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DOCTOR OF PHILOSOPHY

Pragmatic evaluation of group cognitive behavioural therapy for chronic fatigue syndrome

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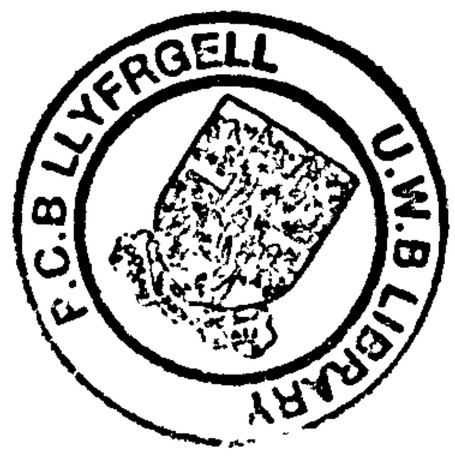
Pragmatic Evaluation of Group Cognitive Behavioural Therapy for Chronic Fatigue Syndrome

Louise Barber

The University of Wales, Bangor

July 2007



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Section One

Abstract

Although cognitive behaviour therapy is recommended by the National Institute for Clinical Excellence as one of the treatments of choice for people suffering with chronic fatigue syndrome (CFS) there is relatively little evidence of the effectiveness of this treatment in group format. Group interventions are often preferred as resources are scarce within the National Health Service and are considered to be more cost effective. There is no cure for CFS and the treatment options that are currently available are reviewed, with particular emphasis on the limited group cognitive behaviour therapy (GCBT) studies. The methodological limitations and generalisability of the findings are questioned followed by implications for clinical practice. Finally the direction of future research is discussed and the need for further trails of group CBT in routine clinical settings.

The research paper investigates the effectiveness of a GCBT for people with CFS. In this pragmatic, non-randomised, controlled design 28 people acted as their own waiting list control by completing a range of measures 8 weeks prior to taking part in GCBT. The intervention consisted of 8 consecutive weeks of 2.5-hour sessions. Significant improvements were found compared to the waiting list in physical and mental fatigue and depressive symptoms. Improvements in quality of life, hope and optimism were also found but no improvements were reported for anxiety levels, pain or physical functioning. Global outcome measurers revealed that the majority of the patients found the treatment beneficial and were satisfied with the results. It is concluded that GCBT is a beneficial treatment that patients find amenable in routine clinical practice for CFS. However further research is indicated to improve subgroup identification and refine intervention programmes.

Contributions to theory and research are presented in the final section research, along with the strengths and limitations of the research and future research suggestions. The contribution to clinical practice is also discussed. Finally the research experience is explored to include personal motivations and the research experience.

Acknowledgements

First of all I would like to thank my supervisor Dr Helen Lyon-Jones for all her support, with my thesis but also personally in my times of woe and worry. You have been a shoulder to cry on and I consider you to be a true friend. Thank you also for the laughter. It means a lot.

Secondly I would like to thank my cohort for just being themselves and giving so freely encouragement and support throughout the course.

And finally and most importantly I would like to say a massive thank you to my precious Travis and Kasia, who have never really known a mum who isn't studying and being assessed. I know I have put you through such an awful lot to get to this stage and I really appreciate the life changes you have made for me. I am sorry for the times I let things get on top of me and although I cannot promise to be less stressed and demonic with you, I can try. You both mean the absolute world to me and I hope I can make you as proud of me, as I am of you.

Section Two

Ethics Proposal

SCHOOL OF PSYCHOLOGY ETHICAL APPROVAL FORM

Please complete all parts to this form.
Please attach consent and information/debriefing sheets to all applications.

Tick one box: ☐ **STAFF project** ☐ **MASTERS project** ☐ **PhD project**
☐ ***CLINICAL PSYCHOLOGY proj*** ☐ ***UNDERGRADUATE project***

Is this an ESRC-funded project? ☐ **YES** ☐ **NO**

Title of project: Effectiveness of a CBT intervention for CFS compared to a waiting list control

Name of researcher(s): Dr Louise Barber

Name of supervisor (for student research): Dr Helen Lyon-Jones Date: 5/07/06

	YES	NO
Is your project in the area of Health and Social Care requiring sponsorship by the University of Wales Bangor? If yes, please **complete your ethics application in COREC format** and **submit an NHS R&D form** alongside it. **You should still complete all sections to this form, but do not need to supply the additional information requested in boxes A or B of Part 1.**	√	
Does your project require scrutiny from an outside body that has its own forms? If yes, please **complete your ethics application using the forms required by that outside body. You should still complete all sections to this form, but do not need to supply the additional information requested in boxes A or B of Part 1.**		√
If a student project, is this part of the supervisor's ongoing research that has been previously reviewed and approved? If yes, please **give the proposal number of the approved research project, and complete all sections of this form.**	Proposal no.	

PART ONE: ETHICAL CONSIDERATIONS

		YES	NO	N/A
1	Will you describe the main experimental procedures to participants[1] in advance, so that they are informed about what to expect?	√		
2	Will you tell participants that their participation is voluntary?	√		
3	Will you obtain written consent for participation?	√		
4	If the research is observational, will you ask participants for their consent to being observed?			√
5	Will you tell participants that they may withdraw from the research at any time and for any reason?	√		
6	With questionnaires, will you give participants the option of omitting questions they do not want to answer?	√		
7	Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?	√		
8	Will you debrief participants at the end of their participation (i.e. give them a brief explanation of the study)?			√

If you have ticked **No** to any of Q1-8, but have **ticked box A** overleaf, please give an explanation on a separate sheet.
[Note: N/A = not applicable]

[1] In questions 1-9, if participants are children, please consider the information that you will supply to the legal guardian in each case.

		YES	NO	N/A
9	Will your project involve deliberately misleading participants in any way?		√	
10	Is there any realistic risk of any participants experiencing either physical or psychological distress or discomfort? If **Yes,** give details on a separate sheet and state what you will tell them to do if they should experience any problems (e.g., who they can contact for help)		√	

If you have ticked **Yes** to 9 or 10 you should normally **tick box B** overleaf; if not, please give a full explanation on a separate sheet.

11	Does your project involve work with animals? If yes, please **tick box B** overleaf.			√	
12	Does your project involve payment of participants? If yes, please **tick box B** overleaf.			√	
13	Do participants fall into any of the following special groups? If they do, please refer to BPS guidelines, and **tick box B** overleaf. **Note that you may also need to obtain satisfactory CRB clearance.**	**Children (under 18 years of age)** N.B. You must ensure that you have made adequate provision for child protection issues in your protocol		√	
		People with learning or communication difficulties N.B. You must ensure that you have provided adequate provision to manage distress		√	
		Patients N.B. You must ensure that you have provided adequate provision to manage distress.		√	
		People in custody		√	
		People engaged in illegal activities (e.g. drug-taking)		√	
		Participants recruited from the Neurology Patient Panel			
		Physically vulnerable adults N.B. You must ensure that there is an appropriately CPR trained member of staff on hand at all times during testing.		√	

There is an obligation on the lead researcher to bring to the attention of the Departmental Ethics Committee any issues with ethical implications not clearly covered by the above checklist.

PLEASE TICK **EITHER** BOX A BELOW OR BOX B OVERLEAF AND **PROVIDE THE DETAILS REQUIRED** IN SUPPORT OF YOUR APPLICATION.

Please tick

A. I consider that this project has **no** significant ethical implications to be brought before the Departmental Ethics Committee.	√

Give a brief description of participants and procedure, including information on (1) hypotheses, (2) participants & recruitment, and (3) research methodology. Please attach consent and debrief forms.

1/
Is a CBT intervention more effective than a waiting list control for managing CFS and improving quality of life in adults

2/
Participants will be recruited through the CFS service by referrals from their GP. They will be sent participant information and a written consent form.

3/
A repeated measure design will used in an effort to enable a waiting list control group that is service friendly and does not elicit much more of a waiting period for the participants and disturb the usual service provision.
A programme start date will be set and eight weeks before the start of the programme everyone on the waiting list, following initial assessment will be sent the batch of questionnaires and the programme start date.

At the start and end of the intervention the participants will complete the same measures again plus the outcome measures at the end of the programme. This enables participants to be their own control group. Eight weeks before the programme start date, questionnaires can be completed at home, with a visit/phone call from the researcher, if required. All other data collection points will be completed at the programme site (Bryn Seiont Hospital).

Please tick

B. I consider that this project **may** have ethical implications that should be brought before the Departmental Ethics Committee, and/or it will be carried out with children or other vulnerable populations.	

Please provide all the further information listed below in a separate attachment.

1. Title of project.
2. The potential value of addressing this issue
3. Brief background to the study
4. The hypotheses
5. Participants: recruitment methods, age, gender, exclusion/inclusion criteria
6. Research design
7. Procedures employed
8. Measures employed
9. Qualifications of the investigators to use the measures
10. Venue for investigation
11. Estimated start date and duration of the study (N.B. If you know that the research is likely to continue for more than three years, please indicate this here).
12. Data analysis
13. Potential offence/distress to participants
14. Procedures to ensure confidentiality and data protection.
15. *How consent is to be obtained (see BPS Guidelines and ensure consent forms are expressed bilingually where appropriate. The University has its own Welsh translations facilities on extension 2036).
16. Information for participants (Provide actual consent forms and information sheets.)
17. Approval of relevant professionals (e.g., GPs, Consultants, Teachers, parents etc.)
18. Payment to: participants, investigators, departments/institutions
19. Equipment required and its availability
20. What arrangements are you making to give feedback to participants? The responsibility is yours to provide it, not participants' to request it.
21. Finally, check your proposal conforms to BPS Guidelines on Ethical Standards in research and sign the declaration. If you have any doubts about this, please outline them.

PLEASE COMPLETE PART TWO OVERLEAF.

PART TWO: RISK ASSESSMENT

			YES	NO	N/A
1	Is there significant potential risk to **participants** in any of the following ways?	Potential adverse effects		√	
		Potential distress		√	
2	Is there significant potential risk to **investigator(s)** in any of the following ways?	Potential risk of violence or other harm to the investigator(s) (e.g., through work with particular populations or through context of research).		√	
		Potential risk of allegations being made against the investigator(s). (e.g., through work with vulnerable populations or context of research).		√	
3	Does the research involve the investigator(s) working alone or away from the School?			√	
4	Does the experimental procedure involve touching participants?			√	
5	Is there significant potential risk to the **institution** in any way? (e.g., controversiality or potential for misuse of research findings.)			√	
6	Is there significant potential risk to other members of staff or students at the institution? (e.g., reception or other staff required to deal with violent or vulnerable populations.)			√	

If you have ticked "yes" to any of the questions in the table above, please outline on a separate sheet the probability and significance of the risks involved and the means proposed for the management of those risks. Where relevant, please also describe the procedures to be followed in the event of an adverse event or emergency.

There is an obligation on the lead researcher to bring to the attention of the Departmental Ethics Committee any risk implications of the research not clearly covered by the above checklist.

PLEASE COMPLETE PART THREE OVERLEAF, THEN SIGN AND DATE THE DECLARATIONS ON THE FINAL PAGE OF THIS FORM.

PART THREE: RESEARCH INSURANCE QUESTIONNAIRE

In the case of student research, this form should be completed by the supervisor.

The purpose of this form is to decide whether the University requires additional insurance cover for a clinical/research trial and the form should be completed and returned to the Insurance Officer for a decision. ***This Questionnaire should be completed for each Research Project that will involve human participation.***

Name of Sponsor:

Title of Research: Effectiveness of a CBT intervention for CFS compared to a waiting list control

Number of subjects (participants) hopefully between 40-50

1 Is your Research going to be based solely upon the following? ***Yes***

a) questionnaires or
b) venepuncture or
c) measurements of physiological processes or
d) collections of body secretions by non invasive methods or
e) the administration by mouth of foods or nutrients or variation of diet other than the administration of drugs or other food supplements or
f) psychological activity (this is outside the Research definition)

If you answered 'YES', please sign and date the form and return it to the Insurance Officer. If you answered 'NO' please complete the remainder of the questionnaire.

2 Attach details of the Research and a copy of the Protocol submission to the Ethics Committee

3 Is the Research to be held in UK?

If "No" please provide full details Yes

4 Who will be involved in conducting the Research?

Myself, CFS service already provided

5 If medical practitioners are involved will they be covered by the MDU(Medical Defence Union) or any other organization? ***Not involved***

6 Does the Research involve use of drugs or surgery? ***No***
7 Are any of the research subjects known to be pregnant? ***No***
8 Are any of the research subjects under 5 years of age? ***No***
9 Is the purpose of the Research
a) investigating or participating in the methods of contraception? ***No***
b) assisting with or altering the process of conception? ***No***
10 Does the Research involve genetic engineering? ***No***

11 Will the Research use a pharmaceutical product designed or manufactured by the Institution? ***No***

12 Proposed commencement date AND period of the Research September 06 (for 6 months)

_____

13 Will the sponsor pay for addition Insurance costs if required NHS insurance
(If 'No' please note that the department must underwrite any additional insurance cost)

14 If other organizations are involved in the Research is UWB the lead organization for the Research Project? *No others involved*

(If 'Yes' please attach all details, including details of any other organizations that will be involved in the trial(s) involving human participation)

If any of the answers to 4 – 10 are "Yes" please provide full details on additional sheets

Signed _____

Dated 5/7/06

Declaration of ethical compliance

This research project will be carried out in accordance with the guidelines laid down by the British Psychological Society and the procedures determined by the School of Psychology at Bangor. I understand that I am responsible for the ethical conduct of the research. I confirm that I am aware of the requirements of the Data Protection Act and the University's Data Protection Handbook, and that this research will comply with them.

Declaration of risk assessment

The potential risks to the investigator(s) for this research project have been fully reviewed and discussed. As an investigator, I understand that I am responsible for managing my safety and that of participants throughout this research. I will immediately report any adverse events that occur as a consequence of this research.

Declaration of data ownership and IPR (for students)

I understand that any data produced through this project are owned by the University and must be made available to my supervisor on request or at the end of the project. I confirm that I am aware of the University's Intellectual Property Policy and that this research will comply with it.

(Chief investigator/supervisor)

Signed:

Date: 5/7/06

(Associate investigator(s)/student(s)

Signed:

Date: 5/7/06

For School Use Only

Reviewer 1 ....
Approved.....Date.....
(name) (signature)

Reviewer 2 ....
Approved.....Date.....
(name) (signature)

Proposal No. .....

APPLICANTS CHECKLIST

All studies except clinical trials of investigational medicinal products

REC Ref:	06/WNo01/34
Short Title of Study:	Effectiveness of group CBT for CFS compared to waiting list control
CI Name:	Dr Louise Barber
Sponsor:	The University of Wales Bangor

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	5/7/06		
NHS REC Application Form, Parts A&B	Mandatory	AB/84609/2		
NHS REC Application Form, Part C (SSA)	○ Yes ● No			
Research protocol or project proposal (6 copies)	Mandatory	15/06	1	
Summary C.V. for Chief Investigator (CI)	Mandatory			
Summary C.V. for supervisor (student research)	○ Yes ● No			
Research participant information sheet (PIS)	● Yes ○ No	15/6/06	1	
Research participant consent form	● Yes ○ No	15/6/06	1	
Letters of invitation to participants	● Yes ○ No	15/6/06	1	
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			
Referees' or other scientific critique report	● Yes ○ No	24/5/06		
Summary, synopsis or diagram (flowchart) of protocol in non-technical language	○ Yes ● No			
Interview schedules or topic guides for participants	○ Yes ● No			
Validated questionnaire	○ Yes ● No			
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 APPLICATION FORM

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 for research administering questionnaires/interviews for quantitative analysis or mixed methodology study

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)
Effectiveness of group CBT for CFS compared to waiting list control

Name of NHS Research Ethics Committee to which application for ethical review is being made:
North West Wales L REC

Project reference number from above REC: 06/WNo01/34
Submission date: 07/07/2006

PART A: Introduction

A1. Title of the research

Full title: Effectiveness of group cognitive behavioural therapy intervention compared to an 8 week waiting list control for managing symptoms and improving quality of life for people with chronic fatigue syndrome

Key words: chronic fatigue syndrome, cognitive behavioural therapy, group intervention, waiting list control, CBT, CFS

A2. Chief Investigator

Title: Dr
Forename/Initials: Louise
Surname: Barber
Post: Trainee Clinical Psychologist
Qualifications: PhD, BSc(Hons)
Organisation: University oof Wales Bangor
Address: Briganntia House
College Road
Bangor
Post Code: LL57 2DG
E-mail: loubarber@aol.com
Telephone: 07796 156676
Fax: 01248 490637

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: 01/09/2006
End date: 01/04/2007
Duration: Years: ; Months: 7

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

- ☐ Commercial product development and/or licensing
- ☐ 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:
Study conducted in one site only that is already used by the CFS service

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.

PART A Section 1

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

Is a group cognitive behavioural therapy more effective than a waiting list control for managing CFS symtoms and improving quality of life in adults.

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

Do CFS symtoms decrease
Do quality of life measures show improvement following the intervention
Do participant & informants find the programme helpful/beneficial

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.)*

CFS is thought to affect up to 1% of the population (Wesseley, 1995). The prognosis for adults with CFS is poor with many remaining disabled and symptomatic for many years (Hotopf & Wessley, 1997). A longitudinal study showed that 91% of patients with CFS who received standard medical care continued to fulfil diagnostic criteria for years after their original assessment (Hill et al., 1999).

The defining characteristic for people suffering with CFS is a debilitating and unexplained severe mental and physical fatigue, not resulting from organic disease or exertion and is not alleviated by rest or sleep. Other associated symptoms can include muscle pain, mood and sleep disturbance (Reeves et al., 2003). It is a condition that can occur in adolescents as well as adults (Chalder et al., 2003). To meet the criteria there must be a minimum duration of six months and a definite onset (not lifelong) and a functional impairment.

In recent years trials have been conducted with CBT, which combines a graded increase in activity with a psychological approach that addresses thoughts about CFS, which may impair recovery. A cognitive behavioural model of CFS assumes that illness related beliefs and cognitions play a central role in CFS and these beliefs in turn influence a person's emotional, behavioural and physiological state.

Several studies have demonstrated that CBT is effective in adults (Sharpe et al., 1996; Deale et al., 1997) and a recent randomised control group study reported CBT to be an effective treatment for adolescents with CFS (Stulemeijer et al., 2005). A review by Price and Couper (1998) concluded that although there was only a limited number of studies reviewed, CBT for adults with CFS improves physical functioning and other relevant outcome such as mood. There is also evidence that CBT is a cost effective treatment (Best & Stevens 1996).

However, there is little in the way of research to explore the effectiveness of group CBT for CFS (Saxty & Hansen, 2005). Group therapy has received some success with other somatic problems such as chronic pain (Basler et al., 1997; Harrison et al., 1997), irritable bowel syndrome (Toner et al., 1998) and hypochondriasis (Stern & Fernandez, 1991).

As the NHS is under considerable financial strain it is important that cost effective interventions are explored so that programmes can be offered to CFS sufferers with the aim of them managing their symptoms more effectively and improving their quality of life.

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.

Established in 1999, the North Wales Chronic Fatigue support service aims to provide patients, diagnosed with CFS, information and skills, designed to improve their overall quality of life. Based on a cognitive behavioural therapeutic model,

the sessions cover pacing, realistic goal setting and dietary advice. At the Caernarfon site the multidisciplinary team consists of a physiotherapist, dietician, clinical psychologist and a GP.

In November 2005 new guidelines for the collection of data were provided for services for CFS in England. A collaborative minimum dataset was established so that effective and comparable evaluations of services could be made. To enable any funds to be allocated to English services for CFS, the minimum dataset must be given to all service users. In Wales, so far, no minimum dataset has been established. This study aims to evaluate group CBT interventions for CFS compared to an 8 week waiting list control, using the minimum dataset and a small selection of other measures (hope optimism and outcome satisfaction), which may potentially be effective outcome measures in CFS management programmes.

A repeated measure design will used in an effort to enable a waiting list control group that is service friendly and does not elicit much more of a waiting period for the participants and disturb the usual service provision.
A programme start date will be set and eight weeks before the start of the programme everyone on the waiting list, following initial assessment will be sent the batch of questionnaires and the programme start date.

At the start and end of the intervention the participants will complete the same measures again plus the outcome measures at the end of the programme (see figure 1 for diagrammatical representation of the procedure). This enables participants to be their own control group. Eight weeks before the programme start date, Questionnaires can be completed at home, with a visit/phone call from the researcher, if required. All other data collection points will be completed at the programme site (Bryn Seiont Hospital).

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.
Postal questionnaire to home	3	20 mins	no additional intervention other than one recieved from CFS service

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

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

No real benefit but there will be a chance to comment on their intervention experience. Potential benefit to other CFS sufferers in the future with potential intervention/programme modifications.

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:

(i)Through referrals to the CFS service.
(ii) Letter or verbally at assessment
(iii) Consent form

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)*

Oxford criteria for CFS see protocol
As the programme/intervention is given in English it is a inclusion criteria that participants be English speakers

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

Not meeting the above criteria.

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.

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.
Participants will sign a consent form which will be sent out to their homes by the service. Participants will have the opportunity to contact the researcher or the lead CFS team member to seek additional information if the require.

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?

1 week then a reminder will be sent to the home to check if they wish to take part or not.

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.)*

n/a see inclusion criteria

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 has been selected for this study.

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?

Please forward copies of the relevant documents.

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

- [x] Peer reviewed scientific journals
- [x] 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
- [x] Other/none e.g. Cochrane Review, University Library

If other/none of the above, give details and justify:

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

Participants will be informed that they can contact the CFS service for the results of the study at their folow up sessions if they require them. There will also be a poster with the results displayed at the Hospital.

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
- ☐ 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
  - ☐ University computers
  - ☐ Private company computers
  - ☑ 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:

Participants wil be fully anonymous and will be identified with a numerical code.

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

At the CFS site by Dr Louise Barber

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

Dr Louise Barber for the duration and Dr Helen Lyon-Jones thereafter.

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

Dr Louise Barber and the CFS service team

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

5 Years 0 Months

Give details of where they will be stored, who will have access and the custodial arrangements for the data:

NHS computer & confidential case records at Bryn Seiont Hospital at Caernarfon
Dr Helen Lyon–Jones

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:
Dr Dave Daley, Senior Research Tutor at the University of Wales, Bangor (see attached)

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

But Dr Dave Daley (as above) has approved the analysis strategy

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

Fatigue questionnaire (see attached protocol)

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

Euroqual, BDI, HADS, Life Orientation test, Hope Scale, SF36 (physical functioning subscale) Pain Visual annalogue scale, global outcome scale (see protocol)

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.

At least 34 but numbers depend on referrals

A51. How was the number of participants decided upon?

Using Cohens (1992)power primer a power calclulation was made. Using low to medium effect size,alpha level of 0.5, and ANOVA test, 34 particpants should yeild maximum power greater than 0.8 to detect 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

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.

Repeated measures ANOVA & t-tests to compare differences before and after intervention

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

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	
[x] NHS Primary Care Trusts or Local Health Boards in Wales	
[ ] 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 Helen Lyon–Jones the team leader for the CFS service and Dr Dave Daley, senior research tutor will supervise the 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.

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

non as it is an evaluation of a current CFS service

A58. Has external funding for the research been secured?

○ Yes ◉ No

If No, what arrangements are being made to cover any costs of the research? If no external funding is being sought, please say so:

Covered by the CFS service current arrangements. The University are sponsers and their ethical approval is being sought in parellel to the COREC application.
For further information contact Paula Gurteen. Tel 01248 383831

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:

The University of Wales Bangor

Status:

○ NHS or HPSS care organisation ◉ Academic ○ Pharmaceutical industry ○ Medical device industry ○ Other

If Other, please specify:

The University are sponsers and their ethical approval is being sought in parellel to the COREC application.
For further information contact Paula Gurteen. Tel 01248 383831

Address:	Clinical Psychology dept Briganntia Building, College Rd, Bangor		
Post Code:	LL57 2DG		
Telephone:	01248 388067	Fax:	01248 383718
E-mail:	d.daley@bangor.ac.uk		

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):*

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: Dr
Forename/Initials: Helen Surname: Lyon-Jones
Post: Lead Psychologist of the CFS service
Qualifications: BSc PhD
Organisation: CFS Service
Address: Bryn Seiont Hospital
Caernarfon Telephone: 01286 662733
Fax:
Postcode: LL55 2YE
E-mail: helen.lyon-jones@nww-tr.wales.nhs.uk

PART A: SUMMARY | EDGE | SUBS

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?

People with serious mental health issues will be identified by the service at assessment stage before they complete questionnaire for the research. The service deals with this by referring the patient to the appropriate specialist agency.

No ethical issues should arise with the proposed study.

PART B: SHORT DECLARATION

– 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: 03/07/2006 (dd/mm/yyyy)

Print Name: Dr Louise Barber

North Wales Research and Development Registration Form

This form should be typewritten and each section completed or marked N/A. Please refer to guidance notes included with this form. Guidance notes are available for text highlighted in yellow, to view the guidance note for the specific question, simply hover with mouse pointer over the highlighted text or refer to separate copy of guidance notes attached. Completion of this form is required for all research projects within North Wales (that is: North East Wales NHS Trust, Conwy & Denbighshire NHS Trust, North West Wales NHS Trust). This form must be accompanied by all supporting material (research protocol, participant questionnaires, participant information sheets etc), please see Section N: 'Documentation required for Full Application'.

Please note, a fully signed hard copy and an electronic version (by e-mail or on disc) of the project registration form plus supporting material must be received by the R&D Office before a project can be reviewed and approved by the relevant Trust.

Research using North Wales NHS Trust resources must not proceed before written approval has been granted by the relevant North Wales NHS Trust and the appropriate Research Ethics Committee.

Please contact your R & D Manager for Submission details (please see Section P).

THIS FORM HAS BEEN PROTECTED
Please use the tab key to take you through the form

Full Title of Study : Effectiveness of a group cognitive behavioural therapy intervention compared to an 8 week waiting list control for managing symptoms and improving quality of life for people with chronic fatigue syndrome.

