Applied Statistics Mini-Project

The effectiveness of an early vocational rehabilitation programme to support the return to work for stroke survivors

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Abstract

Strokes are a leading cause of death and disability in the United kingdom. Only 50% of people return to work post-stroke. The purpose of this study is to assess whether the 'Early Stroke Specialist Vocational Rehabilitation' (ESSVR) is effective at 1) increasing work participation and 2) improving overall health and quality of life, as opposed to usual care. Both non-parametric and parametric tests were used to test the primary outcomes, including chi-squared test, t-test, logistic regression, linear regression and Cox proportional hazard model. We found that the programme increased work participation by 62%, however the programme was significantly more effective in males than in females. Therefore, it is recommended to conduct further research to investigate how to increase the effectiveness of the programme for females. On the other hand, the programme did not seem to increase overall health and quality of life. This may have been due to a limitation in the study, in that linear regression was used, which may not have been the most appropriate choice.

1 Introduction

Strokes are one of the leading causes of both death and disability in the United Kingdom. Although it is widely believed that strokes are mainly associated with elderly people, approximately four in ten stroke incidents occur in people of working age. Of these people, only 50 percent end up returning to work. This can have a negative impact on many stroke victims' lives, especially given the numerous physical, mental and social benefits that working provides. It has been shown that long term unemployment is associated with negative effects such as higher mortality and illness, and poorer mental health. It is also the case that re-employment is associated with a number of positive outcomes including improved self-esteem as well as physical and mental health [1]. Therefore, it is important to find tools to help stroke victims return to work. Although in some cases, health problems resulting from a stroke may limit their ability to work, vocational rehabilitation is a tool which may be used to support them in returning to work faster and more easily.

The 'Early Stroke Specialist Vocational Rehabilitation' (ESSVR) programme is a vocational rehabilitation programme which aids stroke victims' return to work through education, support and communication with employers. In this study we tested the effectiveness of the ESSVR programme. We conducted a clinical trial to assess two primary outcomes. These were whether the programme 1) increased work participation and 2) improved overall health and quality of life, as compared to usual care. We showed that the rate at which the ESSVR participants returned to work was 1.62 times more than those in usual care, but no significant association was found between completion of the programme and general health and wellbeing, as measured in a composite health score.

2 Methods

ESSVR programme

The ESSVR programme used various methods to attempt to support participants in returning to work after having a stroke. The main role of the programme was to provide education and support to the participants, as well as their families and employers. More specifically, the impact of the stroke on each participant with regards to their work was assessed, and relevant work skills were practised to aid them in returning to work. Moreover, various meetings were held with employers and employment advisors to assist a phased return to work.

Subjects

A randomised controlled trial was carried out to assess the impact of the ESSVR programme on post-stroke patients. Participants must have been in work prior to the stroke, with the stroke taking place when the participants were between 18 and 69 years old. Moreover, the trial was limited to the South East, North East, North West and West Midlands of England. Between the 1st of May 2020 and 30th of November 2020, 1058 participants entered the trial.

Randomisation process

Patients were randomised to either the ESSVR (plus usual care) arm or the usual care arm. This was done 1:1, with the final cohort containing 517 participants receiving usual care and 541 receiving ESSVR (plus usual care) treatment. Patients were then followed up regularly for one year after their randomisation date.

Data collection

Baseline data was collected including sex, age, region of residence, pre-stroke work status, hours worked pre-stroke and stroke severity. In order to assess the primary outcomes, work participation was assessed quarterly during interviews. The date that they returned to work was noted, if they did return to work. The final interview for each participant was held approximately one year after their randomisation date. At the interview, each participant was assessed on their health, which was recorded in a health score between 1 and 100. The four main areas that were assessed were: functional ability, social participation, health-related quality of life and mood. Additionally, for each patient in the ESSVR arm, the occupational therapist coordinating their programme recorded whether or not the participant had successfully completed the programme. However, intention-to-treat analysis was used, since this is the gold standard for randomised controlled trials, and avoids bias [2]. Therefore, for the main trial outcomes, those who only partially completed the programme were still considered to be part of the ESSVR group.

Statistics

We split the research question into three main aims as follows.

