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Standardising the intensity of upper limb treatment in rehabilitation medicine

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Abstract

Objective—To describe a treatment protocol for the upper limb that standardises intensity of therapy input regardless of the severity of presentation.

Design—The protocol is described (part one) and feasibility and effect explored (part two).

Subjects—Participants (n=11) had a single ischaemic stroke in the middle cerebral artery territory more than one year previously, and had residual weakness of the hand with some extension present at the wrist and the ability to grasp.

Interventions—Following two baseline assessments, participants attended therapy one hour a day for 10 consecutive working days. Treatment consisted of a combination of strength and functional task training. Outcomes were measured immediately after training, at one month and three months.

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Competing interests

None declared

Outcome measures—Intensity was measured with Borg ratings of perceived exertion. Secondary outcome measures included Action Research Arm Test (ARAT), nine-hole peg test, and goal attainment scale.

Results—Borg scores indicated that the level of intensity was appropriate and similar across all participants despite individual differences in the severity of their initial presentation (median (IQR) = 14 (13-15)). The mean ARAT score significantly increased by 6.8 points ($X^2(3) = 15.618$, $p < 0.001$), and was maintained at three month follow up ($z = -2.384$, $p = 0.016$). The nine-hole peg test also showed a main effect of time and 88% of goals set were achieved.

Conclusions—The physiotherapy protocol standardised intensity of treatment by grading exercise and task-related practice according to the person's residual ability, rather than simply standardising treatment times. It was feasible and well tolerated in this group.

Introduction

Studies into the efficacy of interventions in long term conditions such as stroke are complex, with many potential interacting variables [1]. Taxonomies of therapy have been produced to help define the content of therapy provided [2]. However, definitions of treatment intensity usually focus on the duration of therapy [3][4]. Using this approach, increases in intensity have been shown to result in a better outcomes and so treatment time seems to be an important variable. However, equal time of therapy may not reflect equal intensity of treatment, particularly if there are differences in the content of therapy and severity of the stroke.

The problem in standardising complex interventions such as therapy treatment is particularly evident when studies aim to determine the dose-response relationship. Differences in therapy provision such as content, frequency and intensity of an intervention could bias the results of studies [5]. This remains an important area for investigation as the optimal dose for different forms of upper limb therapy in rehabilitation medicine is currently unknown. A secondary area where intensity of therapy input is also of critical importance is testing the efficacy of novel interventions given in tandem with a participant's "usual" therapy (for example, new forms of repetitive transcranial stimulation [6], virtual reality [7], or robotic-assisted therapy [8]). Here, evaluation of the novel intervention depends critically on the assumption that 'usual care' is matched between patient groups.

We have developed a protocol in response to the need in research trials, and indeed in normal clinical practice, to deliver a more standardised treatment. Rather than defining intensity solely by time spent in therapy, the level of exercise is adjusted to the ability of the individual at baseline.

This paper consists of two parts. Part one describes our approach to structuring the protocol content and controlling intensity. Part two describes the feasibility of using the protocol, and presents some preliminary data regarding its effect.

Methods

PART ONE: THE PROTOCOL

The therapy protocol aimed to improve skill acquisition in the hemi-paretic upper limb and consisted of four blocks of strength training and three blocks of functional task practice. We controlled intensity using different techniques for the strength training and the functional task practice.

Systematic reviews of strength training after stroke have provided evidence for efficacy in reducing impairment [9][10][11] and a small carry over effect to an increase in functional activity [9]. To obtain improvements in strength in people with a hemi-paresis, one study recommended working at a minimum intensity of 60% of one repetition maximum [12]. The authors recommend that three sets of eight to 10 exercises are performed and that the load is adjusted to maintain the minimum desired training target (e.g. 60% - 80% of one repetition maximum) .

Therefore we performed isotonic strength training at 60-80% of maximal isometric voluntary contraction measured in mid range. Where strength could not be measured in mid range the strength exercises were graded according to the Medical Research Council (MRC) scale [13]. Muscles tested as grade one were trained using active-assisted movements and subjects were encouraged to generate as much activity as possible. Those with grade two exercised through available range with gravity eliminated and, wherever possible, eccentrically in the range outside active concentric control. Muscles graded at 3-5 were exercised at the calculated training resistance. The maximal isometric voluntary contraction was re-measured every three training days and the resistance adjusted as necessary to maintain 60-80% of maximum. Three sets of 10 repetitions were performed for each exercise. The movements trained were: wrist extension, finger extension, thumb abduction, and grip strength. These actions were chosen because of their importance to hand function and particularly to tasks requiring grasp and manipulation. Studies investigating the use of repetitive functional training have shown positive results on functional measures. It seems likely that increasing the number of repetitions is important in improving performance [14][15][16][17].

