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Title: The Look After Yourself (LAY) intervention to improve self-management in stroke survivors:

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Running Head: Self-management in stroke survivors

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Abstract

Objective: To test the efficacy of a self-management intervention for stroke survivors vs. usual care.

Methods: Using a quasi-experimental study, participants were recruited from three public Italian hospitals. Questionnaires assessing self-efficacy (SSEQ), quality of life (SF-12), physical performance (SPPB), depression (GDS) and activities of daily living (MBI) were administered at baseline, discharge and two months after discharge. Mixed models with a propensity score were used between experimental group (EG) and control group (CG). Logistic models were used to compare the use of health services.

Results: Eighty-two stroke survivors were enrolled in the EG and 103 in the CG. Self-efficacy in self-management improved in the EG compared to the CG during hospitalization. Improvements from baseline to discharge were found in the EG in the mental component of SF-12 and in MBI. The EG were 8.9 times more likely to contact general practitioners after discharge and 2.9 times to do regular exercise than CG. Notably, EG with higher education benefitted more from the intervention.

Conclusion: The intervention was efficacious in improving self-efficacy, mental health and activities of daily living.

Practice implications: Structured educational interventions based on problem-solving and individual goal setting may improve self-management skills in stroke survivors.

Keywords: self-efficacy; self-management; quality of life; stroke; activities of daily living; patient education.

Introduction

Stroke represents a shocking experience due to its sudden onset and physical and emotional long-term consequences [1]. The transition from hospital to home is considered challenging for stroke survivors because they need to cope with a new sense of self and to adapt or maintain their routine life activities and social life [2]. Stroke survivors and their caregivers frequently perceive uncertainty and a sense of abandonment after hospital discharge [3,4]. Therefore, promoting and reinforcing the ability to cope with this condition after discharge may counteract these feelings.

According to the US Institute of Medicine, "self-management is defined as the tasks that individuals must undertake to live with one or more chronic conditions. These tasks include having the confidence to deal with medical management, role management and emotional management of their conditions" [5]. Five self-management abilities are described by Lorig and Holman: problem solving, decision making, appropriate resource utilisation, partnership with healthcare provider and taking necessary actions [6].

In the last years, growing interest has been paid to strategies that address the long-term consequences after stroke: enhancing self-management and self-efficacy can support individuals and improve their quality of life (QoL) [[7], [8], [9], [10]].

Various international clinical guidelines for stroke recommend offering training based on active problem-solving and individual goal setting to improve self-management skills in stroke survivors [11,12]. A systematic review [9] on self-management programs in stroke survivors delivered in community settings analysed the evidence from 15 RCTs, including 1233 participants; the authors concluded that self-management programs can improve QoL in stroke survivors; nevertheless, the interventions differed in timing, contents, targeted outcomes and theoretical principles. In fact, as found by a systematic meta-review [13] on self-management interventions, there is large variability in the settings where self-management programs are delivered (acute, post-acute, community rehabilitation, home based).

The Chronic Disease Self-Management Program (CDSMP) is an evidence-based intervention [14] for the comprehensive self-management support of medical conditions based on Bandura's self-efficacy theory [15] and developed by the Stanford Patient Education Research Center at Stanford University [16]. While many interventions are informed by theory, the CDSMP systematically incorporated self-efficacy theory [17], which states that one's confidence in achieving a desired behavior predicts the level of success. Self-efficacy can be enhanced through skills mastery, modeling, reinterpretation and social persuasion. Health care professionals may assist patients in making management choices and achieving success in reaching self-selected goals. These strategies are used by the CDSMP to support people in self-managing their conditions. The CDSMP, initially implemented in individuals with arthritis [18], has been adapted for diabetes [19], cancer survivors [20] and other chronic conditions, but never used with stroke survivors.

