FAST INDICATE
STATISTICAL ANALYSIS PLAN FOR THE FINAL ANALYSIS

Study Title:	Clinical efficacy of functional strength training for upper limb motor recovery early after stroke: neural correlates and prognostic indicators		
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1. INTRODUCTION

1.1. STUDY BACKGROUND

Stroke is the single largest cause of adult disability worldwide. Each year, in England alone, approximately 110,000 people suffer a stroke and approximate annual costs are: £2.8 billion direct health and social care costs; £1.8 billion to the wider community in terms of lost productivity and disability; and £2.4 billion in costs to informal carers. The majority of this cost is the result of "rehabilitation and life after stroke". The impact on the NHS is unlikely to fall because the benefits of better preventative and acute care are likely to be offset by an increase in the percentage of older people in the population to 23% in 2031 (16% in 2003), in whom most strokes occur. Stroke rehabilitation is a research priority for the NHS and more widely for Europe.
It is known that physical therapy for motor impairment after stroke is generally effective, that motor recovery occurs most rapidly in the first three months after stroke and that during this period the central nervous system (CNS) probably has most potential for reorganisation. Further progress in the provision of effective therapy for patients early after stroke requires deeper understanding of the process of CNS recovery associated with clinical improvement (mechanisms) and determining which physical therapies should be provided (clinical efficacy) for which stroke survivors (prognostic indicators).
Further progress, therefore, requires neurological investigation of the efficacy of well-characterised interventions for which proof-of-principle is established, and at the same time using these interventions to determine how the CNS responds in the presence of different stroke lesions. This is important because there is a need to establish knowledge of mechanism to improve understanding of why treatment works or does not work.

Investigating efficacy and mechanisms together in this Phase II trial will provide robust information to ensure that subsequent Phase III trials investigate the effectiveness of functional strength training (FST) targeted at the underlying CNS mechanisms of upper limb motor deficits early after stroke in those people most likely to respond. This approach is of critical importance in subsequent trials of neurorehabilitation interventions so that potentially important clinical effects are not diluted by attempting to treat patients for whom other interventions might be more appropriate. More generally, the results of this proposed trial, using conventional physicalmovement performance therapy (MPT) and FST as probes of CNS recovery, are expected to contribute to knowledge of the CNS mechanisms of upper limb recovery after stroke. The need for such research is well recognised.

1.2. STUDY OBJECTIVES

The primary driver for this research is the clinical hypothesis that FST for the paretic upper limb plus the standard amount of protocol-driven CPT (CPT+FST) produces greater improvements in motor impairment and functional ability and is more cost-effective than CPT+MPT in people with upper limb motor impairment early after stroke. The objectives are:

1. To determine whether CPT+FST commenced early after stroke produces greater improvements in upper limb motor recovery than CPT+MPT (clinical efficacy)
2. To identify the similarities and differences in the neural correlates of clinical improvement in upper limb motor function in response to (a) CPT+FST and (b) CPT+MPT (understanding neural and behavioural mechanisms)
3. To determine whether any pre-treatment parameters or any combination of pre-treatment parameters; (a) clinical severity, (b) anatomical location/volume of infarction (derived from structural brain imaging), (c) residual functional anatomy (derived from fMRI), (d) residual structural cortico-cortical and cortico-spinal connectivity (derived from DTI), and (e) brain-

muscle functional connectivity (derived from TMS), are sufficiently predictive of improvement in upper limb motor function to enable physical therapy to be targeted at those stroke survivors most likely to respond (new scientific/clinical principles)

A further objective on cost-effectiveness is not part of the Robertson Centre analysis.

1.3. STUDY DESIGN

The FAST INDICATE trial is a randomised, controlled, observer-blind, 2-group, multi-centre Phase II trial to determine efficacy of CPT+FSTcompared with CPT+MPT for enhancing upper limb recovery, with embedded explanatory measures to determine prognostic indicators for and neural correlates of response to CPT+FST and CPT+MPT.

Randomisation was stratified by clinical cenre, time after stroke (up to 30 days and 31-60 days) and ability to use the paretic upper limb as assessed by the Nine Hole Peg Test (1 peg or less and 2-8 pegs).