For the functional task practice training blocks, tasks were designed to train three different hand functions based on Elliott and Connolly's classification of manipulative hand movements [18]: power grip, within-hand manipulation and fractionated finger control. Subjects could choose an activity from each section. Tasks were initially matched to the individuals' ability on a three level scale as defined by their outcomes on selected subtests of the Action Research Arm Test (ARAT) and Jebsen Taylor Hand Function Test (JTHFT). Figure one shows this process in more detail. Level of intensity was primarily defined using the number of degrees of freedom required at the upper limb to perform tasks. So for level one the whole arm would be supported whilst the hand was used in function; level two allows support at the elbow and level three at the shoulder if necessary. The complexity of the tasks was also different for each level. There were detailed written instructions to guide the therapist.

After determining the intensity level, variability of practice was added, for example, changes in speed whilst maintaining accuracy; in object characteristics (weight, shape, size, frictional properties); amount of visual and physical guidance provided; in amplitude or range of movement; in the predictability of the task (anticipatory control); and in number of repetitions.

Progression was achieved by increasing the number of repetitions; changing the weight or size of the object to make the task more difficult; altering where in the workspace the exercise was carried out, and starting to progress towards less support for the arm proximally and thus more degrees of freedom during the exercise.

Therapists were allowed to choose the method of treatment progression to help to maintain the participant's motivation and to ensure variability of task practice. The key aim was for participants to be working at a level that constantly challenged their ability. Each functional task practice training block lasted 10 minutes during which the participant had to be working

constantly at the task. So whenever they stopped to talk, stretch or rest, the stop watch was stopped as well. In this way, we aimed to ensure that each participant spent the same time working at the same intensity in each exercise area.

Stretches were carried out throughout the treatment sessions in preparation for movement where stiffness was a problem. Participants were also taught to self-stretch at home.

To maximise learning and generalisation of skills the order of exercise within the protocol was randomised [19] using a Latin Squares design[20]. This design ensures that each condition is preceded by a different condition in each row (or in this case, on each treatment day). Any effects due to the order of the exercises are thus balanced out across the treatment days.

Therapists applied the protocol in the same manner giving feedback using faded frequency in line with motor learning principles [21][22], and introducing elements of self-efficacy through exercise progression and self-evaluation of feedback by encouraging subjects to recognise their achievements and suggest ways of progressing the exercises themselves [23].

PART TWO: FEASIBILITY AND EFFECT

The treatment protocol was piloted in 11 subjects with chronic stroke from two different centres. Inclusion criteria were a minimum interval since stroke onset of one year (no upper limit); a single ischaemic stroke in the middle cerebral artery territory; and residual weakness of the hand, with some extension present at the wrist and the ability to grasp. Exclusion criteria were a past or current history of other neurological or psychiatric disease; major systemic illness; intracerebral haemorrhage; significant receptive aphasia; severe neglect; or upper limb spasticity of >2 on the modified Ashworth scale. Each subject had baseline outcome measures taken twice with a two week period in between. They then attended therapy for one hour a day for 10 consecutive working days. Treatment outcomes were measured immediately after training, at one month and at three months (figure two). Outcomes were taken by experienced investigators working to standardised instructions and trained in the methods used. In total there were five different investigators measuring outcomes, three of these investigators were also treating therapists.

The treatment protocol employed detailed written instructions for each exercise choice. Therapists delivering treatment underwent supervised training and received feedback from the protocol author, both during the training period and as the study continued.

In order to measure whether our therapy protocol did indeed deliver similar intensities of treatment, we asked subjects to report their level of work intensity using the Borg rating of perceived exertion scale [24]. The Borg scores were not used to set intensity. Both treatment centres recorded Borg ratings for the session as a whole ($n=10$), but only one centre recorded detailed ratings for each specific exercise type, that is, strength vs. functional training ($n=6$).

The goal attainment scale [25][26][27] was used to ensure a goal oriented approach to treatment and to give an indication of whether meaningful functional change was achieved.

Clinical outcome measures were the Action Research Arm Test (ARAT) [28][29][30] and the nine hole peg test [31].

Analysis

Borg scale measures and goal attainment scale ratings are reported descriptively. We also report the group T-score for the goal attainment scale.

