

# **Quality Control Form**

# Exercise Intervention - Exercise session and/or adherence support activity

Exercise Venue		
Physiotherapist		
Exercise Assistant		
Assessor		
Date		
QC Visit Activity		
Exercise Session Number		
Adherence support activity	assessed	
Please return completed form to		

DAPA Trial Co-ordinator

Clinical Trials Unit, Warwick Medical School.

ISRCTN32612072

Quality Control Form - Exercise Intervention

v1.2\_06/09/2013

## QC for Administrative procedures

Rating 2= satisfactory 1 = minor discrepancy 0 = serious concern N/A = not applicable

*Completed Paperwork: the following forms have been completed correctly and up to date.	Rating	Comments
Pre-exercise assessment forms		
Sign-in sheet		
Handover sheet		
Aerobic session records		
PRT session records		
Quick reference cards		
Group attendance record		
Non-attendance telephone contact forms completed (if applicable)		
Serious adverse event and withdrawal forms (if applicable)		
DAPA folders organised appropriately—e.g. can find any form that is needed, can access completed adherence support forms as needed		
Trial participants details/records kept in secure and identifiable manner		
Administrative staff in the trial office report that they are receiving paperwork/tablet data in the expected time		

#### \*N.B. Completed prior to or as part of visit

Organisational Issues	Rating	Comments
Adequate stocks of trial forms maintained e.g. travel daim forms, non-attendance tel. forms, withdrawal/ SAE		
DAPA equipment is kept in good order, stored and transported safely, and used solely for trial purposes		
The Exercise Assistant helps efficiently with the room prep- aration, meet and greet of participants and is organised within their exercise role for that session (if applicable)		
Signage / directions to DAPA exercise environment appro- priately placed		
Carers aware of procedures affecting them, e.g. Facilities if wish to stay, Sign-in process, Opportunity for feedback		

### QC for Exercise Intervention - Exercise session

Rating 2 = satisfactory 1 = minor discrepancy 0 = serious concern N/A = not applica-

Start time of session:	Rating	Comments
Session sign in completed correctly		
Warm-up completed correctly		
Aerobic session completed correctly—adheres to exercise protocol: effective use of different methods for intensity monitoring; correct timing and mix of intensities		
PRT session completed correctly—adheres to exercise protocol: indications of progressions made; effective intensity monitoring		
Evidence of strategies to support self efficacy: Demonstration; praise; peer support,		
Evidence of use of communication and support strategies appropriate to needs of participants		
Feedback provided to carers at end of session		
Aerobic quick reference cards and guidance laminates used effectively		
PRT quick reference cards and guidance laminates used effectively		
Aerobic session records completed correctly		
PRT session records completed correctly		
Set up and take down of room carried out safely, effectively and on time (use of posters, moving and han- dling of weights, etc.)		
Any adverse events reported to Trial Co-ordinator		
The exercise sessions are well organised; the physiotherapist can explain exercise procedures and adherence elements		
Communication regarding participants progress in exercise session evident between Physiotherapist and Exercise Assistant		
Finish time of session:		

# QC for Exercise Intervention - Adherence Support activity\*

Adherence support activity assessed	Via Observation (✔)	Via documentation (✓)
Target setting Part 1		
6MWT Review		
Target setting Part 2		
Transition planning form / call		
Support telephone calls		
Face to face review		

Rating 2 = satisfactory 1 = minor discrepancy 0 = serious concern N/A = not applica-

Start time of session:	Rating	Comments
Diary or other system used to plan for this and future		
adherence support activities		
Evidence of advanced planning for activity		
(e.g. laminates, forms, folders ready for use in session)		
Evidence of the use of all appropriate elements of		
planned activity		
Appropriate use of communication strategies within		
activity		
With participant		
With carer		
Appropriate form completed for each activity		
Appropriate forms or hand-outs given to participant/carer at end of session		
Evidence of strategies to support self-efficacy—e.g.		
praise, encouragement, problem-solving		
Evidence of recognition of carer burden as a constraint (when applicable) e.g. Target setting		
Finish time of session:		

\*N.B. Completed either through observation or review of completed paperwork

# **Summary of Quality Control Assessment** 1. Satisfactory 2. Minor discrepancies identified (please specify): Action to be taken: -3. Serious concerns identified that will be reported (please specify): Action to be taken: -Next follow up visit required: Routine (1. or 2.) Date arranged Additional repeat visit (3.) Date arranged Name of assessor: \_\_\_\_\_\_ Signature: \_\_\_\_\_\_ If the Interventionist is in agreement with the above comments then please sign here: Physiotherapist: \_\_\_\_\_\_ Signature: \_\_\_\_\_\_ or Exercise Assistant: \_\_\_\_\_\_Signature: \_\_\_\_\_