥ 3; Goldberg, 1992).

At baseline (T^1) the children entered into the study were aged between 5-9 years old (mean=6.95, SD=1.83), nineteen were male and two female. All were in mainstream education. At this time point twenty of these children were also above the cut-off for clinical concern on the SDQ conduct problems subscale (SDQ; Conduct score ≥3; Goodman; 1997, 1999), which is typical of the presentation of ADHD in young children.

Measures

Child Behaviour:

Strengths and Difficulties Questionnaire (SDQ). (Goodman, 1997, 1999)

The SDQ is a 25 item informant-rated behavioural inventory of both positive and negative attributes in children aged 3 to 16 years old. Scoring results in five subscales; hyperactivity (constantly fidgeting or squirming), conduct problems (Often lies or cheats), emotional symptoms (many fears, easily scared), peer problems (picked on or bullied by other children) and prosocial behaviour (often volunteers to help others). The first four of which contribute to a total difficulties score.

The SDQ is a well-validated clinical tool, is relatively brief in administration with good cross-informant correlation (mean 0.34), internal consistency (α 0.73) and test-retest reliability (mean 0.62). It has high discriminant validity, and there is an association between high SDQ scores and an increase in psychiatric risk (Goodman, 2001). Internal consistency was measured using Cronbach's Alpha. The mean Cronbach's alpha for the Hyperactivity scale in this sample at T^1 was found to be 0.46.

The ADHD Rating Scale-IV. (ADHD RS-IV) (DuPaul, Power, Anastopoulos & Reid, 1998)

The ADHD Rating Scale-IV is an 18-item questionnaire requiring the respondent to rate the frequency of DSM-IV symptoms of ADHD. This measure can be parent, teacher or investigator scored: only the parent rated version was utilised in this study. It is a brief measure taking 5-10 minutes to complete, and each item is scored from 0 (never) to 3 (very often). The ADHD RS-IV yields a total score and two subscale

scores (inattention and hyperactivity/impulsivity), and factor analytic studies have indicated that these subscales correspond to the two-dimensional structure in the DSM-IV (DuPaul et al., 1997). It has excellent psychometric properties including a test-retest reliability of 0.93, good internal consistency, and it has been normed in large community and clinical samples (DuPaul et al., 1998). The internal consistency for this measure in this sample was found to be: inattention subscale (Cronbach's α= 0.90) and hyperactive/impulsive subscale (Cronbach's α= 0.87).

Parental Account of Childhood Symptoms (PACS). (Taylor, Sanberg, Thorley, & Giles, 1991).

The PACS is a standardised semi-structured clinical interview used to assess the core symptoms of ADHD. Parents describe the severity and frequency of these symptoms across a range of situations over the previous six months. These descriptions are then rated by trained interviewers on a 4 point scale, (0-3) using criteria validated according to clinical practice (Taylor et al., 1991). The interview takes approximately 30-40 minutes to administer. The PACS also consists of a scale assessing conduct problems, but this was not utilised in this study. The PACS has high inter-rater reliability, good construct validity and has been well validated against clinical judgement (Taylor et al., 1991). Inter-rater agreement in this study was assessed by a second coder rating audio-taped PACS interviews. Based upon five cases, an acceptable intra-class correlation of .79 was found.

Parenting and Mental Health:

The General Health Questionnaire (GHQ 12). (Goldberg, 1992)

The GHQ is a widely used, reliable, well-validated questionnaire designed to assess disturbed mood and is often used as a screening measure for depression. The GHQ-12 was utilised to assess parental depressive symptoms and well-being in this study. The scale assess functioning in four areas; depression, anxiety, social dysfunction and somatic disturbance. Each item is scored on a 4-point category scale; ("less than usual", "same as usual", "more than usual" and "much more than usual"). In this study a bimodal scoring method was used (0-0-1-1), generating a total possible score of 12. This measure has good discriminant validity, and is a reliable and convergent measure (Hardy, Shapiro, Haynes, & Rick, 1999). Internal consistency as assessed by Cronbach's alpha ranged from 0.82 to 0.90 across a number of studies (Goldberg & Williams, 1988). In this sample a high level of internal consistency was found for the GHQ (Cronbach's α= 0.86)

Parental Sense of Competence Scale (PSOC) (Johnston & Mash, 1989).

The PSOC is a 17-item questionnaire that measures two dimensions of parenting self-esteem: Satisfaction and Efficacy. Parenting Satisfaction is linked to feelings of well being in relation to parenting a specific child. Parenting Efficacy examines the parents' sense of control over their child's behaviour. It consists of 17 items, rated on a 5-point Likert scale (strongly agree – strongly disagree). Evidence from factor analytic studies demonstrate that these dimensions are robust, test-retest reliability is high and a cronbach's alpha of .75 has been found for the Satisfaction scale and .76 for the Efficacy scale (Johnson and Mash, 1989). Johnson (1996) found that parents of children with ADHD tend to score lower on this measure than do parents of

'nonproblem' children. The internal consistency for this measure in this sample was found to be: Satisfaction subscale (Cronbach's α= 0.67) and Efficacy subscale (Cronbach's α= 0.64).

