

A1.6 Full Trial Consent Form with Missing Therapist and No Cover

Only for use when one therapist is unavailable at a centre for an extended period

(Form to be on headed paper)

PACE: Pacing, graded Activity, and Cognitive behaviour therapy; a randomised Evaluation

Version 3.7 (full trial – missing therapy), 22.02.2006

Centre Number:

Study Number:

Patient Identification Number for this trial:

CONSENT FORM 2 for eligibility/baseline assessment visit 2

Title of Project: Pacing, graded Activity and Cognitive behaviour therapy: a randomised Evaluation


Full title:

A randomised controlled trial of adaptive pacing, cognitive behaviour therapy, and graded exercise, as supplements to standardised specialist medical care versus standardised specialist medical care alone for patients with the chronic fatigue syndrome / myalgic encephalomyelitis/encephalopathy

Name of Researcher:.....

**Please
initial box**

1. I confirm that I have read and understand the information sheet dated 22 February 2006 (version 18), 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 understand that any of my medical notes may be looked at by responsible individuals from either the trial or regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. []
4. I understand that my GP and other relevant health care professionals involved in my care will be contacted and informed of my participation in the trial and given follow-up information of my progress. I agree for this to happen and for trial

- information to be recorded in my medical notes maintained by these professionals. []
5. I understand that any therapy sessions that I take part in will be video/audio-recorded and may be used for supervision, quality control, and research purposes, and that the recordings will be securely stored. []
6. I understand that in accordance with good practice guidelines, all of my records, notes and video/audio-recordings will be securely stored for twenty years after the end of this study. After this all recordings will be destroyed or permanently deleted. []
7. I agree to researchers contacting me after the trial is over for further follow-up, so long as further follow up has received research ethics committee approval.[]
8. I agree to attend for all the treatment and assessment interviews for the duration of the study. []
9. I agree not to be referred for a different therapy, or to a non-PACE therapist for the duration of my involvement in the study unless arranged by a treating doctor. []
10. If I have moved or lost contact with the clinic and vice versa, I agree that my GP or a relative may be contacted to provide contact details. []
11. I give permission for my NHS number to be recorded to allow my GP to be found through the Office for National Statistics (England) or for my Chi number to be collected for the Information and Statistics Division (Scotland) to allow follow-up information to be obtained for up to five years after the end of the trial, and for the researchers to have access to my paper and electronic records for this purpose. []
12. I agree to take part in the above study, and understand this may involve 15 attendances for a therapy, 3 follow-up research assessment visits and at least 3 attendances with the clinic doctor over the year of the study. []
13. I understand that information collected about me for the trial, including my personal details, a copy of this consent form and all of the questionnaires I complete for the trial, will be held securely by the local trial staff and at the PACE trial coordinating centre at Queen Mary, University of London. I give permission for this to happen. []
14. I understand that the graded exercise/adaptive pacing /cognitive behaviour therapy *[delete as applicable]* is not available at this time and the randomisation will not include this therapy []
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Name of Patient

Date

Signature

Name of Person taking consent
(if different from researcher)

Date

Signature

Researcher

Date

Signature

1 for patient; 1 for research nurse in the trial specific source notes; 1 copy to GP, 1 copy to be kept with hospital notes, 1 copy to go to the PACE trial coordinating centre and original stored in Trial Centre Master File



A1.7 Full Trial Consent Form with Alternative Therapist Providing Cover

Only for use when one therapist is unavailable at a centre for an extended period but cover will be provided by a different therapist

(Form to be on headed paper)

Version 4.3 (pre-randomisation – missing therapist), 22.02.2006 Centre Number: Study Number: ISRCTN54285094 MREC/02/7/89
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CONSENT FORM 2 pre-randomisation (missing therapy)

Title of Project:

Pacing, graded Activity and Cognitive behaviour therapy: a randomised Evaluation

Full title:

A randomised controlled trial of adaptive pacing, cognitive behaviour therapy, and graded exercise, as supplements to standardised specialist medical care versus standardised specialist medical care alone for patients with the chronic fatigue syndrome / myalgic encephalomyelitis/encephalopathy

PIN:

Name of Researcher.....

**Please
initial box**

1 I confirm that I have read and understand the information sheet dated 22 February (version 18), 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 understand that any of my medical notes may be looked at by responsible individuals from either the trial or regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.

4 I understand that my GP and other relevant health care professionals involved in my care will be contacted and informed of my participation in the trial and given follow-up information of my progress. I agree for this to happen and for trial information to be recorded in my medical notes maintained by these

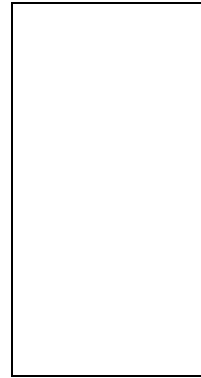


	professionals.	
5	I understand that any therapy sessions that I take part in will be video/audio-recorded and may be used for supervision, quality control, and research purposes, and that the recordings will be securely stored.	
6	I understand that in accordance with good practice guidelines, all of my records, notes and video/audio-recordings will be securely stored for twenty years after the end of this study. After this all recordings will be destroyed or permanently deleted.	
7	I agree to researchers contacting me after the trial is over for further follow-up, so long as further follow up has received research ethics committee approval.	
8	I agree to attend for all the treatment and assessment interviews for the duration of the study.	
9	I agree not to be referred for a different therapy, or to a non-PACE therapist for the duration of my involvement in the study unless arranged by a treating doctor.	
10	If I have moved or lost contact with the clinic and vice versa, I agree that my GP or a relative may be contacted to provide contact details.	
11	I give permission for my NHS number to be recorded to allow my GP to be found through the Office for National Statistics (England) or for my Chi number to be collected for the Information and Statistics Division (Scotland) to allow follow-up information to be obtained for up to five years after the end of the trial, and for the researchers to have access to my paper and electronic records for this purpose.	
12	I agree to take part in the above study, and understand this may involve 15 attendances for a therapy, 3 follow-up research assessment visits and at least 3 attendances with the clinic doctor over the year of the study.	
13	I understand that information collected about me for the trial, including my personal details, a copy of this consent form and all of the questionnaires I complete for the trial, will be held securely by the local trial staff and at the PACE trial coordinating centre at Queen Mary, University of London. I give permission for this to happen.	
14	I understand that the usual adaptive pacing/ cognitive behaviour/ graded exercise therapist [<i>delete as applicable</i>] is not available at this time. I understand that if I am randomised to receive adaptive pacing/ graded exercise/ cognitive behaviour therapy [<i>delete as applicable</i>] I will either: <ul style="list-style-type: none">• receive my therapy from another local PACE therapist who	

has been trained to provide the missing therapy.

or if no other therapist locally is available to cover,

- receive my therapy from a therapist from a different PACE trial centre (some sessions by phone and some face-to-face), alongside face-to-face sessions with a local PACE therapist, who would provide therapy assistance, particularly during the telephone sessions



Name of Patient

Date

Signature

Name of Person taking consent
(if different from researcher)

Date

Signature

Researcher

Date

Signature

1 for patient; 1 for research nurse in the trial specific source notes; 1 copy to GP, 1 copy to be kept with hospital notes, 1 copy to go to the PACE trial coordinating centre and original stored in Trial Centre Master File