1.4. SAMPLE SIZE AND POWER

The protocol (section 'Sample size') states:

The minimum clinically important change in ARAT score of around 6 points translates to an improvement of one level on 6 of the 19 upper limb tasks tested. There are no intra-class correlation coefficient (ICC) estimates in the literature for physiotherapy interventions being assessed using any of our proposed outcomes. ICC values are known to be lower where patient rather than process of care outcomes are being measured, with the ICC being expected to be somewhat lower than 0.05 for patient outcomes. This sample size calculation is based on actual ARAT data from our previous early phase trial. Assuming an ICC of 0.01 in both treatment arms and three centres with a separate therapist for each randomised arm, a sample size of 99 participants per group would have 80% power to detect a clinically important mean difference of 6.2 in ARAT change when analysing data using a two sample t-test, with Satterthwaite correction, applying a 5% 2-sided significance level and allowing for potentially different standard deviations in the CPT+MPT (7.9) and CPT+FST (19.3) groups. To account for clustering in the design (participants within therapist within randomised treatment at each study site) a sample size inflation factor 1+(*m*-1)*ICC is applied where *m* is the cluster size and ICC is the intra-class correlation coefficient. We have investigated this using the SSC software (Health Services Research Unit, University of Aberdeen). Here we have three study sites each with two therapists. Assuming that recruitment is evenly distributed across therapists, the sample size is therefore inflated to 129 evaluable participants per group. The corresponding mean differences in ARAT change that would be detectable in a study of this size for ICCs of 0.02 and 0.03 would be 7.0 and 7.8 respectively, showing that the design is fairly insensitive to assumptions about the ICC. Finally, to allow for an attrition rate of 10%, 144 participants per groups will be recruited – total sample size of 288.

1.5. DEVIATONS FROM THE PROTOCOL

The protocol noted that the analysis methods to be employed would take into account the clustering aspect of the study. However, due to logistical issues the proposed clustering structure (patients within therapist within treatment group) was not carried out for all patients. Therefore the analysis methods noted in the protocol (which took account of the clustering) are no longer valid. All analyses will therefore be carried out as CPT+MPT vs CPT+FST with no clustering.

1.6. STUDY POPULATION

Potential study subjects were screened from either acute in-patient or rehabilitation settings in services provided around Birmingham, North Staffordshire and Norfolk.

1.6.1. INCLUSION CRITERIA (AS NOTED IN THE PROTOCOL)

1. adults aged 18+ years,
2. 2 - 60 days after stroke when they provide informed consent. This time period has been chosen because some people who may meet the criteria for this trial are discharged from stroke services a few days after stroke and they need to be provided with the opportunity to participate. As brain recovery occurs mostly in the first 3 months after stroke participants will be within what is considered to be the critical time window for neural re-organisation;
3. stroke in anterior cerebral circulation territory, cortical and/or subcortical, confirmed by clinical neuroimaging;
4. sufficient voluntary muscle contraction in the paretic upper limb to generate the beginning of prehension i.e score at least 11/33 for Motricity Index pinch section;
5. unable to complete the Nine Hole Peg Test (9HPT) in 50 seconds or less (maximum time for test);
6. no obvious spatial neglect as defined by a score of 0 or 1 on the Extinction and Inattention sub-scale of the NIH Stroke Scale.
7. have no obvious motor dyspraxia or communication deficits as assessed by ability to imitate action with the non-paretic upper limb. This will be assessed by the Research Therapist sitting alongside the potential participant. The Research Therapist will perform 5 upper limb activities and potential subjects will be asked to observe with intent to imitate and then perform the activities. The accuracy of imitation of observed activity will be assessed on the 3-point scale used by Decety[41]: 2 = correctly reproduced action; 1 = incorrectly reproduced action; 0 = not reproduced. Those scoring 8/10 or above will be considered to have the ability to imitate and therefore be included in this proposed trial;
8. were able, prior to the index stroke, to use the paretic upper limb to lift a cup and drink from it;

1.7. STATISTICAL ANALYSIS PLAN (SAP)

1.7.1. SAP OBJECTIVES

The objective of this SAP is to describe the statistical analyses to be carried out by the Robertson Centre for Biostatistics (RCB) for the final analyses of the FAST INDICATE study.

1.7.2. GENERAL PRINCIPLES

All study data will be summarised at entry to the study, after the treatment period (week 6) and after the follow-up period (month 6). Categorical variables will be summarised with the number and proportion of subjects falling in each category as well as the number missing. Continuous variables will be summarised using the number of observations, the number of missing values, mean, median, standard deviation (SD), lower quartile, upper quartile, minimum and maximum values.

All statistical tests will be performed using two-sided tests at the 5% level of statistical significance.

1.7.3. CURRENT PROTOCOL

The current study protocol at the time of writing is version 7.3, dated 15th May 2015. Any updates to the protocol after the approval of this version of the SAP, will be reviewed for their impact on this SAP, which will only be updated if the changes to the protocol require it. If no changes are required to this SAP following future amendments to the study protocol, this will be documented as part of the Robertson Centre Change Impact Assessment processes.

