



FOTOLIA

THIS WEEK'S RESEARCH QUESTIONS

- 959** Do pragmatic rehabilitation and supportive listening at home improve fatigue and physical functioning in patients with chronic fatigue syndrome?
- 960** Is home based ultraviolet B phototherapy for psoriasis cost effective compared with phototherapy at an outpatient department?
- 961** Is there any association between men's socioeconomic status and the treatment they receive for prostate cancer?
- 962** Can an age dependent cut-off value for the D-dimer test for pulmonary embolism improve its validity in older patients?

Treating chronic fatigue syndrome

Determining the optimal treatment for patients with chronic fatigue syndrome or myalgic encephalomyelitis (CFS/ME) is riddled with uncertainties and controversies. A *BMJ* editorial on the topic published earlier this year (*BMJ* 2010;340:c738), for example, has provoked an amazing 48 rapid responses (http://www.bmj.com/cgi/eletters/340/feb11_1/c738). The only evidence based treatments for CFS/ME are cognitive behavioural therapy and graded exercise therapy, but most of the evidence comes from trials undertaken in secondary care.

Alison J Wearden and colleagues have looked at the effectiveness of pragmatic rehabilitation—a collaboratively designed programme of graded increases in activity—and supportive listening delivered at home to patients in primary care with CFS/ME (p 959). Compared with general practitioner treatment as usual, pragmatic rehabilitation somewhat improved fatigue in the short term but did not improve physical functioning, whereas supportive listening provided no benefits.

Despite these modest effects, pragmatic rehabilitation “may provide an additional option to the currently limited list of possibilities,” say editorialists Rona Moss-Morris and William Hamilton (p 934), not least because patients regard it as a more “acceptable” treatment and less stigmatising than a psychiatric approach such as cognitive behavioural therapy.

Home based UVB phototherapy for psoriasis

The *BMJ* tends to publish two kinds of economic evaluation: standalone modelling studies and those accompanying clinical studies, mostly randomised controlled trials. Here Mayke B G Koek and colleagues report the companion study to a Dutch trial that appeared in the *BMJ* last year (*BMJ* 2009;338:b1542). The trial showed that ultraviolet B therapy for psoriasis is as safe and effective at home as in an outpatient unit—and now we know that home therapy is equally cost effective (p 960). Dundee based dermatologists Heather Cameron and Robert Dawe responded to say they had been offering home based phototherapy for more than 10 years, mostly for psoriasis. They were also finding the approach useful, with appropriate supervision, for atopic eczema, for desensitisation treatment of photodermatoses, and for various other conditions (www.bmj.com/cgi/eletters/338/may07_2/b1542#213869).



ST BARTHOLOMEW'S HOSPITAL/SPL

Socioeconomic status and prostate cancer treatment

Inequalities in treatment for cancer are all too common. For prostate cancer the debate has focused on ethnic differences, particularly in the United States, where being African American is associated with higher mortality. Georgios Lyratzopoulos and colleagues from Cambridge



looked at data in an English regional registry on more than 35 000 men with prostate cancer (p 961). Increasing deprivation remained strongly associated with lower odds of having radiotherapy or surgery (odds ratio 0.92, 95% confidence interval 0.90 to 0.94, $P < 0.001$) after adjustment for age, diagnosis period, and tumour morphology. The authors had no data on ethnicity but, given the demographics in eastern England during the study period, they think this factor is unlikely to have biased their findings. Editorialists Kari A O Tikkinen and Anssi Auvinen suggest that future studies should investigate the contribution of various prognostic factors to differences in survival (p 935).