Design

This study included children presenting with signs of early ADHD symptoms from within a randomised controlled design with two conditions; self-directed intervention (PT) and waiting list control (WLC), and at two time points (pre- and post-intervention).

Procedure

Parents and their children were selected using a two stage screening process.

Stage One

ADHD teams within local CAMHS services were invited to participate in the research and to offer self-directed intervention training for clients on their waiting list. These teams were then asked to identify and contact eligible families, inviting them to join the research study.

Stage Two

Parents were then asked to provide written consent to:

i) Be contacted with further details about the study.

ii) To complete four short questionnaires.

iii) Take part in a short telephone based interview about their child's behaviour.

Prior to acceptance into the study parents were sent four questionnaire measures regarding their child's behaviour and parental well-being (SDQ, GHQ, PSOC. & ADHD RS-IV).

If the eligibility criterion for the study was met, on the basis of their child's score on the SDQ Hyperactivity subscale, parents were then asked to provide written consent to:

i) Joining the research intervention trial.

ii) Being randomised into the self-directed parent training intervention (PT) or delayed intervention group (WLC).

Once the baseline data was collected, the study supervisor, using a number generator randomly assigned children to the intervention or delayed intervention group. Parents were then contacted at a time convenient for them and interviewed using the PACS over the telephone.

Intervention

The self-directed parent-training manual used in the intervention was specifically designed for this research by Thompson and Daley (2006). Intervention was delivered in two parts. The first part consisted of a one-day augmentation to the self-directed intervention. The augmentation day aimed to: i) Provide psycho-education about ADHD and the neuropsychological processes at work; ii) Motivate parents by explaining research findings from previous trials of the group-delivered NFPT intervention; iii) Explain and demonstrate the strategies which the manual would teach the parents, and iv) Attempt to tailor the strategies to the unique circumstances

of each parent. The intervention manual involved a one week psycho-educational chapter on ADHD, followed by 6 weekly sessions which concentrated on four key aspects: i) Psycho-education; ii) Parent-child relationships (which included positive parenting, praise, extension of language to encourage emotional self regulation and play); iii) Behaviour training to encourage consistent meaningful limit setting, and iv) Attention training to aid parents to work on improving their child's attention. Parents received weekly telephone calls to remind them to move onto the next week of the programme but not further help of assistance with implementing the intervention. After seven weeks all measures were repeated for participants in both groups.

Data preparation and analysis strategy

In line with recommendations for analysis of data for randomised controlled trials, the data was analysed using an intention to treat analysis. The data of two control group participants was substituted in this way at T^1 and the missing data of five control group participants was replaced at the post-intervention time point (T^2). In this sample a low level of internal consistency was found for the SDQ Hyperactivity subscale at T^1 (Cronbach's α= 0.46), however this was found to be adequate at T^2 (Cronbach's α= 0.70), and as the SDQ is a reliable and well used measure it was decided that further analysis could reliably be performed.

To examine the data for outliers the mean score for each group at each time point was calculated, and outliers that were two standard deviations (SD) above or below this point were removed (of which two were from the intervention group, and one from

the control group). Missing data was then replaced with the new mean for that group, not including the outliers, at that time point.

A Kolmogorov-Smirnov (KS) test was used to examine whether the data conformed to the assumptions of normality. Approximately normal distributions were found for scores on the majority of measures ($Z \geq 1.22$; $p \geq .10$), excepting only scores on the ADHD RS-IV Inattention subscale at T^2, which indicated that the data was non-parametric ($Z \geq 1.44$; $p \geq .03$).

The analysis strategy was to use a repeated-measures analysis of covariance (ANCOVA) to examine the difference between intervention and waiting list control at post-intervention (T^2), with data at baseline (T^1) introduced as covariates to control for differences at this time point. Scores at T^2 were the repeated measure (i.e. time), and intervention (Parent Training (PT) versus Waiting List Control (WLC)) was the between subject variable. In this design an overall main effect of treatment indicates an effect of intervention over waiting-list control. As data on the ADHD RS-IV Inattention subtest were found to be non-parametric the results of this analysis were confirmed by using a Kruskal-Wallis non-parametric test.

Difficulties in recruitment led to a lack of power and so effect sizes were examined in tandem with F values and levels of significance, using the interpretation of η^2 (eta square) as proposed by Green, Salkind and Akey (2000), of small (.01), medium (.06) and large effect sizes (.14).