1.7.4. SOFTWARE

Data will be analysed using SAS for Windows v9.2 or later.

2. ANALYSIS

2.1. STUDY POPULATIONS

The randomised set (RS) consists of all randomised subjects who will be analysed according to the group to which they were randomly allocated.

2.2. BASELINE CHARACTERISTICS

No formal statistical analyses will be carried out on the baseline data. Baseline characteristics will be summarised for each randomised treatment group separately and overall.

The following baseline characteristics will be reported:

Demographic characteristics

- Age (years)
- Sex

Randomisation strata

- Time after stroke (<=30 days, 31-60 days)
- Ability to use paretic upper limb (1 peg or less, 2-8 pegs)
- Clinical centre

Medical History

- Type of stroke
- More paretic side of body
- Site of brain lesion

2.3. EFFICACY ANALYSES

2.3.1. FIRST OBJECTIVE - CLINICAL EFFICACY

To answer the first objective, the primary analysis will compare the change in the efficacy parameters (baseline and week 6) between the treatment groups.

Change in the efficacy parameters (ARAT paretic, ARAT non-paretic, Hand Grip Force, Pinch Grip force, Wolf Motor Function Test (WMFT) – total functional score and 15 individual functional scores, EQ-5D total score, EQ-5D VAS) at week 6 will be analysed using analysis of covariance (ANCOVA) models adjusted for the baseline value and randomisation strata (time after stroke, ability to use paretic upper limb, clinical centre). Adjusted least square means difference and 95% confidence intervals (CIs) will be reported.

Where the outcome distribution deviates from a normal distribution, a log or other appropriate transformation will be applied.

Changes from baseline at month 6 will be analysed as for week 6 changes.

2.3.2. Second Objective – Mechanisms (Explanatory Measures)

To answer the second objective, associations between the changes in TMS and MRI variables will be compared to the changes in clinical efficacy measures (baseline to week 6). The clinical efficacy measures of interest are WMFT total score, ARAT – paretic, pinch force and grip force. Correlations will be carried out for the two treatment groups separately and for the groups combined:

The following TMS/MRI variables will be analysed:

- MRI: Volume of stroke lesion
- MRI: Cortico-cortico anatomical connectivity: FA MNI corpus callosum midline
- MRI: Cortico-cortico anatomical connectivity: Asymmetry ipsilesional:contralesional MNI CSTS
- TMS: Motor Evoked Potential (MEP) – Biceps paretic (percentage of stimulator output at threshold)
- TMS: MEP – Extensor Carpi Radialis paretic (percentage of stimulator output at threshold)
- TMS: Motor Evoked Potential (MEP) – Biceps non-paretic (percentage of stimulator output at threshold)
- TMS: MEP – Extensor Carpi Radialis non-paretic (percentage of stimulator output at threshold)

In addition, the above TMS and MRI data at baseline, week 6 and change will be summarised and compared between the two treatment groups.

2.3.3. Third Objective – Mechanisms (Explanatory Measures)

To answer the third objective, subgroup analyses will be carried out for the change in ARAT paretic at week 6.

The subgroups of interest are the following baseline variables:

- MRI: MNI CST Affected (yes/no)
- MRI: Volume of stroke lesion (above/below median)
- MRI: Cortico-cortico anatomical connectivity: FA MNI corpus callosum midline (above/below median)
- MRI: Cortico-cortico anatomical connectivity: Asymmetry ipsilesional:contralesional MNI CSTS (above/below median)
- TMS: MEP – Biceps paretic (yes/no)
- TMS: MEP – Extensor Carpi Radialis paretic (yes/no)

The treatment effect will be calculated within each level of the subgroup (adjusted as for the first objective) and an interaction term for randomised treatment and baseline covariate will be included in the model.

2.4. Safety Outcomes

2.4.1. Study Disposition

Patient disposition by treatment group will be reported with reasons for withdrawal from study:

- Adverse event (non-serious)
- Participant unwilling to continue in study activities
- Participant withdrew consent
- Participant withdrawn on advice of investigator
- Participant lost to follow-up
- Other

2.4.2. Adverse Events

Adverse events will be reported in two phases: during the treatment period (start date on or after randomisation date and less than week 6 visit date) and during the follow up phase (start date on or after week 6 visit date).

Adverse events will be summarised by treatment group, ordered by system organ class and preferred term.

The following adverse events will be summarised:

- Adverse events
- Related adverse events
- Serious adverse events
- Unexpected serious adverse events

2.4.3. Adverse Reactions

The number and percentage of subjects with adverse reactions for pain and fatigue will be reported in two phases: during the treatment period and during the follow up phase (as defined for the adverse events in section 2.4.2).