IRP Reference Number *(Office Use Only)*:	**MREC No.**
ISRCTN NO.	**LREC No.** 06/WNo01/34

A: PERSONNEL

1) Name & Title of Local Principal Investigator: Dr Louise Barber

2) Position: Trainee Clinical Psychologist

3) Contact Address: University of Wales Bangor, Brigantia Building, College Road, Bangor

4) Contact Telephone Number: 01248 490900 or 07796156676	5) Contact e-mail address: loubarber@aol.com

6) Name & Title of Chief Investigator (if different from above):

Position of Chief Investigator

7) Contact Address:

8) Contact Telephone Number:	9) Contact e-mail address:

10) Name(s) of Other Researchers: Dr Helen Lyon-Jones

Comment [j1]: Page: 1 The investigator responsible for the research site where the study involves specified procedures requiring site-specific assessment. (Contact REC administrator for further details on site specific assessment.) There should be a PI for each research site. In the case of a single site study, the CI and PI will normally be the same person (CI – Chief Investigator. PI = Principal Investigator)

Comment [j2]: Page: 1 The investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites. All applications for ethical review should be submitted by the CI.

11) Contact Address: CFS Service, Bryn Seiont Hospital, Caernarfon, LL55 2YE

12) Contact Telephone Number: 01286 662733

13) Contact e-mail address: helen.lyon-jone@nww-tr.wales.nhs.uk

14) Lead Research Centre: Bryn Seiont Hospital, Caernarfon

15) Other NHS Organisations where the research will take place: n/a

16) Other participating organisations (e.g. University): n/a

17) Name of Academic Supervisor (where appropriate): Dr Helen Lyon-Jones

18) Contact Address: as above

19) Contact Telephone Number: 01286 662733

20) Contact e-mail address: helen.lyon-jones@nww-tr.wales.nhs.uk

21) Title of Course / Qualification that the research relates to, if applicable: Clinical Psychology

B: PROJECT DETAILS

1) Shortened title or acronym: CBT for CFS

2) Clinical Areas covered by project: CFS

3) Lay Summary (up to 250 words) Study to look at the effectiveness of a 8 week CBT intervention for people suffering with chronic fatigue. This will be compared to an 8 week control where the participants have no treatment for 8 weeks while they are on the waiting list. Patients will complete a set of questionnaires 8 weeks before the start of their intervention. They will then complete them again at the start and end of the treatment to enable changes to be monitored.

4) Research Question or hypothesis: Eight week grouop CBT for CFS is superior to an 8 week waiting list control in helping clients to manage their symptoms and improve their quality of life/hope.

5) Aims: To show group CBT for CFS to be superior to a waiting list control.

6) Objectives: To generate more research in the area, building up an evidence base for group CBT for CFS.

7) Methodology (in no more than 10 words) Repeated measures design using questionnaires

8) Outcome Measures: CFS scale, pain scale, quality of life scale, depression and anxiety scale, hope and optimism scale.

9) Type of Participants/Sample: CFS service users

10) Target national sample size, where applicable: na

11) Target local sample size: at least 35

Comment [j3]: Page: 2 If it is a national study, please detail the lead site. If you are carrying out the research across North Wales please detail the site initiating the project.

Comment [j4]: Page: 2 Other sites where the research project is taking place. Trust and External sites to be included.

Comment [j5]: Page: 2 If you are doing an MSc or higher education qualification etc., then please provide the name of the person responsible for you within the academic institute.

Comment [j6]: Page: 2 Directorates, divisions or departments involved within the hospital (e g. Paediatrics)

Comment [j7]: Page: 2 Please write a brief summary in language a layperson would understand.

Comment [j8]: Page: 2 For example Randomised Controlled Trial, Survey or Questionnaire, Cohort Study.

Comment [j9]: Page: 2 ****See WORD or NRR definition ****

Comment [j10]: Page: 1 For example elderly over 75. Specific details as opposed to general group.

Comment [j12]: Page: 1 Size of sample in specific Trust

Comment [j11]: Page: 2 Overall total number expected by study for a multi-site project.

12) Proposed Start Date: 01/09/06 | 13) Proposed End Date: 01/05/07

14) Benefits to the Trust and Wales (include reference to national priorities)
Enable service monitoring and generation of evidence base

15) Are patients or service users involved in any of the following:

i) Identifying the research topic YES ☐ NO ☒ | ii) Undertaking the study YES ☒ NO ☐

iii) Designing the study YES ☐ NO ☒ | iv) Disseminating results YES ☐ NO ☒

16) Can details of this project be listed on the National Research Register (NRR)

YES ☒ NO ☐

17) Details of proposed methods of dissemination: Research journals, conference presentations, team meetings

C: SPONSORSHIP

1) Who will act as Research Sponsor: University of Wales, Bangor

2) Contact Name: Dr Dave daley

3) Contact Address: University of Wales Bangor, Briganntia House, College Road, Bangor

4) Contact Telephone Number: 01248 388067 | 5) Contact e-mail address: d.daley@bangor.ac.uk

6) Name and contact details of persons involved in the study who will require an Honorary Contract (please also see signature section) : n/a

7) Name and contact details of any other person(s) having clinical responsibility for the care of local participants in the study(if this person is different from the Principal or Chief Investigator):

D: INDEMNITY

Name of Institution providing indemnity for each of the following:

1) Research Liability – University of Wales Bangor
2) Clinical Negligence – North west Wales Trust
3) Non-negligent Damage – North West Wales Trust
4) Product Liability (if applicable) n/a

E: FUNDING

1) Funding Organisation: University of Wales, Bangor

2) Commercially Funded Project YES ☐ NO ☒ | 3) Funding Amount *(please complete as appropriate)*: Per Patient: n/a Total:

4) Which Organisation received the grant income? n/a

Comment [j13]: Page: 3 Do you give permission for details of this project to be entered onto the NRR, which is a national database. The NRR is designed to provide a systematic review record of R & D projects proposed, curren and completed or of interest t the NHS. This information will be of value to ...

Comment [j14]: Page: 3 Give a brief description of how the research findings will be disseminated both to those participating in the research and to all those who coul ...

Comment [j15]: Page: 3 The sponsor is the individual, company, institution or organisation who takes ultimate responsibility for the initiation, management q ...

Comment [j16]: Page: 3 All staff involved in the research should hold a full contract with the Trust, therefore staff involved in the research who do not hol ...

Comment [j17]: Page: 3 The person who has overall responsibility of care must be informed. Participation must be recorded in the relevant casenotes. If this resear ...

Comment [j18]: Page: 3 Arrangements must be made to provide indemnification. The NHS provides indemnification to its employees for negligent harm only. You will nee ...

Comment [j19]: Page: 3 (For design, conduct, management and outcome of a research project) rests with the Principal investigator and vicariously with his or h ...

Comment [j20]: Page: 3 Is the responsibility of the relevant NHS Trust and no distinction is made between research and normal clinical practice. Trusts must pr ...

Comment [j21]: Page: 3 This is not a requirement of the EU Directive. It is necessary for an Ethics Committee on a case-by-case basis to direct whether non-negligent (r ...

Comment [j22]: Page: 3 This could include University, WORD, Trust, Pharmaceutical Company, Medical Research Council, Charitable Funds etc.

5) Are there any excess R & D costs to be claimed? YES ☐ NO ☒ (If Yes please specify below

i) Research Costs ☐ ii) NHS Support Costs ☐

iii) Service Treatment Costs ☐ iv) Excess Treatment Costs ☐

F: RISK ASSESSMENT

1) Are there any potential risks resulting from your study that may impact on the Trust?
YES ☐ NO ☒
If YES please specify

2) Will everyone involved in the project be properly trained and working within the limits of their competence? YES ☒ NO ☐

3) Will equipment or devices be used for purposes other than routine use?
YES ☐ NO ☐ N/A ☒

4) Will transparent records of all payments be made available to the Trust on Request?
YES ☐ NO ☐ N/A ☒

5) All researchers are without previous or pending professional disciplinary or legal action in the context of research. YES ☒ NO ☐

G: INTELLECTUAL PROPERTY

Could the research lead to the development of a new product/process, or the generation of significant intellectual property, copyright, design rights or a patent for the Trust? YES ☐ NO ☒

H: DATA MANAGEMENT

1) How will paper and/or electronic data/files be managed during the project? Electronic data will be sored encriptically on the University property laptop and the Trust's PC.

2) What arrangements have been made to store either paper and/or electronic data, biological samples after completion of the project? Sored in the ususal way within the CFS service.

3) How long will data/samples be stored? unlimited within the trust

4) Name and contact details for access to the data following completion of the project:

5) Contact Name: Dr Helen Lyon-Jones

6) Contact Address: CFS Service, Bryn Seiont Hospital, Caernarfon

7) Contact Telephone Number: 01286 662733

8) Contact e-mail address: helen.lyon-jones@nww-tr.wales.nhs.uk

Comment [j23]: Page: 4 These are the costs of the research study itself. They include the costs of data collection and analysis and other activities needed to answer the questions that a piece of research is addressin They can include pay and indirect cost of staff employe to carry out the research study (but also see NHS support costs)

Comment [j24]: Page: 4 These are the additional patie care costs associated with the research study, which would end once the research activity in question has stopped, even if the patient service involved continued to be provid...

Comment [j25]: Page: 4 These are the patient care cost which would continue to be incurred if the patient care service in question continued to be provided after the research activity has stopped.

Comment [j26]: Page: 4 Where patient care is being provided which differs from the normal/standard treatment for the condition (either an experimental treatment or a service in a different location from where it would n...

Comment [j27]: Page: 4 PLEASE NOTE – Irrespective of protocol requirements, any incidents or adverse events reportable under the Trust incident reporting system (IR 1) should be documented using t...

Comment [j28]: You may be required to complete a risk assessment form. Please contact the Trust Risk Manager.

Comment [j29]: Page: 4 Intellectual property can be defined as products of intellectual or creative activity in the form of novel ideas, innovation or research and development (R&D) which can be given legal recogniti...

Comment [j30]: Page: 4 How are you going to store your data? How are you going to use it? How will you keep it confidential? Compliance with the data protection act and caldicott guardian is essential fo...

I: RESOURCES / FINANCE

ASSESSMENT OF IMPACT ON TRUST RESOURCES

1) Staff Time spent on project pre-protocol

Name	Post	Department / Directorate	Hours on Project
N/a			

2) *Estimated Staff Time, over and above standard care, needed for this project* (per year ☐ duration of project ☐ Please use the measure that is most appropriate to your study).
It may help to note "standard care" interventions before completing the research protocol sections.

Name	Post	Department / Directorate	MINUTES/HOURS PER PATIENT						
			STANDARD CARE	ARM A (in addition to standard care)	ARM B (in addition to standard care)	ARM C (in addition to standard care)	ARM D (in addition to standard care)	ARM E (in addition to standard care)	EMPLOYER
N/a									

3) Impact on Patient Care Services over and above standard care (per year ☐ duration of project ☐)

Department	What will be the effect of your research on each patient/ volunteer	Location / Clinic / Ward	Standard Care	Arm A (in addition to standard care)	ARM B (in addition to standard care)	ARM C (in addition to standard care)	Arm D (in addition to standard care)	ARM E (in addition to standard care)
Outpatients	Visits per patient							
	Additional Time per routine visit							
Inpatients	Day stays per patient							
Daycases	Episodes per patient							
Operating Theatre Time	Hours per patient							
Other								

4) Estimated Demand for Support Services over and above standard care (per year ☐ duration of project ☐)

Department	Type of Test	Standard Care	Arm A (in addition to standard care)	Arm B (in addition to standard care)	Arm C (in addition to standard care)	Arm D (in addition to standard care)	Arm E (in addition to standard care)
Haematology							
Biochemistry / Immunology							
Histopathology / Cytology							
Microbiology							
Radiology							
Radiotherapy							
Other (please specify)							

5) *TRAVEL EXPENSES* - Please provide details of any additional travel expenses

6) Estimated Costs of any additional NHS purchased consumables e.g. additional syringes, specimen tubes, tissue culture flasks, stationery, IT consumables.

Item	Number used	Cost per item £	TOTAL COST £
N/A			

7) Are there any additional drug / treatment costs compared to routine patient care ? *YES* ☐ *NO* ☐
If YES, please explain what these are.

Drug	*Number used*	*Cost per Drug £*	*TOTAL COST £*
N/A			

8) Will any equipment be purchased for use with this research project ? NB. Equipment purchased reverts to Trust ownership

Equipment	Number used	Cost per Unit £	TOTAL COST £
N/A			

9) Would you expect your level of library usage to be light, medium or high, or will you never use the service?	Light Use	Medium Use	High Use	Will Never Use
	☐	☒	☐	☐

Comment [j31]: Page: 7
Borrow books and use journals from the library stock, request less than 24 inter-library loans per year

Comment [j32]: Page: 7
Borrow books & use journals from the library stock, ask librarians for assistance in finding information once or twice and request between 25 & 50 inter-library loans a year

Comment [j33]: Page: 7
Borrow books & use journals from the library stock, ask librarians for assistance in finding information frequently and request more than 50 inter-library loans per year

J: PHARMACY	(Only complete if applicable)

Use of Medicinal Products or Medical Devices

1.1 For research involving the use of medicinal products, the Authorised pharmacist for the organisation is required to complete and sign the declaration **(1.5)** below.

a) What arrangements have been made to store, code and administer drugs?

b) Are the premises used to store drugs licensed for the purpose? YES ☐ NO ☐ N/A ☐

c) Pharmacy local emergency contact details (these should be 24-hour)

1.2 DRUG RELATED	(Only complete if applicable)

a) Details of regimens or drugs to be used (including standard treatment) (tick box to confirm supplied) ☐

b) Are drugs provided: free of charge YES ☐ NO ☐ or at reduced cost: YES ☐ NO ☐ (If YES to either, copies of ordering procedure should be supplied (tick box to confirm supplied) ☐

c) If drugs are provided, is commercial stock ☐ or trial packaging ☐ used? (tick as appropriate)
If trial packaging, copies of labels should be supplied (tick box to confirm supplied) ☐

1.3 RECORD KEEPING		What records are required:
a) Receipts YES ☐ NO ☐	b) Issues YES ☐ NO ☐	c) Temperature YES ☐ NO ☐

d) If YES, copy of record requirements supplied (tick box to confirm supplied) ☐

e) Code break held in Pharmacy YES ☐ NO ☐	f) If YES, copy of procedure supplied YES ☐ NO ☐

g) Has the Pharmacy got a copy of the agreed protocol: YES ☐ NO ☐

1.4 GENERAL		
a) Expected patient/participant numbers:	b) Duration of treatment:	c) Number of dispensing visits required:

1.5 I confirm that the arrangements as described in the research with respect to medicinal products in this host organisation are acceptable.

Date:	Signature:

Print Name:

Job Title:

Organisation:

Telephone/fax:

J: PHARMACY (USE OF MEDICINAL PRODUCTS OR MEDICAL DEVICES) /continued

2.1 For research involving the use of medical devices, the authorised Physicist / Bio-engineer /Technician for the organisation is required to complete and sign the declaration **(2.2)** below.

Is an MDA notice of No Objection required? YES ☐ NO ☐ N/A ☐

Explain why not.

2.2 I confirm that the arrangements as described in the research with respect to medical devices in this organisation, with respect to storage, disposal, service and maintenance, decontamination and sterilisation are acceptable

Date:	Signature:

Print Name:

Job Title:

Organisation:

Telephone/fax:

K: IONISING RADIATION (Only complete if applicable)

Exposure to ionising radiation.

1.1 For research involving the use of ionising radiation, both the IR(ME)R Practiitioner for the organisation AND the Radiation Protection Advisor are required to complete and sign the declaration **1.2** below and the RR1 form.

a) What tests will be carried out during the research?

b) What is the frequency of the tests?

c) Where will the tests be carried out ?

Please Note: If your project involves IR(ME)R issues please complete the dedicated IR(ME)R form, available from the R & D Manager

1.2	I confirm that the arrangements as described in the research with respect to ionising radiation are acceptable and I have countersigned the completed RR1 form.
Date:	Signature:
Print Name:	
Job Title:	**IR(ME)R Practitioner**
Organisation:	
Telephone/fax	

1.3	I confirm that the arrangements as described in the research with respect to ionising radiation are acceptable and I have countersigned the completed RR1 form.
Date:	Signature:
Print Name:	
Job Title:	**Radiation Protection Advisor**
Organisation:	
Telephone/fax	

L: SIGNATURE SECTION

Clinical Director	Signature:
Date:	Print Name:
Directorate/General Manager	Signature:
Date:	Print Name:
Support Services (if appropriate)	Signature:
Date:	Print Name:
Clinical Supervisor	Signature:
Date: 5/07/06	Print Name: Dr Helen Lyon-Jones

As **Clinical Supervisor** you are responsible for the care of the participants, you are also responsible for the actions of the researcher in relation to the patients until the issue of an Honorary Contract

If the Research is being undertaken for a degree or higher degree, the signature of the **Academic Tutor** is required to validate the scientific merit of this proposal.

Academic Tutor	Signature:
Date: 5/07/06	Print Name: Dr Dave Daley

If the Research involves the use of personal data, the signature of the relevant **Data Protection Officer/Information Security Manager** is required.

Data Protection Officer / Information Security Manager	Signature:
Date:	Print Name:

If the Data Protection Officer / Information Security Manager advised that advice should be sought from the local Caldicott Guardian, the signature of the **Caldicott Guardian** is required.

'I confirm that the arrangements to deal with Patients-Identifiable information are lawful and the use of data requested as described in the proposed research is compliant with Data Protection Principals.'

Caldicott Guardian	Signature:
Date:	Print Name:

Comment [j34]: Page: 11
Have management reporting arrangements for the research been made clear to your line manager and head of department?

Comment [j35]: Page: 11
If you are awaiting the issue of an Honorary Contract, your Clinical Supervisor will need to sign accepting care for the participants until the Honorary Contract is issued.

M: Declaration by the Principal (Local) Investigator:

- 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 Principals underpinning the Declaration of Helsinki, and Good Practice Guidelines on current proper conduct of research.
- If the research is approved, I undertake to adhere to the study protocol without unagreed deviation and to comply with any conditions set out in the letter sent by the North West Wales Trust Internal Review Panel, notifying me of this.
- I undertake to inform the North West Wales Trust Internal Review Panel of any changes in the protocol, and to submit reports setting out the progress of the research (at least annually) plus a final report on conclusion of the project.
- 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 obtain appropriate approval from the Trust Data Protection Officer to process personal data.
- I give my consent for information about non-commercial research to be extracted from this application for inclusion where appropriate in the National Research Register.
- I understand that personal data about me as a researcher in this application will be held by the Internal Review Panel and its operational managers.
- I understand that research records/data may be subject to inspection for audit purposes if required in future.
- I understand my responsibility to conform with Health and Safety Regulations and the Principals of the Research Governance Framework within the organisation(s) where the research will take place.
- I have carried out a risk assessment of the project, identified the hazards involved and assessed the risks arising from those hazards. The risks arising from these hazards will be controlled through normal clinical procedures unless indicated otherwise.
- I am aware that incident reporting is a mandatory requirement.
- I understand my responsibility to ensure the research is properly supervised and that equipment and devices are used within their specification limits.

Signature of Local Principal Investigator	Print Name	Date
	Dr Louise Barber	05/07/06
Signature of Chief Investigator (if there is no Local Investigator)	Print Name	Date

Please return completed forms to: Research & Development Department at the appropriate Trust (See Guidance Notes for details of individual contact addresses)

Comment [j36]: Page: 12
Insert relevant Trust name

Comment [j37]: Page: 12
Insert relevant Trust name

N: Documentation Required for Full Application

Completed and signed Trust Project Registration Form

Protocol

Participant Information Sheet

Participant Consent Form (if applicable)

All Validated and Non-Validated Questionnaires

Letter of Sponsorship

Sponsorship indemnity insurance certificate

Evidence of indemnity

Evidence of Funding Confirmation (if applicable)

Agreements, where applicable: Trust/University
Trust/Trust
Clinical Trials Agreement
Pharmaceutical Company

Evidence of current Clinical Trials Authorisation (MHRA) (if applicable)

Curriculum Vitae

Risk Assessment (if applicable)

Completed Honorary Contract Application (if applicable)

Research and Development approval cannot be granted until all relevant and fully completed documentation has been received

O: Office Use Only

MREC Ref No. (if applicable)

ISRCTN No. (if applicable)

LREC Approved: Yes ☐ No ☐ LREC Ref No:

If not yet approved name of NHS LREC to which application is being made:

Date received by Research and Development Office:

Date Reviewed

Outcome of IRP: Approved ☐ Subject to Revisions ☐ Refusal ☐

Date of final Trust approval:

Approval signed off by R & D Director/Chairman

Name: **Title:**

Signature:

Appendix A

Research Protocol

North West Wales Clinical Psychology Programme (NWCPP)
Large Scale Research Project
Research Protocol

1. Project title

Effectiveness of a group cognitive behavioural therapy intervention compared to an 8-week waiting list control for managing symptoms and improving quality of life for people with chronic fatigue syndrome.

2. Supervision

Dr Helen Lyon-Jones

3. Background

Health services care for many people who suffer with fatigue and it appears to be a normal consequence of life (Risdale, 1989). Many of these people suffer with a physical of psychological disorder that cause the fatigue but there are some with disabling and chronic fatigue, which is medically unexplained. CFS is thought to affect up to 1% of the population (Wesseley, 1995). The prognosis for adults with CFS is poor with many remaining disabled and symptomatic for many years (Hotopf & Wessley, 1997). A longitudinal study showed that 91% of patients with CFS who received standard medical care continued to fulfil diagnostic criteria for years after their original assessment (Hill et al., 1999).

The defining characteristic for people suffering with CFS is a debilitating and unexplained severe mental and physical fatigue, not resulting from organic disease or exertion and is not alleviated by rest or sleep. Other associated symptoms can include muscle pain, mood and sleep disturbance (Reeves et al., 2003). It is a condition that can occur in adolescents as well as adults (Chalder et al., 2003). To meet the criteria there must be a minimum duration of six months and a definite onset (not lifelong) and a functional impairment. Although there are differing definitions for CFS (see table 1) the standard UK definition was proposed in 1991 and became known as the Oxford criteria (Sharpe, et al., 1991).

Post infectious fatigue was listed as a subcategory, with the same symptoms of CFS but with a proven infectious episode. Substance abuse and psychosis are exclusion criteria but psychiatric disorder is not, although it can be noted and stratified later if required (Wesseley, Hotopf & Sharpe, 1998). The condition is estimated to affect 2.6% of a representative sample from primary care practice (Wessley et al., 1997).

Table 1: Case definitions for chronic fatigue syndrome

	CDC*-1988 Holmes et al. (1988)	CDC-1994 Fukuda et al. (1994)	Australian Lloyd et al. (1994)	UK Sharpe et al. (1991)
Minimum duration (months)	6	6	6	6
Functional impairment	50% decrease in activity	Substantial	Substantial	Substantial
Cognitive or neuropsychiatric symptoms	May be present	May be present	Required	Mental fatigue required
Other symptoms	6 or 8 required	4 required	Not specified	Not specified
New onset	Required	Required	Not required	Required
Medical exclusions	Extensive list of known physical causes	Clinically important	Known physical causes	Known physical causes
Psychiatric exclusions	Psychosis, bipolar disorder, substance abuse	Melancholic depression, substance abuse, bipolar disorders, psychosis, eating disorder	Psychosis, bipolar, substance abuse, eating disorder	Psychosis, bipolar, eating disorder, organic brain disease

*Centers for Disease Control (CDC)

Treatments

Many people suffering with CFS in the community attend their GPs for assessment and treatment (Price & Couper, 1998) but there are also those who attend alternative practitioners when they have become disappointed with orthodox approaches to treatment. People can often be referred on to a number of specialist clinics and this wide variety of approaches highlights the uncertainty and sometimes disagreement amongst sufferers and doctors about the cause of the condition.

Opinions about the causes fall into mainly physical or psychological explanations. However with many conditions such irritable bowel syndrome, CFS and back pain,

there is an increasing awareness of the interaction between the psychological and physical factors in development and maintenance of the condition.

People have often been advised to rest and limit the demands on the body to promote recovery and limit deterioration. This can however lead to a further impairment to their quality of life (Price & Couper, 1998). In recent years trials have been conducted using Cognitive Behavioural Therapy (CBT), which combines a graded increase in activity with a psychological approach that addresses thoughts about CFS, which may impair recovery.

CBT is based on a biological psychosocial conceptualization of the patient's problems and includes psychotherapeutic, informational, behavioural and problem solving components. A cognitive behavioural model of CFS assumes that illness related beliefs and cognitions play a central role in CFS and these beliefs in turn influence a person's emotional, behavioural and physiological state. Such treatments apart from efficacy issues do not presuppose causal factors but rather considers perpetuating factors thus embracing a holistic approach to the condition.

Several studies have demonstrated that CBT is effective in adults (Sharpe et al., 1996; Deale et al., 1997) and a recent randomised control group study reported CBT to be an effective treatment for adolescents with CFS (Stulemeijer et al., 2005). A review by Price and Couper (1998) concluded that although there were only a limited number of studies, CBT for adults with CFS improves physical functioning and other relevant outcome such as mood. There is also evidence that CBT is a cost effective treatment (Best & Stevens 1996).

However, there is little in the way of research to explore the effectiveness of group CBT for CFS (Saxty & Hansen, 2005). Group therapy has received some success with other somatic problems such as chronic pain (Basler et al., 1997; Harrison et al., 1997), irritable bowel syndrome (Toner et al., 1998) and hypochondriasis (Stern & Fernandez, 1991).

Soderberg and Evengard (2001) treated 14 CFS patients with short-term group therapy using a supportive and goal-oriented format. Patients reported that sharing their experiences had been valuable but the results did not provide conclusive evidence of the programmes effectiveness. Saxty and Hansen (2005) reported good results for the effectiveness of group CBT for CFS but they only had a small sample of six patients.

Group therapy is becoming increasingly popular as it is a more cost effective way to treat patients (Abbey, 1996) and may be useful for reducing time spent on a waiting list. It is argued to be particularly advantageous where an intervention has a significant psych-educational component. It is also thought that peer support might have therapeutic benefits and be appropriate for a condition such as CFS which is not well understood by the general population and the professionals (Saxty & Hansen, 2005).

Background

Established in 1999, the North Wales Chronic Fatigue support service aims to provide patients, diagnosed with CFS, information and skills, designed to improve their overall quality of life. Based on a cognitive behavioural therapeutic model, the sessions cover pacing, realistic goal setting and dietary advice. The multidisciplinary team consists of a physiotherapist, dietician, clinical psychologist and a GP based at a CFS service in Caernarfon.