Following the example of Sonuga-Barke et al. (2001), with the aim of facilitating ease of interpretation and reducing multiple testing, two composite scores were created and analysed: (1) an index of ADHD combined z-transformed interview and questionnaire scores (SDQ Hyperactivity score, ADHD RS-IV Hyperactive/Impulsive and Inattention subscales, and PACS ADHD score), and (2) an index of Parental Well-Being when combined z-transformed GHQ and PSOC scores (GHQ total, and PSOC Efficacy/Satisfaction subscales). PSOC Efficacy scores were reversed scored for this purpose.

Clinical significance

Two criteria were employed to assess the clinical significance of treatment effects. The Reliable Change Index (RCI; Jacobson and Truax, 1991), and an examination of whether scores on the SDQ Hyperactivity Subscale, had reduced to below the clinical threshold. An operationalised definition of clinical significance presented by Jacobson and Truax (1991) is 'the level of functioning subsequent to therapy places that client closer to the mean of the functional population than it does to the mean of the dysfunctional population'. In essence what this means is it captures the degree to which the client's score has been normalised. This was achieved by calculating the mid-point between identified normative scores on the SDQ Hyperactivity subscale, and the pre-intervention scores of the present study. The percentage of participants whose post-intervention scores on this measure fell below this median point, to become closer to the mean of the normative population, were proposed to have achieved a clinically significant change.

Description of sample: comorbidity

Table 1 displays the mean percentage of participants in this sample who exhibited hyperactivity, conduct and emotional problems divided by group, as compared to established British normative data (Meltzer, Gatward, Goodman, & Ford, 2000). In addition to clinically significant scores on the SDQ Hyperactivity subscale, all participants' mean scores were in the abnormal range for Total Difficulties, Conduct Problems, Peer Problems and Impact on overall distress and functioning. The WLC group also fell within the abnormal range on the Pro-social subscale, and were in the borderline range for Emotional Symptoms.

[insert table 1 here]

Results

Using a series of one-way Analysis of Variance (ANOVA), significant differences were found between the two groups at baseline on the GHQ, the ADHD RS-IV Inattention subscale and also on the composite score of Parental Well-Being. These findings are summarised in Table 2 and show that, despite randomisation, the WLC group children had significantly higher scores for symptoms of inattention, and WLC parents had higher scores for depression at baseline. Therefore further analysis using an Analysis of Covariance (ANCOVA) was used to control for any influence of baseline scores on scores found at T^2.

[insert table 2 here]

Influence of intervention on child behaviour

Using a series of one-way Analysis of Covariance (ANCOVA) significant differences were found between the two groups at post-intervention on the composite score of ADHD, and the individual scores on the PACS ADHD subscale, and SDQ Hyperactivity subscale. Medium to large effect sizes (eta square) were found for all measures of child behaviour, indicating that considerable differences existed between the groups. In the PT group, the mean score for all measures reduced from baseline to post-intervention. However mean scores on all measures of child behaviour for the WLC group were raised at post-intervention.

These findings are summarised in Table 3 and show that the children in the PT group experienced a significant reduction in ADHD symptoms, particularly hyperactivity, as compared to children in the WLC group, even when differences found at T^1 were controlled for.

Influence of intervention on parental well-being

Using a series of one-way Analysis of Covariance (ANCOVA) significant differences were found between the two groups at post-intervention on the composite score of Parental Well-Being and individual scores on the GHQ and PSOC Satisfaction.

In the PT group, the mean score on both the PSOC Satisfaction and Efficacy subscales improved from baseline to post-intervention, whereas the control group parents mean scores increased on all measures of parental well-being. Although PSOC Efficacy failed to achieve statistical significance, this measure yielded a large effect size indicating that differences existed between the two groups, with the PT group parents reporting higher levels of efficacy post-intervention.

[insert table 3 here]

Non-intention to treat analysis

To examine whether trends in the intention to treat data were mirrored in the raw data, a tentative repeated analysis was conducted. All data was found to be parametric and approximately normal distributions were found for scores on all measures ($Z \geq 0.33$, $p. \geq 0.13$).

Influence of intervention on child behaviour

Using a series of one-way Analysis of Covariance (ANCOVA) no significant differences were found between the two groups at post-intervention ($p<.05$). However small to large effect sizes (eta square) were found for all measures of child behaviour, indicating that differences existed between the groups. In line with the results found for the intention to treat data, the intervention group mean score on all measures of child reduced from baseline to 7-week follow-up. However mean scores on all measures of child behaviour for the control group were higher than those found for intervention at post-intervention follow-up.