LATEST RESEARCH:

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Risk factors for future misconduct

Can risk factors for professional misconduct be identified while doctors are still in training? Janet Yates and David James speculated that some of the doctors who experience serious difficulties in their professional lives might also have had problems at medical school. They did a retrospective multicentre study comparing the anonymised medical school records of 59 doctors who'd been found guilty of serious professional misconduct by the General Medical Council in 1999-2004 with those of 236 matched controls. The results suggested that male sex, a lower socioeconomic background, and early academic difficulties at medical school could be risk factors for subsequent misconduct. But the authors emphasise that the study was small and its findings should be interpreted with caution—most doctors with risk factors, they say, are unlikely to make it to a GMC disciplinary hearing (doi:10.1136/bmj.c2040).



MARK THOMAS

Response on bmj.com

“To anyone who has genuine myalgic encephalomyelitis (ME), it would have been obvious that the sort of interventions used in the FINE trial would not make the participants well or improve their functional ability or energy”

Linda A Crowhurst, patient with ME

EDITORIAL by Moss-Morris and Hamilton

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Cite this as: *BMJ* 2010;340:c1777 doi: 10.1136/bmj.c1777

This is a summary of a paper that was published on bmj.com as *BMJ* 2010;340:c1777

Nurse led, home based self help treatment for patients in primary care with chronic fatigue syndrome: randomised controlled trial

Alison J Wearden,¹ Christopher Dowrick,² Carolyn Chew-Graham,³ Richard P Bentall,⁴ Richard K Morriss,⁵ Sarah Peters,¹ Lisa Riste,¹ Gerry Richardson,^{6,7} Karina Lovell,⁸ Graham Dunn,³ the Fatigue Intervention by Nurses Evaluation (FINE) trial writing group, on behalf of the FINE trial group

STUDY QUESTION Are pragmatic rehabilitation and supportive listening, delivered at home by specially trained general nurses, effective at improving fatigue and physical functioning in chronic fatigue syndrome/myalgic encephalomyelitis or encephalitis (CFS/ME)?

SUMMARY ANSWER Compared with general practitioner (GP) treatment as usual, pragmatic rehabilitation modestly improved fatigue at the end of treatment but not at one year follow-up and did not improve physical functioning, whereas supportive listening provided no benefits.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Pragmatic rehabilitation has been successful in secondary care. Pragmatic rehabilitation delivered to patients with CFS/ME in primary care by trained general nurses produced small but unsustainable improvements in symptoms but did not improve physical functioning.

Design

We carried out a randomised, single blind, controlled trial. Participants were independently randomised to pragmatic rehabilitation, supportive listening, or GP treatment as usual. Pragmatic rehabilitation—which incorporates a graded return to activity—and supportive listening—which uses non-directive counselling techniques—were delivered at home over 18 weeks by one of three adult specialty general nurses who had received four months training in each intervention.

Participants and setting

A total of 296 patients from 186 general practices in north west England aged 18 or over who fulfilled the Oxford criteria for CFS/ME were included in this study.

Primary outcomes

Scores on the Chalder et al fatigue scale and the SF-36 physical functioning scale were measured before treatment, at the end of treatment (20 weeks), and one year after finishing treatment (70 weeks from recruitment).

Main results and the role of chance

A total of 257 (87%) of the 296 patients were followed up to 70 weeks. In an intention to treat analysis of data collected immediately after treatment (20 weeks), patients allocated to pragmatic rehabilitation had significantly improved fatigue but not physical functioning compared with patients allocated to GP treatment as usual (effect estimate -1.18 , $P=0.021$ and effect estimate -0.18 , $P=0.950$, respectively). At 70 weeks, no statistically significant differences in fatigue or physical functioning were found between patients allocated to pragmatic rehabilitation and those assigned to GP treatment as usual. At 20 weeks, patients allocated to supportive listening had significantly poorer physical functioning than those allocated to GP treatment as usual ($P=0.005$), but at 70 weeks these two groups did not differ significantly on either primary outcome.

Harms

There were no harmful events related to trial treatments.

Bias, confounding, and other reasons for caution

Three nurse therapists delivered both treatments. Our checks showed treatment fidelity.

