The Nature stroke study; NASTRU - A randomised controlled trial of nature-based post-stroke fatigue rehabilitation

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Keywords: Clinical trial, enriched environment, everyday occupations, horticulture therapy, quality of life.

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Abstract

Fatigue is common after stroke and contributes to disability and impaired quality of life. Currently, there is insufficient evidence on the efficacy of any intervention for post-stroke fatigue. The aim of the study was to examine whether 10 weeks Nature-based rehabilitation (NRB) as add-on to standard care may improve post-stroke fatigue, perceived value of everyday occupations, function, activity and participation compared to standard care only (Clinical Trial.gov Identifier: NCT02435043, 2012/352, 05-06-2015). The study was carried out as a single blinded two-armed randomised controlled trial. Stroke survivors identified through routine 3-month follow-up visit (sub-acute) or medical records (chronic stroke > 1 year earlier) were randomised to Standard care + NBR or Standard care only. Blinded evaluations were conducted at follow-up 8 and 14 months after randomisation. The primary outcomes were post-stroke fatigue (Mental Fatigue Scale, total score) and perceived value of everyday occupations (Oval-pd) 8 months after randomisation. About a quarter of the screened patients were eligible; half accepted to participate and 101 were randomised, mean age 67 years, 60% female. The patients with sub-acute stroke were highly compliant with the intervention. Fatigue decreased to a value below the suggested cut-off for mental fatigue (<10.5) in the intervention group but not in the control group; no statistically significant differences were found though between the groups. Conclusion: NASTRU is the first randomised study on NBR for patients with post stroke fatigue. NBR was feasible and well tolerated. The study was underpowered due to difficulties in recruiting participants. No significant differences were detected between intervention and control group. A larger RCT is warranted. Keywords: clinical trial, enriched environment, everyday occupations, horticulture therapy, quality of life.

Background

It is reported that 23 to 75% of people recovering from stroke suffer from fatigue (1). Post-stroke fatigue (PSF) affects the individual's quality of life, function and can negatively interfere with rehabilitation (1, 2). There is insufficient evidence on the efficacy of any non-pharmacological intervention for PSF (3-6). Improvement of health, in terms of increasing rates of self-rated values in everyday occupations (7), has been shown after nature-based rehabilitation in groups suffering from exhaustion disorders (8). The environment is considered to play an essential role enhancing the neurological recovery of function (9) especially Enriched Environment (EE), which, compared to standard housing conditions, offers greater possibilities for social and physical stimulation and interaction (10) and has been found to have positive effects on neural plasticity and promote functional recovery after stroke (11). One to three months after stroke is a critical period of neuro-rehabilitation as neural plasticity reaches its peak. However, significant improvements may still occur later especially if EE and multi-sensory stimulation are applied in the rehabilitation setting (12). Nature-based rehabilitation (NBR) offers EE and multiple sensory stimuli through *doing* and *being* activities (13-15).

The aim of this randomised controlled trial was to examine whether NBR, as add-on to standard care, could influence post-stroke fatigue and the perceived value of everyday occupations at 8 months (primary

outcome), and 14 months after randomisation (secondary outcome) and the further secondary outcomes targeting disability, health related quality of life, anxiety and depression at 8- and 14-month follow-up.

Methods

Design

This study was conducted as single blinded two-armed randomised controlled trial (Clinical Trials.gov Identifier: NCT02435043). Patients were enrolled between February 2013 and August 2014. Blinded evaluation, by an occupational therapist (OT), was conducted 8 and 14 months after randomisation. The last follow-up was completed in November 2015.

Participants

We asked patients who had suffered from a stroke, living in the catchment area of the Skåne University Hospital, 50–80-years-old, independent in personal-ADL, reporting post stroke fatigue to participate in the study. Patients with dementia, severe aphasia, not fluent in Swedish and/or with severe comorbidities were excluded. The participants were included between February 2013 and August 2014. Patients in the sub-acute group were identified through a routine 3-month follow-up visit, while the chronic group was identified through review of medical records of all patients who had had a stroke during 2011. A nurse specialising in stroke interviewed all potential participants by phone (first assessment for eligibility) and performed a more detailed screening assessment by telephone or face-to-face (second assessment for eligibility) of the individuals who preliminarily matched the study criteria. The final assessment for eligibility was performed by a physician specialised in stroke (last author and PI: H.P-R). All participants provided a written informed consent.