Aim 1: Investigate whether pre-stroke work status, number of hours worked pre-stroke or stroke severity affect the successful completion of the ESSVR programme. For each association, the null hypothesis was that there was no association between the variables and completion of ESSVR. Firstly, in order to gauge the general correlations between these variables and ESSVR completion, non-parametric tests were carried out. Chi-squared tests were performed for the exposures pre-stroke work status and stroke severity. A t-test was then used for the exposure pre-stroke weekly work hours (hours worked). Next, a parametric test was used to better understand how these exposures affected the outcome. A single logistic regression was performed with these exposures, as well as covariates sex and age. We then stratified the results by sex, and performed two separate logistic regressions for males and females.

Aim 2 (Primary outcome 1): Investigate whether the programme increased work participation compared to usual care. A cox proportional hazards model was used to test how the ESSVR programme affected the time taken for the participants to return to work. "Returned to work" was taken to be the event. The binary value of the allocation to either ESSVR or usual care was used as the exposure, and the outcome was the time taken to return to work. This was calculated as the difference in days between the randomisation

date and the date that the participant returned to work. We assumed a null hypothesis of no association. The covariates stroke severity, sex and age were added to the model. In order to visualise the results, a Kaplan-Meier curve was plotted. Next, the analysis was stratified by sex, with two separate cox models used for the 688 males and 370 females. Finally, it was investigated whether this aim differed between the first six months and second six months after randomisation. In order to do so, a time-split cox model was implemented, which was split at 183 days. The time group was included as an interaction term with the allocation group.

Aim 3 (Primary outcome 2): Investigate whether the allocation into the ESSVR programme affected the patients' overall health. The second primary outcome was to investigate whether the allocation into the ESSVR programme affected the patients' overall health, as measured by the health score. This was done using a linear regression, with the null hypothesis that there is no association. The covariates sex, age and stroke severity were included. This was then stratified by sex in two separate linear regressions.

3 Results

Aim 1

Firstly, we investigated factors affecting the successful completion of ESSVR. Chi-squared tests indicated that both pre-stroke work status and stroke severity are correlated with the completion of the programme, with $X^2 = 11.04$ and $X^2 = 11.04$ respectively (for $p < 0.05$). However, a t-test showed no significant association between pre-stroke weekly work hours (hours worked) and successful ESSVR completion.

Logistic regression was then used to test the association between the exposures work status, hours worked, stoke severity, and the outcome successful ESSVR completion. The covariates sex and age were included. This is shown in table 1. Permanent and self-employed work status both have a positive correlation with ESSVR completion, as compared to the reference category casual work status. Self-employed work status has the largest effect. The exponent of the coefficient tells us that the odds of self-employed participants completing the ESSVR programme is 2.49 times that of casually employed participants. Severe strokes, as well as the covariate age, both show a negative effect on the odds of ESSVR completion. When age increases by one year, the odds of completing the programme decreases by approximately 3%.

Next, the analysis was stratified by sex. In females, none of the variables are significant, as shown on the left in table 2. In males, only severe strokes are significantly different from mild strokes, as the odds of those with severe strokes completing the programme is $1 - \exp(-0.8672) = 0.58$ times less than the odds of those with mild strokes. This is shown on the right in table 2.

	Estimate	exp(Estimate)	Std. Error	z value	Pr(>|z|)
Intercept	2.0466	7.7415	0.9104	2.25	0.0246
Pre-Stroke Work Status					
Contractor	0.3016	1.3520	0.3778	0.80	0.4247
Fixed Term	0.1385	1.1485	0.3317	0.42	0.6762
Permanent	0.6189	1.8568	0.3092	2.00	0.0453
Self-Employed	0.9108	2.4863	0.4131	2.20	0.0275
Stroke Severity					
Moderate	-0.0026	0.9974	0.2162	-0.01	0.9903
Severe	-0.8429	0.4304	0.2721	-3.10	0.0020
Pre-Stroke HPW	0.0013	1.0013	0.0099	0.13	0.8953
Male	0.2151	1.2399	0.2094	1.03	0.3042
Age	-0.0272	0.9731	0.0133	-2.04	0.0412

Table 1: Correlations of exposure variables with ESSVR completion. **(Aim 1)**

Aim 2

Our second aim was to test whether completion of the the ESSVR programme affected the time taken for the participants to return to work post-stroke. This was tested by using a Cox proportional hazards model. As seen in table 3, the rate at which the ESSVR participants returned to work is 1.62 times, or 62% higher than those in usual care. Stroke severity, sex and age were included as covariates. Of these, the rate that males returned to work is 17% higher than females, as seen in the exponent column. Moreover, those with severe strokes have a significantly lower rate of returning to work compared to those with mild strokes. The Kaplan-Meier curve is shown in figure 1.