Generalisability to other populations

Our findings indicate that pragmatic rehabilitation can be delivered effectively in primary care by general nurses, but severely affected patients may require longer treatment by more experienced therapists.

Study funding/potential competing interests

The UK Medical Research Council (G200212) and the UK Department of Health funded the trial. The study was sponsored by the University of Manchester. The trial authors declare no competing interests.

Trial registration number

International Standard Randomised Controlled Trial Number IRCTN74156610

ROBUST TREATMENT EFFECT ESTIMATES COMPARED WITH GENERAL PRACTITIONER TREATMENT AS USUAL FOR FATIGUE AND PHYSICAL FUNCTIONING SCALE

	Effect estimate	95% confidence interval	Standard error	P value
Chalder et al fatigue scale (11 items)*				
20 weeks				
Pragmatic rehabilitation	-1.18	-2.18 to -0.18	0.51	0.021†
Supportive listening	+0.19	-0.67 to +1.05	0.44	0.663
70 weeks				
Pragmatic rehabilitation	-1.00	-2.10 to +0.11	0.56	0.076
Supportive listening	-0.32	-1.24 to +0.60	0.47	0.497
SF-36 physical functioning scale (%)‡				
20 weeks				
Pragmatic rehabilitation	-0.18	-5.88 to +5.52	2.90	0.950
Supportive listening	-7.54	-12.76 to -2.33	2.65	0.005§
70 weeks				
Pragmatic rehabilitation	+2.57	-3.90 to +9.03	3.28	0.435
Supportive listening	-4.87	-10.74 to +0.99	2.98	0.103

*Lower scores indicate better outcomes; † $P\leq 0.05$; ‡Higher scores indicate better outcomes; § $P\leq 0.005$.

Cost effectiveness of home ultraviolet B phototherapy for psoriasis: economic evaluation of a randomised controlled trial (PLUTO study)

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Cite this as: *BMJ* 2010;340:c1490 doi: 10.1136/bmj.c1490

This is a summary of a paper that was published on bmj.com as *BMJ* 2010;340:c1490

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Research: Home versus outpatient ultraviolet B phototherapy for mild to severe psoriasis (*BMJ* 2010;340:b1542)

STUDY QUESTION Is home based ultraviolet B phototherapy for psoriasis cost effective compared with phototherapy provided at an outpatient department?

SUMMARY ANSWER Yes, home phototherapy is no more expensive than outpatient based treatment and is cost effective.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

The PLUTO study showed that home ultraviolet B phototherapy is at least equally effective and safe as outpatient based phototherapy for psoriasis. This study provides evidence that home phototherapy is also cost effective.

Design

We performed an economic evaluation alongside a pragmatic randomised clinical trial, comparing two treatments for their total costs to society. In addition, the difference in costs was compared with the difference in quality adjusted life years (QALYs) and with the difference in number of days with a relevant treatment effect ($\geq 50\%$ improvement of baseline psoriasis severity).

Source(s) of effectiveness

Ultraviolet B phototherapy for psoriasis at home and in an outpatient setting were compared (PLUTO study). Patient selection and administration of both interventions reflected routine practice. In total, 196 adults with psoriasis who were clinically eligible to receive narrow-band ultraviolet B phototherapy were included and randomised. The dermatologists carried out the assigned treatment as they would normally.

Data sources

Costs to society included costs of the intervention, consultations, medication, travelling, and productivity losses. Costs were assessed by multiplying the volume of resource use by the unit costs. The data obtained to measure absence from work were not representative of

absence due to phototherapy. Additional data and literature led to the conclusion that short term absence is often compensated for during normal working hours. Therefore, the costs due to short term absence from paid and unpaid work were considered negligible. Analyses were performed at the end of phototherapy (mean 17.6 weeks from baseline) and—for an unselected, consecutive group of 105 patients followed up after the end of phototherapy—at one year after the end of phototherapy (mean 68.4 weeks from baseline).