We calculated mean Action Research Arm Test (ARAT) scores for the purposes of comparison with other research but used non-parametric tests to analyse the change in median ARAT score over time. Friedman's ANOVA and post hoc Wilcoxon tests were applied with Bonferroni corrections so that all post hoc effects were reported at the 0.0167 level of significance.

Data from the nine-hole peg test were calculated as pegs placed per second and then presented as a ratio of unaffected hand/affected hand. Exploration of the data from the hemiparetic hand demonstrated violations of the assumption of normal distribution and therefore we used the same non-parametric tests as for the Action Research Arm Test in the analysis.

Results

There were no adverse events during the trial. The treatment protocol was well tolerated and no treatment sessions were missed or curtailed. Eleven subjects completed training but three subjects were then lost to three month follow up. At baseline, the group of subjects had a mean (SD) age of 60 (14) years, and were a mean (SD) of 36 (27) months from stroke onset. Five (45%) of the subjects were female.

Therapists reported no difficulties in implementing the protocol and both therapists and patients expressed satisfaction with the functional, goal based approach to treatment. The total treatment time spent per therapy session varied between participants.

Borg scores for the overall effort of the training protocol were available for 10 of the 11 participants. The median score was 14 points, with an interquartile range (IQR) of 13 to 15. Borg scores for the separate elements of the training programme (strength training and functional task training) were only available for six of the 11 participants. The strength training median (IQR) was 16 (14-17), and functional task training was 14 (13-15).

Sixteen goals in total were set by the 11 subjects. Nine goals were reached as planned and five goals were exceeded meaning that 88% of the goals set were successfully reached. The goal attainment scale T-scores for the group were calculated as 32.94 at baseline and 54.26 at follow up (a T-score of >50 is considered a successful outcome).

Results of the clinical outcome measures are reported for the eight subjects who completed all outcome measurements. There was no significant difference between first and second baseline measures (Wilcoxon Signed Rank Test: ARAT, $z = -1.095$, $p = 0.375$; nine hole peg test, $z = -0.527$, $p = 0.688$) demonstrating stability of arm function prior to the intervention. For all further analyses we have used the 2nd baseline measure to represent baseline values. Table one displays the outcome data at each of the four time points. Mean ARAT score increased by 6.8 points, an improvement considered to be clinically significant.

There was a significant main effect of time on the ARAT score ($X^2(3) = 15.618$, $p < 0.001$). Post hoc tests confirmed that this was due to improvement immediately after training ($z = -2.533$, $p = 0.008$) and that this was maintained at one ($z = -2.254$, $p = 0.008$) and three month ($z = -2.384$, $p = 0.016$) follow up.

For the nine-hole peg test there was no significant change in values from the unaffected hand over time ($F(3, 21) = 0.165$, $p = 0.919$), indicating that any change in ratio scores was due to changes in the affected hand. For the ratio scores, a significant overall main effect of time was demonstrated ($X^2(3) = 7.700$, $p = 0.045$).

Discussion

We have developed and implemented an upper limb treatment protocol that has standardised intensity of therapy input despite differences between individuals in baseline impairment and in the length of time spent in therapy. We have also demonstrated a statistically significant change in this specific intervention group of chronic stroke patients.

One weakness of this study is that although we can show a main effect of therapy, we cannot know if this is related specifically to the therapy provided, or if there is a placebo effect of the active intervention. A well designed blind, placebo-controlled, evaluative study is necessary to establish whether the specific content and intensity of the therapy was the cause of the change. This could also examine whether the same outcome can be achieved at different time points of recovery and with diagnoses other than stroke. A further weakness of this study is that the outcome rater was not blind to the physiotherapy intervention.

The Borg ratings of perceived exertion for the overall training programme support the argument that our protocol adequately standardised the intensity of therapy. Borg ratings of 13 and 17 respectively correspond to around 66% and 80% of a person's maximal effort [32] [33]. The median score for the protocol as a whole was 14, with a range of 13 to 15, and is therefore likely to represent a value within our target training area of 60 – 80% of maximum. To our knowledge, no other study has attempted to measure intensity of input in this way. Time spent in therapy is instead used as a controlling factor. However, in our study the absolute amount of time in therapy did vary considerably between individuals. Stronger subjects, for example, completed the strength training faster than weaker subjects, who may be slower in generating power or require more rest time between repetitions.