Baseline examination

The baseline examination, including the National Institute of Health Stroke Scale (NIHSS) score (16), Montreal Cognitive Assessment (MoCA) (17) and all outcome measurements were performed by H.P-R and an OT

Randomisation

After baseline evaluation, the patients were randomised into control, respective, intervention group by using opaque envelopes. The computational preparation of the adapted block randomisation lists was performed by using the SPSS Software (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). The sub-acute group, respectively, chronic-group were separately randomised.

Intervention

Patients randomised to the intervention underwent a 10-week long NBR programme in groups of up to eight patients at Alnarp Rehabilitation Garden. The programme started within two weeks after

randomisation and was scheduled for two days a week, with each day's session lasting for three and a half hours. The NBR programme was grounded in horticultural therapy supported by a multimodal rehabilitation team that utilised the garden/nature for multi-sensory stimulation for physical, emotional and cognitive stimulation (13). The 2 hectare size garden contains places for work as well as rest and contemplation (doing and being), and is divided into two major areas: *The Nature Area* (informal and non-cultivated) and *The Cultivation and Gardening Area* (formal and cultivated). It is further subdivided into different garden rooms, each designed with special properties for supporting restorative activities or facilitates meaningful horticulture and garden activities (15).

Follow-up assessments 8 and 14 months after randomisation

All follow-ups were performed by a single OT with a very long-standing experience in stroke care and assessment. The OT was blinded to the allocation of the participants.

Outcome measurements

The primary outcomes in the study were the total score of post-stroke fatigue measured with Mental Fatigue Scale, (MFS) and the total scores for each dimension of perceived value of everyday occupations (Oval-pd) eight months after randomisation. The secondary outcomes were post-stroke fatigue and perceived value of every day occupation 14 months after randomisation and disability (mRS), anxiety (HAD), depression (HAD) and health related quality of life (EQ-5D) and 8 and 14 months after randomisation.

MFS (17, 18) is a 15-item self-assessment multidimensional questionnaire developed to measure mental fatigue in individuals with neurological disorders such as stroke and traumatic brain injury. The questionnaire has 15 items that concern issues such as fatigue in general, sensitivity to stress, sleeping disorders, concentration difficulties, sensitivity to sensory stimuli (e.g. sound, smell). Ratings of each item described are based on duration, frequency and intensity and can vary between 0 and 3 (0=normal function; 3=maximal symptom). A total score is calculated. Healthy population is reported to score a total score of < 5, where as a MFS score above 10 is indication of mental fatigue (19).

Oval-pd measures perceived values of everyday occupations (20). This self-assessment instrument consists of 26 statements on perceived value of everyday occupation, which the participant has performed during the last month. For each statement, five response alternatives are given: not at all, rather seldom, rather often and very often. The instrument is composed of three core dimensions: concrete, symbolic and self-reward value and has high validity and reliability (20). The total scores for each dimension are calculated.

The modified Rankin Scale (mRS) measures the degree of disability or dependence and is the most widely used clinical outcome measure in randomised clinical stroke trials (21). The scale runs from 0-6, from absence of symptoms to death. Disability is rated: 1 no significant, 2 slight, 3 moderate, 4 moderately severe and 5 severe.

EQ-5D 3L is a generic and widely used questionnaire on health related quality of life consisting on five questions covering: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Three response alternatives are provided: no problem, minor problem and total problem. Based on the categorical answers, a 5-digit number is settled and a total score is received, by using a tariff (22). The total score can have values between – 0.59 and 1.0, where 1.0 corresponds to full health. We used the UK-tariff (223).

Hospital Anxiety and Depression Scale (HAD) is a widely used screening questionnaire on depression and anxiety. A score (0–21) for depression and anxiety is calculated respectively. The different values are grouped into categories as follows: 0–7 no depression/anxiety; 8–10 risk for depression/anxiety and ≥ 11 possible depressions/anxiety (24).