New research

In November 2005 new guidelines for the collection of data were provided for services for CFS in England. A collaborative minimum dataset was established so that effective and comparable evaluations of services could be made. To enable any funds to be allocated to English services for CFS, the minimum dataset must be given to all service users. In Wales, so far, no minimum dataset has been established. This study aims to evaluate group CBT interventions for CFS across one of the services in North Wales using the minimum dataset and a small selection of other measures (hope optimism and outcome satisfaction), which may potentially be effective outcome measures in CFS management programmes.

4. Research questions

Eight consecutive weekly group CBT sessions are superior to an 8-week waiting list control in helping clients manage their symptoms and improve quality of life.

5. Participant recruitment

Participants are to be consecutive referrals to the specialist clinic, usually from the patients GP. If patients are eligible for the study GP's will be informed of their participation. As part of the usual care all patients who were referred to the service are assessed by means of a detailed history and psychometric measures. This is done in an hour and a half long clinical interview with an experienced Clinical Psychologist and GP from the Chronic fatigue Syndrome service, who ultimately make the decision as to whether to accept patient onto the programme. Patients are eligible if they were aged over 18 years of age and meet the Oxford criteria (Sharpe, et al., 1991, see definition for the UK above). All participants have medically unexplained, disabling fatigue for at least 6 months, and with a definite onset. Patients should have previously undergone routine investigations to rule out possible organic explanations for their fatigue.

If patients meet the above criteria and have no other serious mental health issues they will be invited to take part in the CBT intervention. In the event of information being disclosed that would require the breaking of confidentiality or the referral to specialist services, a member of the Chronic Fatigue Syndrome service would report back to the patients GP recommending that a referral be made.

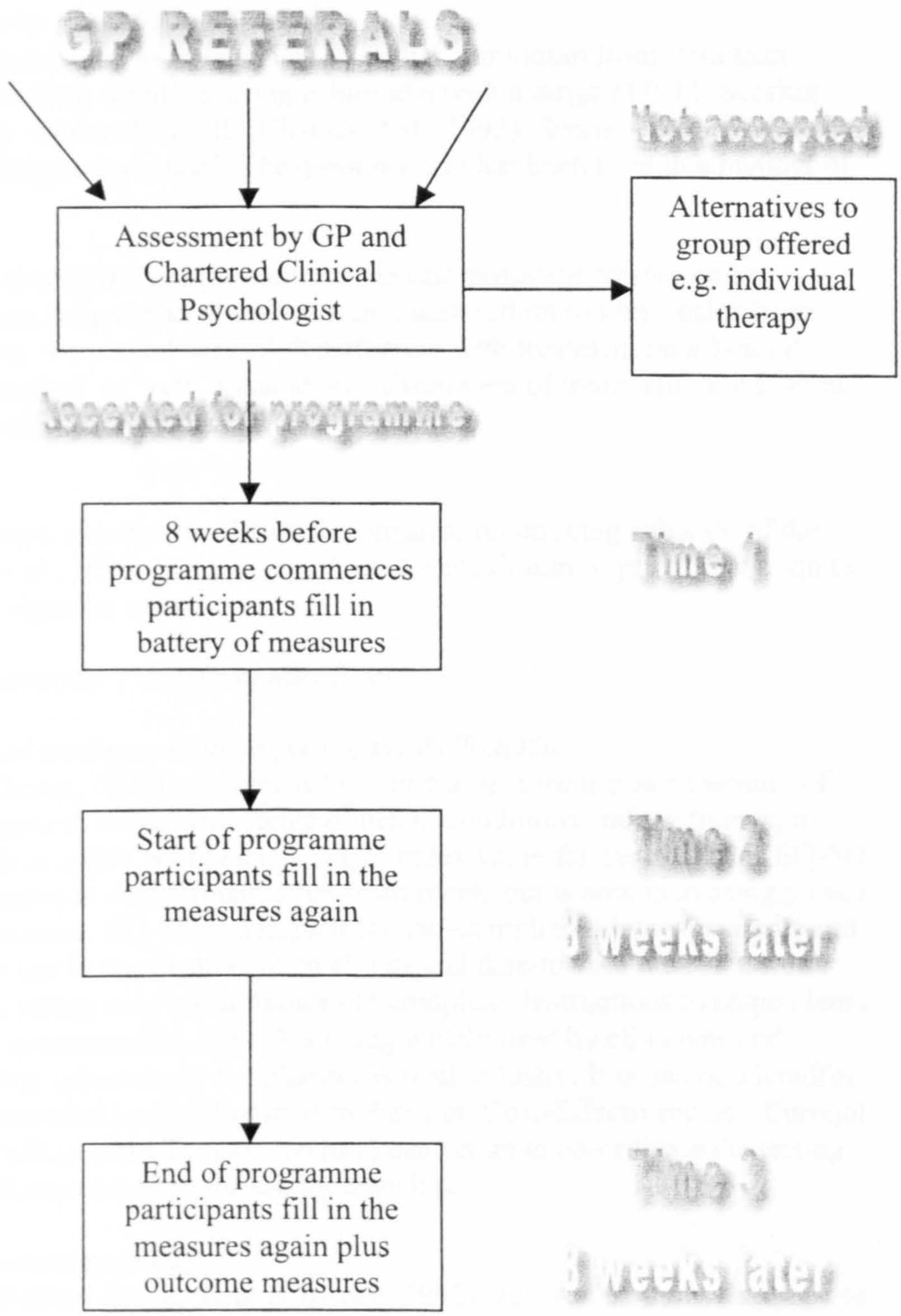
Hopefully there should be a potential of approximately 40 to 50 participants able to take part.

6. Design and procedures

A repeated measure design will used in an effort to enable a waiting list control group that is service friendly and does not elicit much more of a waiting period for the participants and disturb the usual service provision.

A programme start date will be set and eight weeks before the start of the programme everyone on the waiting list, following initial assessment will be sent the batch of questionnaires and the programme start date. The treatment will be the usual service and participants will have to fill in measures as they would at the start and end of their 8-week programme (see figure 1 for diagrammatical representation of the procedure). This enables participants to be their own control group. Eight weeks before the programme start participant will complete their questionnaires at home, with a visit/phone call from the researcher, if needed. All other data collection points will be completed at the relevant programme site.

Figure 1: Procedure/design



7. Measures (see appendix)

Demographic details about the participant will be collected along with employment details.

Fatigue Questionnaire (Chalder et al., 1993)
Eleven fatigue symptoms are each rated on a 4-option continuum from 'less than usual' to 'much more than usual'. Scoring is bimodal with a range of 0-11. Scoring gives an empirically validated cut off (Chalder et al., 1993). Scores of 4 or more indicate excessive fatigue 'caseness'. The questionnaire has been used in a number of other CFS studies.

Global self-ratings and rating of informant (at the last treatment session only)
Overall improvement, fatigue and disability were measured on 6-point scales from 'very much better' to 'very much worse'. Satisfaction with treatment on a 7-point scale from 'very satisfied' to 'very dissatisfied'. Usefulness of treatment on a 5-point scale from 'very useful' to 'no use at all'.

SF-36
Functional impairment was measured with the physical functioning subscale of the SF-36 (Jenkinson et al., 1996) Scores range from 0 = maximum physical limitation to 100 = ability to do vigorous activity.

Pain visual analogue scale – as part of the SF-36

Quality of Life visual analogue scale as part of the EUROQOL
EQ-5D (EuroQol Group, 1990) is a standardised instrument for use as a measure of health outcome. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status. EQ-5D was originally designed to complement other instruments but is now increasingly used as a 'stand alone' measure. EQ-5D is designed for self-completion by respondents and is ideally suited for use in postal surveys, in clinics and face-to-face interviews. It is cognitively simple, taking only a few minutes to complete. Instructions to respondents are included in the questionnaire. EQ-5D is being widely used by clinicians and researchers including, increasingly the pharmaceutical industry. It is one of a handful of measures recommended by the Washington Panel on Cost-Effectivenesss. (Euroqol team, 2005) In the UK, a NHS Task Group has been set up to co-ordinate the testing of EQ-5D as an outcome measure for use by clinicians

Beck Depression Inventory (BDI)
The BDI- Second Edition (Beck, Steer & Brown, 1996) included 21 items designed to assess the intensity of depression in terms of 21 symptom-attitude categories. Each statement is ranked to reflect the severity of the symptom from neutral to maximum severity. Values of 0 to 3 are assigned to each statement and in some categories two equivalent statements labelled a and b are given to indicate that they are the same level. The BDI has internal consistency of .92 (based on outpatient sample) and rest-retest reliability of .93 ($p < .001$). Content validity between BDI and BDI II was .93 ($p < .001$) (Beck, Steer & Brown, 1996).

Hospital and Anxiety and Depression Scale
The HADS (Zigmond & Snaith, 1983) is a fourteen-item scale with a 7-item sub-scale measuring depression and a 7-item sub-scale measuring anxiety. Each statement is ranked reflect the severity of the symptom and a value of 1 to 4 is assigned to it. The HADS is extensively used in clinical settings and has good validity when compared to similar measures and internal consistency of .89 on both sub-scales and a re-test reliability in 6 months or less of .72 ($p < .001$) for each sub-scale and .74 ($p < .001$) for the total scale (Savard et al, 1998).

Life Orientation test (optimism)
This 10-item measure of dispositional optimism includes four filler items, three positively worded items, and three reversely coded items. Participants rated each item on a 5 point Likert scale ranging from 1 = 'strongly disagree' to 5 = 'strongly agree.' Higher scores correspond with higher levels of optimism. This has been shown to have adequate reliability and adequate predictive and discriminate validity (Scheier et al.,1994).

State Hope Scale
The adult State Hope Scale (Snyder et al., 1996) was developed from a dispositional Hope Scale (Snyder et al., 1991) and consists of 6 hope items, which are designed to measure the extent to which someone has goal directed cognitions. There are two sub-scales. The agency sub-scale is made up of three items, which measures the degree to which an individual has the perceived motivation to move towards their goals and the pathways sub-scale is made up of three items to measure the degree to which an individual has the perceived ability to generate workable routes to goals. The items are rated on an eight point Likert type scale ranging from, 1 = 'Definitely false' to 8 = 'Definitely True.' The scale has been demonstrated to have good internal reliability and validity (Snyder et al., 1991; Snyder et al., 1996).

8. Data management and analysis

Data will be stored in the usual manner within the service. All paper files are kept in the strictest confidence under lock and key. The data will also be stored anonymously electronically on an SPSS database with only the programme team members and the researcher having access to it.

Repeated measures ANOVA & t tests, correlation

Using Cohen's (1992) power primer a power calculation was made to determine how many participants are needed in each group.

Effect Size assumed to be enough to see a difference by eye medium. Low to medium reported in review (Price & Couper, 1998) ($f = .40$) and significance criteria set at .05 then the necessary sample size per group = 34. As participants are in both control and intervention group it is reasonable to assume that this is achievable

9. Proposed journals

Review
Journal of Health Psychology

Research paper
Journal of Psychosomatic Research

10. Ethical/Registration issues

I do not foresee any problematic aspects to the proposal as for as ethical practices are concerned as the intervention is going to be run in the usual manner. No disruption should be made to the CFS service provided. As participants have to fill in questionnaires as part of the requirement of the programme, there is very little change other than some of the participants who are on the waiting list will have to fill in an extra batch of questionnaires 8 weeks before the programme commences and extra measures will be taken from participant informants (e.g. partner, parent child etc.)

11. Risk assessment

There should be no potential risks to either myself as the researcher or any of the participants.

12. Data storage

Data for the project will be stored in the usual manner within the trust. Client's paper files are kept locked in drawers on trust premises under the charge of the programme leaders. An electronic database will be created to store the data unanimously and this will be stored on the researchers laptop. She will adhere to the trusts policy on keeping this equipment safe and secure.

13. Timetable

01/07/06	COREC ethical approval
01/09/06	Begin data collection
21/10/06	1st written progress report
17/02/06	2nd written progress report

24/03/06	Data collection completed
mid June TBA	Deadline final

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Appendix B

Invitation letter

English and Welsh Versions

CFS Service
Bryn Seiont Hospital
Caernarfon
Gwynedd
North Wales
LL55 2YE

Date

Dear Sir/Madam

We are looking forward to seeing you shortly at the CFS programme. All patients receiving a CFS intervention are routinely required to complete a questionnaire before and after their treatment. This enables the clinicians to monitor the patient's progress.

Relatively little research has been conducted into the effectiveness of the group interventions for people with CFS and more is needed to help plan future services. Dr Louise Barber is a Trainee Clinical Psychologist who will be carrying out research of this kind, supervised by Dr Helen Lyon-Jones, at the Caernarfon CFS service as part of her doctoral thesis.

We would like to invite you to take part in this research by allowing her access to the questionnaires you complete and completing an extra set of questionnaires 8 weeks before the programme commences.

Please read the enclosed participant information and if you decide that you wish to take part in the study please complete and return, in the pre-paid envelope, the consent form and the questionnaires.

With many thanks in anticipation of your help with this.

Yours Sincerely,

Dr Louise Barber
Trainee Clinical Psychologist

Dr Helen Lyon-Jones
Clinical Psychologist

Gwasanaeth Syndrom Lludded Cronig (CFS)
Ysbyty Bryn Seiont
Caernarfon
Gwynedd
Gogledd Cymru
LL55 2YE

Dyddiad

Annwyl Syr/Fadam,

Edrychwn ymlaen at eich gweld yn y rhaglen CFS cyn bo hir. Mae gofyn i bob claf sy'n derbyn ymyriad CFS lenwi holiadur cyn ac ar ôl eu triniaeth. Mae hyn yn galluogi'r clinigwyr i fonitro sut mae'r claf yn dod ymlaen.

Cymharol ychydig o ymchwil sydd wedi cael ei gwneud i effeithiolrwydd ymyriadau grŵp i bobl â CFS ac mae angen mwy er mwyn helpu i gynllunio gwasanaethau yn y dyfodol. Seicolegydd Clinigol dan hyfforddiant yw Dr Louise Barber a fydd yn gwneud ymchwil o'r math yma, dan oruchwyliaeth Dr Helen Lyon-Jones, yng ngwasanaeth CFS Caernarfon fel rhan o'i thesis ar gyfer doethuriaeth.

Hoffwn eich gwahodd i gymryd rhan yn yr ymchwil hon trwy ganiatáu iddi gael mynediad i'r holiaduron yr ydych yn eu llenwi a thrwy lenwi set ychwanegol o holiaduron 8 wythnos cyn i'r rhaglen ddechrau.

Darllenwch y wybodaeth amgaeedig i gyfranwyr ac os byddwch yn penderfynu eich bod am gymryd rhan yn yr astudiaeth llenwch y ffurflen gydsynio a'r holiaduron a'u hanfon yn ôl yn yr amlen â stamp.

Diolch yn fawr i chi ymlaen llaw am eich cymorth.

Yn gywir,

Dr Louise Barber
Seicolegydd Clinigol dan Hyfforddiant

Dr Helen Lyon-Jones
Seicolegydd Clinigol

Appendix C

Participant information proforma

English and Welsh Versions

Study to look at the effectiveness of an intervention for CFS

You are invited to take part in a study looking at the effectiveness of the service you will be receiving for chronic fatigue syndrome (CFS). Services to help people manage the symptoms of CFS are relatively new. There is evidence to show that group cognitive behavioural therapy (CBT) is helpful to CFS sufferers but more research is needed. Research can often help to devise new services or improve old ones. The intention of this study to gather information collected as part of the service and to assess whether people experience positive changes as a result of the 8 week programme.

Why have I been asked to take part?
Anyone who is accepted on to a CFS programme at Caernarfon from September 06 to April 06 is invited to take part in the study.

What will I have to do?
It is a requirement of attending the CFS programme, that patients complete questionnaires at the start and end of the programme and also at follow up session. To participate in this research study you will be requested to complete an extra set of questionnaire 8 weeks in advance of the programme.

Where will I fill in the questionnaires?
You will receive questionnaires by post 8 weeks before the programme starts. These can be completed at home and returned to the service in a stamped addressed envelope. Then questionnaires are completed at the first and last session of the programme. This can be done at home or in the clinic. Help can be given to complete the questionnaires if it is required.

Will I be able to discuss my participation in the study?
A telephone number, address and e-mail address will be provided so that, if you require it, you can discuss your participation in the study or find out any more information.

Who is responsible for the information and who will have access to it?
The researcher and the programme team will be responsible for the information and only they will have access to it.

What will the information be used for?
The programme team keep a database of the information of all the people who attend the programme so that they can monitor how people do. For the purpose of this study, the researcher Dr Louise Barber will also monitor any changes made as a result of completing the programme. This information will be used as part of her clinical doctoral training and may be published in an academic journal.

Who can connect me to the research?
All information obtained in connection with the study will be held in strict confidence. No one other than the programme team and the researcher will be able to connect you with the information collected, as each participant will be coded on the database. Your identification will be kept strictly confidential in all publications and other outcomes.

How long will the study last?
Information will be collected by the researcher for approximately 8 months and then the results will be analysed. The study should be fully completed in June 2007.

Can I find out the results of the study?
Contact can be made through your service if you would like to be notified of the results of the study. This could be done at your follow up session or at a later date.

Do I have to participate and can I change my mind?
Participation is totally voluntary and you are free to withdraw from the research component of the study, any time should you change your mind. There will be no consequence for your treatment should you wish to withdraw form participation in the study. However, the completion of questionnaires at various time points is required as part of the CFS service you will be receiving.

What if I have further questions?
You can contact the researcher at;

Address
CFS service
Bryn Seiont Hospital
Caernarfon
LL55 2YE
Tel: 01286 662733

E-Mail
loubarber@aol.com

Address
Dr Louise Barber
Trainee Clinical Psychologist
University of Wales, Bangor
Brigannta house
College Road
Bangor
Gwynedd

Ffurflen wybodaeth i gyfranwyr

Effeithiolrwydd ymyriad therapi ymddygiadol gwybyddol grŵp o'i gymharu â grŵp rheolaeth ar restr aros 8 wythnos ar gyfer rheoli symptomau a gwella ansawdd bywyd pobl â syndrom lludded cronig

Rydym yn eich gwahodd i gymryd rhan mewn astudiaeth sy'n edrych ar effeithiolrwydd y gwasanaeth byddwch yn ei dderbyn ar gyfer syndrom lludded cronig. Mae gwasanaethau i helpu pobl i reoli symptomau Syndrom Lludded Cronig yn gymharol newydd. Ceir tystiolaeth i ddangos bod therapi ymddygiadol gwybyddol grŵp (CBT) yn help i bobl sy'n dioddef o Syndrom Lludded Cronig ond mae angen mwy o ymchwil. Mae ymchwil yn aml yn gallu ein helpu i ddyfeisio gwasanaethau newydd neu wella hen wasanaethau. Bwriad yr astudiaeth hon yw hel gwybodaeth a gasglwyd fel rhan o'r gwasanaeth ac asesu a yw pobl yn profi newidiadau cadarnhaol o ganlyniad i'r rhaglen 8 wythnos.

Pam y gofynnwyd i mi gymryd rhan?
Mae unrhyw un sy'n cael ei dderbyn ar raglen Syndrom Lludded Cronig yng Nghaernarfon o Fedi 06 i Ebrill 07 yn cael gwahoddiad i gymryd rhan yn yr astudiaeth. Bydd eich meddyg teulu yn cael gwybod os byddwch yn penderfynu cymryd rhan.

Beth fydd yn rhaid i mi ei wneud?
Un o ofynion mynychu'r rhaglen Syndrom Lludded Cronig yw bod cleifion yn llenwi holiaduron ar ddechrau a diwedd y rhaglen a hefyd yn y sesiwn ddilynol. Er mwyn cymryd rhan yn yr astudiaeth ymchwil hon bydd gofyn i chi lenwi set ychwanegol o holiaduron 8 wythnos cyn dechrau'r rhaglen.

Ble byddaf yn llenwi'r holiaduron?
Byddwch yn derbyn yr holiaduron trwy'r post 8 wythnos cyn i'r rhaglen ddechrau. Gallwch eu llenwi gartref a'u hanfon yn ôl i'r gwasanaeth mewn amlen wedi ei chyfeirio â stamp. Yna byddwch yn llenwi holiaduron yn sesiwn gyntaf ac olaf y rhaglen. Gellwch chi wneud hyn gartref neu yn y clinig. Cewch gymorth i lenwi'r holiaduron os bydd angen. Byddwn yn gofyn i chi hefyd a wnaiff rhywun sy'n agos atoch (partner, mab/merch, cyfaill etc) roi gwybodaeth amdanoch trwy lenwi holiadur byr iawn ar ddiwedd y rhaglen i ddweud sut rydych chi wedi dod ymlaen ers dechrau'r rhaglen.

A fyddaf yn gallu trafod fy nghyfraniad i'r astudiaeth?
Byddwn yn rhoi rhif ffôn, cyfeiriad a chyfeiriad e-bost fel y gallwch drafod eich cyfraniad i'r astudiaeth neu gael mwy o wybodaeth os bydd angen.

Pwy sy'n gyfrifol am y wybodaeth a phwy fydd yn cael mynd ati?
Bydd yr ymchwilydd a thîm y rhaglen yn gyfrifol am y wybodaeth a dim ond nhw fydd yn cael mynd ati.

Ym mha ffordd bydd y wybodaeth yn cael ei defnyddio?
Mae tîm y rhaglen yn cadw cronfa ddata o wybodaeth o'r holl bobl sy'n mynychu'r rhaglen fel y gallan nhw fonitro sut mae pobl yn dod ymlaen. At bwrpas yr astudiaeth hon, bydd yr ymchwilydd Dr Louise Barber yn monitro unrhyw newidiadau sydd wedi digwydd o ganlyniad i gwblhau'r rhaglen. Bydd y wybodaeth hon yn cael ei defnyddio fel rhan o'i hyfforddiant clinigol at ei doethuriaeth ac mae'n bosib y bydd yn cael ei chyhoeddi mewn cylchgrawn academaidd.

Pwy sy'n gallu fy nghysylltu â'r ymchwil?
Bydd yr holl wybodaeth a ddaw i law mewn cysylltiad â'r astudiaeth yn cael ei chadw'n gwbl gyfrinachol. Ni fydd neb heblaw tîm y rhaglen a'r ymchwilydd yn gallu eich cysylltu â'r wybodaeth a gaiff ei chasglu, gan y bydd pawb sy'n cymryd rhan yn cael ei nodi yn ôl cod ar y gronfa ddata. Bydd eich manylion yn cael eu cadw'n gwbl gyfrinachol yn yr holl gyhoeddiadau a chanlyniadau eraill.

Beth fydd hyd yr astudiaeth?
Bydd gwybodaeth yn cael ei chasglu gan yr ymchwilydd am ryw 8 mis ac yna bydd y canlyniadau'n cael eu dadansoddi. Dylai'r astudiaeth fod wedi ei chwblhau'n llwyr erbyn mis Mehefin 2007.

A allaf i ddod o hyd i ganlyniadau'r astudiaeth?
Gallwch gysylltu â'ch gwasanaeth os hoffech gael gwybod am ganlyniadau'r astudiaeth. Gallwch gwneud hyn yn eich sesiwn ddilynol neu'n nes ymlaen.

Oes rhaid i mi gymryd rhan ac a gaf i newid fy meddwl?
Rydych yn cymryd rhan o'ch gwirfodd ac rydych yn rhydd i dynnu'n ôl o'r elfen ymchwil o'r astudiaeth ar unrhyw adeg os byddwch yn newid eich meddwl. Ni fydd unrhyw effaith ar eich triniaeth os byddwch yn dymuno tynnu'n ôl o'r astudiaeth. Ond mae gofyn i chi lenwi holiaduron ar wahanol adegau fel rhan o'r gwasanaeth Syndrom Lludded Cronig y byddwch yn ei dderbyn.

Beth os oes gen i ragor o gwestiynau?
Gellwch chi gysylltu â'r ymchwilydd yn;

Cyfeiriad
Gwasanaeth Syndrom Lludded Cronig
Ysbyty Bryn Seiont
Caernarfon
LL55 2YE
Ffôn: 01286 662733

E-bost:
loubarber@aol.com

Cyfeiriad
Dr Louise Barber
Seicolegydd Clinigol dan Hyfforddiant
Prifysgol Cymru, Bangor
Brigantia
Ffordd y Coleg
Bangor
Gwynedd

Appendix D

Participant Consent Form

English and Welsh Versions

Patient code:

CONSENT FORM

Effectiveness of group cognitive behavioural therapy intervention compared to an 8-week waiting list control for managing symptoms and improving quality of life for people with chronic fatigue syndrome

Name of Researcher: Dr Louise Barber

Please initial box

1. I confirm that I have read and understand the information sheet dated 25th July 2006 (version 2) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I agree to take part in the above study. ☐

Name of Patient	Signature	Date
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Signature	Date

1 for patient; 1 for researcher; 1 to be kept with hospital notes

Cod y claf:

FFURFLEN GYDSYNIO

Effeithiolrwydd ymyriad therapi ymddygiadol gwybyddol grŵp o'i gymharu â grŵp rheolaeth ar restr aros 8 wythnos ar gyfer rheoli symptomau a gwella ansawdd bywyd pobl â syndrom lludded cronig

Enw'r Ymchwilydd: Dr Louise Barber

Rhowch eich blaenlythrennau yn y bocs

1. Cadarnhaf fy mod wedi darllen a deall y daflen wybodaeth ddyddiedig Gorffennaf 25 2006 ☐ (fersiwn 2) mewn perthynas â'r astudiaeth uchod a fy mod i wedi cael y cyfle i ofyn cwestiynau.

2. Deallaf fy mod i'n cymryd rhan o'm gwirfodd a'm bod yn rhydd i dynnu'n ôl ar unrhyw adeg ☐ heb roi rheswm a heb i hynny effeithio ar fy ngofal meddygol neu hawliau cyfreithiol.

