

Finding the right pace for treating chronic fatigue syndrome

PACE trial shows that two treatments can safely help patients



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Chronic fatigue syndrome (CFS) is a chronic disabling condition of unknown cause and no certain treatment. Some 250,000 to 500,000 people suffer from it in the United Kingdom, the difference in prevalence depending on how it is defined. Some differentiate myalgic encephalomyelitis (ME) from CFS, whereas others think it is the same condition. This difficulty in defining it is but one of the controversies that affect CFS, the others being what causes it and how to treat it. The controversy has in the past led to demonstrations to the Department of Health, petitions to government and debates in parliament. Patient organisations complain that the National Health Service does not take CFS seriously, does not provide appropriate health services, and that patients are denied benefits to which they are entitled, leading to poverty and hardship.

One way to resolve controversy is through science, and the PACE trial was designed with the help of a patient charity, Action for ME, to provide some much needed evidence regarding safety and effectiveness of

commonly available treatments. The National Institute of Healthcare and Clinical Excellence (NICE) had previously recommended two rehabilitative interventions, cognitive behaviour therapy (CBT) and graded exercise therapy (GET), but this was on the basis of a few small trials. In contrast, patient organisations had reported concerns that CBT and GET were ineffective, or even harmful, with one patient survey finding that 50% of patients reported that GET had harmed them. Patient organisations supported pacing and specialist medical care as alternatives. The PACE trial was therefore designed to test safety and effectiveness of these four interventions.

The trial design

PACE stands for Pacing, graded Activity, and Cognitive behaviour therapy: a randomised Evaluation. The trial compared the effectiveness and safety of four interventions for patients attending six hospitals with CFS. The four interventions included three therapies:

Adaptive Pacing Therapy (APT or Pacing) involved an assessment of daily activities and capacity, with mutual negotiation of a programme of rest, balanced with activity, based on the presumption that energy reserves

are finite and should not be overdrawn. Occupational therapists delivered the treatment.

Cognitive Behaviour Therapy (CBT) involved structuring daily rest, activity and sleep, and a gradual return to normal activity, with assessment of illness beliefs and coping strategies, all individually negotiated in collaboration with the patient. Clinical psychologists and nurse therapists delivered the treatments.

Graded Exercise Therapy (GET) involved an assessment of physical capacity and mutual negotiation of an individually designed graded aerobic exercise programme, with feedback and mutual planning of new goals. Physiotherapists delivered the treatment.

These therapies were provided individually over 15 sessions spread over five months. All participants were also offered at least three sessions of specialist medical care (SMC). The fourth group received SMC alone. All treatments were described in manuals for both clinicians and patients, and therapy integrity was confirmed by independent assessors.

Specialist Medical Care involved explanation of the diagnosis, being given general advice on how to manage CFS, and appropriate medications to help sleep, pain and other symptoms. CFS specialist doctors delivered the treatment.

640 patients were recruited into the trial and followed up three times over one year after randomisation. The main eligibility CFS criteria required that fatigue was the principal symptom for six months, with disability and no alternative diagnosis that could explain the illness. We stratified randomisation by two alternative definitions of CFS and ME, and by comorbid depressive illness. The primary outcomes were self-rated fatigue and physical function, while secondary outcomes included a more objective walking test (how far one can walk in six minutes). Safety outcomes included all adverse events, and independent scrutineers judged how serious the adverse events were and whether they were reactions to trial treatments.

What the trial showed

The PACE trial was published in *The Lancet* in March this year. The complete paper and web appendix are freely available to download on: www.thelancet.com

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CBT and GET were more effective in improving both fatigue and physical function than either SMC alone or APT. This was the case no matter how we defined CFS or ME or whether patients also had a comorbid depressive illness, suffered by a third of our patients. By a year, some six out of ten patients made a clinically useful improvement in both fatigue and function after both CBT and GET, compared to about four out of ten for APT and 45% for SMC alone. About three out of ten were within normal population ranges for both fatigue and function a year after both CBT and GET; about twice the numbers than for APT and SMC alone.