Influence of intervention on parental well-being

Using a series of one-way Analysis of Covariance (ANCOVA) significant differences were found between the two groups at post-intervention on the measure of parental satisfaction ($F(1, 14) = 8.41, p<.01$). Large effect sizes were also found for GHQ, PSOC Satisfaction and a small effect size was found for PSOC Efficacy indicating that differences continued to exist between the two groups. The Parental Well-Being

composite did not generate a significant effect size but this may have been attributable to the small numbers involved.

In the intervention group, the mean score on the PSOC Satisfaction and Efficacy subscales, and Parental Well-Being subscale reduced from baseline to 7-week follow-up, whereas the control group parents mean scores increased on all measures of parental well-being, excepting only PSOC Efficacy.

Clinical Change

Using RCI criteria for clinically significant change in overlapping populations (Jacobson & Truax, 1991), to examine SDQ Hyperactivity T^2 scores as compared to the normative data for 5-10 year olds (Meltzer, Gatward, Goodman, & Ford, 2000) suggested that 30% of children in the PT group showed clinically significant change at T^2 as compared to 0% of the children in the WLC group. Utilising clinical cut-off criteria on this measure, 30% of the PT group children, as compared to 0% of the children in the WLC group, had post-intervention scores that had fallen below the level of clinical concern (SDQ; Hyperactivity score ≥ 6; Goodman, 1997, 1999).

Discussion

This study sought to examine the efficacy of a self-directed parent-training intervention for children with hyperactivity. Using an intention to treat analysis the results of this study suggest that the intervention condition effected a reduction in ADHD symptoms, particularly hyperactivity, and an improvement in measures of parental well-being compared to results found for the waiting list control.

Additionally, a third of the children in the intervention group showed clinically significant change and had fallen below the level of clinical concern post-intervention on a measure of hyperactivity. No such improvements were found for the control group children.

Although the power in the current study was limited, these findings suggest that NFPT self-directed intervention may be efficacious for use in young children presenting with symptoms of ADHD. This study supports the findings of Bor, Sanders and Markie-Dadds (2002) who found that parent-training approaches to intervention in ADHD can effect both clinically significant changes in child behaviour and improve parental well-being. It also contributes to the emerging literature on the efficacy of self-directed interventions with similar populations (Sanders et al., 2000b; Markie-Dadds & Sanders, 2006).

Limitations

The primary limitation of this study was recruitment difficulties as, despite an extended period of data collection, the final sample (n=21) was smaller than anticipated. Anecdotal evidence suggests that recently implemented Service and Financial Framework (SaFF) targets, as set by the National Service Framework (NSF) for child services in Wales, (stipulating that all patients be seen within six months), may have created internal CAMHS waiting lists which impacted on the typical numbers of children awaiting ADHD assessment. Therefore, conclusions drawn from this study should be treated with caution, as generisability is limited. However this data will now be incorporated into an ongoing study, which will continue to recruit participants.

As the current study relied primarily on parental reports of child symptoms it could be argued whether improvements in ratings translated into actual change, or whether they were influenced by parental expectations. However, parental report of child ADHD symptoms has been found to be both accurate and reliable (Faraone, Biederman, & Milberger, 1995) and in this study a range of were measures employed, including a clinical interview, that showed a high degree of concordance. Despite randomisation some differences were found two exist between the two groups at baseline, although this was controlled for in the subsequent analysis.

Finally, the time available meant that it was only possible to examine the efficacy of intervention at one time-point, and in the absence of a longer-term follow-up it is not possible to say whether the gains found for SDI will be maintained. However, Songua-barke et al. (2001) have demonstrated the stability of the therapist led version of the NFPT, so it may be that the impressive results of this study would remain in the longer term.

Clinical Implications and Further Research

Further evaluation of SDI's should address some of the methodological issues already raised herein such as; augmenting parental reports with independent observation and/or teacher reports, and long-term follow-up to examine the maintenance of gains. Previous evaluations of SDI as compared to group-based delivery of parent training interventions have found continuing gains in child behaviour beyond the intervention phase (Sanders et al., 2000b) and it would be interesting to see whether the self-directed version of the NFPT had a similar level of ongoing impact. Additionally an

examination of any changes that occur in parenting practices, in addition to gains in parental well-being, would be an interesting avenue to pursue.

Despite positive outcomes for other measures of child behaviour, reductions in reported child inattention in the intervention group failed to reach statistical significance. Consideration of this finding may suggest the possibility that psychosocial interventions have greater immediate impact with hyperactive symptoms, and this necessitates further detailed examination of the clinical subtypes of ADHD to establish whether differential response to psychosocial intervention exists, in both the short and long-term (Pelham, 2001).

Similarly, despite an overall improvement in measures of parental well-being, the Efficacy scale of the PSOC failed to achieve statistical significance. The PSOC has been found to tap into distinct aspects of parental self-esteem (Johnson & Mash, 1989), and whilst feelings of satisfaction in parenting are likely to increase in the short-term, in response to positive changes in child behaviour, it may take longer for this to translate into feelings of efficacy, as skills are unlikely to have been fully mastered. Again it would be interesting to see how scores on this measure would change over time.