Sample size

No power calculations were carried out due to lack of reliable data for calculations. Instead, the study was limited by the period of funding.

Statistical analyses

Outcome variables were analysed according to the intention to treat principle, i.e. all randomised and correctly included patients were included in the statistical analysis. All variables were summarised, including mean/median values and min and max. The change of the outcomes was compared between the groups using the Wilcoxon rank sum test and within the groups using the Wilcoxon signed rank test. Missing data were not imputed. Results were considered statistically significant when $p < 0.05$.

Results

A total of 851 potential participants were identified. After the second screening assessment, 345 persons were found to be eligible, 137 were though excluded as they met at least one of the exclusion criteria. Of the remaining 208 individuals, 107 did not want to participate and 101 (73 sub-acute and 28 chronic stroke) were finally included (Figure 1). Altogether, 51 individuals were randomised to the intervention (37 sub-acute and 14 chronic) and 50 to the control group (36 sub-acute and 14 chronic).

Common reasons alleged for not wanting to participate were: feeling too tired to participate, feeling that the trip to the rehabilitation garden would be too demanding or that the rehabilitation programme would interfere with other activities. The recruitment was more successful during the winter because more individuals decline participation in summer being already involved in outdoors activities such as golf, gardening or other nature-based/related activities.

Thirty-seven (73%) of the 51 participants; 78 %with sub-acute stroke and 57% with chronic stroke, completed the intervention.

Four participants, 2 from the intervention and 2 from the control group, died between randomisation and the first follow-up. Baseline characteristics of the included participants are presented in Table 1.

Patients in both the intervention group and the control group improved over time, concerning MFS, mRS, HAD anxiety and HAD depression, but we found no significant evidence supporting that patients in the intervention group improved more.

The distribution of the number of participants in each MFS category at baseline, 8 and 14 months is shown in figure 2. At baseline, 58% of all participants scored above the cut-off score of 10.5 suggesting the presence of mental fatigue: (intervention group 11.41 and control group 12.43). Both groups improved between baseline and the first follow-up. The intervention group scored below 10.5 at follow-up (8.9 and 9.67 at 8 and 14 months, respectively) while the control group did not (11.06 and 11.47 at 8 and 14 months, respectively) (Table 2).

The mean mRS score improved between baseline and 8 months in both groups (intervention $p = 0.0019$, control $p = 0.0124$ and between baseline and 12 months in the intervention group ($p = 0.0016$), but not in the control group ($p = 0.1642$).

Both groups had a mean score in HAD anxiety at baseline between 7 and 8 indicating “risk for anxiety”. The HAD anxiety scores were lower at the first follow-up compared to baseline in the intervention, but not in the control group (intervention $p = 0.0047$, control $p = 0.1182$). The HAD anxiety scores reached a range below 7 indicating “ no anxiety” in the intervention group at 8 and 14 months, while the score of the control group remained above 7 (Table 2).

Both groups had a mean score in HAD depression within the normal range at baseline; both groups’ depression scores were lower at the 8-month follow-up than at baseline (intervention $p = 0.0275$, control $p = 0.0032$). (Table 2). The EQ5D score did not change statistically significantly within any of the groups over time (Table 2).

No significant differences in improvement were found between the two groups over time for MFS, Oval-pd, mRS, HAD anxiety, HAD depression and EQ5D (Table 2).

Discussion

In this clinical trial, we were not able to show that NBR improved different important outcomes for patients that suffer from post-stroke fatigue; however, NBR proved to be feasible and the participants showed good compliance with NBR. Thus, NASTRU contributes with new knowledge to the field of stroke rehabilitation.

There is lack of evidence concerning interventions that can improve long-term outcomes for this patient group (3). The mean MFS score (primary outcome), a score >10.5 indicating the presence of significant fatigue, reached <10.5 in the intervention group, while it remained > 10.5 in the control group both 8 and 14 months after stroke. As for HAD, anxiety score reached the normal range in the intervention group at 8

and 14 months, while the control group remained in the borderline abnormal range during the whole follow-up, indicating that nature-based rehabilitation may have had some impact on post-stroke fatigue and anxiety. The participants in both the intervention and the control group improved over time, concerning fatigue, disability, and anxiety but no statistically significant differences in the level of improvement were found between the intervention and the control group for any of the outcome measurements; however, no definitive conclusions can be drawn as our study is probably underpowered. Hence, more and larger studies are needed.