3. Derived Variables

Age is calculated as: (Randomisation date – date of birth)/365.25

ARAT will be calculated according to the validated score sheet.

Grip force and pinch force will be analysed as the maximum out of the (up to) three measurements taken at each visit.

Pain – reported on four consecutive visits (either behavioural or verbal) and this is confirmed as an adverse event during each phase

Fatigue – two consecutive visits where the fatigue is confirmed as an adverse event during each phase

Related adverse events – any adverse event reported with a causality of 'definitely', 'likely' or 'possibly' related. Events with a missing causality will be considered as 'related'.

EQ5D score – each of the 5 questions are scored as 1, 2 or 3 in the case report form and the standard weighted score is assigned.

The weighted scores are calculated by subtracting the relevant weight coefficients from 1 (Perfect health). The constant term is used if there is any item with a response greater than level 1. The N3 term is used if any item is at level 3. For example, the algorithm for computing the score for the health state 21223 is:

$1 - (0.081 + 0.069 + 0 + 0.036 + 0.123 + 0.236 + 0.269) = 0.186$

4. DATA LISTINGS

No listings will be provided in the report. An excel file (or files) will be created containing all the data in the database (including derived calculations) to be sent to the Chief Investigator.

5. DOCUMENT HISTORY

This is version 1.0 of the statistical analysis plan, initial creation.

6. TABLE SHELLS

Protocol: FAST INDICATE
Population: Randomised

Table 1.1
Randomisation details, by treatment group and overall

Variable	Statistic	Treatment A (n= XXX)	Treatment B (n= XXX)	All (n= XXX)
Time after stroke	N	XX	XX	XX
	<= 30 days	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	31-60 days	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Ability to use paretic upper limb	N	XX	XX	XX
	1 peg or less	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	2-8 pegs	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Site	N	XX	XX	XX
	Birmingham	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Norwich	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Staffordshire	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Protocol: FAST INDICATE
Population: Randomised

Table 1.2
Demographic characteristics

Variable	Statistic	Treatment A (n= XXX)	Treatment B (n= XXX)	All (n= XXX)
Age (years)	N	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	Std Dev	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Min – Max	XX – XX	XX – XX	XX – XX
	Interquartile range	XX – XX	XX – XX	XX – XX
	Missing	XX	XX	XX
Gender	N	XX	XX	XX
	Male	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Female	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Protocol: FAST INDICATE
Population: Randomised

Table 1.3
Medical history

Variable	Statistic	Treatment A (n= XXX)	Treatment B (n= XXX)	All (n= XXX)
Type of stroke	N	XX	XX	XX
	Ischaemic	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Haemorrhagic	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
More paretic side of the body	N	XX	XX	XX
	Left	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Right	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
Side of brain lesion	N	XX	XX	XX
	Left	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)
	Right	XX (XX.X%)	XX (XX.X%)	XX (XX.X%)

Protocol: FAST INDICATE
Population: Randomised

Table 2.1a
ARAT during the study – non-paretic

Variable	Statistic	Treatment A (n= XXX)	Treatment B (n= XXX)	All (n= XXX)
Baseline	N	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	Std Dev	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Min – Max	XX – XX	XX – XX	XX – XX
	Interquartile range	XX – XX	XX – XX	XX – XX
	Missing	XX	XX	XX
Week 6	N	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	Std Dev	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Min – Max	XX – XX	XX – XX	XX – XX
	Interquartile range	XX – XX	XX – XX	XX – XX
	Missing	XX	XX	XX
Month 6	N	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	Std Dev	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Min – Max	XX – XX	XX – XX	XX – XX
	Interquartile range	XX – XX	XX – XX	XX – XX
	Missing	XX	XX	XX

Similar tables to table 2.a:
Table 2.1b – ARAT paretic
Table 2.1c – Grip force
Table 2.1d – Pinch force
Table 2.1e – WMFT total score
Table 2.1f1 to 2.1f15 – WMFT functional scores
Table 2.1g – EQ5D score
Table 2.1h – EQ5D VAS

Protocol: FAST INDICATE
Population: Randomised

Table 2.2a
Change (Visit 2 – Visit 1) in ARAT non-paretic during the study

Visit 2 – Visit 1	Treatment	Number with data at both visits	Mean (std) at Visit 1	Mean (std) at Visit 2	Change, mean (std)	Least squares mean difference (95% confidence interval) of change between treatment groups	P-value
Week 6 – baseline	A	XX	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	X.X (X.X, X.X)	0.XXX X
	B	XX	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)		
Month 6 – baseline	A	XX	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	X.X (X.X, X.X)	0.XXX X
	B	XX	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)		