Serious adverse reactions to trial treatments were uncommon (2% or less for all four interventions), with no differences between arms. The proportions of patients with a serious deterioration, which can sometimes happen with CFS, did not differ between treatment arms.

Only 5% dropped out of trial follow up, and 11% or less withdrew from treatment, with no differences between treatment arms on either measure.

Conclusions

We concluded that both cognitive behaviour therapy and graded exercise therapy were safe and moderately effective additions to specialist medical care, compared to both adaptive pacing therapy and specialist medical care alone. Adaptive pacing therapy showed no additional benefit when added to specialist medical care alone. NICE responded that the PACE trial results re-affirmed their guidance on the management of CFS.

Assessing the Contribution of Family Data

Prof. Dave Curtis has described in the *Annals of Human Genetics* the evaluation of a novel statistical approach for identifying genetic variants which contribute to disease risk. The problem is that large numbers of different variants may contribute to a disease and that some may be very rare. This means that even if one studies a sample of several hundred subjects suffering from a disease there may only be a handful of them who have the variant in question. Then it can be hard to tell whether the variant actually affects disease risk or whether it is occurring in a few affected subjects purely by chance.

The paper shows that one can gain useful information from studying the relatives of subjects found to possess the variant.

For example, if a relative has the same disease and is found also to carry the



variant then this provides further evidence that the variant really does influence disease risk.

The paper shows that this approach can be very economical. One may gain more information from studying half a

dozen relatives than from hundreds of additional unrelated subjects. Thus this approach should prove useful in aiding the identification of genetic risk factors contributing to many human diseases, including mental illness.

Therapeutic relationship in treatment of psychosis

Extensive research has shown that the quality of the therapeutic relationship between the patient and the clinician is a most important factor for the success of psychological treatments. In practically all forms of psychotherapy a more positive therapeutic relationship predicts more favourable outcomes.

Does this also apply to psychiatric treatment of patients with psychosis, i.e. outside conventional psychotherapy? Psychiatric treatment of patients with psychosis is different from psychotherapy. The overall duration of psychiatric treatment varies between one encounter and several decades; the length of meetings is not fixed; treatment can happen at different places such as a hospital, an out-patient office or the patient's home; treatment involves pharmacological, psychological and social interventions and – at least potentially – also coercive measures. So, do all these differences affect the importance of the therapeutic relationship?

A recent systematic review of the literature showed that only a limited number of rigorous studies have addressed this. The review identified nine methodologically sound studies that

prospectively tested the association between the quality of the therapeutic relationship with outcomes. The three outcomes were hospitalisations, symptom levels and functioning during an observation period following the assessment of the relationship. The review found some, but not overwhelming evidence that the therapeutic relationship predicts outcomes also of complex psychiatric treatment in patients with psychosis. The effect size is rather small, but still equivalent to effect sizes found in psychotherapy.

The review concludes that the quality of the therapeutic relationship does matter in the usually complex treatment of patients with psychosis. When clinicians manage to establish and maintain a better relationship with their patients, outcomes tend to be more positive. The clinical implications are the quality of therapeutic relationships should be emphasised in the routine work of all services treating patients with psychosis and that clinicians should receive appropriate training and supervision in skills that may help to establish and maintain positive relationships with their patients.

Upcoming Events

New Tower Hamlets Research Forum

A multi-disciplinary research forum is running in Tower Hamlets exclusively for the support, dissemination, and discussion of local mental health research. Meetings, chaired by Prof. Dave Curtis, will typically comprise a 30-minute research presentation, with a 10-minute discussion, followed by a 20-minute workshop to provide education and support for new research, e.g. around issues such as funding,

methodologies, recruitment, etc.

Meetings will take place from 12.30-1.30 on the fourth Monday of each month in the Multi-purpose room (1st floor), Tower Hamlets Centre for Mental Health, Mile End Hospital. All Trust staff are welcome; please feel free to bring your lunch along to the meetings.