A recent meta-analysis of parent training approaches conducted by Lundahl, Risser and Lovejoy (2006) revealed that SDI represented a flexible and economic intervention option, which resulted in positive effects for both children and their parents, that were comparable to those found for other, more traditional modes of delivery. Although further research evaluation is needed, especially in comparison to

traditional modes of delivery, the current study supports the findings of Sonuga-Barke et al. (2001), who examined the efficacy of a group-based version of the NFPT, and suggests that self-directed NFPT may be a viable option in response to increasing primary care waiting list demands, in order to promote social and emotional well-being in children with ADHD and their families.

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Table 1: Baseline clinical and non-clinical (normative) means and standard deviations for SDQ (Goodman, 1997, 1999).

Measures	Non-clinical Meltzer, Gatward, Goodman & Ford (2000) (n=5855)	Intervention (n=10)	Control (n=9)
Hyperactivity Score	3.6 (2.7)	9.22 (0.92)	8.55 (1.42)
Conduct Problems Score	1.6 (1.7)	5.5 (2.12)	5.78 (2.22)
Emotional Symptoms Score	1.9 (2.0)	3.7 (2.79)	4.11 (3.18)
Peer Problems Score	1.4 (1.7)	4.3 (2.9)	4.89 (2.2)
Pro-social Behaviour Score	8.6 (1.6)	6.4 (1.84)	4.44 (3.47)
Impact Score	0.3 (1.1)	4.4 (2.67)	4.55 (3.47)
Total Difficulty Score	8.6 (5.7)	22.4 (6.02)	23.33 (4.87)

Table 2: Differences between intervention and control group measures at baseline

Measures			F	p	η^2
	Intervention (n= 10) Mean(SD)	Control (n= 11) Mean(SD)			
ADHD Composite	-0.62 (2.6)	0.57 (2.8)	1	0.33	0.05
Well Being Composite	-1.04 (1.32)	0.94 (2.33)	5.59	0.03*	0.23
PACS ADHD	19.1 (7.22)	22.9 (5.2)	1.95	0.18	0.09
ADHD RS-IV Hyperactive/Impulsive	21 (5.25)	21.64 (6.07)	2.41	0.14	0.11
ADHD RS-IV Inattention	19.4 (5.17)	22.55 (4.99)	5.40	0.02*	0.25
SDQ Hyperactivity	9.22 (0.92)	9.1 (1.04)	0.08	0.78	0.00
GHQ	1.44 (1.89)	5.55 (4.08)	8.42	0.01**	0.31
PSOC Efficacy	22.4 (1.26)	23.3 (2.05)	1.31	0.27	0.06
PSOC Satisfaction	26.8 (5.71)	30.82 (5.42)	2.74	0.12	0.13

* = Significant at .05 level

** = Significant at .01 level

Table 3: Analysis of Covariance (ANCOVA) comparing differences between intervention and control groups on measures of ADHD and parental well-being.

Measures	Time 1		Time 2		F	p	η^2
	Intervention (n= 10) Mean(SD)	Control (n= 11) Mean(SD)	Intervention (n=10) Mean(SD)	Control (n= 11) Mean(SD)			
ADHD	-0.62	0.57	-1.99	1.8	5.63	0.03*	0.24
Composite	(2.6)	(2.8)	(4.15)	(2.06)			
Well Being	-1.04	0.94	-1.91	1.74	13.84	0.00**	0.44
Composite	(1.32)	(2.33)	(1.2)	(2.14)			
PACS	19.1	22.9	15.7	24.9	9.70	0.01**	0.35
ADHD	(7.22)	(5.2)	(7)	(4.41)			
ADHD RS-IV	21	21.64	17.8	22.4	4.02	0.06	0.18
Hyp/Imp	(5.25)	(6.07)	(6.48)	(3.32)			
ADHD RS-IV	19.4	22.55	18.4	22.7	1.66	0.20	0.06
Inattention$	(5.17)	(4.99)	(6.7)	(2.64)			
SDQ	9.22	9.1	7.3	9.2	6.52	0.02*	0.27
Hyperactivity	(0.92)	(1.04)	(2.36)	(1.4)			
GHQ	1.44	5.55	2	7.45	4.69	0.04*	0.21
	(1.89)	(4.08)	(2.26)	(4.87)			
PSOC Efficacy	22.4	23.3	17.6	23.36	6.34	0.21	0.26
	(1.26)	(2.05)	(2.55)	(5.78)			
PSOC	26.8	30.82	26.6	32.91	14.55	0.01**	0.45
Satisfaction	(5.71)	(5.42)	(4.03)	(2.26)			

* = Significant at .05 level

** = Significant at .01 level

$ = As this variable was non-parametric this result has been confirmed non-parametrically using a Kruskal-Wallis test.