Main results

Incremental costs to society for home treatment ranged from €48 (95% CI €-77 to €174) at the end of phototherapy to €124 (€-155 to €403) at one year after the end of phototherapy. Benefits were a gain of 0.0052 QALY (-0.0244 to 0.0348) and 0.0267 QALY (-0.024 to 0.078) respectively. Incremental costs per QALY came to €9276 and €4646, both well below the standard of €20 000 per QALY. At the end of the study, there was a difference in mean number of days with a relevant treatment effect of 6.1 (-41.1 to 53.2), resulting in an incremental cost of €20 per additional day with a relevant treatment effect.

Results of sensitivity (or scenario) analysis

Main areas of uncertainty were the calculation of QALYs, costs of absence from work, and costs of home treatment. Calculating QALYs using a different instrument for measuring quality of life did not change the conclusions. Assuming that costs of absence were not negligible or using invoice tariffs to calculate costs of both treatment arms did increase the costs into dominated strategies—home phototherapy being more beneficial and saving money.

Limitations

Because the home care organisations did not release commercially sensitive information on pricing, the societal costs of home phototherapy had to be based on invoice tariffs and were therefore probably overestimated. During the one year follow-up QALYs were estimated with multilevel models rather than from direct measurement of health related quality of life. Although this theoretically reduces precision, we consider that QALYs were accurately predicted.

Study funding/potential competing interests

This study was supported by the Netherlands Organisation for Health Research and Development (ZonMw). All researchers are independent of the funding body and had no competing interests.

MEAN COSTS OF HOME VERSUS OUTPATIENT ULTRAVIOLET PHOTOTHERAPY FOR PSORIASIS

Cost item	Mean costs (€) at end of phototherapy		
	Home therapy	Outpatient therapy	Difference (95% CI)
Phototherapy*	577	275	301 (257 to 346)
Consultations with dermatologist	69	92	-23 (-41 to -6)
Consultations with general practitioner	5.0	2.6	2.4 (-1.2 to 6.1)
Medication	77	95	-18 (-53 to 17)
Travel costs	9	153	-144 (-171 to -117)
Productivity losses from work	65	135	-70 (-180 to 40)
Total costs	801	752	48 (-78 to 174)

*Costs of home treatment had to be based on invoice tariffs, costs of outpatient treatment were calculated from a societal perspective.

Population based time trends and socioeconomic variation in use of radiotherapy and radical surgery for prostate cancer in a UK region: continuous survey

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EDITORIAL by Tikkinen and Auvinen

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Cite this as: *BMJ* 2010;340:c1928
doi: 10.1136/bmj.c1928

This is a summary of a paper that was published on bmj.com as *BMJ* 2010;340:c1928

STUDY QUESTION Is there any association between patients' socioeconomic status and use of radiotherapy or radical surgery for the treatment of prostate cancer?

SUMMARY ANSWER After a diagnosis of prostate cancer, men from lower socioeconomic groups were substantially less likely to be treated with radiotherapy or radical surgery.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Optimal management of men with early prostate cancer is uncertain, and this might give rise to differential treatment patterns among different groups of patients. After a diagnosis of prostate cancer, men from lower socioeconomic groups were substantially less likely to be treated with radiotherapy or surgery, even when factors such as hospital of diagnosis and stage at presentation were taken into consideration.

Participants and setting

This survey examined information from about 35 171 men aged ≥ 51 who received a diagnosis of prostate cancer in 1995-2006. All were from the East of England Government Office region.

Design

Longitudinal survey of data from a UK regional cancer registry.