Feeling too tired to participate or feeling that the trip to the rehabilitation garden or the rehabilitation programme would be too demanding were common reasons for not wanting to participate. The participants with sub-acute stroke were highly compliant with the intervention indicating that the rehabilitation programme was well accepted.

Improvement between baseline and 8 months was found for most of the outcome measurements in both the intervention and the control groups, while very little to no improvement was seen between 8 and 14 months. The initial improvement may partially be explained by spontaneous improvement in the sub-acute (3 months after stroke) group as the results of the study are driven by the sub-acute group, which is much larger than the chronic group (data not shown). The study procedure, especially the baseline examination by the physician specialised in stroke and the OT as well as the follow-up by the OT may have had a positive impact on both groups and contributed to the improvement. As both groups improved, it may difficult to show any additional effect of a specific additional treatment/intervention.

The study participants were recruited from an unselected total population of patients with mild to moderate stroke. As in most of RCTs in rehabilitation (25), a large number of people were screened for participation but few could finally be included. The alleged reasons for not wanting to participate highlight important aspects to be taken into consideration while designing future rehabilitation programmes and studies, especially if targeting post stroke fatigue. The rehabilitation facilities should be accessible with as little effort as possible. Furthermore, it is important to design outdoor environments suitable for nature based rehabilitation even in winter.

Methodological considerations.

We chose to conduct a RCT because it is the method that provides the strongest scientific evidence. The randomisation procedure was performed without problems. However RCTs, which are very well suited for testing easily standardised treatments , may be a blunt instrument for evaluating complex interventions such as rehabilitation where multiple processes, outcomes and stakeholders interact (26); therefore, we also performed an interview study of the intervention group for which results will be presented elsewhere.

We had planned to include at least twice as many participants, but we did not succeed despite an extended inclusion period. The difficulties in recruiting participants in rehabilitation RCTs are well described (27); in our study, there were additional difficulties that have been discussed earlier in this

paper. Even if the number of participants is rather large in the context of RCT in rehabilitation, the relatively small sample size may have affected the results.

Great efforts were made to ensure blind follow-up as far as possible. The OT was blinded to the participant's group allocation throughout the whole length of the study. We carefully reviewed all assessments before start to ensure that no questions that could encourage the participants to reveal whether they had participated in nature based rehabilitation would be asked during the follow-up. The participants were instructed at baseline and before every follow-up not to reveal the allocation to the OT. Yet, some participants revealed the allocation during follow-up. However, we do not believe that this has affected the results.

The intention-to-treat analysis may be a weakness in the analysis and may have affected the results.

Our findings may indicate that the instruments we chose to study the primary and secondary outcomes may not be sufficiently sensitive to change.

Conclusions

We have performed the first randomised study on nature-based intervention for patients with post stroke fatigue. About a quarter of the screened patients were eligible, and half of them participated in the study where finally 101 participants were randomised. The patients with sub-acute stroke were highly compliant with the intervention. No significant differences were detected between the intervention and the control group. The study provides a solid foundation for future studies in the field.

Declarations

Ethics approval

The regional ethical committee in Lund, Sweden, approved the study (Dnr 2012/352). All participants provided a written informed consent for participating in the trial.

Consent for publication

All participants provided a written informed consent for publication.

Availability of data and material

Availability of data and materials: the datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing of interests

The Authors declare that there is no conflict of interest.

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Author contributions

AMP: Concept and design of the study, intervention. Drafted and wrote the article, revised it critically for important intellectual content. Literature search, Tables and Figures. Acquisition of data; analysis and interpretation of data.

KS: Drafted the article and revised it critically for important intellectual content. Figures and tables. Acquisition of data, analysis and interpretation of data.

BN: Concept and design of the study, analysis and interpretation of data, revised the article critically for important intellectual content.