Date	Title
22 Aug	<i>Psychotic-like phenomena in clinical and non-clinical populations</i>
26 Sept	<i>Service-related project: perceptions of local psychology provision</i>
24 Oct	<i>The impact of a psychiatric admission on South Asian patients and their families</i>
28 Nov	<i>Medical research topic</i>
26 Dec	<i>Bank Holiday (no meeting)</i>

Presented by
Dr. Charlie Heriot-Maitland
Jonathan Buhagiar
Rupa Kataria
TBC

If you would like to present your own research in 2012, please email the title of your presentation, and your preferred monthly slot, to: charlie.heriot-maitland@eastlondon.nhs.uk

'The Long Goodbye': Cognitive Analytic Therapy with Carers of People with Dementia

By **Drs. Michelle Hamill**
and **Kate Mahony**,
Clinical psychologists

Dementia is a progressive condition in which changes in cognition and emotion reduce a person's ability to function in everyday life. The Alzheimer's Research Trust reports that dementia affects 750,000 people in the UK. It is estimated that two thirds of people with dementia are living in the community and that over 600,000 people are acting as their primary carers saving the UK economy in excess of £6 billion every year (Alzheimer's Society, 2009). The well-being of carers is an important issue for public health care because of the negative health consequences that they may experience as a result of caring and which can jeopardise the care they can offer (see Duijnste M. *Caring for a demented family member at home: objective observation and subjective evaluation of the burden* pp. 359-379 in Jones G & Miesen B (Eds) *Care Giving in Dementia*. London: Routledge, 1992). The NICE-SCIE guideline (2006) on supporting people with dementia recommends that carers have access to a range of psychological therapies. The importance of attending to carers' well-being gains even more prominence due to the expected increase in numbers of elderly persons with dementia and their carers over time.

In Newham, services for carers provided by the Mental Health Trust are often focused on those caring for adults of working age with mental health problems. In addition, there are no Admiral Nurses, whose role elsewhere is to focus on the needs of carers of people with dementia. The Psychotherapy for Older Adults service (PTOA) is a specialist psychotherapy service set up by clinical psychologists, which accepts referrals from within Newham's Mental Health Care of Older People's service (MHCOOP). All interventions are measured with the CORE (Clinical Outcomes in Routine Evaluation).

Increasingly, the PTOA is addressing the mental health needs of carers of people with dementia, regardless of their age. As a specialist service with expertise in psychological therapy and dementia we are well placed to address carers' psychological needs and to facilitate their understanding of dementia. Central to providing a responsive therapeutic service



for carers is the joint working of the PTOA clinical psychologists with the Diagnostic Memory Clinic (DMC) and the Dementia Care Team (DCT). This helps to establish a relatively seamless relationship with families and good joint working with the other professionals in the teams where carers' mental health can be assessed and provided for at various points along the dementia journey. Within the borough anyone with a formal diagnosis of dementia will generally have been seen by the DMC or Old Age Psychiatrists and will therefore be known to the service. We also work closely with the local branch of Alzheimer's Society, ensuring good links between the PTOA and voluntary sector.

CAT people

Whilst a range of psychotherapeutic approaches are practised in the PTOA, we have found that Cognitive Analytic Therapy (CAT) has been a particularly useful model when working with carers of people with dementia. In a paper written for the *British Journal of Psychotherapy* (August 2011), we raise the issue of service delivery and provision of psychological therapy services to family carers of people with dementia and discuss how CAT proves to be a flexible therapeutic model for this work.

Cognitive Analytic Therapy (CAT) was developed by Dr. Anthony Ryle in an attempt to deliver effective, time-limited psychotherapy to patients being seen in the NHS (see Ryle A & Kerr IB. *Introducing Cognitive Analytic Therapy: Principles and Practice*. Chichester: John Wiley and Sons, 2002). CAT is proposed as a safe and accessible intervention

for a wide variety of presenting and underlying psychological and mental health problems, it has a developing evidence base and a strong commitment to research.