Appendix 3.a

Notes for contributors to 'British Journal of Clinical Psychology'

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The British Psychological Society

Notes for Contributors

The *British Journal of Clinical Psychology* publishes original contributions to scientific knowledge in clinical psychology. This includes descriptive comparisons, as well as studies of the assessment, aetiology and treatment of people with a wide range of psychological problems in all age groups and settings. The level of analysis of studies ranges from biological influences on individual behaviour through to studies of psychological interventions and treatments on individuals, dyads, families and groups, to investigations of the relationships between explicitly social and psychological levels of analysis.

The following types of paper are invited:

- Papers reporting original empirical investigations
- Theoretical papers, provided that these are sufficiently related to the empirical data
- Review articles which need not be exhaustive but which should give an interpretation of the state of the research in a given field and, where appropriate, identify its clinical implications
- Brief reports and comments

1. Circulation

The circulation of the Journal is worldwide. Papers are invited and encouraged from authors throughout the world.

2. Length

Papers should normally be no more than 5000 words, although the Editor retains discretion to publish papers beyond this length in cases where the clear and concise expression of the scientific content requires greater length.

3. Reviewing

The journal operates a policy of anonymous peer review. Papers will normally be scrutinised and commented on by at least two independent expert referees (in addition to the Editor) although the Editor may process a paper at his or her discretion. The referees will not be aware of the identity of the author. All information about authorship (including personal acknowledgements and institutional affiliations) should be confined to the title page (and the text should be free of such clues as identifiable self-citations, e.g. 'In our earlier work...').

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Registered users: Click the LOGIN button from the menu and enter your user name and password for immediate access. Click 'Author Login'.

2) Follow the step-by-step instructions to submit your manuscript.

3) The submission must include the following as separate files:
- Title page consisting of manuscript title, authors' full names and affiliations, name and address for corresponding author -
  A title page template is available to download.
- Abstract
- Full manuscript omitting authors' names and affiliations. Figures and tables can be attached separately if necessary.

4) If you require further help in submitting your manuscript, please consult the Tutorial for Authors -
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Authors can log on at any time to check the status of the manuscript.

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- Contributions must be typed in double spacing with wide margins. All sheets must be numbered.
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- Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form consistent with text use. Unnecessary background patterns, lines and shading should be avoided. Captions should be listed on a separate page. The resolution of digital images must be at least 300 dpi.
- For articles containing original scientific research, a structured abstract of up to 250 words should be included with the headings: Objectives, Design, Methods, results, Conclusions. Review articles should use these headings: Purpose, Methods, Results, Conclusions:
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Code of Conduct, Ethical Principles and Guidelines
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- Full article text (double-spaced with numbered pages and anonymised)
- References (APA style). Authors are responsible for bibliographic accuracy and must check every reference in the manuscript and proofread again in the page proofs
- Tables, figures, captions placed at the end of the article or attached as separate files

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SECTION 4

CONTRIBUTIONS TO THEORY, CLINICAL PRACTICE AND LEARNING

Contributions to Theory, Clinical Practice and Learning

Attention Deficit Hyperactivity Disorder (ADHD) in childhood has been the focus of a considerable amount of clinical and research interest, and the development of efficacious psychosocial interventions for this clinical group has gained pace of recent years (Sonuga-Barke, Daley, Thompson, Laver-Bradbury, & Weeks, 2001; Hoath & Sanders, 2002). However, very few researchers have examined the efficacy of self-directed interventions (SDI) and their utility in responding to an increasing number of children awaiting assessment and intervention for ADHD (see Elgar & McGrath, 2003).

The current study aimed to examine the efficacy of a self-directed version of the New Forest Parent Training package (NFPT; Weeks, Laver-Bradbury, & Thompson, 1999), which was especially adapted for this research by Thompson and Daley (2006), for use with young children exhibiting symptoms of ADHD. The following paper is a further consideration of the issues raised through the undertaking of this research, and the resultant findings, with particular reference to the potential implications for theoretical development, future research and impact upon clinical practice.

Implications for research and theory development

The main finding of this study was that parentally reported symptoms of ADHD, particularly hyperactivity, were observed to have reduced as a function of psychosocial intervention with a self-directed version of the NFPT. In addition improvements found in measures of parental well-being were achieved for those

parents participating in the intervention condition. Although the power in this study was limited, these results appear to be consistent with previously reported gains found for parent training approaches to intervening with ADHD (e.g. Bor, Sanders and Markie-Dadds, 2002) and specifically those found for therapist delivered NFPT (Sonuga-Barke et al., 2001). However, therapist-led parent training has tended to receive more efficacious outcomes in the literature when compared directly to SDI (Sanders, Markie-Dadds, Tully, & Bor, 2000b), which necessitates further research into the optimal mode of delivery and cross-programme evaluations.