When we stratify the analysis by sex, we notice that the ESSVR programme increases the rate of returning to work for both sexes as opposed to usual care, as shown in figure 2. In females, the ESSVR programme increases the rate of returning to work by 32%, whereas in males, the programme increases the rate by 82%. Severe strokes were only significantly different to mild strokes in men. Finally, our time-split cox model shows no significant interaction term between ESSVR and the two time groups (< 183 days and > 183 days), as its p-value is 0.47. Therefore, we cannot conclude that the effect of ESSVR on time taken to return to work varies between the first 6 months and second 6 months.

Aim 3

Finally, we investigated whether completion of the ESSVR affects patients' health scores. Linear regression showed significant negative coefficients for age, moderate strokes and severe strokes. However, no significant association was found between completing the ESSVR programme and health score. This can be seen in table 4. For each year increase in age, participants' health score decreased by $1 - exp(0.1679) = 0.15$, or 15%.

The analysis was then stratified by sex. The ESSVR programme still did not significantly

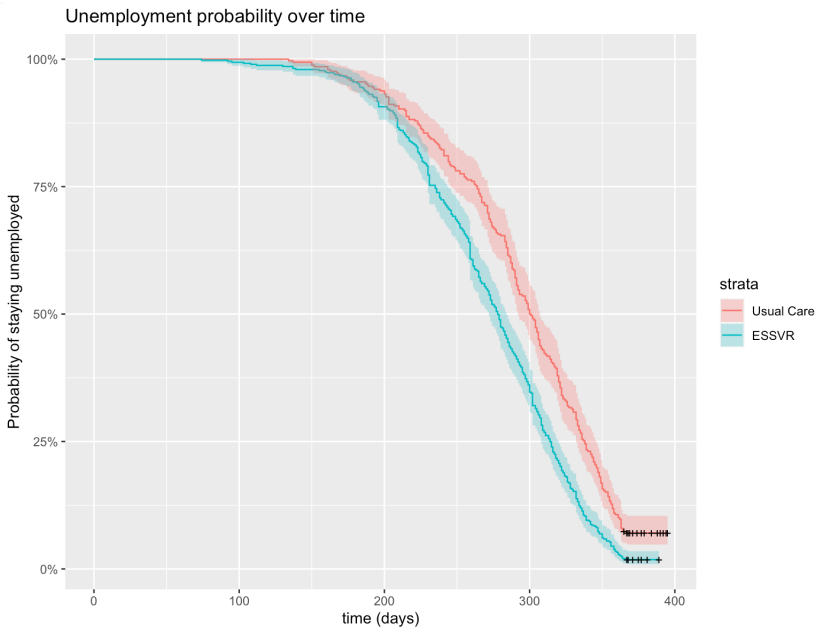

Figure 1: Kaplan-Meier curve of unemployment probability over time.

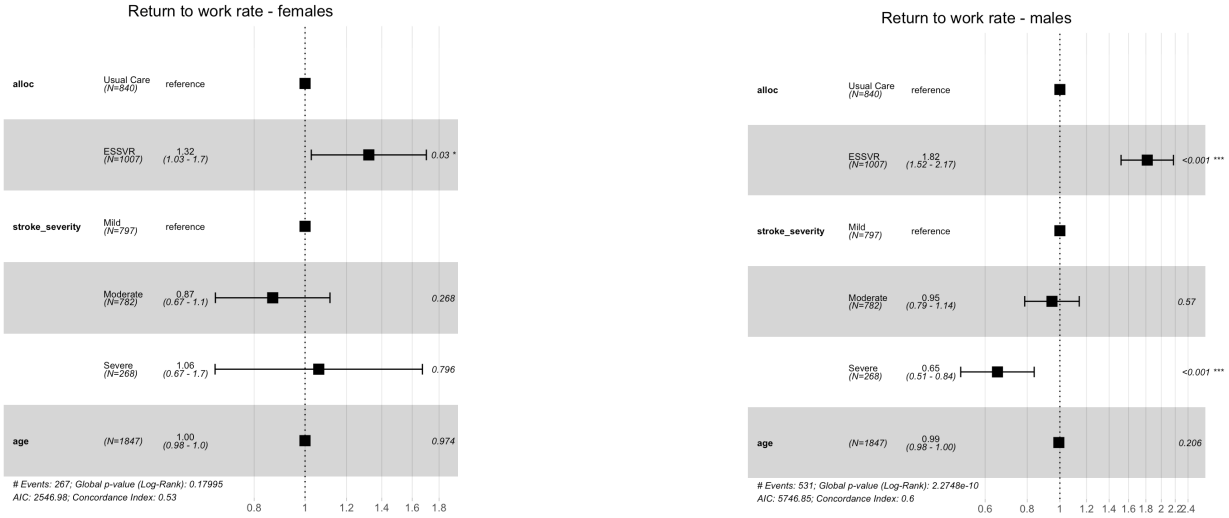

Figure 2: Stratification of cox model by sex.