Initial analysis offers preliminary support for the value of a CAT approach to working psychotherapeutically with carers of people with dementia, which is illustrated in our paper with a case study. Given its focus on relationships, CAT helps to make sense of how the caring role can trigger unhelpful coping patterns in the carer, which can be linked to early experiences as well as the wider social and cultural environment, (Ryle & Kerr, 2002), whilst also keeping the person with dementia in mind. By integrating cognitive and analytic models of understanding, CAT lends itself to working psychotherapeutically with carers who are balancing the provision of practical day-to-day care with the emotional and unconscious struggles that can arise as a result of changes in their relationships and role when caring for someone with dementia. The awareness of cultural and social norms in CAT is especially helpful given the cultural diversity in East London. CAT helps to provide a therapeutic space to make sense of the caring role in context of carers' lives and to find new possibilities within the caring role. Through its sensitivity to endings CAT also acknowledges and facilitates the associated grieving process in dementia.

Further research and thought about psychological service delivery for carers is required. For more information, please contact: michelle.hamill@eastlondon.nhs.uk

OTHER NEWS

EU register of clinical trials launched online

The European Medicines Agency has launched the online Clinical Trials register containing information about clinical trials authorised in the EU, whether they take place in on. It includes clinical trials conducted by both industry and research institutions. The information is rendered public once the clinical trial has been authorised. The aim of this official public register is to make clinical research on pharmaceuticals more transparent for patients and others and to avoid unnecessary duplication of clinical trials.

Sponsors will provide and update the information in the register via the national competent authority (MHRA in the UK). See <https://www.clinicaltrialsregister.eu/>

Publication of 'GAfREC: a harmonised edition'

The Department of Health has published the latest edition of GAfREC. This is a policy document of the UK Health Departments covering the principles, requirements and standards for research ethics committees, including their remit, composition, functions, management and accountability. This harmonised edition revises and replaces editions of the policy previously issued separately in England and Scotland in 2001. It also applies in Wales and Northern Ireland. This harmonised edition comes into effect on 1 September 2011. www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474

Government response to NHS future forum

The Government response to the report from the NHS Future Forum contains a number of commitments relating to research. We are working with colleagues on the delivery of these commitments. See: www.nihr.ac.uk/about/Pages/Government_response_to_NHS_Future_Forum.aspx

Upcoming Events

Autumn Seminars in the Unit for Social & Community Psychiatry

The S&CP regularly holds seminars to present to work of its members. These seminars are free, open to the public and held from 14:00-15:00 in the Lecture Theatre, Academic Unit, Newham Centre for Mental Health. For more information, call Carolanne Ellis on 020 7540 4210.

Date	Title	Presented by
5 Sep	Modelling of group music therapy for acute adult psychiatric inpatients	Catherine Carr
12 Sep	Institutional Care	Winnie Chow
19 Sep	Communication in psychiatric outpatients	Laura Thompson
26 Sep	Process research in psychotherapy for BPD	Kirsten Barnicot
3 Oct	PhD related research	Domenico Scaringi

Recent Publications

Notification of the following publications has been received since circulation of the last newsletter. Don't be shy!! Please send copies of papers or reference details to the Research Office (ResearchOffice@eastlondon.nhs.uk) so they can be included in this list and made available to interested staff.

Balcombe L, Phillips L & Jones J. (2011) *To attend or not attend: factors that influence engagement with CAMHS by young people and their parents following an episode of deliberate self-harm.* **Mental Health Practice**. (In press)

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Brugha TS, Taub N, Smith J, Morgan Z, Hill T, Meltzer H, Wright C, Burns T, Priebe S, Evans J, Fryers T (2011) *Predicting outcome of assertive outreach across England.* **Social Psychiatry and Psychiatric Epidemiology**. [Epub ahead of publishing]

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Coid J & Ullrich S. (2011) *Prisoners with psychosis in England and Wales: Diversion to psychiatric inpatient services?* **Int J Law Psychiatry**. 34(2):99-108.

Coid J & Yang M. (2011) *The impact of psychopathy on violence among the household population of Great Britain.* **Soc Psychiatry Psychiatr Epidemiol**. 46(6):473-480.

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Curtis D. (2011) *Assessing the Contribution Family Data Can Make to Case-Control Studies of Rare Variants.* **Ann Hum Genet**.

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