The smaller group (n=6) from one treatment centre, were additionally asked to rate the two different approaches (strength versus functional training) separately. The strength training elements of the protocol were rated as more effortful by participants; however, functional task training still remained within the right area of intensity with a small IQR. This indicates that the combination of a predefined starting level depending on baseline ability, and the approach taken by the therapists to constantly challenge the participant's abilities, did result in a similar intensity of exercise despite individual differences.

The implementation of the protocol as a whole was fairly straightforward and there were no reported difficulties with the functional task training from the four therapists involved. We started with describing three different tasks for each area of function but more options could easily be added. The precise exercises may not necessarily be important; rather the grading of intensity through control over degrees of freedom in the upper limb, and task complexity being set at a level where the participant is constantly challenged, are likely to be the key factors.

For the strength training blocks, some subjects were not able to lift the calculated training weight. This might be because the maximal strength was tested as a maximal isometric contraction in mid range whereas the training was carried out through available range. Further protocol development could look at the feasibility of using isotonic measures to calculate training resistance.

We achieved a surprising therapy treatment compliance rate of 100%. We believe that this may have been because we provided transport by taxi for most study participants and because the subjects themselves felt subjectively that they were benefitting from the intervention. The delivery of therapy daily for ten working days may also have made attendance easier as participants tended to devote the two weeks to therapy and arrange other engagements outside this time. It is also possible that subjects may have prioritised

treatment that they received in a research trial if they believed that this was a one off chance to benefit from something extra or special over and above ‘usual’ therapy.

Future work will involve an evaluative study to determine whether the protocol is effective when compared to placebo, and to investigate whether varying the dose of a controlled intensity of therapy results in measureable differences in clinical outcome. The different elements of the protocol may also be examined for their relative effectiveness.

Clinical Messages

- Standardisation of therapy is important, both in research evaluating the dose-response relationship and in clinical trials assessing the efficacy of adjuncts to ‘usual’ care.
- It is feasible to use a protocol to standardise intensity of intervention despite baseline differences in impairment and ability.

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Appendix

Contributors

Contribution	Initials of contributing author
Writing the paper	AW, JCR, JM
Editing the paper	AW, PT, MD, RO, NW, GC, RG, VDL, JCR, JM
Initiating the study	PT, NW, RG, JCR, JM
Designing the study	AW, PT, NW, RG, JCR, JM
Carrying out the study	AW, PT, MD, RO, GC, VDL, JM
Monitoring progress	AW, PT, MD, JCR, JM
Deciding on the analytic strategy	AW, PT, JCR, JM
Final approval of version to be published	AW, PT, MD, RO, NW, GC, RG, VDL, JCR, JM
Guarantor	JM

AW = Amanda Wallace, JCR = John Rothwell, JM = Jon Marsden, PT = Penelope Talleli, MD = Michele Dileone, RO = Rupert Oliver, NW = Nick Ward, VDL = Vincenzo Di Lazzaro, RG = Richard Greenwood

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Figure 1.
Standardisation of the functional tasks. Each activity has detailed written instructions including how to grade each level

Plan of the study **Figure 2.**

Table 1

summary of group results over time. Data reported are: Borg ratings of perceived exertion = median (IQR); Goal Attainment Scale (GAS) = t score (greater than 50 is considered a statistically significant outcome); ARAT (Action Research Arm Test) mean = mean (SD); ARAT median = median (IQR); 9HPT ratio in pegs per second of affected hand/unaffected hand = mean (SE). All values are rounded correct to 2 decimal places.

Outcome measure	n	Baseline	Immediate outcomes	One month follow up	Three month follow up	Statistical test result	p value
Borg overall Median (IQR)	10	N/A	14 (13 – 15)	-	-	-	-
Borg strength Median (IQR)	6	N/A	16 (14 – 17)	-	-	-	-
Borg function Median (IQR)	6	N/A	14 (13 – 15)	-	-	-	-
GAS	11	32.94	54.26	-	-	>50 = significant	significant
ARAT Mean (SD)	8	31.38 (4.35)	38.13 (4.57)	38.63 (4.25)	38.13 (4.90)	N/A	N/A
ARAT Median (IQR)	8	31.00 (21.50 - 43.25)	36.50 (28.25 – 49.50)	35.50 (32.00 – 48.75)	39.00 (29.00 – 48.75)	$\chi^2(3) = 15.618$	<0.001
9HPT	8	0.18 (0.09)	0.20 (0.09)	0.19 (0.09)	0.21 (0.09)	$\chi^2(3) = 7.700$	<0.05