3. Cytunaf i gymryd rhan yn yr astudiaeth uchod ☐

_____ _____
Enw'r Claf Llofnod Dyddiad

_____ _____
Enw'r person sy'n derbyn y cydsyniad (os yn wahanol i'r ymchwilydd) Dyddiad Llofnod

_____ _____
Ymchwilydd Llofnod Dyddiad

1 i'r claf; 1 i'r ymchwilydd; 1 i'w chadw gyda'r nodiadau ysbyty

Appendix E

Participant informant information proforma

English and Welsh Versions

Effectiveness of group cognitive behavioural therapy intervention compared to an 8-week waiting list control for managing symptoms and improving quality of life for people with chronic fatigue syndrome

You are invited to take part in a study looking at the effectiveness of the service your associate/relative has received for chronic fatigue syndrome. Services to help people manage the symptoms of Chronic Fatigue Syndrome are relatively new. There is evidence to show that group cognitive behavioural therapy (CBT) is helpful to Chronic Fatigue Syndrome sufferers but more research is needed. Research can often help to devise new services or improve old ones. The intention of this study to gather information collected as part of the service and to assess whether people experience positive changes as a result of the 8-week programme.

Why have I been asked to take part?
Anyone who is accepted on to a Chronic Fatigue Syndrome programme at Caernarfon from September 06 to April 06 is invited to take part in the study. You have been asked as a designated relative or associate of someone who has taken part in this research.

What will I have to do?
To participate in this research study you will be requested to complete a very brief questionnaire about your relative/associates progress since completing the chronic fatigue syndrome programme.

Where will I fill in the questionnaire?
This can be completed at home and returned to the service in the stamped addressed envelope provided.

Will I be able to discuss my participation in the study?
A telephone number, address and e-mail address will be provided so that, if you require it, you can discuss your participation in the study or find out any more information.

Who is responsible for the information and who will have access to it?
The researcher and the programme team will be responsible for the information and only they will have access to it.

What will the information be used for?
The programme team keep a database of the information of all the people who attend the programme so that they can monitor how people do. For the purpose of this study, the researcher Dr Louise Barber will also monitor any changes made as a result of completing the programme. This information will be used as part of her clinical doctoral training and may be published in an academic journal.

Who can connect me to the research?
All information obtained in connection with the study will be held in strict confidence. You will not be asked to provide your name and no one other than the programme team and the researcher will be able to connect you with the information collected, as each participant will be coded on the database. Your identification will be kept strictly confidential in all publications and other outcomes.

How long will the study last?
Information will be collected by the researcher for approximately 8 months and then the results will be analysed. The study should be fully completed in June 2007.

Can I find out the results of the study?
Contact can be made through your service if you would like to be notified of the results of the study.

Do I have to participate and can I change my mind?
Participation is totally voluntary and you are free to withdraw from the research study, any time should you change your mind. There will be no consequence for your relative/associate's treatment should you wish to withdraw from participation in the study.

What if I have further questions?
You can contact the researcher at;

Address
Chronic Fatigue Syndrome service
Bryn Seiont Hospital
Caernarfon
LL55 2YE
Tel: 01286 662733

E-Mail
loubarber@aol.com

Address
Dr Louise Barber
Trainee Clinical Psychologist
University of Wales, Bangor
Brigannta house
College Road
Bangor
Gwynedd

Ffurflen wybodaeth i gyfranwyr sy'n rhoi gwybodaeth

Effeithiolrwydd ymyriad therapi ymddygiadol gwybyddol grŵp o'i gymharu â grŵp rheolaeth ar restr aros 8 wythnos ar gyfer rheoli symptomau a gwella ansawdd bywyd pobl â syndrom lludded cronig

Rydym yn eich gwahodd i gymryd rhan mewn astudiaeth sy'n edrych ar effeithiolrwydd y gwasanaeth y mae eich cyfaill/perthynas wedi ei dderbyn ar gyfer syndrom lludded cronig. Mae gwasanaethau i helpu pobl i reoli symptomau Syndrom Lludded Cronig yn gymharol newydd. Ceir tystiolaeth i ddangos bod therapi ymddygiadol gwybyddol grŵp (CBT) yn help i bobl sy'n dioddef o Sydrom Lludded Cronig ond mae angen mwy o ymchwil. Mae ymchwil yn aml yn gallu ein helpu i ddyfeisio gwasanaethau newydd neu wella hen wasanaethau. Bwriad yr astudiaeth hon yw hel gwybodaeth a gasglwyd fel rhan o'r gwasanaeth ac asesu a yw pobl yn profi newidiadau cadarnhaol o ganlyniad i'r rhaglen wyth wythnos.

Pam y gofynnwyd i mi gymryd rhan?
Mae unrhyw un sy'n cael ei dderbyn ar raglen Syndrom Lludded Cronig yng Nghaernarfon o Fedi 06 i Ebrill 07 yn cael gwahoddiad i gymryd rhan yn yr astudiaeth. Rydych chi wedi cael gwahoddiad am eich bod wedi eich enwi fel perthynas neu gyfaill i rywun sydd wedi cymryd rhan yn yr ymchwil hon.

Beth fydd rhaid i mi ei wneud?
Er mwyn cymryd rhan yn yr astudiaeth ymchwil hon bydd gofyn i chi lenwi holiadur byr iawn am sut mae eich perthynas/cyfaill wedi dod ymlaen ers cwblhau'r rhaglen syndrom lludded cronig.

Ble byddaf yn llenwi'r holiadur?
Gallwch ei lenwi gartref a'i anfon yn ôl i'r gwasanaeth yn yr amlen wedi ei chyfeirio â stamp sy'n cael ei darparu.

A fyddaf yn gallu trafod fy nghyfraniad i'r astudiaeth?
Byddwn yn darparu rhif ffôn, cyfeiriad a chyfeiriad e-bost fel y gallwch drafod eich cyfraniad i'r astudiaeth neu gael mwy o wybodaeth os bydd angen.

Pwy sy'n gyfrifol am y wybodaeth a phwy fydd yn cael mynd ati?
Bydd yr ymchwilydd a thîm y rhaglen yn gyfrifol am y wybodaeth a dim ond nhw fydd yn cael mynd ati.

Ym mha ffordd bydd y wybodaeth yn cael ei defnyddio?
Mae tîm y rhaglen yn cadw cronfa ddata o wybodaeth o'r holl bobl sy'n mynychu'r rhaglen fel y gallan nhw fonitro sut mae pobl yn gwneud. At bwrpas yr astudiaeth hon, bydd yr ymchwilydd Dr Louise Barber yn monitro unrhyw newidiadau a wnaed o ganlyniad i gwblhau'r rhaglen. Bydd y wybodaeth hon yn cael ei defnyddio fel rhan o'i hyfforddiant clinigol at ei doethuriaeth ac mae'n bosib y bydd yn cael ei chyhoeddi mewn cylchgrawn academaidd.

Pwy sy'n gallu fy nghysylltu â'r ymchwil?
Bydd yr holl wybodaeth a ddaw i law mewn cysylltiad â'r astudiaeth yn cael ei dal yn gwbl gyfrinachol. Ni ofynnir i chi roi eich enw ac ni fydd neb heblaw tîm y rhaglen a'r ymchwilydd yn gallu eich cysylltu â'r wybodaeth a gaiff ei chasglu, gan y bydd pawb sy'n cymryd rhan yn cael ei nodi yn ôl cod ar y gronfa ddata. Bydd eich manylion yn cael eu cadw'n gwbl gyfrinachol yn yr holl gyhoeddiadau a chanlyniadau eraill.

Beth fydd hyd yr astudiaeth?
Bydd gwybodaeth yn cael ei chasglu gan yr ymchwilydd am ryw 8 mis ac yna bydd y canlyniadau'n cael eu dadansoddi. Dylai'r astudiaeth fod wedi ei chwblhau'n llwyr erbyn mis Mehefin 2007.

A allaf i ddod o hyd i ganlyniadau'r astudiaeth?
Gallwch gysylltu â'ch gwasanaeth os hoffech gael gwybod am ganlyniadau'r astudiaeth.

Oes rhaid i mi gymryd rhan ac a gaf i newid fy meddwl?
Rydych yn cymryd rhan o'ch gwirfodd ac rydych yn rhydd i dynnu'n ôl o'r astudiaeth ymchwil ar unrhyw adeg os byddwch yn newid eich meddwl. Ni fydd unrhyw effaith ar driniaeth eich perthynas/cyfaill os byddwch yn dymuno tynnu'n ôl o'r astudiaeth.

Beth os oes gen i ragor o gwestiynau?
Gellwch chi gysylltu â'r ymchwilydd yn;

Cyfeiriad
Gwasanaeth Syndrom Lludded Cronig
Ysbyty Bryn Seiont
Caernarfon
LL55 2YE
Ffôn: 01286 662733

E-bost:
loubarber@aol.com

Cyfeiriad
Dr Louise Barber
Seicolegydd Clinigol dan Hyfforddiant
Prifysgol Cymru, Bangor
Brigantia
Ffordd y Coleg
Bangor
Gwynedd

Appendix F

Informant consent form

English and Welsh Versions

Patient code:

INFORMANT CONSENT FORM

Effectiveness of group cognitive behavioural therapy intervention compared to an 8-week waiting list control for managing symptoms and improving quality of life for people with chronic fatigue syndrome

Name of Researcher: Dr Louise Barber

Please initial box

1. I confirm that I have read and understand the information sheet dated 25th July 2006 ☐ (version 2) for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, ☐ without giving any reason, without my relative/associates medical care or legal rights being affected.

3. I agree to take part in the above study. ☐

Name of informant	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Signature	Date

1 for informant; 1 for researcher; 1 to be kept with hospital notes

Cod y claf:

FFURFLEN GYDSYNIO'R PERSON SY'N RHOI GWYBODAETH

Effeithiolrwydd ymyriad therapi ymddygiadol gwybyddol grŵp o'i gymharu â grŵp rheolaeth ar restr aros 8 wythnos ar gyfer rheoli symptomau a gwella ansawdd bywyd pobl â syndrom lludded cronig

Enw'r Ymchwilydd: Dr Louise Barber

Rhowch eich blaenlythrennau yn y bocs

1. Cadarnhaf fy mod wedi darllen a deall y daflen wybodaeth ddyddiedig Gorffennaf 25 2006 ☐
   (fersiwn 2) mewn perthynas â'r astudiaeth uchod a fy mod i wedi cael y cyfle i ofyn cwestiynau.

2. Deallaf fy mod i'n cymryd rhan o'm gwirfodd a'm bod yn rhydd i dynnu'n ôl ar unrhyw adeg ☐
   heb roi rheswm a heb i hynny effeithio ar ofal meddygol neu hawliau cyfreithiol fy mherthnasau/cyfeillion.

3. Cytunaf i gymryd rhan yn yr astudiaeth uchod ☐

_____ _____ _____

Enw'r person sy'n rhoi gwybodaeth Llofnod Dyddiad

_____ _____ _____

Enw'r person sy'n derbyn y cydsyniad (os yn wahanol i'r ymchwilydd) Dyddiad Llofnod

_____ _____ _____

Ymchwilydd Llofnod Dyddiad

i'r claf; 1 i'r ymchwilydd; 1 i'w chadw gyda'r nodiadau ysbyty

Appendix G

Initial information Form

Chronic Fatigue Service Initial Information Form

D.o.b	dd	mm	yr	Name or initials
Date now	dd	mm	yr	Address or area
Gender		m	f	Telephone no.

Ethnic group (tick one)	Occupation (tick one)
o Asian/Asian British o Black/Black British o Chinese o Mixed o White o Other	o Currently employed full or part-time o Temporarily discontinued because of fatigue-related symptoms o Indefinitely discontinued because of fatigue related symptoms o Other (specify)
Marital status o Single o Married o Divorced o Living with partner	Hours per week of paid employment, voluntary work, training or education (specify hrs & type of work)

CLINICAL DATA
(for office use only, do not complete this section)

Group no.		Time point	control	start	end	FU 1	FU 2
Months since onset of symptoms (patient defined)		o Diagnosis (Oxford criteria) o Co-morbidity (specify)					
Patients primary goal (optional)							
Chalder Fatigue Scale		Total		Mental		Physic	
BDI							
HADS		Depression		Anxiety			
Pain & QoL VAS score		Pain		Qual of Life			
SF36 – Physical functioning							
Hope							
Optimism							
Global Improvement							
Independent measure							

Appendix H

Chalder Fatigue Scale

Chalder Fatigue Scale

We would like to know more about any problems you have had with feeling tired, weak or lacking in energy in the last month. Please answer all the questions by ticking the answer that applies to you most closely. If you have been feeling tired for a long while, then compare yourself to how you felt when you were last well.

	Less than usual	No more than usual	More than usual	Much more than usual
Do you have problems with tiredness?				
Do you need to rest more?				
Do you feel sleepy or drowsy?				
Do you have problems starting things?				
Do you lack energy?				
Do you have less strength in your muscles?				
Do you feel weak?				
Do you have difficulty concentrating?				
Do you make slips of the tongue when speaking?				
Do you find it more difficult To find the correct word?				
	Better than usual	No worse than usual	Worse than usual	Much worse than usual
How is your memory?				

Appendix I

Beck Depression Inventory-Fast Screen

BDI-Fast screen

Please read the group of statements carefully then pick out the one statement in each group that best describes the way you have been feeling during the past two weeks, including today! Tick the box beside the statement you picked. If several statements in the group seem to apply equally well, tick the box with the largest number.

1		5	
	I do not feel sad		I feel the same about myself as ever
	I feel sad much of the time		I have lost confidence in myself
	I am sad all the time		I am disappointed in myself
	I am so sad or unhappy that I cannot stand it		I dislike myself
2		6	
	I am not discouraged about my future		I don't criticise or blame myself more than usual
	I feel more discouraged about my future than I used to be		I am more critical of myself than I used to be
	I do not expect things to work out for me		I criticise myself for all of my faults
	I feel my future is hopeless and will only get worse		I blame myself for everything bad that happens
3		7	
	I do not feel like a failure		I don't have any thoughts of killing myself
	I have failed more than I should have		I have thoughts of killing myself but would not carry them out
	As I look back, I see lots of failures		I would like to kill myself
	I feel I am a total failure as a person		I would kill myself if I had the chance
4			
	I get as much pleasure as I ever did from the things I enjoy		
	I don't enjoy thinks as much as I used to		
	I get very little pleasure from the things I used to enjoy		
	I can't get any pleasure from the things I used to enjoy		

Appendix J

Hospital Anxiety and Depression Scale

Hospital Anxiety and Depression Scale (HADS)

Please read each item and place a tick in the box opposite the reply that comes closest to how you have been feeling in the past month. Do not take too long over your replies and please answer each question.

I feel tense or 'wound up'		**I feel as though I am slowed down**	
Most of the time		Nearly all of the time	
A lot of the time		Very often	
Time to time, occasionally		Sometimes	
Not at all		Not at all	
I still enjoy the things I used to enjoy		**I get a sort of frightened feeling like 'butterflies in my stomach'**	
Definitely as much		Not at all	
Not quite so much		Occasionally	
Only a little		Quite often	
Not at all		Very often	
I get a sort of frightened feeling like something awful is about to happen		**I have lost interest in my appearance**	
Yes definitely and quite badly		Definitely	
Yes but not too badly		I don't take as much care as I should	
A little but it doesn't worry me		I may not take quite as much care	
Not at all		I take just as much care as ever	
I can laugh and see the funny side of things		**I feel restless as if I have to be on the move**	
As much as I always could		Very much indeed	
Not quite so much now		Quite a lot	
Definitely not so much now		Not very much	
Not at all		Not at all	
Worrying thoughts go through my mind		**I look forward with enjoyment to things**	
A great deal of the time		As much as I ever did	
A lot of the time		Rather less than I used to	
From time to time but not often		Definitely less than I used to	
Only occasionally		Hardly at all	
I feel cheerful		**I get sudden feeling of panic**	
Not at all		Very often indeed	
Not often		Quite often	
Sometimes		Not very often	
Most of the time		Not at all	
I can sit at ease and feel relaxed		**I can enjoy a good book or radio or TV programme**	
Definitely		Often	
Usually		Sometimes	
Not often		Not often	
Not at all		Very seldom	

Appendix K

SF-36 Physical Functioning Scale

SF-36 Physical Function

These questions are about activities you might do during a typical day.
Please tick ONE box for each question.

Does your health limit you in these activities?

Activities	Tick one box for each question		
	Yes limited a lot	Yes limited a little	No not limited at all
Vigorous activities, such as running lifting heavy objects, participating in strenuous sports			
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf			
Lifting or carrying groceries			
Climbing several flights of stairs			
Climbing one flight of stairs			
Bending kneeling or stooping			
Walking more than a mile			
Walking about half a mile			
Walking about 100 yards			
Bathing or dressing yourself			

Pain Rating

Please make a mark along the line to describe the severity of your pain

No Pain _____ **Pain as bad as possible**

Appendix L

Life Orientation Test – Modified State

Life Orientation Test –Modified (State)

Answer according to your own feelings, rather than how you think "most people" would answer. Tick the answer that best fits how you feel right now in the space provided.

	Agree a lot	Agree a little	Neither agree or disagree	Disagree a little	Disagree a lot
Right now I expect the best					
If something can go wrong for me right now it will					
Right now I am looking on the bright side of things					
Right now I am optimistic about my future					
Right now I hardly expect things to go my way					
Right now things are not working out the way I want them too					
Right now I'm a believer that 'every cloud has a silver lining'					
Right now I don't count on good things happening to me					

Appendix M

Adult Hope Scale

Adult State Hope scale

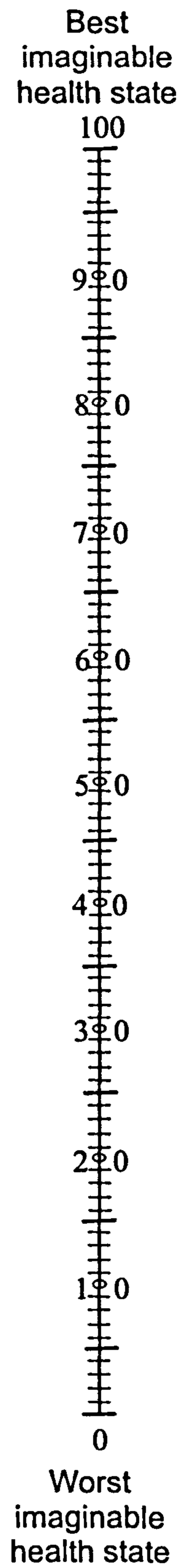
Please take a few moments to focus on yourself and what is going on in your life at this moment. Tick the answer that best fits how you feel right now in the space provided.

	Definitely false	Mostly false	Some-what false	A little false	A little true	Some-what true	Mostly true	Definitely true
If I should find myself in a jam, I could think of many ways to get out								
At the present time I am energetically pursuing my goals								
There are lots of ways around any problem that I am facing now								
Right now I see myself as being pretty successful								
I can think of many ways to reach my current goals								
At this time, I am meeting the goals I have set for myself								

Appendix N

Euroqual –Quality of Life Measure

We would like you to indicate on this scale (by making a mark) how good or bad your own health is today in your opinion.



Appendix O

Clinical Global Improvement Scale

Clinical Global Improvement Scale

These next questions are about the changes, usefulness and satisfaction with the programme and are to be answered by **YOU.**
Please tick **ONE** box

	Very much better	Much better	A little better	No change	A little worse	Much worse	Very much worse
Overall change in myself							
My fatigue levels							
My level of handicap							

	Very satisfied	Quite satisfied	Slightly satisfied	Neither	Slightly dissatisfied	Quite dissatisfied	Very dissatisfied
Satisfaction with outcome							

	Very useful	Quite useful	A bit useful	Not really useful	No use at all
How useful was the treatment					

We would really appreciate any other comments you think are relevant

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Appendix P

Informant Global Improvement Scale

Clinical Global Improvement Scale for informant

These next questions are about the changes, usefulness and satisfaction with the programme as answered by **the person closest to you (e.g, partner, family member, someone you live with).** ***Tear off and return in the pre-paid envelope.***

Please tick **ONE** box

	Very much better	Much better	A little better	No change	A little worse	Much worse	Very much worse
Overall change in other							
Their fatigue levels							
Their level of handicap							

	Very satisfied	Quite satisfied	Slightly satisfied	Neither	Slightly dissatisfied	Quite dissatisfied	Very dissatisfied
Satisfaction with outcome							

	Very useful	Quite useful	A bit useful	Not really useful	No use at all
How useful do you think the treatment has been to them					

We would really appreciate any other comments you think are relevant

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Appendix P

COREC Approval Letter

r Rheolaeth Ymchwil Ymddiriedolaeth GIG Gogledd Orllewin Cymru
Panel Arolygu Mewnol

Wales NHS Trust Research Governance Committee

Internal Review Panel

North West Wales NHS Trust, Ysbyty Gwynedd
Clinical Academic Office
North Wales Clinical School
Bangor, Gwynedd
LL57 2PW

Telephone/Facsimile: 01248 - 384.877
Email: Rossela.Stoicescu@nww-tr.wales.nhs.uk

7th September 2006

PRIVATE & CONFIDENTIAL
Dr L Barber
School of Psychology
University of Wales, Bangor
Brigantia Building, Penrallt Road
Bangor
Gwynedd LL57 2AS

Dear Dr Barber

Review: Barber 06/34: 'The effectiveness of group CBT intervention compared to an 8 week waiting list control for managing symptoms and improving quality of life for people with chronic fatigue syndrome'

The above research project was reviewed at the meeting of the Trust Research Governance Committee / Internal Review Panel held on 7 September 2006.

I have pleasure in confirming that the Internal Review Panel is pleased to grant Trust approval to proceed at the North West Wales NHS Trust sites.

The Committee would like to make the following suggestion: A well designed research, with a careful consent process appropriate to this group. It might help with the statistical analysis if this would be presented as a simple analysis, not a group trial (see Baldwin JCP Nov 2005).

The study should not commence until the Ethics Committee reviewing the research has confirmed final ethical approval (favourable opinion).

As part of the regular monitoring undertaken by the Trust's Research Governance Committee you will be required to complete short progress reports. This will be requested on an bi-annual 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 report may result in withdrawal of approval.

All research conducted at the North West Wales NHS Trust sites 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 R&D Office.

If you would like further information on any other points covered by this letter please do not hesitate to contact me. On behalf of the Committee, may I take this opportunity to wish you every success with your research.

Yours sincerely

Rossela Staicesan

pp Dr K D Griffiths
Consultant Biochemist
R&D Director, Assistant to the Medical Director
Chairman Trust Research Governance Committee

Appendix Q

School of Psychology Approval Letter

From: Paula Gurteen <p.gurteen@bangor.ac.uk>
Subject: **Ethics application no. 813**
Date: 14 September 2006 18:11:22 BDT
To: Louise Barber <psp053@bangor.ac.uk>, loubarber@aol.com

Dear Colleagues,

Effectiveness of a CBT intervention for CFS compared to a waiting list control (project no. 813)

Your amended research proposal referred to above has been reviewed by the School of Psychology Research Ethics Committee and they are satisfied:

(i) That the research proposed accords with the relevant ethical guidelines.

(ii) That the research proposed is appropriate for sponsorship by the University of Wales, Bangor.

Approval is granted subject to you submitting Welsh translations of your information/consent and debrief forms to me.

If you wish to make any non-trivial modifications to the research project please inform the committee in writing before proceeding. Please also inform the committee as soon as possible if research participants experience any unanticipated harm as a result of participating in your research.

You should now forward the application to COREC and to the appropriate Local Research Ethics Committee (LREC). **If you need a signature on the form regarding research sponsorship by the University, and/or a letter confirming this sponsorship, please send the final version of your COREC form to me and I will make arrangements for this.**

The NHS Research Ethics Committee expect one of the investigators to make an oral presentation in support of the proposal at their meeting. You will be contacted by their committee with details as to the date and place of the meeting at which your proposal will be considered.

You may not proceed with the research project until you are notified of the approval of the Local Research Ethics Committee and have R&D approval from the relevant NHS Trusts.

The approval for this project is given on the understanding that you will complete a review form on the project when requested; to this end I would be grateful if you could complete the form below and return it to me.

Yours sincerely

Paula Gurteen

Coordinator - School of Psychology Research Ethics & Governance Committee

Section Three

Review Paper

Group Cognitive Behavioural Therapy and Other Treatments for Chronic Fatigue Syndrome: A Review of the Literature.

Louise Barber

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

Address for correspondence: Louise Barber, North west Wales Clinical Psychology Programme (NWCPP), School of Psychology, University of Wales, Bangor, Gwynedd, LL57 2DG (e-mail: loubarber@aol.com)

Abstract

This review explores the evidence for treatment options available to people with chronic fatigue syndrome (CFS), focusing on the very limited body of research into group cognitive behavioural therapy (CBT). As yet no review paper has explored the application of group cognitive behaviour therapy, as there are so few studies. There is evidence that CBT is an effective individual therapy for people with chronic fatigue syndrome and it appears that group therapy may also be a successful and cost effective means of managing the symptoms of CFS. The methodological limitations and generalisability of the findings are questioned followed by implications for clinical practice. Finally the direction of future research is discussed and the need for further trails of group CBT in routine clinical settings.

Introduction

Health services care for many people who suffer with fatigue, which appears to be a normal consequence of life (Risdale, 1989). Of these, some suffer with a physical or psychological disorder that causes fatigue, but others experience disabling and chronic fatigue, which is medically unexplained. Chronic fatigue syndrome (CFS) otherwise known as myalgic encephalomyelitis (ME) became apparent in the early 80s and has been highlighted as the "post-modern illness of our time" (Zavestoski et al., 2004). CFS has been labelled as a "controversial illness" (Taylor, Friedberg & Jason, 2001) and has been strongly debated, sometimes provoking hostility (Gibson, 2006) between researchers, clinicians, support groups and patients who variously contest its existence, aetiology and treatment (Huibers & Wessley, 2006). Although much contention remains there does appear to be an increasing consensus for the multifactorial model of CFS (Afari & Buchwald, 2003).

ME "inflammation of the brain and spinal cord with muscle pain," refers to a medical explanation for the symptoms, which remains unsupported. It implies that a medical cure is needed and is often preferred by patients who believe a biomedical label gives scientific validity to their illness. However, the medical and research community tend to prefer the term CFS as it lacks causal inferences and allows for a multifactorial approach. There is evidence that patients with more pessimistic perceptions of themselves, their symptoms and stressor appraisals may perpetrate or exacerbate their psychosocial and physical dysfunction (Afari & Buchwald, 2003). In the last two decades research has yielded little advancement in the understanding of the pathophysiology of the condition (Siegel et al., 2006).