PG: Concept of the study, revised the article critically for important intellectual content and interpretation of data.

IFP: Concept and design of the study, analysis and interpretation of data, revised the article critically for important intellectual content.

MÅ: Analysis and interpretation of data. Revised the article critically for important intellectual content.

HPR: the PI of the study. Concept and design of the study. Drafted and wrote the article, revised it critically for important intellectual content. Literature

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Tables

Table 1

BASELINE	Total N=101	Intervention N=51	Control N=50
Age mean (min, max)	67 (47-80)	67 (47-79)	66 (48-80)
Female (%)	60 (60)	27 (53)	33 (66)
First ever stroke n (%)	78 (77)	42 (84)	36 (73)
Ischemic stroke n (%)	89 (88)	42 (82)	47 (94)
Haemorrhagic stroke n (%)	11 (11)	8 (16)	3 (6)
stroke severity (NIHHS), median (min-max)	0 (0-5)	0 (0-5)	1 (0-5)
Cognitive functioning (MOCA), mean (min-max)	26 (3-30)	26 (14-30)	25 (3-30)
Disability (mRS)			
mRS 0, n (%)	0 (0)	0 (0)	0 (0)
mRS 1, n (%)	18 (18)	7 (14)	11 (22)
mRS 2, n (%)	38 (38)	22 (43)	16 (32)
mRS 3, n (%)	42 (42)	20 (39)	22 (44)
mRS 4, n (%)	3 (3)	2 (4)	1 (2)
mRS 5, n (%)	0 (0)	0 (0)	0 (0)

Characteristics of the study population at baseline.

Table 2

		Baseline	8-month	14-month
Mental Fatigue Scale (MFS)				
Intervention	N	45	45	46
	Mean	11.41	8.90	9.67
Control	N	41	39	38
	Mean	12.43	11.06	11.47
Difference between intervention and control			p = 0.9108	p = 0.8065
Perceived values of everyday occupations (Oval-pd) dimension: *concrete*				
Intervention	N	50	47	47
	Mean	21.76	21.33	21.58
Control	N	49	40	40
	Mean	21.75	22.29	21.82
Difference t between intervention and control			p=0.2393	P=0. 5324
Perceived values of everyday occupations (Oval-pd) dimension: *symbolic*				
Intervention	N	50	47	47
	Mean	22.17	22.73	21.65
Control	N	49	40	40
	Mean	22.76	23.58	23,79
Difference between intervention and control			p = 0.4529	p = 0477
Perceived values of everyday occupations (Oval-pd) dimension: *self-rewarding*				
Intervention	N	50	47	47
	Mean	22.88	22.77	22.32
Control	N	49	40	40
	Mean	22.60	22.86	23.61
Difference between intervention and control			p = 0.7680	p=0.0627
Disability (mRS)				
Intervention	N	51	46	45
	Mean	2.33	1.91	1.87
Control	N	50	42	41
	Mean	2.26	2.00	2.05
Difference between intervention and control			p = 0.8038	p = 0.1803
Anxiety (HAD)				
Intervention	N	51	48	47
	Mean	7.63	6.27	6.30
Control	N	50	44	41
	Mean	7.94	7.39	7.20
Difference between intervention and control			p=0.4299	p=0.6961
Depression (HAD)				
Intervention	N	51	48	47
	Mean	5.37	4.33	4.74
Control	N	50	44	41
	Mean	5.86	4.68	4.90

Difference between intervention and control			p = 0.3117	p = 0.1368
Health related quality of life (EQ5D)				
Intervention	N	51	48	47
	Mean	0.57	0.60	0.61
Control	N	49	44	40
	Mean	0.56	0.61	0.60
Difference between intervention and control			p = 0.9487	p = 0.8237

Fatigue (MFS), perceived values of everyday occupations (Oval pd), disability (mRS), anxiety (HAD), depression (HAD) and health related quality of life (EQ-5D) at baseline, 8-month and 14-month follow-up in the intervention and control group. The change in outcomes was compared between the groups using the Wilcoxon rank sum test.