Only reported for subjects with data at both visits

Similar tables to table 2.2a:
Table 2.2b – ARAT paretic
Table 2.2c – Grip force
Table 2.2d – Pinch force
Table 2.2e – WMFT total score
Table 2.2f1 to 2.2f15 – WMFT functional scores
Table 2.2g – EQ5D score
Table 2.2h – EQ5D VAS

Protocol: FAST INDICATE
Population: Randomised

Table 2.3a
Correlations (change from baseline to week 6) for MRI: Volume of stroke lesion

Clinical Efficacy Variable	Statistic	Treatment A (n= XXX)	Treatment B (n= XXX)	All (n= XXX)
WMFT total score	Correlation co-efficient P-value	X.XXXX 0.xxxx	X.XXXX 0.xxxx	X.XXXX 0.xxxx
ARAT paretic	Correlation co-efficient P-value	X.XXXX 0.xxxx	X.XXXX 0.xxxx	X.XXXX 0.xxxx
Pinch force	Correlation co-efficient P-value	X.XXXX 0.xxxx	X.XXXX 0.xxxx	X.XXXX 0.xxxx
Grip force	Correlation co-efficient P-value	X.XXXX 0.xxxx	X.XXXX 0.xxxx	X.XXXX 0.xxxx

Similar tables to table 2.3a:
Table 2.3b – MRI: Cortico-cortico anatomical connectivity: FA MNI corpus callosum midline
Table 2.3c - MRI: Cortico-cortico anatomical connectivity: Asymmetry ipsilesional:contralesional MNI CSTS
Table 2.3d – TMS: MEP – Biceps paretic (percentage of stimulator output at threshold)
Table 2.3e – TMS: MEP – Extensor Carpi Radialis paretic (percentage of stimulator output at threshold)
Table 2.3f – TMS: MEP – Biceps non-paretic (percentage of stimulator output at threshold)
Table 2.3g – TMS: MEP – Extensor Carpi Radialis non-paretic (percentage of stimulator output at threshold)

Similar tables to table 2.1a/2.2a (baseline and week 6 only):
Table 2.4a/2.5a – MRI: Volume of stroke lesion
Table 2.4b/2.5b – MRI: Cortico-cortico anatomical connectivity: FA MNI corpus callosum midline
Table 2.4c/2.5c - MRI: Cortico-cortico anatomical connectivity: Asymmetry ipsilesional:contralesional MNI CSTS
Table 2.4d/2.5d – TMS: MEP – Biceps paretic (percentage of stimulator output at threshold)
Table 2.4e/2.5e – TMS: MEP – Extensor Carpi Radialis paretic (percentage of stimulator output at threshold)
Table 2.4f/2.5f – TMS: MEP – Biceps non-paretic (percentage of stimulator output at threshold)
Table 2.4g/2.5g – TMS: MEP – Extensor Carpi Radialis non-paretic (percentage of stimulator output at threshold)

Similar tables to table 2.2b (ARAT paretic, baseline and week 6 only) will be produced for each level of the subgroup variables:
Table 2.6a – MRI: MNI CST Affected (no)
Table 2.6b – MRI: MNI CST Affected (yes)
Table 2.7a – MRI: Volume of stroke lesion (below median)
Table 2.7b – MRI: Volume of stroke lesion (above median)
Table 2.8a – MRI: Cortico-cortico anatomical connectivity: FA MNI corpus callosum midline (below median)
Table 2.8b – MRI: Cortico-cortico anatomical connectivity: FA MNI corpus callosum midline (above median)
Table 2.9a - MRI: Cortico-cortico anatomical connectivity: Asymmetry ipsilesional:contralesional MNI CSTS (below median)
Table 2.9b - MRI: Cortico-cortico anatomical connectivity: Asymmetry ipsilesional:contralesional MNI CSTS (above median)
Table 2.10a – TMS: MEP – Biceps paretic (no)
Table 2.10b – TMS: MEP – Biceps paretic (yes)
Table 2.11a – TMS: MEP – Biceps paretic percentage of stimulator output at threshold (below median)
Table 2.11b – TMS: MEP – Biceps paretic percentage of stimulator output at threshold (above median)
Table 2.12a – TMS: MEP – Extensor Carpi Radialis paretic (no)
Table 2.12b – TMS: MEP – Extensor Carpi Radialis paretic (yes)
Table 2.13a – TMS: MEP – Extensor Carpi Radialis paretic percentage of stimulator output at threshold (below median)
Table 2.13a – TMS: MEP – Extensor Carpi Radialis paretic percentage of stimulator output at threshold (above median)