Although there are several definitions of the condition, there is disagreement about the reliability of these definitions. Some believe that it is only the people with the most severe form who have 'authentic CFS/ME' and this should be a distinct category from those suffering with less severe symptoms. Others believe that it is a spectrum, from those that are extremely incapacitated to those with less severe symptoms.

Prevalence

There is a distinct lack of epidemiological data regarding CFS in the UK so prevalence estimates are usually based on extrapolations from other countries (NICE, 2006). The condition is thought to affect between 0.2-0.7 % of the population in Western countries (Evengard & Klimas, 2002) and is a socio-economic burden (Reynolds, Vernon, Bouchery & Reeves, 2004). The prognosis for adults with CFS is poor with many remaining disabled and symptomatic for many years (Hotopf & Wessley, 1997). A longitudinal study showed that 91% of patients with CFS who received standard medical care continued to fulfil diagnostic criteria for years after their original assessment (Hill, Tiersky, Scavalla, Lavietes & Nelson, 1999).

Characteristics

The defining characteristic for people suffering with CFS is a debilitating and unexplained severe mental and physical fatigue, not resulting from organic disease. Post exertion fatigue is part of the CFS picture but the fatigue does not correspond with the level of exertion and is not alleviated by rest or sleep. It is unlike normal fatigue and can be triggered by minimal activity. Other associated symptoms can include muscle pain, mood and sleep disturbance (Nisenbaum, Reyes, Unger & Reeves, 2004) and unrefreshing sleep (Guilleminault, et al., 2006). It is a condition that can occur in adolescents as well as adults (Chalder, Goodman, Wessley, Hotopf & Meltzer 2003) and symptoms can fluctuate in severity and intensity (NICE, 2006).

Co-morbidity

CFS sufferers can sometimes present with symptoms of other illnesses and can often receive multiple diagnoses. Disentangling different illnesses can be difficult, especially with conditions that do not have a biomarker. Co-morbid conditions can often include, irritable bowel syndrome, fibromyalgia, depression, multiple chemical sensitivity and Gulf war syndrome.

Lifetime psychiatric disorders were reported in 50% of patients suffering with CFS who took part in a Dutch study (Prins, Bleijenberg, Rouweller, Van der Meer, 2005). Prins found current diagnosis of psychiatric disorder in 32.2% of the sample of 264

people with CFS. Lifetime and current mood disorders were reported from 37.1 and 18.9% respectively and lifetime and current anxiety disorders were reported from 19.7 and 13.3% respectively. Estimating the actual prevalence of co morbidity is difficult due to differing CFS criteria, research methods and symptom overlap (Wessley, Hotopf & Sharpe, 1998). Prins et al. (2005) found no differences in fatigue severity and functional impairment following CBT between patients with and without psychiatric diagnosis, concluding that psychiatric co-morbidity did not predict the outcome of CBT therapy.

Diagnosis

The impact of CFS is often exacerbated by uncertainties about diagnosis and management. Diagnosis can be challenging for a number of reasons. As already stated, there is no biomarker or diagnostic laboratory test so health care professionals need to exclude other illnesses by means of extensive testing. Similarly, the symptoms of CFS are also common to other illnesses and often people with CFS do not 'look ill' despite their disability. Finally, symptoms may vary from person to person and often vary considerably over time within individuals.

To meet CFS criteria there must be a minimum duration of six months and a definite onset (not lifelong) and substantial functional impairment. Although there are differing definitions for CFS (see table one below) the standard UK definition was proposed in 1991 and became known as the Oxford criteria (Sharpe et al., 1991).

Post infectious fatigue was listed as a subcategory, with the same symptoms of CFS but with a proven infectious episode. Substance abuse and psychosis are exclusion criteria but psychiatric disorder is not, although it can be noted and stratified later if required (Wesseley, et al., 1998).

[Insert table one]

The major criticism of the diagnostic definitions is the relationship between somatic symptoms and psychiatric disorder. Certain psychiatric disorders, especially depression and anxiety, present a major overlap with the CFS criteria but this is an unfortunate consequence of having a multiple symptom requirement criteria. It appears that increasing somatic symptoms, correlate with higher prevalence of psychiatric disorders (Katon & Russo, 1992; Wessley, Chalder, Hirsch, Wallace & Wright, 1996).

A recent review asserted the need for an appropriate diagnosis of CFS sub-types (Jason, Corradi, Torres-Harding, Taylor & King, 2005). The authors argue that sub-typing individuals with CFS on sociodemographic, functional disability, viral, immune, neuroendocrine, neurology, automatic and genetic biomarkers can assist clarification for clinicians and researchers who can become confused by heterogeneous symptom profiles. Efforts have been made to sub-type patients but no one method has been superior at sub-typing or suggesting treatments more appropriate for individuals with similar presentations.

Pathophysiology

Infectious, immunological, neuroendocine, sleep and psychiatric mechanisms have been explored as possible causes for CFS (Afari & Buchwald, 2003) but as yet the aetiology remains elusive. There has been the suggestion that the central nervous system may be involved in the pathophysiology of the syndrome and this has been explored by means of neuroimaging, cognitive testing, neuropeptide assays and autonomic assessment, still with limited success.

Generally magnetic resonance imaging and positron emisson tomography studies are consistent in reporting some abnormalities in CFS sufferers but the functional significance and clinical utility of these findings require more clarification (Cope & David, 1996). With regard to cognitive testing, eighty five percent of those questioned complained of cognitive problems (Grafman, 1994) and cognitive impairment amongst CFS sufferers correlates with their degree of functional impairment (Christodoulou, et al, 1998) and affects aspects of daily life (Tiersky et al., 2001). Deluca et al's (2004) study highlighted information processing speed as a potential reason for cognitive

impairment. Also neuroendocrine studies have reported abnormalities in the hypothalamic-pituitary adrenal axis and serotonin pathways suggesting altered responses to stress (Parker, Wessley & Cleare, 2001). A review by Afari & Buchwald (2003) asserted that the research linking abnormalities in hypothalamic-pituitary axes function, hormone stress response and serotonin neurotransmission to CFS are the most robust evidence to date. However none of the findings appear to be sufficient to explain the cause of CFS, but are more likely to be a consequence of the persistence of symptoms linked to the syndrome (Cleare, 2004)

Many studies have reported low level immune system activation in CFS sufferers and some findings suggest that the severity of physical symptoms, cognitive impairment and perception on impairment could be associated with the degree of cellular immune activation (Cruess et al., 2000). Although many viruses have been proposed as etiological agents in CFS there has been no consistent evidence so far that pinpoints a specific infection and some patients have no viral evidence. Afari & Buchwald (2003) argue that it is improbable that a single infectious agent is responsible for CFS; rather a group of infections may trigger or perpetuate the symptoms.

Treatments

CFS is currently incurable. The main management procedures utilise models that are symptomatic and psychosocial. Since a landmark report published in 2002 by the Chief Medical Officers Working Group (CMO Report) the government ring fenced £8.5 million for CFS/ME treatment centres with the commitment to allocate more in the future. Affective treatments are needed as it is estimated that CFS/ME may be costing the UK as much as £3.5 billion a year in medical services, lost income and social benefits. There is also evidence that the sooner a patient receives treatment the better the chance of improvement (Centre for Disease Control, CDC, 2007). It is unknown what percentage of patients recover as the condition follows an apparently random cyclical course, alternating between periods of well-being and illness. Studies at the CDC report 40-60% of people with CFS making a partial or total recovery. However, much more longitudinal research is needed in order to validate this data.

Many people suffering with CFS in the community attend their GPs for assessment and treatment (Price & Couper, 1998) but there are also those who attend alternative practitioners when disappointed with orthodox approaches to treatment and greater research is needed to validate them. These 'alternative' treatments can include special diets (Behan, Behan & Horrobin, 1990), vitamins (Martin, Ogston & Evans, 1994), herbal therapies and energy healing (Afari et al., 2000). However there is a dearth of properly controlled trials of these approaches. Two low quality trials found beneficial effects of homeopathic remedies and osteopathy (Awdry, 1996; Perrin, Edwards & Hartley, 1998) and one small randomised control trial reported overall beneficial effects of massage therapy (Field et al. 1997). One treatment that did show positive effects in health and functioning in a controlled trial was magnesium sulphate (Cox, Campbell & Dawson, 1991) although three subsequent reports failed to replicate this result (Reid, Chalder, Cleare, Hotopf & Wessley, 2000).

In China Zang, Liu, Wu and Peng (2006) have commenced a systematic review of trials of acupuncture for adults and children with CFS to assess the efficacy and safety of acupuncture compared to other interventions such as graded exercise and cognitive behavioural therapy. Similarly, there are some promising findings in China where trials report success rates of improving symptoms ranging from 88.9% to 94.2% (Ni, 2002; Liu, 2004).

Certainly the wide range of specialist clinics to which CFS sufferers are referred highlights the lack of clarity amongst both patients and practitioners regarding both cause and treatment of CFS. Putative causes fall into mainly physical or psychological explanations. However as with many other conditions such as irritable bowel syndrome and chronic pain, there is an increasing awareness of the interaction between the psychological and physical factors in development and maintenance of CFS.

Whilst the National Institute for Health and Clinical Excellence (2006) recommends the 'therapies of first choice' to be graded exercise therapy (GET) or cognitive behavioural therapy (CBT) for CFS there is still no cure. These therapies have been

shown to demonstrate benefits with adults and children suffering with mild to moderate effects (more severe CFS appears more resistant to improvement).

Individual Therapies

Graded Exercise Therapy (GET)

CFS sufferers are often advised to rest and decrease activity to promote recovery and limit deterioration; this can however lead to significant symptom increase and further impairment to quality of life (Price & Couper, 1998). GET is an individually tailored, self-management approach, which involves physical assessment, education and mutually agreed goal setting. An achievable baseline of physical activity is set with planned increases in intensity and duration. The exercise programme takes into account the patients current activities and preferences and also their objectives, emotional factors and sleep patterns.

Although there is now good evidence that GET is effective for some patients it is unclear what the mechanisms of change are. One theory is that patients gradually increase their exercise and reverse the deconditioning effects of the CFS by improving their overall fitness and functioning. Another is that they decrease symptom monitoring and activity reduction.

Moss-Morris, Sharon, Tobin & Baldi (2005) showed that a simple graded exercise intervention is more effective than standard medical care. They reported decreases in mental and physical fatigue and improvements in physical functioning following the programme It has been proposed that GET relies less heavily on the availability of a skilled therapist meaning it is possibly more accessible and cost effective (Moss-Morris et al., 2005). In a the recent Cochrane review Edmond, McGuire and Price (2004) concluded that there is encouraging evidence that some patients may benefit from exercise therapy and that it is a promising treatment for CFS but more higher quality research is needed with different patient groups and additional outcomes that can also measure quality of life, adverse effects and cost effectiveness over time.

Individual Cognitive Behaviour Therapy (ICBT)

The cognitive-behavioural model for CFS suggests that people become trapped in a vicious cycle perpetuated by maladaptive behaviours, cognitive misinterpretations and illness beliefs that maintain symptoms and disability (Wessely, et al., 1998). In recent years intervention trials have been conducted, which combine a graded increase in activity with a psychological approach that addresses thoughts about CFS that may impair recovery.

Several studies have demonstrated that CBT is effective in adults (Sharpe et al., 1996; Deale, Chalder, Marks & Wessely, 1997) and a recent randomised control group study reported CBT to be an effective treatment for adolescents with CFS (Stulemeijer et al., 2005). A review by Price and Couper (1998) concluded that although there were only a limited number of CBT trials for adults with CFS, but they do appear to improve physical functioning and other relevant outcome such as mood. There is also evidence that CBT is a cost effective treatment (Best & Stevens 1996).

However a survey of patient groups reported that only 7% of respondents found cognitive behaviour therapy helpful compared to 26% who believed it made them worse and 67% who reported no change (Abbott, 2006). However it must be noted that this may be a skewed sample as it could be that predominately people who have experienced unsuccessful treatments are the ones who have had the condition longer and may seek out the support of patient groups.

Multi Convergent Therapy

One somewhat eclectic individual treatment intervention that combines approaches such as CBT and graded exercise therapy in a holistic treatment referred to as Multi Convergent Therapy (MCT) has shown promising results in a preliminary study (Thomas, Sadlier & Smith, 2006). The technique was originally developed to treat a whole range of problems such as anxiety, irritable bowel syndrome and other functional syndromes such as CFS. In a constantly individualised therapy aspects such as breathing and relaxation techniques, connective tissue massage and psychodynamic counselling were combined in a tailored programme. The therapy sessions were

unlimited and no two patients received the same programme. Thomas et al. (2006) compared 12 participants to patients on a waiting list, who after approximately 10, one hour long sessions, showed some improvements. Improvements were also found in their relaxation control group and the authors predict even better results when the relaxation component is replaced (removed for research purposes) in the therapeutic melange.

The study is encouraging as it shows objective improvements in cognitive performance and conforms to the type of individualised therapy suggested by the ME/CFS Working party (2001). However the highly individualised nature of the programme means that the treatment is not amenable to group therapy and may be more costly. For research purposes a more formal detailed protocol is needed to permit useful comparisons with other promising treatments.

Group Therapies

Mindfulness Based Cognitive Therapy

Mindfulness is a way of paying attention to current experiences. People are taught to observe their thoughts, emotions and sensations, without judging the importance, truth or value of them or without trying to change or avoid them. It is believed that regular practice of mindfulness skills increases self-acceptance and self-awareness and improves the ability to make adaptive choices (Baer, 2003).

Surawy, Roberts & Silver (2005) used mindfulness training in a series of three group sessions with men and women on a hospital waiting list. They suggest that when carried out within the framework of a clear cognitive rational the mindfulness training groups can be more effective than the waiting list for improving mood, quality of life and physical functioning. The authors admit that the participants in their study had gained some previous understanding of the CBT approach and activity scheduling in earlier sessions with a consultant psychiatrist and they do not know to what extent this may have influenced the findings. They also note that mindfulness based cognitive

therapy may not be very beneficial to patients who believe exclusively in a purely physical explanation for their illness.

Non-Specific Group Therapy

Group therapy as yet is a novel treatment for CFS but this form of therapy is becoming increasingly popular as it is a cost effective way to treat patients (Abbey, 1996). It can have its advantages over individual therapy as it may be useful for reducing time spent on a waiting list and can be particularly advantageous where an intervention has a significant psych-educational component and deals with a condition that is as yet not fully understood by the general population or the medical profession (Saxty & Hansen, 2005). Group therapy allows for peer support and validation, which can have therapeutic benefits to a population that has to deal with uncertainty and sometimes disbelief from non-sufferers (Taylor, 2004).

Group therapy has received some success with other somatic problems such as chronic pain (Basler, Jaekkle, & Kroener-Herwig, 1997; Harrison, Hall & Round, 1997), irritable bowel syndrome (Toner et al., 1998) and hypochondriasis (Stern & Fernandez, 1991) but there appears to be very little in the way of research to explore the effectiveness of group CBT for CFS (Saxty & Hansen, 2005). Group therapy is becoming increasingly popular as it may be efficient at reducing waiting list times and because it has a relatively low cost (Abbey, 1996). However trials to assess group therapy for CFS are distinctly lacking at the moment. Price and Couper (1998) reviewed all randomised control trials of CBT and concluded that the evidence for the effectiveness of group CBT for CFS is unsatisfactory, which was due in part to methodological issues.

Soderberg and Evengard (2001) treated 14 CFS patients with short-term group therapy using a supportive and goal-oriented format or otherwise non-specific therapy. Patients reported that sharing their experiences had been valuable but the results did not provide conclusive evidence of the programmes effectiveness and it is difficult to draw any firm conclusions regarding efficacy. All the participants in the study were females and fatigue was not consistently measured. The researchers reported group therapy that

consisted of supportive counselling rather than CBT in the true sense and they also failed to collect follow up data, so will not be included in the summary.

Integrative/Self Help Group Therapy

There have also been a number of American studies carried out that use some CBT type strategies but include other material and differing techniques, so again it is difficult to tease apart whether the CBT strategies themselves are effective although they are worth mentioning not least because some of these integrative rehabilitation programmes are receiving federal funding to develop and evaluate the effects of these consumer driven programmes.

Examples of these include integrative rehabilitation programmes, which have produced preliminary evidence of positive effects such as decreased fatigue (Chalder, Wallace & Wesley, 1997), physical and occupational functioning (Sadlier, Phil, Evans, Phillips, & Broad, 2000) and psychological distress (Soderberg & Evenguard, 2001). However these and other rehabilitation programmes have a number of limitations. Firstly they are usually pilot studies or only give preliminary evidence of efficacy. Other limitations include, small sample size, lack of control groups, non-randomisation or all three.

One recent randomised clinical study aims to address these shortcomings and gives evidence that their consumer driven programme can impact on symptom severity and quality of life (Taylor, 2004). However this study recruited through self-help groups, physicians and by advertisement in papers, radio and TV. Participants also received $300 to support goal attainment, service acquisition and travel expenses. The programme differs from the standard CBT type format in that participants had eight sessions of an illness management group that occurred bi-weekly over a period of four months. They then received 7 months peer counselling. No clinical psychologist or qualified CBT therapist was involved in the trial.

Another trial of note is that of Pardaens, Haagdorens, Wambeke, Van den Broeck & Van den Houdenhove (2006). Pardaens et al. combined the CBT approach with GET in a six-month prospective outcome study. They used a multidisciplinary approach that

included input from a cognitive behavioural therapist. The researchers report that there were significant improvements on nearly all health related quality of life measures on pre and post-intervention measures. However there were very little changes in the exercise capacity measures and these occurred mainly in the less fit group, who improved more compared to their fitter counterparts. The researchers themselves question the relevance of using exercise capacity measures when evaluating treatment outcomes. However they reported significant improvements on all the SF-36 sub-scales except role limitations attributed to emotional problems. The decrease in the mean total for the symptom checklist was not significant. Scores on the causal attribution list however did improve significantly. The exercise and strength measures only had moderate improvements with the majority being non-significant. The study included 116 patients but unfortunately only used female participants. The intervention does not appear to be very cost effective as the intervention duration is six month with twice weekly sessions in the first month. Furthermore, lack of follow up data prohibits the evaluation of the long-term benefits.

Group Cognitive Behaviour Therapy (GCBT) Studies

The evidence for GCBT will now be explored. Once again a dearth of GCBT studies persists and clearly there exists inadequate quality research to enable meta-analysis. However a review of the data available will be presented and summarised below in table two.

[Insert table two]

1. Saxty and Hansen (2005)

Saxty and Hansen reported evidence for the effectiveness of GCBT for CFS but the intervention only involved a small sample of six participants. They took patients from a waiting list and entered them into a treatment group, which involved 10 sessions of one hour spread over 18 weeks. The group met weekly for the first 4 sessions then fortnightly for the next 5 sessions, with a final session 4 weeks later. The group was facilitated by a senior psychiatric nurse with CBT training and experience at treating

patients with CFS on an individual basis. A cognitive behavioural therapist trainee also facilitated the group.

All patients showed improvements for fatigue, general health and social adjustment on pre and post-group measures, except one patient who scored the same on anxiety and depression and one patient who scored worse on the post treatment General Health Questionnaire. This was maintained at the 3-month follow up for fatigue but not for general health and social adjustment. In terms of global outcome measures good results were obtained. All patients found the treatment 'useful' or 'better than useful' and everyone was 'moderately' or 'very satisfied' with the outcome. The majority also reported less fatigue and less 'handicap'. Unfortunately the study does only have a small sample of all female patients and so it is difficult to generalise from the findings. The researchers conclude that a controlled trial is now needed to confirm that GCBT is beneficial for CFS sufferers. It is however a useful pilot study especially as it allowed patients to evaluate their perception of the usefulness of the programme. This study also demonstrates that it is an acceptable form of therapy as indicated by the high attendance rates and satisfaction ratings.

2. Bazelmans, Prins, Van der Meer & Bleijenberg (2005)

Bazelmans et al. uses a non-randomised waiting list control design to study the effectiveness of CBT on a group of unselected patients with CFS in two centres in the Netherlands. The treatment consisted of 12 two-hour sessions over 6 months. There were 31 patients in the GCBT but two dropped out from the programme. Thirty-six were allocated to a waiting list control and were free to undertake routine treatment, which was not monitored. Although patients in the waiting list control were offered GCBT after the six-month waiting period, the authors do not document take up or outcome there of.

A non-significant interaction effect was found in favour of GCBT on the fatigue measure. Functional impairment did not change in the GCBT but declined in the waiting list control. Furthermore, avoidance of activity also increased after GCBT and deceased in the waiting list control group, which goes against what would be expected.

No interaction effects were found for daily-observed fatigue, daily observed pain, hours working, and self-efficacy, focusing on bodily symptoms, psychological well-being and depression. Despite these poor findings 37% of the participant reported improvement. Unfortunately this study was handicapped by therapists inexperienced in GCBT and also too much time may have been spent on relaxation delaying the start of patients graded activity programme.

3. Wittkowski, Toye & Richards (2004)

Wittkowski and colleagues recruited participants through referrals for psychological therapy. Participants attended an eight-week consecutive programme of one and a half hour's duration with a fifteen-minute break for socialising. The participants completed the measures at pre, mid and post-treatment with a follow up at three months. The questionnaire scorer was blind to the stage of assessment.

Only descriptive statistics were given due to the small sample size but the results do suggest that GCBT led to reductions in physical and mental fatigue, fatigue related symptoms, anxiety and depression. However only the median score and ranges were given for the five people. The researchers also failed to collect measures relating to functional ability, citing instead anecdotal evidence of increased functional ability.

All patients were female and again as the sample size was so small it is difficult to generalise the findings. One other possible criticism of this trial is that the group sessions were developed and facilitated by two trainee clinical psychologists only (albeit by supervision of a qualified clinical psychologist) in the absence of a multidisciplinary team.

4. O'Dowd, Gladwell, Rogers, Hollonghurst & Gregory (2006)

This is the most recent and extensive GCBT trial carried out to date. It was commissioned by the Health Technology Assessment Programme as a result of an identified gap in the research literature.

The trial consisted of a double-blind randomised control trial comparing three interventions, namely, group cognitive behavioural therapy (GCBT), education and support group (EAS) and standard medical care (SMC). Follow up data was collected at six and twelve months. One hundred and fifty three people took part in the study with approximately two thirds of the participants being female.

No effect was found in cognitive function or quality of life as a result of the participants being in the CBT group. Three outcome measures showed statistically significant differences between the groups. The GCBT group had higher SF-36 mental health scores, less fatigue and faster walking speed than people in the SMC group. Similarly, they were less fatigued and could walk faster than those in the EAS group. Although no other statistical differences were found between the groups it is noted that there was trend towards an improvement in the CBT group with many of the other measures. Scores remained largely unchanged at 6 and 12 months although the walking speed increased somewhat over time.

Although a cost-effectiveness analysis of the intervention was intended this proved very difficult due to the quality of the data and so this objective was not met and no reliable conclusions were made. One of the limitations of the study was that participants were referred from their GP's without having a specialist diagnosis of CFS. Furthermore, although this was a large well-funded project, none of the participants had a clinical interview prior to their randomisation, so their suitability for group treatment was not assessed, meaning that in routine clinical practice some of the patients may not have received the group intervention. This highlights how randomised control trials are often not in line with normal clinical practice.

Clinical Implications and Future Research

There do appear to be a variety of different treatment options in existence for CFS, but not all are readily available. Clearly all types and modalities of CFS intervention (as at present) need to be more fully evaluated as it appears that the only good evidence based treatments are CBT and GET. Funding for alternative treatments is a contentious issue

but anecdotal evidence and preliminary findings suggest that some of the alternative therapies, such as acupuncture may be viable. Clinicians need to be aware of the range of treatments available, as the heterogeneous nature of the condition will mean that some treatments will work for some and not for others. Keeping up to date with the ever-evolving treatment literature is imperative.

Although the evidence is limited it does appear that GCBT can be effective and amenable for the management of symptoms for people with CFS. More research is needed to explore the effectiveness of group therapy compared to individual therapy and to look at the cost effectiveness of each type of therapy. Also delivery of the intervention needs to be explored. The small body of evidence for GCBT varied greatly in the number and make up of the delivery team. For this type of complex condition it seems intuitive that a multidisciplinary team would be an ideal standard for the CBT intervention delivery but this needs to be explored with clinical trials. Researchers need to be aware of criticism aimed at randomised control trials for CFS as discussed by Quarmby et al. (in press) and aspire to conduct research that can easily be generalised to routine clinical practice.

The debate about sub-grouping CFS sufferers into activity avoidance and over doers is also one which could greatly affect how treatment is delivered to individuals. This has obvious implications for group therapy and whether it is appropriate to have two different sets of sufferers in the same therapeutic group. It could be that a skilled CBT practitioner could manage two sets of patients within the same group and there may be benefits for the group members in doing this, as fellow sufferers may act as powerful cogent role models.

Finally the review of the GCBT included a wide range of outcome measures, making it difficult with so few studies to pool the data or compare the findings. Researchers do not often include scale information, reliability or validity details. To enable research to be compared more meaningfully, it is of up-most importance that a set of standardised outcome measures be collated. This must include a good mix of different variables to encompass the wide variations of differing CFS symptoms. For this to occur there

needs to be an influx of research that uses both extensively used measures but also tests out the feasibility of other outcome measures.

There is a distinct lack of follow up data for interventions, especially regarding the group-based format. As CFS is considered to have long-term impact and the intervention gives strategies and techniques to manage rather than cure it is essential to gather follow up data. Many patients may feel 'better' whilst coming to group for a variety of different reasons but there is a need to know if potential improvements can be maintained or extended following the end of the intervention. Studies also need to consider evaluating the appropriate duration of the follow ups and whether further psycho-educational material be given post intervention.

Finally, drop out rates are very important for assessing how acceptable an intervention is to its patient group. Group intervention trials should consider being explicit about these but also consider analysing potential differences between patients who are good attendees and those who miss many sessions or drop out entirely. This information could be important for efforts to sub-type or indeed to tailor the programme to meet a differentiation of treatment and management needs.

