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16 June 2011

Your ref:
Our ref: FOI 2011/63

Dear Mr. Riley

FREEDOM OF INFORMATION REQUEST

Thank you for your Freedom of Information Act (FOIA) request dated 19th May 2011 which was received on 20th. I am pleased to provide the information below in response.

Primary outcomes:
As described in the paper published in the Lancet, changes were made to the analysis strategy after the protocol was submitted for publication. These changes were all made before data were examined and approved by the independent trial steering committee. This is normal practice in clinical trials. These included changing the scoring of the Chalder fatigue questionnaire from bimodal to Likert (continuous), in order to improve its sensitivity to change, and changing the primary outcomes from composite to simple measures to aid interpretability.

As explained in the published response to correspondence received by the Lancet (including your own published letter making a very similar point), the authors used a different population study to that mentioned in the protocol to derive the normal range scores for the SF36 physical function scale as they believed this to be most representative study for the trial sample (Bowling et al, 1999).

You ask for information about primary outcomes that is not held, but further information regarding primary outcomes will be made available in future papers that the authors plan to publish.

Secondary outcomes:
In table 6, the maximal CDC associated symptom count is eight, the "ninth" symptom being fatigue. A symptom was counted as present if scored as "more often than not", or more frequently than that.
Regarding adverse outcomes, the decision to change reduction of SF36 score by 20 or more points from one assessment to two consecutive assessments was taken to prevent one-off independent illnesses, such as an infection, from being regarded as a serious deterioration.

Additional comments:
Regarding figures 2F and 2G, the figures show unadjusted means and 95% confidence intervals. It is recommended that subgroup analyses should be tested using a suitable interaction term (International Conference on Harmonisation Guideline E9, Statistical Principles for Clinical Trials), which was done and reported in the paper. Since the unadjusted values are available and were published in the figures, the unadjusted means and 95% confidence intervals for these figures are given below:

	CBT	APT	SMC	GET
Physical function - meets international criteria				
Baseline	37.2 (34.2, 40.3)	36.0 (32.8, 39.3)	39.1 (36.4, 41.8)	37.1 (34.2, 40.0)
12 weeks	50.1 (45.7, 54.5)	41.5 (37.4, 45.6)	47.1 (43.3, 50.9)	46.6 (42.5, 50.8)
24 weeks	53.9 (49.0, 58.7)	42.3 (38.0, 46.6)	49.6 (45.2, 53.9)	54.4 (49.7, 59.0)
52 weeks	56.2 (50.8, 61.6)	45.1 (40.1, 50.1)	51.6 (46.6, 56.6)	56.6 (51.3, 61.9)
Physical function - meets London ME criteria				
Baseline	39.9 (36.9, 43.0)	37.4 (33.6, 41.2)	38.8 (35.3, 42.2)	37.5 (34.4, 40.6)
12 weeks	52.4 (48.0, 56.8)	42.3 (37.6, 47.0)	47.8 (43.6, 51.9)	49.9 (45.6, 54.2)
24 weeks	55.3 (50.1, 60.4)	44.6 (39.6, 49.6)	51.2 (46.1, 56.3)	57.4 (52.5, 62.3)
52 weeks	59.3 (53.7, 65.0)	46.4 (40.6, 52.2)	53.2 (47.9, 58.5)	59.9 (53.9, 66.0)

CBT = cognitive behaviour therapy, APT = adaptive pacing therapy, SMC = specialist medical care, GET = graded exercise therapy.

The information you have requested regarding the six minute walking test is not held.

Other requests for data:
As to all of your other requests for results and data, this information is exempt under Section 22 of the FOIA 2000 on the basis that the authors intend to publish these in the future.

If you are dissatisfied with this response, you may ask the College to conduct a review of this decision. To do this, please contact the College in writing (including by

fax, letter or email), describe the original request, explain your grounds for dissatisfaction, and include an address for correspondence. You have 40 working days from receipt of this communication to submit a review request. When the review process has been completed, if you are still dissatisfied, you may ask the Information Commissioner to intervene. Please see www.ico.gov.uk for details.

Yours sincerely

Paul Smallcombe
Records & Information Compliance Manager

Bowling A, Bond M, Jenkinson C, Lamping DL. Short form 36 (SF-36) health survey questionnaire: which normative data should be used? Comparisons between the norms provided by the Omnibus Survey in Britain, The Health Survey for England and the Oxford Healthy Life Survey. *J Publ Health Med* 1999, **21:** 255–70.