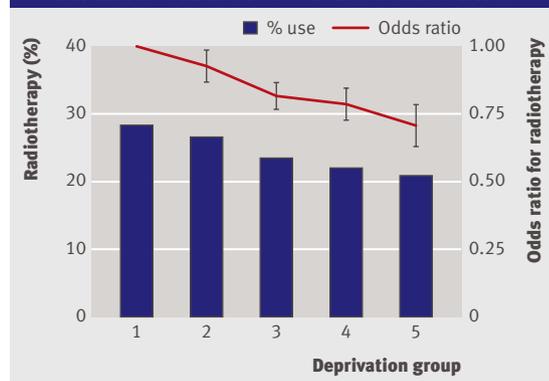
Primary outcomes

Use of radiotherapy and radical surgery. Socioeconomic status according to fifths of small area deprivation index.

Main results and the role of chance

During the study period, the proportion of patients treated with radiotherapy remained at about 25%, while use of radical surgery increased significantly (from 2.9% (212/7201) during 1995-7 to 8.4% (854/10 211) during 2004-6; $P < 0.001$). Both treatments were more commonly used in least deprived compared with most deprived patients (28.5% v 21.0% for radiotherapy and 8.4% v 4.0% for surgery). In multivariable analysis with adjustment for age, diagnosis period, and morphology, increasing deprivation remained strongly associated with lower odds of radiotherapy or surgery (odds ratio 0.92 (95% confidence interval 0.90 to 0.94), $P < 0.001$, and 0.91 (0.87 to 0.94), $P < 0.001$, respectively, per incremental deprivation group). There were consistently concordant findings with multilevel models for clustering of observations by hospital of diagnosis (17 hospitals in the study region). Whether the hospital of diagnosis was a district general hospital or a tertiary referral centre did not influence the patterns of hospital level differences for either treatment. There were also consistently concordant findings obtained when the analysis was

TREATMENT WITH RADIOTHERAPY IN MEN WITH PROSTATE CANCER ACCORDING TO SOCIOECONOMIC STATUS



restricted to 15 916 of 27 970 patients (57%) diagnosed during 1998-2006 for whom information on stage was available, as well as when the analysis was sequentially restricted to different age (≤ 70 v > 70), stage (I-II v III-IV), diagnosis period (first subperiod v 2001-6), and morphology groups. In particular, these findings indicate that differences in stage at diagnosis are unlikely to explain the observed socioeconomic differences in management and, similarly, that variation in case mix or clinical practice between different hospitals is also unlikely to explain such differences.

Bias, confounding, and other reasons for caution

We could not examine the potential effects of comorbidity or patients' preferences for treatment, which could both be confounders. The findings could reflect true socioeconomic differences in patients making a positive choice for either radical or non-radical management or socioeconomic differences in patient-clinician interactions about management. Although we had no data on ethnic group, given the demographic features of the reference population during the study period, this factor is unlikely to have biased the findings. The increasing use of surgery over time probably represents changes during the study period in availability of surgical expertise, criteria for selecting patients, or patients' preferences for surgery.

Generalisability to other populations

Although the findings are concordant with other evidence, they may not be generalisable to patients with prostate cancer outside the study context and period, particularly for countries where men with prostate cancer are more commonly managed with radical surgery.

Study funding/potential competing interests

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.



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Potential of an age adjusted D-dimer cut-off value to improve the exclusion of pulmonary embolism in older patients: a retrospective analysis of three large cohorts

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Cite this as: *BMJ* 2010;340:c1475 doi: 10.1136/bmj.c1475

This is a summary of a paper that was published on *bmj.com* as *BMJ* 2010;340:c1475

STUDY QUESTION Can an age dependent cut-off value for the D-dimer test for pulmonary embolism improve its validity in older (>50 years) patients?

SUMMARY ANSWER Yes, the new cut-off value, combined with clinical probability assessment, greatly increased the proportion of older patients in whom pulmonary embolism could be excluded without reducing safety.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

In older patients, the D-dimer test has a lower specificity and is therefore less useful for ruling out pulmonary embolism. This study derived and validated an age adjusted D-dimer cut-off value, which greatly increased the proportion of older patients with suspected pulmonary embolism in whom the diagnosis could be safely excluded.