Summary

There are a number of different management packages in existence for people with CFS but only a few of these have limited evidence for their effectiveness. In reviews individual CBT and GET show the most promise but as yet very few trails have explored CBT in a group format. This review identified only four studies and methodological limitations and design problems meant that meta-analysis was precluded. However GCBT research looks promising and may be a cost-effective means of management of symptoms for people with CFS in services, which often have to work within very restrictive financing. Future research needs to consider which patients benefit from the group therapies so that potential sub-groups can be identified and how amenable the therapy is to patients. Furthermore trials need to ascertain which discipline is best suited to execute the intervention and what outcome measures are

most appropriate for evaluating the treatment so that meaningful comparisons and meta-analyses can be made.

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Table 1: Case definitions for chronic fatigue syndrome

	UK Sharpe et al. (1991)	CDC-1994 Fukuda et al. (1994)	Australian Lloyd et al. (1994)	Canadian Carruthers et al. (2003)
Minimum duration (months)	6	6	6	6
Functional impairment	Substantial	Substantial	Substantial	Substantial
Cognitive or neuropsychiatric symptoms	Mental fatigue required	May be present	Required	Two or more required
Other symptoms	Not specified	4 required	Not specified	At least 1 symptom from 2 of the following manifestations; automatic neuroendocrine immune
New onset	Required	Required	Not required	Required
Medical exclusions	Known physical causes	Clinically important	Known physical causes	Known physical causes
Psychiatric exclusions	Psychosis, bipolar, eating disorder, organic brain disease	Melancholic depression, substance abuse, bipolar disorders, psychosis, eating disorder	Psychosis, bipolar, substance abuse, eating disorder	Not specified

*Centre for Disease Control (CDC)

Appendix 2: Table 2, Characteristics of group CBT studies

Author & year	Diagno.	Model used	No.	Mean (SD) age	No. of sessions	Session length	Design	Main Measures	Outcome	Follow up
Bazelmans et al. (2005)	CDC (Fukuda et al., 1994)	GCBT V Wait control	29 in CBT group	37.4 (8.6)	12 sessions over 6 months	2 hours	Non-randomised waiting list control	CIS-Fatigue SCL-90 SIP-8 BDI Self efficacy	Non sig + No change No inter No inter No inter	None specified
Saxty & Hensen (2005)	CDC (Fukuda et al., 1994)	GCBT	6	41.67 Median Female only	Weekly for first 4 sessions then every 2 weeks for the next 5	1 hour	Prospective outcome No control	Fatigue Quest. SAS GHQ Global ratings	Improve Improve Improve Good	None specified
Wittkowsk et al. (2004)	CDC (Fukuda et al., 1994)	GCBT	5	43 Median Female only	8 consecutive weeks	1.5 hours	Prospective outcome No control	Fatigue Quest. PFRS HADS	Improve Improve Improve	All improvements largely maintained at 3 months
O'Dowd et al. (2006)	CDC (Fukuda et al., 1994)	GCBT v EAS v SMC	52 v 50 v 50	41.1 (11.9) Two thirds female	8 sessions fortnightly	2 hours	Double blind randomised control	Fatigue Quest HADS SF-36 GHQ Neuro tests Health Status	Improve on mental health, fatigue levels and walking speed	Follow up at 6 and 12 months. Improvements found in CBT maintained at 6 months

Note; CIS-Fatigue = Dimensional assessment of chronic fatigue, fatigue subscale (Vercoulen, Swanink, Fennis, Galama, Vab der Meer & Bleijenberg (1994), SCL = Symptom checklist (Arrindell & Etteman, 1986), SIP-8 = Sickness Impact Profile (Berger, Bobbit, Carter, & Gibson), BDI= Beck Depression Inventory (Beck, Steer & Brown, 1996), Fatigue Quest = Fatigue questionnaire (Chalder et al. 1993), SAS – Work and Social Adjustment Scale (Marks, 1986), GHQ = General Health Questionnaire-12 item (Goldberg, 1972), Global Self = Global self rating of programme and improvement, PFRS = Profile of fatigue related symptoms (Ray, Weir, Phillips & Cullen, 1992), HADS = Hospital anxiety and depression scale (Zigmond & Snaith, 1983).

Appendix Q

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Section Four

Research Paper

A pragmatic evaluation of group cognitive behavioural for chronic fatigue syndrome

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Abstract

Although chronic fatigue syndrome (CFS) is an incurable condition there is growing evidence that individual cognitive behavioural therapy (ICBT) is an effective intervention for the treatment and management of its symptoms. However to date there is a lack of research concerning group cognitive behavioural therapy (GCBT). The aim of the present study is to explore the effectiveness of GCBT in a routine clinical setting. In this pragmatic, non-randomised, controled design 28 people acted as their own waiting list control by completing a range of measures 8 weeks prior to taking part in GCBT. The intervention consisted of 8 consecutive weeks of 2.5-hour sessions. Significant improvements were found compared to the waiting list in physical and mental fatigue and depressive symptoms. Improvements in quality of life, hope and optimism were also found but no improvements were reported for anxiety levels, pain or physical functioning. Global outcome measurers revealed that the majority of the patients found the treatment beneficial and were satisfied with the results. It is concluded that GCBT is a beneficial treatment that patients find amenable in routine clinical practice for CFS. However further research is indicated to improve subgroup identification and refine intervention programmes.

Introduction

Chronic fatigue syndrome (CFS) is an incurable condition consisting of severe fatigue lasting at least 6 months accompanied by a range of other symptoms including sleep disturbance, difficulties with concentration and memory, headaches and other pains (Fukuda et al., 1994; Sharpe et al. 1991). Although as yet the cause is unknown there are a range of different interventions used in the treatment and management of CFS. However only graded exercise and ICBT appear to have good evidence of their effectiveness (Price & Couper, 2000; Whiting et al., 2001). Whilst CBT has shown to be effective, even at follow up (Prins et al., 2001; Deale, Husain, Chalder & Wessley, 2001) there appears to be a distinct lack of data concerning the effects of group cognitive behavioural therapy (GCBT). There is a clearly identified gap in the research and standardised outcome measures are needed to give comparable data (O'Dowed, Gladwell, Rogers, Hollinghurst & Gregory, 2006).

Group therapy is becoming increasingly popular as a cost effective intervention in clinical services (Abbey, 1996). It can have its advantages over individual therapy as it may be useful for reducing time spent on a waiting list and can be particularly advantageous where an intervention has a significant psychoeducative component and deals with a condition that is as yet not fully understood by the medical profession or general population (Saxty & Hansen, 2005). Group therapy also enables a peer support element that is not available in individual therapy but can have therapeutic benefits to CFS sufferers who often face misunderstanding and disbelief from non-sufferers (Taylor, 2004).

However to date there is a distinct lack of GCBT trials. Price and Couper (1998) reviewed all randomised control trials of CBT and concluded that the evidence for the effectiveness of GCBT for CFS is unsatisfactory, which was due in part to methodological issues. Furthermore, although several ICBT studies have reported positive results for CFS, they have been subjected to criticism for selecting participants who are not taking antidepressants or have co-morbid psychiatric problems and are more active (Carruthers, Jain, Meirleir et al., 2003). This could reduce the generalisability to the broader CFS population and brings into question the clinical validity.

A recent study by Quarmby, Rimes, Deale, Wessley and Chalder (in press) compared the outcomes of ICBT in randomised control trial to those in routine practice. The results in the randomised control trial showed superior results compared to those in routine practice. The authors suggest this effect may be due to patient selection, in that the randomised control trials are very selective in who they chose for their trials. Similarly patients for the RCT may have self-selected where the study has been advertised publicly. Other factor for consideration are that therapists are often involved in the research and may be somewhat more 'evangelical' than therapists in routine clinical practice. They may also adhere more strictly to a specific treatment protocol, than their colleagues in routine service. Therefore it appears that Quarmby et al. do not champion a randomised control trial design for this type of intervention study.

A small number of GCBT studies have been carried out. Saxty and Hansen (2005) preliminary study reported that most patients showed improvements for fatigue, general health and social adjustment on pre and post-group scores. However, one scored the same on anxiety and depression and one scored worse on the post treatment GHQ. This was maintained at the 3-month follow-up for fatigue but not for general health and social adjustment. In terms of global outcome measures good results were obtained with all participants finding the treatment 'useful' or 'better than useful' and all being 'moderately' or 'very satisfied' with the outcome. The majority also reported to being 'less fatigued' and 'less handicapped.'

The study was limited by a small sample of six all of which were female and so it is difficult to generalise from the findings. The researchers themselves concluded that a controlled trial is now required to ascertain if GCBT may be more beneficial. This was however a useful pilot study especially as it allowed patients to evaluate their satisfaction and perception of usefulness of the programme. It also demonstrated that it is an acceptable form of therapy as indicated by the high attendance rates and satisfaction ratings.

Another study that showed positive results albeit with a small, all female sample is that of Wittkowski, Toye and Richards (2004). Only descriptive statistics were given

due to the sample size of five but the results do suggest that GCBT led to reductions in physical and mental fatigue, fatigue related symptoms, anxiety and depression. However the researchers failed to collect measures relating to functional ability but instead cite anecdotal evidence of an improvement in this domain. Another criticism of this trial is that the group sessions were developed and facilitated by two inexperienced but supervised trainee clinical psychologists and there does not appear to be any other input from a multidisciplinary team.

Bazelmans, Prins, Van der Meer & Bleijenberg (2005) used a larger sample size in their non-randomised, waiting list control design to study the effectiveness of CBT on a group of unselected patients with CFS in two centres in the Netherlands. Although patients in the waiting list control were offered GCBT following the six-month waiting period, the authors do not give any indication of the take up or subsequent outcome following the programme.

An insignificant interaction effect was found in favour of GCBT for fatigue. Functional impairment did not change in the GCBT but declined in the waiting list control. Furthermore, avoidance of activity also increased after GCBT and decreased in the waiting list control group. No interaction effects were found for daily observed fatigue, pain, hours working, self-efficacy, focusing on bodily symptoms, psychological well-being or depression. Twenty-seven of the twenty-nine GCBT participants rated their improvement of which 37%were positive. The authors admit the study was limited as inexperienced facilitators were employed and relaxation was over emphasised to the detriment of the graded activity components.

The most superior GCBT trial to date is that of O'Dowd, Gladwell, Rogers, Hollonghurst & Gregory (2006). This double-blind, randomised, controlled trial compared three interventions; group cognitive behavioural therapy (GCBT), education with support group (EAS) and standard medical care (SMC). Follow-up data was collected at six and twelve months. Of the one hundred and fifty-three participants, two thirds were female.

They reported no significant change in cognitive function or quality of life as a result of participation in the GCBT group. Three outcome measures showed statistically

significant differences between the groups. The GCBT reported higher SF-36 mental health scores, less fatigue and improved walking speed compared to those in the SMC group. These improvements persisted when compared to those in the EAS group. Although no other statistical differences were found between groups it is noted that there were improvements for GCBT group in many of the other measures. Scores remained largely unchanged at 6 and 12 months, although the GCBT walking speed increased somewhat.

Whilst a cost-effectiveness analysis of the intervention was intended the researchers ran into difficulties and so this objective was not met and no reliable conclusions were made. One of the limitations of the study was that participants were referred from their GP's without having a specialist diagnosis of CFS. Similarly, although this was a large, well-funded project none of the participants had a clinical interview prior to their randomisation, so their suitability for group treatment was not assessed. In routine clinical practice some of the patients may not have received the intervention. The finding of Quamby et al. (in press) highlights the fact that randomised control trials are somewhat contrived and reinforces the need for good reliable trials that closely reflect routine clinical practice.

The aim of the present study is to investigate the effectiveness of GCBT for CFS in a routine clinical setting therefore addressing one of the concerns raised by Quarmby and colleagues regarding ecological validity and generalisation of findings to other specialist CFS outpatient care. The hypothesis is that an eight-week GCBT intervention will be superior to an eight-week waiting period on measures of quality of life, mental health and fatigue.

Method

Ethics

Approval was obtained from the Local Research Ethics Committee to monitor the effectiveness of group CBT for adult CFS sufferers in an NHS service in North Wales. Participants gave written informed consent for their data to be used in the present study.

Participants

Participants were consecutive GP referrals to the specialist clinic in North Wales. As part of their usual care a medical practitioner and a clinical psychologist assessed all patients using a detailed interview and psychometric measures. Patients were eligible to take part in the study if they were over 18 years old and met the Oxford criteria (Sharpe, et al., 1991). This specifies the presence of medically unexplained, new onset disabling fatigue of at least 6 months duration and mental, as well as, physical fatigue. All participants had also been deemed amenable and appropriate for group work.

Using Cohen's (1992) power primer a calculation was made to determine how many participants were needed in each group prior to commencement. Effect Size needed was assumed to be enough to see a difference by eye (medium). Low to medium effect sizes had been reported in review [Price & Couper, 1998 (f = .40)] With the significance criteria set at 0.05 then the power calculation deemed a necessary sample size per group to be 34.

As is often the way, this number was not achieved due to a lower rate of referrals than was expected. Of the 30 patients assessed as suitable for a group programme, two subsequently withdrew from treatment before the start of the intervention for unspecified reasons. Three groups of 8 to 10 patients were completed. Of the 28 who took part in the study 35.7% (10) were taking antidepressants at assessment and throughout treatment. All the patients classed themselves as white British (English/Welsh). Further demographics are outlined below in table one.

[Insert Table One]

Design

In line with Quarmby et al.'s (2006) concerns regarding the ecological validity of randomised control trials, it was decided to devise a novel repeated measures design, where patients act as their own control. This resulted in a waiting list control group that was 'service friendly' in that the waiting period to treatment was not artificially increased, service level agreements were not compromised, and co-morbid patients or those on medication were not excluded from the protocol. Thus the research design more closely resembles what happens in routine clinical treatment in a hardworking, part-time NHS service.

Procedure

Eight weeks prior to the programme date, people on the waiting list were sent a bilingual letter inviting them to take part in the research. Participant information and consent forms were enclosed along with a battery of psychometrics. Those who agreed to take part completed the psychometrics and returned them with the signed consent form in a pre-paid envelope provided.

As in routine clinical practice, participants completed a battery of questionnaires at the start and end of the 8-week intervention. For the purposes of the study the battery was extended to include participant outcome measures and positive psychological measures. Similarly, at the end of the programme the views of the patients 'significant others' were assessed. They were asked to consent in writing to provide their perception of the outcome of the intervention. As patient's family and friends are often greatly affected by the condition and are usually involved with the patients throughout the programme their feedback seems wholly relevant, enhancing the ecological validity of the study. The design is set out pictorially below in figure one.

[Insert Figure One]

Measures

Having collected the participants basic demographic and employment details the following measures were used:

Fatigue Questionnaire (Chalder et al., 1993)

This 11-item fatigue scale asks patients to rate their fatigue on a 4-point scale from 'less than usual' to 'much more than usual'. Scoring can be bimodal with a range of 0-11 or on a Likert scale with a maximum of 33. Although scoring gives an empirically validated cut off (Chalder et al., 1993) the Likert scoring system was employed in this study as it is more sensitive to change. Chalder's scale has been demonstrated to have good internal consistency (Cronbach alpha .88) with the physical and mental subscales having scores of .84 and .82 respectively. In the present study, data at time one (8 weeks pre-treatment) a Cronbach's alpha of .79 for the overall scale, .79 for the physical factor and .74 for the mental factor is reported.

Beck Depression Inventory-Fast Screen for Medical Patients (BDI-FS)

The BDI- FS (Beck, Guth, Steer & Ball, 1997) consists of seven items derived from the larger BDI-II (Beck, Steer & Brown, 1996). This was designed to assess the intensity of depression in terms of 21 symptom-attitude categories. The Fast Screen was developed to assess depression specifically in patients reporting with co-morbid somatic and behavioural symptoms, otherwise attributable to biological, medical or substance abuse problems. Each statement is ranked for symptom severity from neutral (0) to maximum severity (3). The BDI-FS has internal consistency of .84 (based on outpatient sample) and test-retest reliability of .93 ($p < .001$). In the present study a Cronbach's alpha of .74 was reported.

Hospital and Anxiety and Depression Scale

The HADS (Zigmond & Snaith, 1983) is a fourteen-item scale with two 7-item sub-scales measuring depression and anxiety. Like the BDI-FS each statement is ranked for symptom severity (0-3). The HADS is extensively used in clinical settings and has good validity. It has internal consistency of .89 on both sub-scales and a re-test reliability in 6 months or less of .72 ($p < .001$) for each sub-scale and .74 ($p < .001$) for the total scale (Savard et al, 1998). Scores above 10 indicate 'caseness' on each of the subscales. In the present study a Cronbach's alpha of .56 for anxiety and .75 for depression was reported.

Physical Functioning Measure as Part of the Short Form General Health Survey (SF-36)

The SF-36 (Ware & Sherbourne, 1992) was developed to measure general health in primary care and consists of 36 items. These measure 8 dimensions, including physical and social functioning and role limitations due to physical and emotional problems. Internal co-efficiency correlations for the 8 scales of 0.60 - 0.81 with a median value of 0.76 have been reported. High inter-item correlations have been reported for the sub scales with high Cronbach's alpha ratings of between 0.76 to 0.90. Similarly, good test re-test reliability levels, with coefficients ranging from 0.43 to 0.90 has been reported (Jenkinson, Layte, Wright, Coulter, 1996). For the purpose of this study, functional impairment was measured using the physical functioning subscale of the SF-36 and pain levels. There are ten items with scores ranging from 0 (maximum physical limitation) to 100 (vigorous activity). An increase of 10 or more in the baseline score on the physical functioning subscale determines clinically significant improvement (Garratt et al., 1993). In the present study a Cronbach's alpha of .87 was reported.

Pain Visual Analogue Scale as Part of the Short Form General Health Survey (SF-36)

The visual analogue scale was also taken from the general health survey (SF-36). Participants had to rate along a line their level of pain from no pain to pain as bad as possible.

It is now widely accepted that treatment may help to make the patient more in control. This may lead to improvements in quality of life, optimism and hope for the future.

For this reason positive psychological measures that have not previously been used in CFS research were added for evaluation as potential future outcome measures.

Quality of Life Visual Analogue Scale as Part of the EUROQOL (EQ-5D)

The EQ-5D (EuroQol Group, 1990) is a standardized measure of health outcome. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value of health status. The EQ-5D was originally designed to complement other instruments but is now increasingly used in isolation. The EQ-5D is designed for self-completion by respondents and is ideally suited for use in postal surveys, or face-to-face interviews. Only the visual analogue scale of the Euroqual was used in this study. Instructions to respondents are included in this measure since the EQ-5D is now widely employed by clinicians and researchers. In the UK, a NHS Task Group has been set up to evaluate its use as a clinical outcome measure.

Life Orientation Test (Optimism)

This 10-item measure of dispositional optimism includes four filler items, three positively worded items, and three reversely coded items. Participants rated each item on a 5 point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). Where higher scores correspond with increasing of optimism. This has been shown to have adequate reliability, predictive validity and discriminate validity (Scheier et al.,1994). In the present study a Cronbach's alpha of .90 was reported.

State Hope Scale

The adult State Hope Scale (Snyder et al., 1996) was developed from a dispositional Hope Scale (Snyder et al., 1991) and consists of 6 hope items, which are designed to measure goal directed cognitions. It is comprised of two sub-scales. The 'agency' sub-scale is made up of three items, which measures the perceived motivation to move towards goals. The 'pathways' sub-scale is made up of three items, which measure the perceived ability to generate workable routes to goals. The items are rated on an eight point Likert type scale ranging from, 1 (Definitely false) to 8 (Definitely True). This scale has been demonstrated to have good internal reliability and validity (Snyder et al., 1991; Snyder et al., 1996). In the present study a Cronbach's alpha of .79 was reported.

Global Self-Ratings and Rating by Other Informant (following the intervention)
Overall improvement, fatigue and disability were measured on 6-point scales from 'very much better' to 'very much worse'. Similarly, satisfaction with treatment on a 7-point scale from 'very satisfied' to 'very dissatisfied' and usefulness of treatment on a 5-point scale from 'very useful' to 'no use at all'.

Aim of the study

As very little research has been conducted to explore the effectiveness of GCBT for CFS. This study aims to use a repeated measure waiting list control to find out if GCBT is an effective treatment in routine clinical practice.

The hypothesis is that patients will show changes in outcome scores after the 8-week GCBT compared to an 8-week waiting list control.

Intervention

The therapy consisted of 8 sessions, over an eight-week period and was facilitated by a clinical psychologist, GP, dietician and a physiotherapist, all of whom have 8 years experience of GCBT for CFS sufferers. Each session lasted two and a half hours with a fifteen-minute break, for refreshment and chat. Table two (below) shows the standard programme agenda. All the therapists adopted a positive, informal and friendly approach. Throughout the programme members of the group were encourage to focus on solutions and reward themselves with regular treats. Conversely they were discouraged from excessive symptom focus. Regular time for joke telling was scheduled to further facilitate a non-adversarial atmosphere and increase acceptability of the intervention. Links between sense of humour and self-reported physical health appears to be well supported (Bennet & Longacner, 2006). Similarly there a growing body of empirical data to support the popular belief that laughter benefits health (Mahony, Burroughs & Lippman, 2002). Patients who missed any of the 8 sessions were sent the literature that accompanied the session and the homework handouts.

[Insert Table Two]

Data Preparation

Every 5th entry on the database was checked against the questionnaire to identify inputting errors. Every variable was also checked with frequency tables to ensure that no number was outside the valid range. Items were reversed and recoded as appropriate so that subscale totals could be analysed.

Exploratory data analysis was used to examine the data for normality and suitability for parametric analysis. The data was checked for normality using a one sample Kolmogorov-Smirnov test of goodness-of-fit for all the computed variables ($Z \leq = .579$, $p \geq = .242$). As non-significant result indicates normal distribution, all variables in the analysis demonstrated a parametric distribution and were suitable for parametric analysis.

Analysis Strategy

All analyses were performed using SPSS version 11. Repeated measures analysis of covariance (ANOVA) was used, a parametric equivalent of t-tests for identifying statistical differences between some or all of the means of the groups by comparing them to the grand mean. Bonferroni adjusted pairwise comparisons were used to look for differences between the time points as there is some doubt whether the Tukey test affords sufficient protection from inflation type one errors (Kinear & Gray, 2004). Adjustments were made for the multiple comparisons. All participants completed all the time point measures, although one participant refused to fill in one of the measures as he 'disagreed with its theoretical assumptions', hence there is very little missing data.

Results

All patients attended at least 5 of the eight sessions and more than half the patients attended all eight sessions. Segal, Williams and Teasdale (2002) report 4 sessions to be a minimum requirement to be able to evaluate treatment effectiveness. The data file was split and t-tests were used to look for differences between those who attended all 8 sessions and those who didn't. No significant differences were found for all the baseline measures. The overall attendance rate for the 28 patients was 90.2%. Table three below shows the results of the repeated measure ANOVA's.

[Insert Table Three]

Fatigue Outcome

Results of the repeated measures ANOVA demonstrated significant intervention related reductions in physical and mental fatigue scores. Bonferroni adjusted pairwise comparisons in table three demonstrates significant difference between the pre and post intervention outcome but not the waiting list and pre intervention scores. This indicates that patients fatigue scores improved as a function of the intervention and not as a function of waiting for the intervention. Large effect sizes were found for both scores (Kilner & Gray, 2004).

Mood measures

Significant intervention related reductions were found in both sets of depression scores. Bonferroni adjusted pairwise comparisons demonstrates significant difference between the pre and post intervention outcome, but not the waiting list and pre intervention scores. This also indicates that patient's depressive symptoms scores improved as a function of the intervention and not as a function of waiting for the intervention. Large effect sizes were again found for both scores.

No significant difference was found for HADS Anxiety.

Pain and Physical Functioning

Although pain levels reduced slightly following the intervention no significant differences were found. Similarly, no significant differences were found in relation to physical functioning.

Positive Psychological Measures

Significant intervention related increases were found for both optimism and hope. Bonferroni adjusted pairwise comparisons demonstrates significant difference between the pre and post intervention outcome, but not the waiting list and pre intervention scores. This indicates that patient's optimism and hope scores improved as a function of the intervention and not as a function of waiting for the intervention. Large effect sizes were again found for both scores.

With regard to the quality of life measure, significant differences were found between the different time points. However Bonferroni adjusted pairwise comparisons show that the difference was significant between the waiting list and post intervention scores indicating that patient's quality of life increased in the waiting list control and continued to increase following the intervention.

[Insert Figure Two to Seven]

Table four shows the self-reported global outcome measures at the end of treatment. Twenty (85.7%) class themselves as better to some degree with 14.3% (4) rating themselves as 'about the same' or 'worse'. With regard to their fatigue 71.4% (20) people rate themselves as better to some degree with 28.6% (8) people rating themselves as 'the same' or 'worse'. With regard to their disability/restrictions 64.3% (18) people regarded themselves as better to some degree with 35.7% (10) people classing themselves as 'the same' or 'worse'.

Twenty five (89.3%) classed themselves as satisfied to some degree with the outcome of the intervention, with 7.1% (2) 'neither satisfied or dissatisfied' and 3.6% (1) rating

themselves as 'slightly dissatisfied' with the outcome. Everyone found the intervention useful to some degree with 64.3% (18) finding it 'very useful'.

[Insert Table Four]

Generally the qualitative feedback was positive. Many people commented on the benefit of 'validation'. Their process of being listened to, believed and supported by the therapy team and other CFS sufferers starts at the assessment stage and continues throughout the intervention. Some patients also report the benefits of the social aspects and the realisation that they are not alone. However limitations of this study mean that a full analysis of the qualitative feedback from the participants is beyond its scope.

Although people did not return their informant global outcome measures. What data was returned is summarised in table five below.

[Insert Table Five]

Discussion

These findings largely support the hypothesis that GCBT will have beneficial effects on fatigue and other variables. Positive effects on both mental and physical fatigue were found compared to the waiting list control that showed no significant changes. This supports preliminary GCBT findings of Saxty and Hansen (2005) and Wittkowski et al. (2004) who reported improvements in self-reported fatigue in their small sample. It also supports the other, more comprehensive GCBT study of O'Dowd (2006) who suggested that GCBT helped to reduce both mental and physical fatigue.

With regard to mood, the intervention appeared to be effective at reducing depressive symptoms, but not the waiting control. However anxiety remained fairly stable with no significant difference following intervention. These findings partly support the previous preliminary GCBT findings that showed little or no change in depression outcome scores and anxiety. Bazelman et al (2005) found no changes in psychological well being or depression and Wittkowski et al. (2004) also found depression and anxiety symptoms to remain fairly stable following their interventions.