Figures

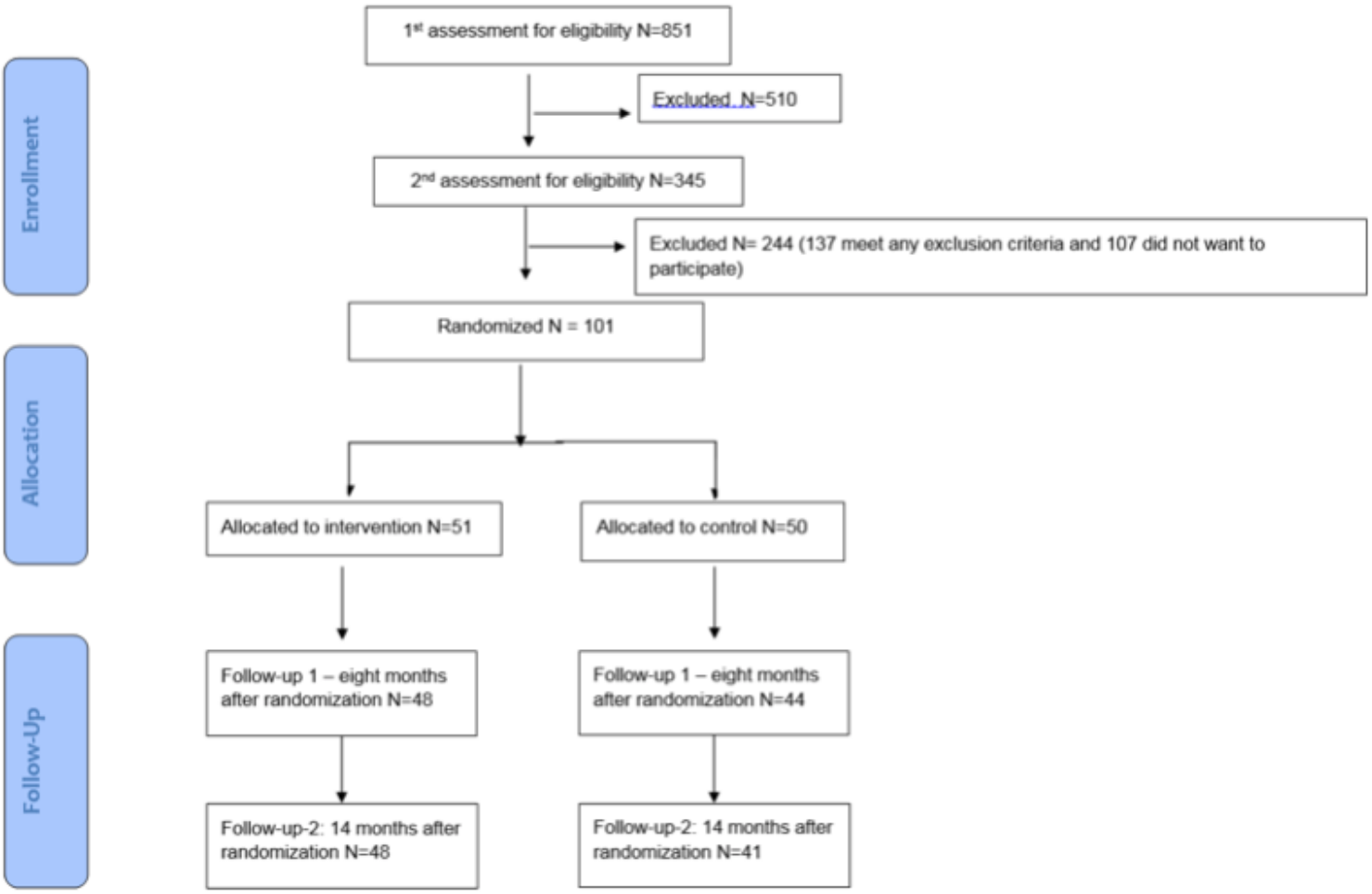

Figure 1

Enrolment, allocation and the randomization of patient for the RTC NASTRU stroke rehabilitation.

Supplementary Files

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- CONSORT2010Checklist.doc