The findings of the current study are important as not only do they contribute to the existing literature on psychosocial interventions for ADHD, but they also add to the emerging research on the efficacy of self-directed modes of delivery. However, relatively low participant numbers and the identified limitations mean that direct extrapolation of these results may be limited.

Limitations

Despite randomisation, an initial exploration of the data revealed that some differences continued to exist between the two groups at baseline. Although these differences were controlled for in analysis it would be interesting to see how the parents scoring highly on the GHQ would respond to SDI. Although Sonuga-Barke, Daley and Thompson (2002) found that poor parental mental health predicted poorer child ADHD symptoms immediately post-intervention for group delivered NFPT, it was not found to be a moderator of child behaviour in the longer-term. However, it is not inconceivable that without therapist involvement or additional support with which

to address personal difficulties, parental mental health would have a more detrimental impact upon a self-directed mode of delivery.

Although overall gains were found in child ADHD symptoms for the intervention group, improvements in one measure of inattention were not found to be significantly different to that found for waiting list control children. This may simply be due to the fact that in using a measure of hyperactivity as entry criteria, this may have served to excluded primarily inattentive children from the study, or equally have resulted in a sample who's primary area of concern was hyperactivity; making them more attuned to changes in this area. This finding may also be suggestive that psychosocial intervention exerts differential impact with different subtypes of ADHD presentation, or that the post-intervention measurement point may have masked effects that a longer-term follow up would be better able to identify. For example, it may be that psychosocial interventions require more time to effect change with inattentive subtypes, or equally that they have greater short-term impact with hyperactive difficulties (Pelham, 2001). Unfortunately, as the scope of this study meant that only pre-, and post-intervention scores were obtained it was not possible to examine the longer-term impact of intervention.

Although participants were selected on the basis of ADHD symptoms they were not screened out on the basis of comorbid difficulties. Studies to date have shown that ADHD is a consistent predictor of the presence of comorbid conduct disorder (Biederman et al., 1992; Scahill et al., 1999) and so it was not surprising that the current sample appeared to also have high degree of comorbidity. Promisingly, the data so far collected appears to suggest that SDI may also have impact on comorbid

behavioural difficulties, and this is in line with results found for therapist led interventions (Jones, Daley, Hutchings, Bywater, & Eames, In press; Danforth, Harvey, Ulaszek, & Eberhard McKee, 2006). Future studies should further address this by examining issues of specificity.

The finding that gains in parental sense of efficacy had failed to achieve statistical significance may be suggestive of differential effects of intervention on aspects of parental self-esteem in the short-term (Ohan, Leung, & Johnson, 2000), but equally might be indicative of a short-coming in SDI, in that parents may require additional support, that is not provided by this mode of delivery. It is well documented that setting boundaries and firm consequences for problematic behaviour may paradoxically result in a temporary increase in these behaviours (Campbell, 2002), and that without adequate therapist support, in holding them through change, parents may experience difficulty in staying motivated. In an effort to address this issue, further research is needed to determine the optimal level of therapeutic assistance required in delivering such interventions thus balancing efficacy with accessibility and cost (Elgar & McGrath, 2003).

An intention to treat analysis is routinely used in randomised controlled trials as the most conservative way of accounting for missing data, however, it is also important to examine the original data, and to compare the results of both. Data collection will now continue, led by the current study supervisor, and the permutations of this will be examined in the resultant analysis.

Treatment Acceptability and Fidelity

Future evaluations of self-directed interventions should pay particular attention to the perceived acceptability of such treatment to parents, as this has been strongly associated with positive outcomes for psychosocial intervention (Nock & Kazdin, 2001). Gaining insight into parental attitudes towards SDI versus traditional psychosocial treatments would be useful in determining families' potential to effect positive change with SDI.

An important area for further investigation is how to ensure treatment fidelity when using a self-directed mode of delivery. Without doing so it is difficult to conclusively extrapolate that gains found are due to the effect of intervention or, equally important, what aspects of the treatment appear have particular utility. Possible ways in which this could have been achieved in the present study include the addition of a measure examining parental knowledge, and practice, of techniques presented in the manual, which could form part of the weekly check-in phone-call or could be included as part of the post-intervention battery of measures.

Implications for Clinical Practice

Professional Implications

Although discussion so far has focussed primarily on the positive implications of this research the potential impact of SDI on the role of health care professionals, and specifically clinical psychologists, must be acknowledged. A move towards the development of SDI or manual-based treatments ties in with a more general shift in this direction, as the clinical psychology role appears to move increasingly away from primary care. Rather than feel threatened by developments in service provision, there

is a need to adapt to the potentially changing landscape. Such interventions, if well validated and efficacious, should be viewed for their potential as an adjunctive benefit rather than threatening alternative, and may have the greatest clinical application in use with those on the waiting list for clinical services or clients whose problems are considered to be below the clinical threshold, and not requiring immediate therapist involvement, as has been effectively trialled with adult populations (Gould, 1993).