By way of explanation, mood measures are, perhaps, not that appropriate as outcome measures in CFS intervention studies. The anticipation or experience of taking part in group therapy, for some people may be a novel and perhaps stressful experience. It is also impossible to control for naturally occurring adverse events that effect mood. However in their individual CBT trial Deal et al (1997) also reported similar stability of mood. Alternatively, anxiety was particularly high for this clinical sample and so may have needed additional input. Comparing to other group means can help to decipher whether the scores are abnormally high.

Clinical symptoms and their severity as measured by the baseline can vary considerably from study to study and this further emphasises the need for a good set of standardised outcome measures so that research can be compared meaningfully. In the largest GCBT trail to date O' Dowd at al. (2006) did have very similar baseline measures to the present study for their mean HADS scores (10.3 and 8.7 for anxiety

and depression) suggesting that this sample was no more psychologically distressed than theirs.

The current intervention did not have any significant effects on functional impairment or pain levels, which again reflects O'Dowd et al.'s findings. They also found no change on the physical functioning as measured by the SF-36. This also supports the findings of Bazelmans et al (2005) who also reported no significant improvement in physical impairment or daily observed pain.

Although, non-significant improvements between pre and post were reported for quality of life. This difference was significant between waiting list and post intervention. Again this is in line with the quality of life improvements reported in Taylor (2004) who utilised some CBT techniques in her individual and group therapy trial. In the current study the improvements appeared to take place whilst the participants were on the waiting list and continued to improve following the intervention. This could in part be explained by the anticipatory element of their wait (and hope of better management) and is further supported by the results for hope and optimism, which also showed improvements in the 8-week waiting period before the intervention. There was anecdotal evidence from participants that the assessment process alone is beneficial as it is a validating experience. People can often find it hard to get better if people do not believe they are ill in the first place.

There was an improvement for optimism scores in the waiting list condition and this improvement continued after the intervention. However only the improvement between pre and post intervention reached significance. There was a similar pattern with hope as patients improved whilst on the waiting list but this improvement did not reach significance. However the improvement in hope following the intervention did reach significance. This demonstrates a greater improvement as a result of the intervention. This study appears to be unique in so far as it is the only study that has explored hope and optimism as potential outcome variable with patients with CFS. It also appears that the outcome measures are effective at demonstrating the changes that occur as a result of taking part in the GCBT intervention. It is recommended that other studies also explore the effectiveness of these measures as potential outcome measures following intervention. As the GCBT aims to help patients manage their

condition and utilises changes in cognitions to help achieve this it seems intuitive that positive psychological measures be used in conjunction with the standardised mood, pain and functioning measures, which are perhaps less sensitive to change.

Perhaps another strength of the present study is the absence of participant drop out. This has not been the case for other clinical studies, especially graded exercise trials for CFS (e.g. Moss-Morris, Sharon, Tobin & James, 2005). Once patients had started this programme no one dropped out, which implies that the treatment was acceptable to them and is consistent with the therapists aim to make the programme intrinsically rewarding.

Another point for consideration is that this study allowed for the inclusion of patients that were involved in disputes regarding disability benefit or in litigation claims. However in trials of individual CBT for CFS results show that engagement in claims predicted less favourable outcomes after CBT (Deal, Husain, Chalder & Wessley, 2001; Prins, Bazelmans, Van der Werf, Van der Meer & Bleijenberg, 2002). In the present study one patient was part way through a works tribunal and another was in dispute regarding his invalidity benefits. Both these patients failed to show any positive effects in their outcome scores and the study would have shown even better outcomes if these two patients were excluded from the analysis. However it was decided to include them so that the results reflect a typical routine clinical sample. In light of these findings, future intervention programmes may wish to postpone intervening with such patients until a time after their disputes or claims are settled, so that the patient can get the full benefits of a GCBT. Conversely, emotive issues (such as disputes with family or neighbours) can arise for any of the patients taking part in any group therapy and therapists must allow for the fact that 'life can get in the way.'

However one potential limitation to the study is it is a relatively small sample size and so the results should be viewed with some caution. Another limitation of the study is that it does differentiate between different symptoms. Even though information is routinely collected regarding symptom profiles this was not analysed during the study. Many of the patients differed in their experience of the condition and how they managed it. It could be that the intervention has different effects for different symptoms or personality types (e.g. the integral focus on pacing helps goal oriented

people avoid over activity bursts). Future research that addresses the issue of definition and sub-typing might help address this issue.

It is important to note that evidence from randomised trials does not guarantee that success in routine service practice for everyone (Huibers & Wessley, 2006). As this trial demonstrates GCBT does not elicit positive result for everyone and there is still much to be learnt about the symptom control and management of CFS. Qualitative research could be used to try to evaluate why the therapy worked for some and not others and this may be a future direction for CFS research.

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Figure One:

Presentation of Procedure/Design

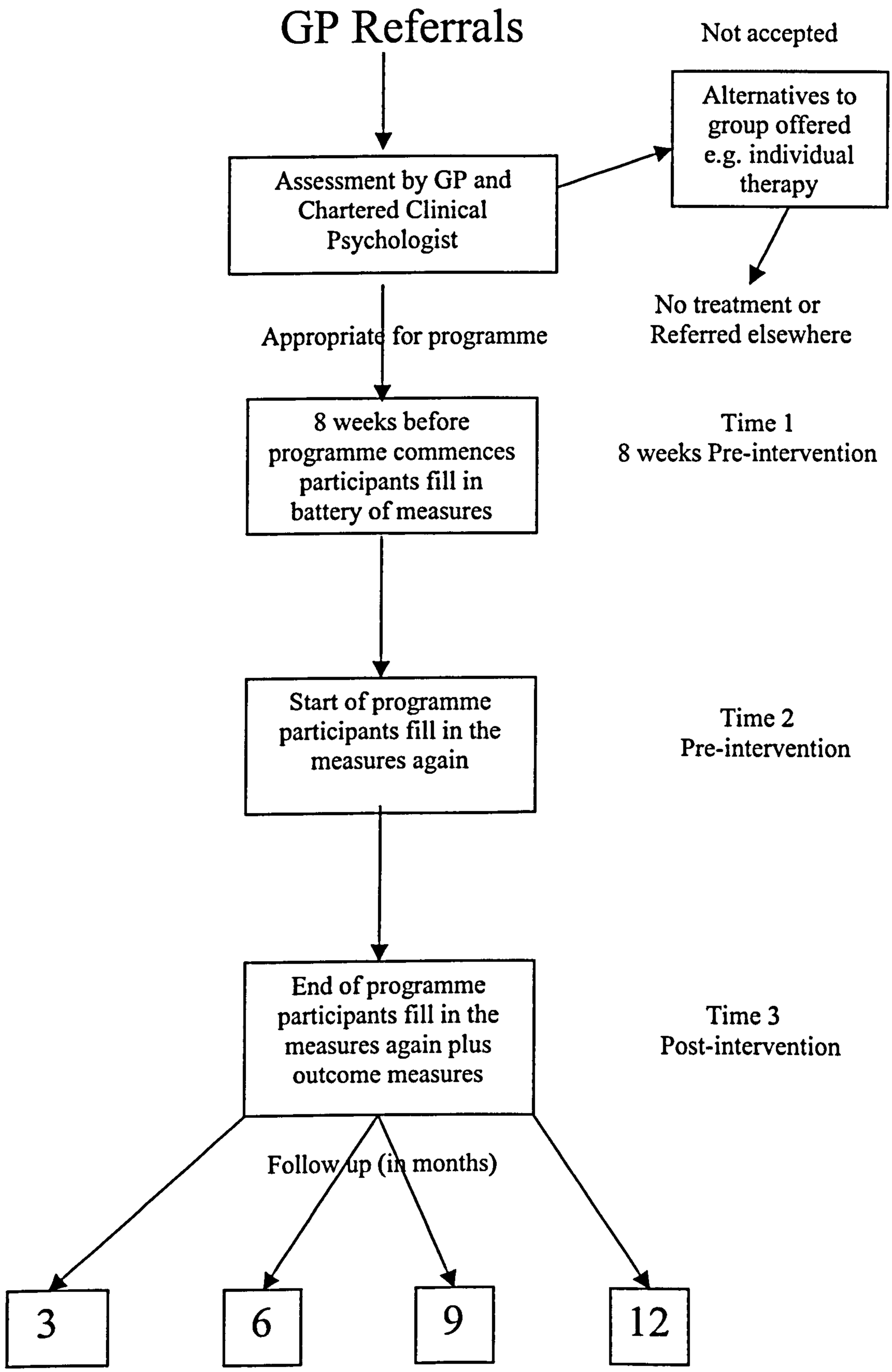

Figure Two to Figure Seven

Figure 2:
Changes in mental fatigue

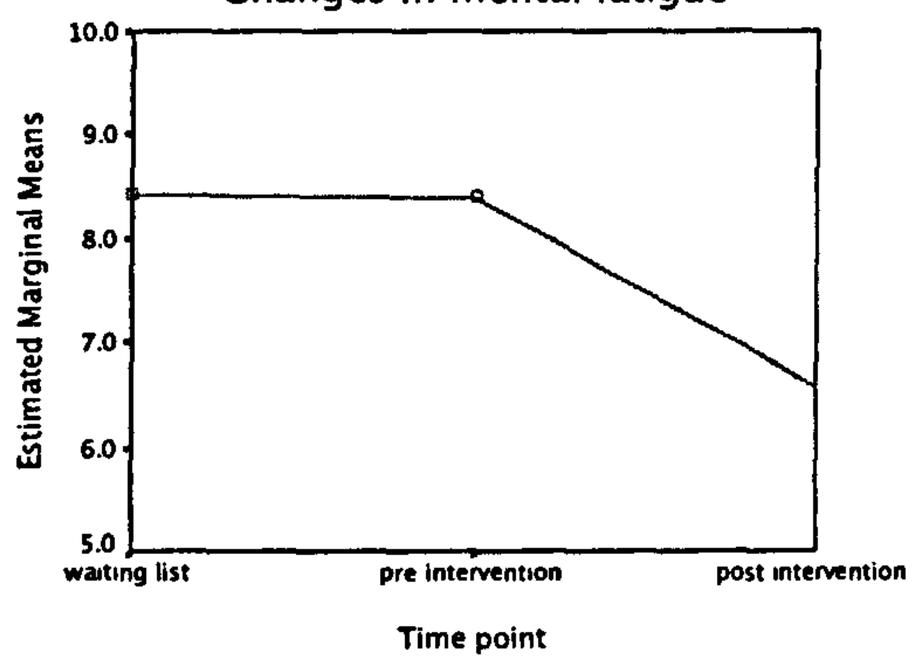

Figure 3:
Changes in physical fatigue

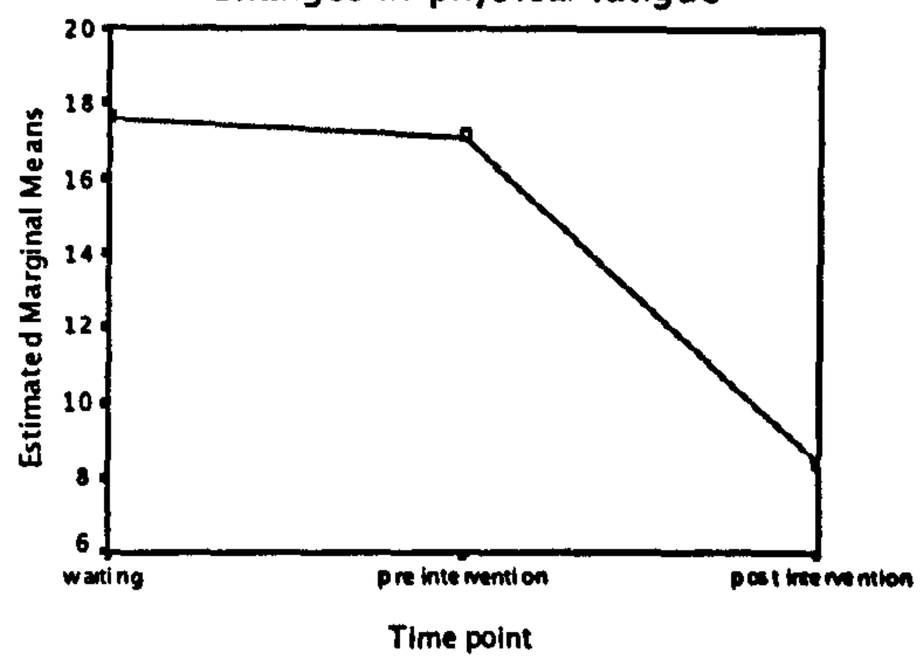

Figure 4:
Changes in depression (BDI-FS)

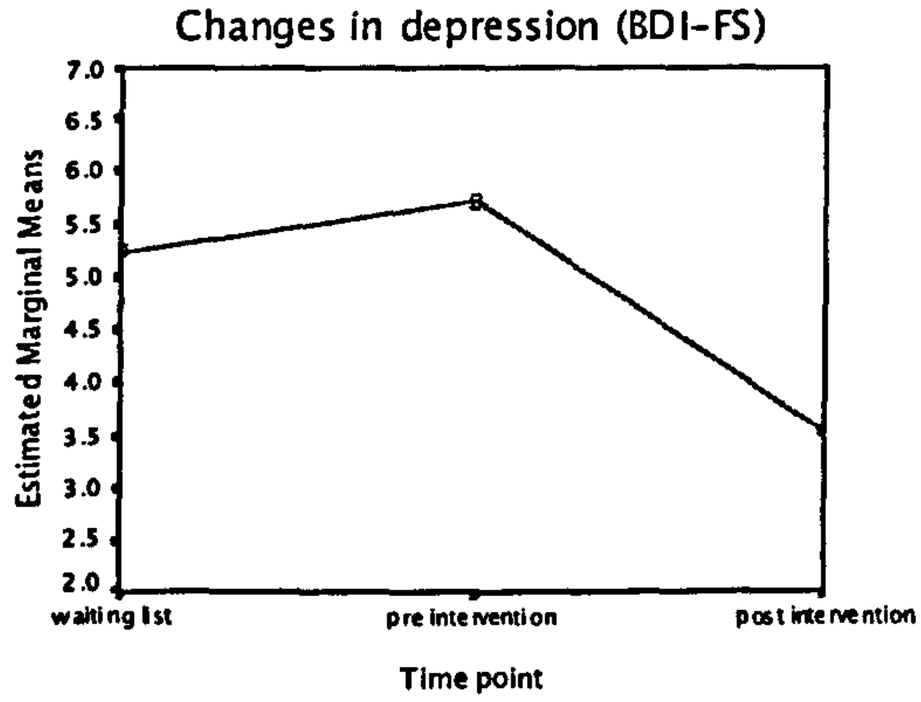

Figure 5:
Changes in optimism

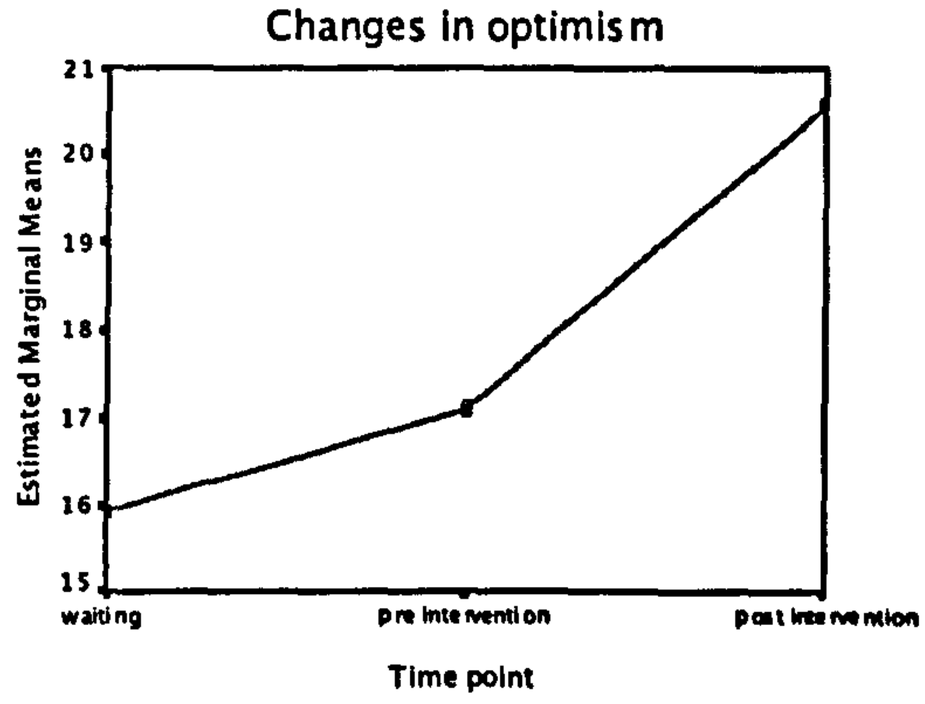

Figure 6:
Changes in hope

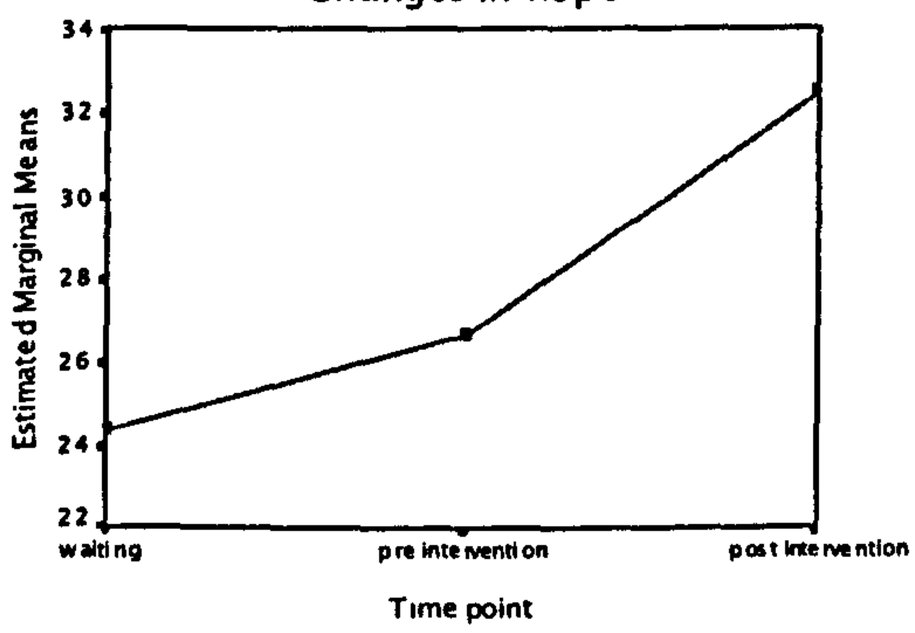

Figure 7:
Changes in quality of life

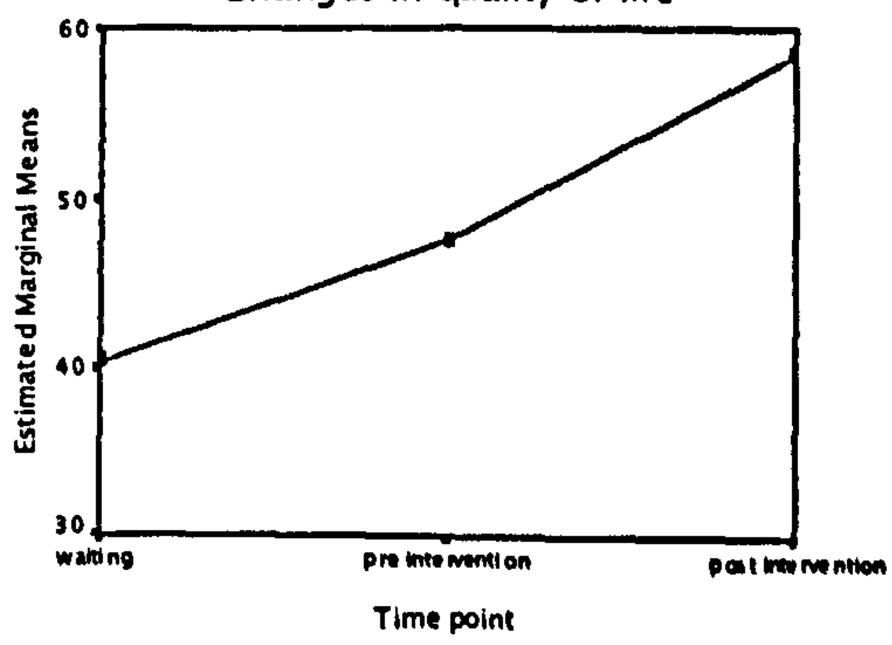

Table One:

Demographics of patients receiving CBT

Characteristics	Mean (SD) ($N = 28$)
Age (years)	43.07 (13.24)
Fatigue duration (years)	3.73 (3.15)
Described percentage disability (%)	60.18 (14.37)
	N (%)
Gender	
Male	11 (39.3)
Female	17 (60.7)
Occupation	
Full or part time employed	10 (35.7)
Temporarily discontinued due to symptoms	5 (17.9)
Indefinitely discontinued due to symptoms	11 (39.3)
Other including retired	2 (7.1)
Marital status	
Single	6 (21.4)
Married	11 (39.3)
Divorced	3 (10.7)
Living with partner	8 (28.6)
Onset type	
Sudden	12 (42.9)
Gradual	16 (57.1)

Table Two:

Standard Programme Agenda for CFS

Start Time	Activity	Facilitator	Time Set
10.00am	Welcome, warm up, agenda	Psychologist/GP	5 mins
10.05am	Brisk walk to music (timed) Physiotherapist to note gait and posture	Pysiotherapist	15 mins
10.20am	Homework, diary and pacing review Diaphragmatic breathing	Psychologist/GP Physiotherapist	30 mins
10.50am	Relaxation session Autogenic training Mindfulness meditation Self hypnosis	Dietician/Psychologist	20 mins
11.10am	Break One to one diary review	 GP/Psychologist	15 mins
11.25am	Stretch and movement	Physiotherapist/Dietician	20 mins
11.45am **Session** 1 2 3 4 5 6 7 8	**Psycho educative components** Introduction/CBT rational for CFS Benefits of exercise Pacing and goal setting Sleep management Stress management Pain & strange sensations Nutrition 1 & 2 Mindfulness and preparation for the future	 Psychologist/GP Physiotherapist Psychologist Psychologist Psychologist Psychologist/GP Dietician Psychologist/GP	40 mins
12.25am	Summation & Homework setting	Psychologist/GP	5 mins

Table Three:

Mean and standard deviation scores for the waiting list control, pre and post

Measure	Waiting list	Pre-treatment	Post treatment	F value (d.f)	Pairwise Bonferroni comparisons	Effect size d.
	Mean (SD)					
Physical fatigue	17.61(2.86)	17.11(3.08)	11.11(5.97)	28.31 (2,54)**	T1 = T2 > T3	.512
Mental fatigue	8.43(1.95)	8.40(2.22)	6.57(3.30)	7.72(2,54)**	T1 = T2 > T3	.222
BDI-FS Depress	5.25(3.12)	5.71(3.14)	3.54(3.02)	11.43(2,54)**	T1 = T2 > T3	.300
HADS Depress	9.32(3.41)	9.60(4.02)	7.14(3.66)	16.72(2,54)**	T1 = T2 > T3	.382
HADS Anxiety	10.57(3.65)	12.18(3.86)	10.46(3.57)	3.34(2,54)	T1 = T2 = T3	-
SF-36 Physical	20.36(4.13)	20.39(4.78)	20.79(5.58)	.23(2,54)	T1 = T2 = T3	-
Pain	38.21(28.90)	39.18(28.17)	37.21(26.76)	.11(2,54)	T1 = T2 = T3	-
Optimism	15.92(7.86)	17.11(6.08)	20.57(6.20)	8.17(2,54)**	T1 < T2 < T3	.232
Hope	24.39(7.64)	26.61(8.89)	32.46(7.38)	15.15(2,54)**	T1 < T2 < T3	.359
Euroqual of life	40.44(21.04)	47.63(20.25)	58.52(18.35)	7.56(2,52)**	T1 < T2 < T3	.225

Table Four:

Global outcome scores at the end of treatment (n = 28)

	Very much better	Much better	A little better	About the same	A little worse	Very much worse
Overall	2	8	14	3	1	–
Fatigue	–	9	11	5	1	2
Disabled/restricted	1	6	11	7	2	1

	Very satisfied	Moderately satisfied	Slightly satisfied	Neither	Slightly dissatisfied	Moderately dissatisfied	Very dissatisfied
Satisfaction with outcome	12	9	4	2	1	–	–

	Very useful	Moderately useful	Useful	Not particularly useful	No use at all
Usefulness of treatment	18	8	2	–	–

Table 5:

Informant global outcome scores at the end of treatment (n = 18)

	Very much better	Much better	A little better	About the same	A little worse	Very much worse
Overall	5	5	2	4	2	–
Fatigue	1	7	4	2	3	1
Disabled/restricted	2	6	3	5	1	1

	Very satisfied	Moderately satisfied	Slightly satisfied	Neither	Slightly dissatisfied	Moderately dissatisfied	Very dissatisfied
Satisfaction with outcome	6	5	2	3	2	–	–

	Very useful	Moderately useful	Useful	Not particularly useful	No use at all
Usefulness of treatment	11	2	2	1	2

Appendix R

Behavioural and Cognitive Psychotherapy Information

Notes for Contributors

Behavioural and Cognitive Psychotherapy

Submission

Articles written in English and not submitted for publication elsewhere, should be sent to:
Paul Salkovskis
Editor
Behavioural and Cognitive Psychotherapy
Department of Psychology
Institute of Psychiatry
De Crespigny Park
Denmark Hill
London SE5 8AF
UK

Manuscript preparation

Four complete copies of the manuscript must be submitted. Manuscripts should include a statement of
any financial or other relationships that might lead to a conflict of interest. If there is no conflict of
interest, this should be specified. In the case of any doubt, details should be sent to the editor in an
accompanying letter. Original figures should be supplied at the time of submission. Articles must be
typed double-spaced throughout on standard sized paper (preferably A4) allowing wide margins all
round. Where unpublished material, e.g. behaviour rating scales, therapy manuals, etc. is referred to in an
article, copies should be submitted to facilitate review.
Manuscripts will be sent out for review exactly as submitted. Authors who want a blind review should
mark three copies of their article 'review copy' omitting from these copies details of authorship and other
identifying information. Submission for blind review is encouraged.
Abbreviations where used must be standard. The Système International (SI) should be used for all units;
where metric units are used the SI equivalent must also be given. Probability values and power statistics
should be given with statistical values and degrees of freedom. (e.g. $F(1,34)$ - 123.07, $p<.001$), but such
information may be included in tables rather than the main text.
Spelling must be consistent within an article, either using British usage (*The Shorter Oxford English*
dictionary), or American usage (*Webster's new collegiate dictionary*). However, spelling in the list of
references must be literal to each original publication.
Details of style not specified here may be determined by reference to the

Publication manual of the
American Psychological Association or the style manual of the British Psychological Society.
Articles should conform to the following scheme:
(a) *Title page*. The title should phrase concisely the major issues. Author(s) to be given with
departmental affiliations and addresses, grouped appropriately. A running head of no more than 40
characters should be indicated.