Participants and setting

Consecutive inpatients and outpatients with clinically suspected pulmonary embolism from general and teaching hospitals in Belgium, France, the Netherlands, and Switzerland were included.

Design, size, and duration

This retrospective multicentre cohort study included three sets of patients—a derivation set to develop the new cut-off value and two validation sets. All patients underwent a sequential diagnostic investigation for pulmonary embolism consisting of a clinical probability calculation, a D-dimer test, and, finally, computed tomography or leg venous compression ultrasonography, or both. Patients were then

followed-up at three months to check for any missed venous thromboembolic events. This study used data from the 5132 patients with an “unlikely” score for pulmonary embolism from the initial clinical probability assessment.

To derive a new D-dimer cut-off value, we divided patients aged >50 in the derivation set into 10 year age groups. We constructed receiver operating characteristics (ROC) curves of the D-dimer test for each age group to find the best cut-off value (with a sensitivity of 100% and the highest corresponding specificity), and linear regression analysis produced the optimal increase in D-dimer cut-off value per patient year.

Main results and the role of chance

The new D-dimer cut-off value was defined as (patient's age×10) µg/l in patients aged >50 years. In 1331 patients in the derivation set with an “unlikely” score from clinical probability assessment, pulmonary embolism could be excluded in 42% with the new cut-off value compared with 36% with the traditional cut-off value (<500 µg/l). In the validation sets, the increase in the proportion of patients with a D-dimer test result below the new cut-off value compared with the old cut-off value was 5% and 6%. This absolute increase was largest among patients aged >70 years, ranging from 13% to 17% in the three cohorts. In these age groups, the number needed to test for one negative test result decreased from six with the old cut-off value to three with the new value. This means that, with the new cut-off value, imaging tests such as computed tomography or ventilation-perfusion (V/Q) scintigraphy should be necessary in only half the patients aged >70 with suspected pulmonary embolism. The failure rates (false negative results) for all ages were 0.2% (95% CI 0.0% to 1.0%), 0.6% (0.3% to 1.3%), and 0.3% (0.1% to 1.1%) for the three cohorts, respectively.

Bias, confounding, and other reasons for caution

The new cut-off value has not been studied prospectively.

Generalisability to other populations

Two different D-dimer assays (Tinaquant and Vidas) were used in the validation cohorts, and no difference was found between them in the false negative rate for the age adjusted cut-off value. However, the study may not have been sufficiently powered to detect a difference between the two tests, and it is unknown how the new cut-off value will perform in other D-dimer assays.

Study funding/potential competing interests

There was no funding for the study and the authors declare no competing interests.

PROPORTIONS OF OLDER PATIENTS WITH NEGATIVE D-DIMER TEST RESULTS BY DIFFERENT CUT-OFF VALUES*

D-dimer cut-off value	Derivation cohort	Validation cohort 1	Validation cohort 2
Conventional value†			
Patients below cut-off value:			
Number	211/863	294/1039	254/1098
Percentage (95% CI)	24 (22 to 27)	28 (26 to 31)	23 (21 to 26)
Patients with false negative result:			
Number	0/211	0/294	0/254
Percentage (95% CI)	0 (0 to 1.8)	0 (0 to 1.3)	0 (0 to 1.5)
Age adjusted value†			
Patients below cut-off value:			
Number	294/863	404/1039	355/1098
Percentage (95% CI)	34 (31 to 37)	39 (36 to 42)	32 (30 to 35)
Patients with false negative result:			
Number	1/294	5/404	1/355
Percentage (95% CI)	0.3 (0.1 to 1.9)	1.2 (0.5 to 2.9)	0.3 (0.1 to 1.6)

*Patients aged >50 years with unlikely clinical probability of pulmonary embolism.

†Cut-off values for D-dimer test: conventional value=500 µg/l, age adjusted value=(age×10) µg/l.