Parental ADHD

Although examination of parental ADHD was omitted from this research, studies have revealed that ADHD is a highly heritable condition and therefore it is likely that the parents of children identified as having symptoms of hyperactivity or inattention will themselves have ADHD (Todd et al., 2001; Faraone, Biederman, Mennin, Gershon, & Tsuang. 1996). Sonuga-Barke et al. (2002) found that poorer outcomes for parent training were associated with maternal ADHD symptoms. A possible explanation for this outcome may be that in order to sufficiently implement behavioural strategies at home the parents are required to fully engage, attend and organise themselves; exactly the abilities that need fostering in ADHD.

However, Psychogiou, Daley, Thompson, Goodson and Sonuga-Barke (in press) reported that mothers scoring high on ADHD symptoms also expressed more positive attitudes in relation to their emotional relationships and interaction with their child with ADHD. This may mean that there is scope for assisting these parents, by means of additional support or adjunctive elements, in managing their own symptoms to in turn aid their management and relationship with their child (Daley & Thompson, in

press). Therefore future studies could assess parental ADHD prior to intervention with a view towards tailoring SDI to accommodate these difficulties.

School Intervention

As has been well documented in the literature, ADHD is not a disorder limited to the home situation in isolation, and can affect the child's wider familial and social contexts, resulting in a detrimental impact upon their classroom behaviour and academic performance (Campbell, 2002; Merrell & Tymms, 2001). Therefore an ideal intervention would offer an integrative approach to the treatment of ADHD.

Pelham, Wheeler and Chronis (1998) found greater effect sizes for psychosocial interventions when directly implemented in the setting in which the problem behaviours were observed. Most school-based interventions cover the same behaviour management advice as offered to parents albeit tailored to the classroom environment (Chronis, Jones, & Raggi, 2006). However, these approaches can face the same limitations posed by traditional methods of delivery found in parent training formats in that they represent significant financial and resource implications for the institutions involved. An interesting next step in the application of SDI may be to systemically address the difficulties found in ADHD, by adapting interventions for self-directed use by teaching staff, which could also be used in parallel with parent-focussed intervention.

Process and Personal Issues arising from this study

In the course of conducting this research a number of practical difficulties were encountered. Combining this research with ongoing clinical work was often

challenging as a number of families requested an evening telephone-call due to work commitments; practically this necessitated returning home from work in the evening and immediately commencing research calls. Not only was it often frustratingly difficult to initially contact the families, but once an appointment to re-contact them had been arranged, frequently there would be no reply, it would prove to be inconvenient or occasionally mobile phones could be disconnected for extended periods of time.

Difficulties with recruitment meant that the period of data collection was extended for longer than initially planned and this impacted on the time available between analysis and write-up. This resulted in what was an extremely challenging time personally, that necessitated employing the myriad research and academic skills that I had acquired during my time on the programme.

Motivating factors in deciding to take on this research study included the desire to be involved in something that had the potential to have immediate real-world clinical utility and impact. ADHD was an area that I had not had a great deal of clinical experience in and so the idea of deepening my understanding of ADHD was of interest. Having heard that Dr Dave Daley was developing a self-directed version of the New Forest Parent Training program, and that very few studies had looked at this mode of delivery with a child ADHD population, I enquired about the possibility of framing a large-scale research project around an evaluation of its efficacy.

In undertaking this research I expected to obtain a realistic idea of what it was like to conduct a real-world research. Through the process of working within a clinical

population and speaking, albeit briefly, to those at the point of seeking help when they are most in need of advice and support, and I feel that I came to have an understanding of the real impact that ADHD can have on families. I appreciate that although the roles of researcher and clinician are distinct in many ways, they are not are not mutually exclusive, and whilst bearing in mind the need to respect boundary issues, clinical experience can be invaluable in working with such populations sensitively to gain access to their experience.

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Word counts for each section excluding references, appendices and tables

Title	**12**
Summary	**214**
Section 1: Ethics Proposal	**3230**
Section 2: Literature Review	**7993**
Section 3: Empirical Paper	**4999**
Section 4: Discussion Paper	**2121**
Total	**18569**

Additional word counts for each section

General (Contents pages, acknowledgements etc)	**557**
Section 1: References	**1179**
Section 2: References	**4721**
Section 3: References	**1147**
Section 4: References	**756**

Appendices

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Information sheets and consent forms	**1839**
Research Questionnaires	**2045**
Approval letters	**2185**
Total	**14816**

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