Page 2

(b)*Abstract*. The abstract should include up to six keywords which could be used to describe the
article. This should summarize the article in no more than 200 words.
(c)*Text*. This should begin with an introduction, succinctly introducing the point of the paper to
those interested in the general area of the journal. *Attention should be paid to the Editorial*
Statement which appears in the January and July issues at the back of the Journal. References
within the text should be given in the form Jones and Smith (1973) or (Jones & Smith, 1973).
When there are three or up to and including five authors the first citation should include all
authors; subsequent citations should be given as Williams et al. (1973). Authors with the same
surname should be distinguished by their initials. The approximate positions of table and figures
should be indicated in the text. Footnotes should be avoided where possible.
(d)*Reference notes(s)*. A list of all cited unpublished or limited circulation material, numbered in
order of appearance in the text, giving as much information as possible about extant manuscripts.
(e)*References*. All citations in the text should be listed in strict alphabetical order according to
surnames. Multiple references to the same author (s) should be listed chronologically, using a, b,
etc., for entries within the same year. Formats for journal articles, books and chapters should
follow these examples:
BECKER. M. R., & GREEN, L. W. (1975). A family approach to compliance with medical
treatment: A selective review of the literature. *International Journal of Health Education, 18,* 173-
182.
THARP, R. G., & WETZEL, R. J. (1969). *Behaviour modification in the natural environment.*
New York: Academic Press.
ROSKIES, E., & LAZARUS, R. S. (1980). Coping theory and the teaching of coping skills. In P.
O. Davidson & S. M. Davidson (Eds), ***Behavioural** medicine: Changing health lifestyles*. New

York: Brunner/Mazel.
(f)*Footnotes*. The first, and preferably only, footnote will appear at the foot of the first page of
each article, and subsequently may acknowledge previous unpublished presentation (e.g.
dissertation, meeting paper) financial support, scholarly or technical assistance, or a change in
affiliation. A concluding (or only) paragraph must be the name and full mailing address of the
author to whom reprint requests or other inquiries should be sent.
(g) *Tables*. Tables should be numbered and given explanatory titles.
(h)*Figure captions*. Numbered captions should be typed on a separate page.
(i)*Figures* Original drawings or prints must be submitted for each line or half-tone illustration.
Figures should be clearly labelled and be camera-ready wherever possible.

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Section Five

Contributions to Theory, Clinical Practice and Learning

Contributions to Theory, Clinical Practice and Learning

Louise Barber

University of Wales, Bangor

Introduction

Although there is a growing body of evidence that individual cognitive behaviour therapy (ICBT) is an effective form of management for chronic fatigue syndrome (CFS) there are very few studies that demonstrate the effectiveness of group cognitive behaviour therapy (GCBT). This research has provided a better insight into which group treatments have been carried out and compared their relative strengths and limitations. It also indicates where there are research gaps, highlighting possible avenues for future study. The empirical paper puts forward evidence for the effectiveness of GCBT and contributes to the burgeoning CFS literature. The research has high ecological validity and can be generalised to other CFS services with implications for theory development, research and clinical practice. These implications were not fully discussed in the empirical paper and will be addresses more comprehensively now.

Implications for Future Research and Theory Development

In short, the findings from the empirical paper overall support the growing evidence that GCBT can be an effective form of management for people suffering with CFS. A number of outcome measures were used to demonstrate this, as discussed below.

The study utilised the minimum dataset that has been put forward recently as a way of standardising the research carried out in England. It appears to date to be the first study of its kind that uses this dataset with GCBT for CFS sufferers. Other measures were also included as a way of assessing positive psychological outcome measures. The psychometric properties of all measures employed is provided in detail in the research paper.

Fatigue Levels

The results demonstrated that the multidisciplinary GCBT intervention is successful at reducing both physical and mental fatigue and supports the previous group findings (O'Dowd, Gladwell, Rogers, Hollonghurst & Gregory, 2006; Saxty and Hansen, 2005; Wittkowski, Toye & Richards, 2004). It also supports the earlier ICBT research that found reductions in fatigue levels due to the intervention (Sharpe et al., 1996;

Deale, Chalder, Marks & Wessely, 1997). Conversely, it is not in line with Bazelmans, Prins, Van der Meer & Bleijenberg (2005) who found no interaction effects for daily observed fatigue. However findings from their study should be viewed with caution due to the design and analysis limitations as discussed in the review paper.

Mood Measures

With regard to mood, the study demonstrated a reduction in depressive symptoms. However, anxiety remained fairly stable with no significant differences following intervention. These findings partly support the previous preliminary GCBT findings that showed little or no change in depression and anxiety outcome scores (Bazelman et al., 2005). Wittkowski et al. (2004) had very similar finding to this trial with a very small drop in anxiety but a larger reduction in depression. However no statistical analysis was performed in this study due to a small sample size. It again partly supports the findings of O'Dowd et al. (2006) who reported improvements in the patients in the GCBT arm of their trial. One possible explanation for the mixed results could be that baseline anxiety and depression may vary significantly between the participants in different trials. However as different mood measures are used in the limited GCBT trials and co-morbid mental health issues are not always documented, it is difficult to compare data. The participants in this trial did have anxiety levels above the clinical cut off point, at baseline, according to their HADS scores but this was in line with the participants in the other larger GCBT trial (O'Dowd, 2006). However reductions in anxiety levels were reported in their trial following the intervention.

Pain and Functional Impairment

The intervention did not have any significant effects on functional impairment or pain levels, which is in line with the research by O'Dowd et al. (2006) who also found no change on the physical functioning as measured by the SF-36. This also consistant with the findings of Bazelmans et al (2005) who reported no significant improvement in physical impairment or daily-observed pain. The other two GCBT studies (Saxty & Hansen, 2005; Wittkowski, et al., 2004) did not report data regarding pain or functional impairment. This suggests that GCBT is not effective, at least in the short term for reducing pain or improving functional impairment and as such future studies

may consider dropping these outcome measures. However it could be that with good quality follow up data it transpires that pain and functional impairment do improve as a result of the patients use of CBT self management strategies. Removal of the measurement of these variables at this stage may be understandable but perhaps premature. Future studies may also consider splitting the grouping of participants as not all CFS sufferers report pain although most report significant functional impairment.

Positive Psychological Variables

Although non significant differences between pre and post intervention there was an improvement in the reported quality of life of the participants and a significant difference between waiting list and post intervention. This is in line with the quality of life improvements reported in Taylor (2004) who utilised some CBT techniques in her individual and group therapy trial. In the current study the improvements appeared to take place whilst the participants were on the waiting list and continued to improve following the intervention. This could in part be explained by the anticipatory element of their wait post assessment and is further supported by the results for hope and optimism, which also showed improvements in the 8-week waiting period before the intervention. None of the GCBT trials, to date, report on quality of life of the participants.

The two other positive psychological variables utilised in this study showed an improvement for optimism scores in the waiting list condition and this improvement continued after the intervention. However only the improvement between pre and post intervention reached significance. There was a similar pattern with hope as patients improved whilst on the waiting list but this improvement did not reach significance. However the improvement in hope following the intervention did reach significance. This demonstrates a greater improvement as a result of the intervention but it also appears that people had become more hopeful and optimistic as a result of being placed on a waiting list for GCBT.

This study is unique in so far as it is the only study that has explored hope and optimism as potential outcome variables with patients with CFS. It does appear that the outcome measures are effective at measuring the changes that occur as a result of

taking part in the GCBT intervention. As it is the first known study that uses these measures it is recommended that other studies also explore the effectiveness of these as potential outcome tools. It would seem wholly relevant that a treatment and management intervention would seek to increase psychological well-being. A study where the participants are not their own control may be helpful as it appears the expectation of the group may be enough to elicit a change. As the GCBT aims to help patients manage their condition using changes in cognitions it seems intuitive that positive psychological measures are employed along side more conventional psychometrics that have not always been demonstrated to show positive changes. However, more research is needed to fully assess the potential of positive psychological variables as outcome measures.

Global Outcome Measures

Generally patients report very positive feedback regarding the treatment and its success rate. This is in line with the findings of Saxty and Hansen (2005) who, although have a small sample size report very encouraging findings on the same global outcome measures. This highlights how GCBT is an acceptable form of treatment for patients. This study also goes one stage further to include an independent measure from people close to the participant. However with more than a third of this informant data missing it is very difficult to make any generalisations about how participant's friends/family evaluate the service or rate the participants' change as a result of the programme.

Informant data therefore needs to be viewed with some caution. The level of missing informant data could be explained variously. Two of the participants stated that they did not have anyone to fill in the informant questionnaire. It was not possible in the time allocation to 'chase up' these non-returners or seek further ethical approval to begin telephone interviews. As they failed to return their informant consent I had to assume that they wished to decline to take part in the research. Future studies may consider interviewing them or collecting additional information regarding participant's progress as a result of the intervention.

Valid and Comparable Data

Further research to develop better outcome measures and the need for standardised outcome measures is of up-most importance so that different treatments can easily be evaluated. The minimum English dataset used in this research seems an obvious starting point albeit augmented with independent measures.

Triangulation and increased validity is needed to support the self-report measures often used in trials such as this. Reliance on self-report measures alone can be criticised for self-report biases that influence the data and subsequent analyses. Independent measures, such as exercise capacity measures, have been used in other trials to help manage CFS. However, it was decided not to include any exercise capacity measures as recent research had found that they did not appear to be useful in evaluating therapeutic success in patients with CFS (Pardaens, Haagdorens, Van Wambeke, Van den Broeck & Van Houdenhove, 2006). Also as some patients struggle to limit their activities and tend to make themselves ill by overdoing activities. It appeared to be countering intuitive to measure their improvement by way of strenuous capacity procedures. However measures to support self-report data is useful. Other options such as reaction times and memory testing could be employed in future studies.

There also appears to be criticism about the validity of CBT trials, which this research study addresses. Individual CBT trials have often excluded participants who are taking antidepressants, have co-morbid psychiatric problems or are more active (Carruthers, Jain, Meirleir et al., 2003). This could reduce the generalisability to the broader CFS population and brings into question the clinical validity of such trials. Quarmby, Rimes, Deale, Wessley and Chalder (in press) discuss how more clinically relevant data is needed in routine services. This study does include patients who are less active and taking antidepressants. Similarly patients with ongoing disputes related to their health were included. Interestingly, those with legal or work related disputes did not report improvements and found the intervention less useful. Therefore the research results would be greatly enhanced by excluding these people and future studies may consider doing this. As the CFS service involved in this research would not always routinely exclude them from group services it was decided to include their findings in the research.

In this respect the study has relatively high ecological validity and takes place within a routine clinical practice with a multidisciplinary team. It includes both males and female, which is relatively uncommon in GCBT research, of varying ages, and does not exclude people who are taking antidepressants or have co-morbid psychiatric problems. It also does not exclude people who are less active unless they are physically unable to attend the group sessions. Common practice in the CFS service involved in the research is to offers clients who are unsuitable for group therapy a number of individual sessions. This individual data was not collected. However if this is standard routine practice in other services then future research may wish to compare the outcomes of ICBT and GCBT. Although this type of research does not meet the 'gold standard' of randomised control trials, as long as researchers document why people are excluded from the group therapy then the research would have high ecological validity and can be compared to other CFS services who operate the same service delivery.

Limitations of the study

The study does not seek to differentiate between different symptoms. Although information is routinely collected regarding what symptoms the patient suffers from this was not analysed during the study. Many of the patients differed in their experience of the condition and how they managed it. It could be that the intervention works particularly well on one type of symptoms or for someone with a particular coping style (e.g. one who finds it difficult not to overdo things). With regards to the participants in this group the differences could be quite striking. For example there was a number of very active people whom, when well, used to participate in many physical and strenuous activities such as climbing, skiing, mountain biking and running. These people often struggled with 'not overdoing it' and had a strong desire to return to their previous fitness levels. Often when given their stretch and movement programmes, they began by doing double if not more then the recommended sets of stretch and movement exercises allocated to them by the physiotherapist. The cost was to pay for it later by physical or mental exhaustion. On the other hand there appeared to be a subset of people, who had often had the condition for a longer period who found it difficult to raise their activity baseline and appeared to be anticipating a

resulting 'crash' if they did too much. Future research that addresses the issue of definition and sub-typing can help to address this issue in future intervention trials.

Implications for Clinical Practice

Group therapy can have its advantages over individual therapy in that it can be useful for reducing waiting lists and can enable more patients to be seen at the same time. It is becoming increasingly popular as a cost effective intervention in clinical services (Abbey, 1996) but as yet no evaluation of its cost effectiveness for CFS has been successfully carried out. The results from this study do show that GCBT can be an effective form of therapy and future studies need to compare group and individual trials and make efforts to evaluate their cost-effectiveness. Saxty and Hansen (2005) assert that group therapy can be particularly advantageous where an intervention has a significant psych-educational component, such as CFS and deals with a condition that is as yet not fully understood by the medical profession or general population. Group therapy also enables a peer support element that is not available in individual therapy but can have therapeutic benefits to CFS sufferers who often have to deal with uncertainty and sometimes disbelief from non-sufferers (Taylor, 2004).

Very little is known about the best delivery of a GCBT. This study utilises a multidisciplinary team consisting of a general practitioner, clinical psychologist, dietician and physiotherapist. In areas where CFS services are scarce or non-existent this study may better inform what service provision and staffing is required, although more research is needed to further assess the cost effectiveness of such a team. This study is also in line with the other GCBT studies that discloses the format of the CBT intervention, which can be helpful to other routine services although again more research is needed as the GCBT programmes can vary, especially in the taught elements and the duration of the intervention. To be able to become an efficient cost effective alternative to ICBT then a standardised protocol needs to be produced and tested. This could be achieved easily if routine clinical services openly produced research that could be analysed. The creation of the English minimum dataset and this research that builds preliminary GCBT studies appears to be a step in the right direction.

As mentioned earlier one issue that confounds research of this kind is the heterogeneous nature of CFS (CFS/ME working group, 2002). Without a sound knowledge of the condition and its potential sub-groups then good research into successful interventions will be flawed. More work is needed to try and establish a standardised definition to include sub-groups so that treatments can be tailored according to the sub-group. Recent research looking at active and passive patients (Bazelmans, Prins & Bleijenberg, 2006) is very encouraging. They discuss two distinct sub-groups who comparable to the two different types of patients identified in this research. The 'relatively active' subgroup are distinguished by non-accepting and demanding cognitions leading to bursts of activity, where as the 'passive' patients are anxious that activity may worsen their symptoms hence they avoid activity. Bazelmans et al. recommend different treatment manuals for these two different types of CFS sufferers and consider ways to determine activity patterns. If research of this kind proves fruitful then GCBT research needs to address the issue of separate manual protocols in future research and also how outcome measures and baselines are evaluated.

It is important that potential gains made as a result of CBT are maintained and extended after treatment ends. Deal et al. (2001) show that CBT interventions can be effective in the long term, although follow up studies do indicate that complete recovery of CFS is uncommon (Anderson, Permin & Albrecht, 2004). There is also little evidence of what is considered an appropriate follow up period. As the condition is by definition long term and is often relapsing in nature then the current service offers follow up sessions at 3, 6, 9 and 12 months. Although not available yet this data will clarify whether further improvements are made or whether the improvements due to the intervention are maintained. This will have implications for services for CFS and the funding needed to run them. Future research needs to consider trying to assess what is the optimum follow up duration so services can apply this and what follow up sessions should include.

Time constraints of this study do not allow for long term follow up data at this stage but data will be available in due course and participants will be followed up to assess the longevity of the effects of the intervention.

Drop out rates could give an indication of how acceptable an intervention is. It could be that a high drop out rate indicates that the intervention is too rigid and only accommodates a small percentage of the patient group. In individual behavioural interventions drop out rates are reported to be high at around 15 and 19% (Whiting et al., 2001). Drop out rates and number of sessions attended by the patients in this study were exceptionally good. No one dropped out of the intervention once it had started and the majority of the patients attended all 8 sessions. This implies that group CBT is most amenable to the patients. Although the qualitative written comments were not included in the research paper due to word restrictions they do tend to support this notion. People often commented on enjoying the group and feeling validated by meeting people with the same condition.

Qualitative data was collected along with the global outcome measures from both the participant and their informant but financial and time constraints meant that this data could not be adequately analysed and is therefore not included in the research paper. This kind of data is usually particularly useful to informing clinical practice. The written feedback from the participant at the end of the programme does appear to be very encouraging with many participants reporting to having enjoyed the group.

A significant proportion of the self-reports include some reference to finding the social aspect and the validation of meeting other sufferers a very useful and enjoyable aspect of the programme. This supports the authors (e.g. Saxty & Hansen, 2005; Taylor, 2004) who advocate that group therapy can be advantageous for peer support and have therapeutic benefits to CFS sufferers who often have to deal with uncertainty and sometimes disbelief from non-sufferers. It is also put forward as having potential advantages over individual therapy where an intervention has a significant psych-educational component and deals with a condition that is as yet not fully understood.

Participants were always given homework and this often included reading handouts and reviewing psychoeducational material covered in the sessions. They were always advised to share these with their significant others at home as this helped others understand the condition and the management. Many people reported to thinking that

it would be a good idea to have a session that partners could come along and this may be a consideration for service developments and future research intervention. As follow up sessions have historically had reduced attendance rates, it could be an ideal time to invite partners along. This could be an important element for some people who find the condition particularly detrimental to relationships and family dynamics. Perhaps future research could compare the outcomes with and without partners, family or friends being involved in the group sessions.

There also appears to be a lack of qualitative data in this domain. Psychometrics are helpful at looking at outcomes but do not often give the full picture, often lack depth and may not often be that useful to routine clinical practice. Group therapy can be in danger of reducing peoples experiences of 'having a voice' and it is important to understand the deeper meanings that people ascribe to their recovery or management. One of the strengths that clinical psychologists have is that they allow people to tell their story. Good qualitative research is needed to analyse these stories to enrich the growing body of research into GCBT. Interviews or indeed focus groups can be effective for generating this type of rich data that can be informative to good clinical practice. Survey research and structured interviews can often keep the participant at arms length and never really discover the complexity and deeper meaning that a concept such as taking part in a GCBT intervention has to the individual and their life circumstances.

Qualitative research has often been 'attacked' as being subjective, value-laden and the soft option because it does not begin with the assumptions made by positivist scientists, who have tended to be viewed as objective, neutral and value free (Marshall & Rossman, 1999). However many contemporary qualitative theorists highlight the ways in which quantitative research is not value free and objective in that it is researcher led and therefore the researcher brings their own biases and perspective to the work (Finlay & Gough, 2003). Within the positivist paradigm, theories and research methods have often viewed the individual as a rational decision-maker and ignored the social context. Qualitative methods allow the opportunity to incorporate the social and cultural aspects into the theory and it is believed can provide a more complete description the experience of taking part in a GCBT intervention.

Using return to work as an outcome measure is a good indication of the progress or management of CFS and data about work status and number of hours worked was collected in this study. However return to work can often be a lengthy process, with gradual rehabilitation and is not always the best option for some people. Lifestyle changes are often considered as a result of the CBT therapy and people can actively make a decision to reduce their work related stress by giving up work or reducing their hours for the sake of their health. In these instances return to work does not appear to be a valid outcome measure. In this study at least one patient decided to reduce his working week and another decided to take a full break from work for eight weeks whilst he completed the intervention. For this reason the return to work data was not formally analysed.

One possible outcome measure that may have greater validity to be considered is GP contact time. Hamilton, Hall and Round (2001) found in a retrospective, controlled analysis of general practitioners consultations that CFS patients consulted their GP's almost twice as much as matched control patients. Future research could look at reductions in GP consultations as a potential outcome measure following a CBT intervention but this is more in line with the longitudinal research and could perhaps be gathered with follow up data.

Contributions to learning

Choosing CFS as a research topic for my thesis reflects an interest in this particular client group and also in group therapy work. I will try to elaborate on how these interests have developed.

Firstly as a lay-person one cannot have failed to miss the controversy that surrounds an illness such as CFS/ME not only as to the name of the illness but also as to the authenticity. I know of three people who suffer with it and have had many an argument, with non-sufferers (largely uneducated ones to begin with) about the 'genuineness' of the people who have the symptoms. I think one client summed it up nicely by saying that her male partner called it DFS (sofa syndrome) implying that she and others like her were plain lazy.

Like depression, a condition it is often closely associated with, statistics confirmed that it appeared women seemed to suffer more than men and so my 'feminist hackles' were raised and I desired a better understanding of the condition and also to 'hear the stories' of more people who suffered with it. If the condition was mainly psychosomatic as some people thought then clinical psychologists were well trained to be able to offer help.

The dynamics of group therapy have interested me since my earlier group work with drug and alcohol abusers, when I observed how useful group therapy could be and how sometimes group member seem to find a better understanding or feel more comfortable with people who are in the same boat. The humour that is often generated in a group situation also seems to aid the therapeutic alliance, although this can obviously depend on group member's characteristics. This service's particular emphasis on the use of humour to aid the group and multidiciplinary dynamics is also appealing to my own particular personality style. Humour is often advocated as an 'important lubricant' to good teamwork (Palmer, 2000) and I fully support this notion.

The whole CFS programme has been an uplifting experience that helped me to re-evaluate certain aspects of my life and also helped to shape my perception of my future training requirements. The mindfulness theme that aids the relaxation and helps to ground people in the here and now was also helpful to me in the difficult personal times that I faced, especially at the beginning of the project. I think more training and an experience of a full mindfulness programme would be beneficial to my own personal development but would also be an effective therapeutic tool to use with clients.

Research perspective

The whole research experience has helped to consolidate previous research experiences and build research confidence. It is all too easy to view research as an overwhelming and daunting prospect, which of course it can be, especially when a qualification depends on it. However I have learnt that good planning and avoidance of procrastination can be highly advantageous qualities when faced with a project

such as this. There is still obviously room for improvement with me but I do feel that I have developed these skills considerably during the last six to twelve months.

In past research projects I often wondered (naively) why when participants were so difficult to come by, it was that clinical services with 'clients on tap' did not undertake and publish more research. Working within the service where I have undertaken the research project it is now quite clear. Audits can be a real pressure on professional's time and to have to generate extra published research would be a logistical nightmare without the extra time and funding. At the moment within the constraints of the NHS provision it seems unlikely that 'the average clinician' will have the luxury (I use this term very loosely) that I did when I undertook this project.

Furthermore the 'ethical hoops' of Central Office for Research Ethics Commmittc (COREC), Research and Development and School of Psychology ethics applications all added to the research stress and delayed data collection commencement. Even though I believe I was diligent and prompt in getting my applications submitted the whole process seemed very lengthy and with hindsight I would try to begin this process even sooner. A simultaneous ethical application submission, if at all possible would have speeded the whole process up.

One of the things I became very aware of whilst planning the research was how dogmatic some researchers can be about doing 'good quality research.' While I am all for good quality research I believe the term has been too tightly bound to the kind of research which is actually quite removed from routine clinical practice. The 'gold standard' RCT do have their place and are easy to compare and contrast but are often very difficult to achieve especially on limited resources. I also feel that they are often removed from what really happens in clinical practice and often lack ecological validity. My fierce determination to try to achieve a good quality research design that was not too far removed from routine clinical practice and did not impose unnatural constraints on the participants and the hardworking, part time service was occasionally met with exasperation. However it was very validating to find recent research (Quamby et al., in press) that supported my ideas around the research design of this project.

The whole research preparation and my desire to incorporation a qualitative component to the research study left me feeling that research in the clinical psychology arena was not developing in the same way as it was in psychology in general. This may be a biased or uneducated opinion but there appeared to be a lack of qualitative research supervisors and therefore limited opportunities to undertake qualitative research. This was quite surprising to me as I came into the discipline thinking that clinical psychologists would be at the forefront of the paradigm shift towards a more phenomenological paradigm.

The use of qualitative methods is now well established in social, developmental and health psychology. Qualitative research involves researchers' active engagement with participants and acknowledges that understanding is constructed, and multiple realities exist in the complex and dynamic social world (Banister, Burman, Parker, Taylor, & Tindall, 1996). Researchers who advocate the approach assert that qualitative methods are theory generating, inductive, aiming to gain valid knowledge and understanding by representing and illuminating the nature and quality of people's experiences. With this methodology, participants are encouraged to speak for themselves, personal accounts are valued, and emergent issues within the accounts are attended to. The developing theory is, thus, firmly and richly grounded in personal experiences rather than a reflection of the researcher's *a priori* frameworks. In this way insight is gained into the meanings people attach to their life experiences.

Qualitative research can allow the incorporation of the social world into the research, thus giving insights into individuals' perspectives, which would otherwise have been invisible or at best touched upon in quantitative methods (Griffin & Phoenix, 1994). Taking part in a GCBT is one of those life experiences and should be explored using methods to enable a richer and fuller understanding of the patient's experience. Hopefully future research will consider using alternative methods to evaluate treatment and management programmes for CFS sufferers.

After being very optimistic about getting at least the required number of participants to fulfil the power calculation criteria I was somewhat disappointed to achieve less

than this. However with a part time service that relies on GP referrals this aspect of the research was completely out of my control. However when compared to the relatively few GCBT studies conducted to date this research is of a high calibre, especially for its efforts to promote ecologically valid findings that can be generalised to other CFS services that utilises a GCBT approach to CFS.

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Section Six

Word Count

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Word Counts	56
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Excluded Total:	15141
Overall Total:	**34968**