	Estimate	Pr(>|z|)
Intercept	2.6060	0.0904
Pre-Stroke Work Status		
Contractor	1.2618	0.2800
Fixed Term	0.0473	0.9228
Permanent	0.7555	0.1143
Self-Employed	0.6794	0.3492
Severity		
Moderate	0.1483	0.6673
Severe	-0.7879	0.1409
Pre-Stroke HPW	0.0109	0.4961
Age	-0.0439	0.0643

	Estimate	Pr(>|z|)
Intercept	2.1936	0.0519
Pre-Stroke Work Status		
Contractor	0.1830	0.6834
Fixed Term	0.2169	0.6394
Permanent	0.5310	0.1984
Self-Employed	0.9664	0.0608
Severity		
Moderate	-0.1198	0.6692
Severe	-0.8672	0.0070
Pre-Stroke HPW	-0.0063	0.6242
Age	-0.0198	0.2197

Table 2: ESSVR completion logistic regression with exposure variables in rows (stratified by sex with Left: Female, Right: Male). **(Aim 1)**

	coef	exp(coef)	se(coef)	z	p
ESSVR	0.49	1.62	0.07	6.52	0.00
Severity					
Moderate	-0.09	0.92	0.08	-1.15	0.25
Severe	-0.32	0.72	0.11	-2.90	0.00
Sex = Male	0.16	1.17	0.08	2.05	0.04
Age	-0.00	1.00	0.00	-1.07	0.28

Table 3: Time taken to return to work Cox Regression with exposure variables in rows. **(Aim 2)**

affect the health score for either sex. Males had the same significant associations as in the general logistic regression, however in females, only severe strokes had a significant negative correlation with health score.

4 Discussion

In this study, we showed that the ESSVR programme increased the rate at which stroke victims returned to work by 62%. This result was reinforced when stratifying by sex, as both men and women in the programme showed an increased rate of return to work. However, the programme seems to have been much more effective in men than in women.

When accounting for covariates, it was shown that males return to work 17% faster than females. Then, when the analysis was then stratified by sex, it was shown that the ESSVR programme increased men's rate of return to work by 82%, and women's by 32%. This is a difference of 50%, much higher than the expected difference of 17%. Therefore, it is

	Estimate	Std. Error	t value	Pr(>|t|)
Intercept	55.3087	3.3643	16.44	0.0000
ESSVR	1.3821	0.8402	1.65	0.1003
Severity				
Moderate	-4.4728	0.9119	-4.90	0.0000
Severe	-8.5549	1.2636	-6.77	0.0000
Sex = Male	-3.7234	0.8861	-4.20	0.0000
Age	-0.1679	0.0544	-3.09	0.0021

Table 4: Health score Linear Regression with exposure variables in rows.**(Aim 3)**

recommended that further research be done to investigate how the programme can be made more suitable and effective for women. As expected, severe strokes had a negative effect on returning to work compared to mild strokes. This issue may be difficult to address since it is possible that the reason for this is due to physical limitations of patients who experienced severe strokes. Another surprising result was that the effectiveness of the ESSVR programme did not significantly change between the first six months and the last six months from randomisation.

On the other hand, we found no significant association between the completion of the programme and patients' health and quality of life, as measured in the health score. This result is surprising given the known positive association between working and overall health and quality of life. One possible explanation for this result is that the intention-to-treat analysis lowered the statistical power of the study. Another possibility is that the health score did not adequately take the effects of working into account. The most likely reason for this unexpected result is the fact that linear regression was used on a bounded outcome variable. Since health score values can only take a value between 1 and 100, linear regression may not have been the best choice of analysis, which is one major limitation of the study. However, it is of course still possible that the programme indeed has no effect on health and quality of life.

Although we cannot conclude from this study that the ESSVR programme improves stroke victims' quality of life, we can conclude that it helps them get back to work quicker. Therefore, we would recommend that the programme is rolled out to more areas in the UK in order to increase post-stroke work participation.

References

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