To our knowledge, no structured self-management programs exist in Italy for stroke survivors in post-acute settings. For this reason, we adapted the contents of the CDSMP to stroke survivors and developed the Look After Yourself (LAY) intervention (Fugazzaro et al., unpublished data, 2019). The primary aim of our study was to test the efficacy of the LAY intervention on self-efficacy in self-management behaviors, quality of life and physical and functional performance in post-acute stroke compared with usual care. Secondary aims were to test the efficacy of the intervention on healthcare services utilization and physical activity recovery after discharge and to explore the role of educational level.

Method

Study design and setting

The LAY study is a two-arm, quasi-experimental study. The reason for choosing this study design is that a self-management program has an immediate impact on the culture, organization of the rehabilitation ward and on the behavior of healthcare professionals. Besides, it is usual for hospitalized patients in their rehabilitation phase to share care facilities (e.g. rehabilitation gym),

information and behaviors. Thus, to avoid incurring the risk of contamination bias, we implemented the experimental intervention in two out of three hospitals involved in the study and used the third hospital as a control group.

Participants were recruited from the Physical Medicine and Rehabilitation Units of three public hospitals in the Emilia Romagna region, Italy: Sant'Orsola Malpighi Hospital, Bologna (BO); Azienda Unità Sanitaria Locale- IRCCS, Reggio Emilia (RE); Nuovo Ospedale Civile S. Agostino-Estense, Baggiovara (MO). All patients enrolled in BO received the usual care, while those enrolled in RE and MO received the experimental intervention. The usual care provided in each of the participating units is similar: patients from Stroke Units are admitted to the physical medicine and rehabilitation units to receive treatment and assistance in the early post-acute phase from a multidisciplinary team. The teams are composed of physicians, nurses, physiotherapists, speech therapists, psychologists, and social workers. The care provided by the units focuses on the recovery of independence in the basic activities of daily living (B-ADL), and tailored to the patients' clinical conditions and progressive recovery.

The study procedures were approved by the Ethics Committees (BO:29/2014/O/Sper; RE:2014/0008420; MO:44/2014) of the participating units.

Participants

The study sample included consecutive adult patients recruited at their first stroke in the 3 Italian Rehabilitation Units.

Inclusion criteria were: age ≥18; first ever stroke; presence of a caregiver able to help patient to participate in the SM program; mild/moderate to severe disability (Modified Barthel Index <70/100); patient willingness to sign the informed consent form.

Exclusion criteria were: previous stroke requiring rehabilitation; severe cognitive impairment (Mini-Mental State Examination MMSE<15/30); severe communication disability (Communication Disability Scale ≥3); life-threatening diseases (i.e. severe heart failure, respiratory insufficiency, advanced cancer, sepsis, etc.).

Intervention

The LAY intervention is an adaptation of the Stanford Chronic Disease Self-Management Program (CDSMP) for stroke patients in post-acute settings. It consists of 6 group sessions (for patients and their caregivers) and 2 individual sessions (for patients). The six weekly group sessions each lasted 1/1.5 hours, a maximum of 8 participants were involved. Sessions were conducted by health care professionals (physiatrists, physiotherapists, nurses) and delivered in the early post-acute phase of the inpatient rehabilitation during hospitalization. If patients did not complete the sessions during the hospital stay, they were offered the opportunity to complete them in the hospital in the 2 months after discharge.

The specific topics discussed in the group sessions were: the management of the emotions, good communication and request for help, sleep quality, management of medical therapy, pain and fatigue, nutrition, falls prevention, physical activity, community resources, planning of the future (Figure 5).

The first individual session was led by a physiotherapist at the beginning of the program and was devoted to self-management principles and to the concept of an "action plan" (AP) helping the patient to make his/her first own plan. The second individual session was conducted before hospital discharge by a physiotherapist and focused on strategies to avoid the risk of falling, techniques to get up safely after a fall, training the patient on specific balance exercises and reinforcing collaborative goal-setting. The individual sessions lasted about 20-30 minutes. The healthcare professionals taking part in the research team were trained by an expert on the CDSMP model, with emphasis on small group management, collaborative goal-setting, communication skills and key-elements to support self-management.

To support the self-management process, patients were provided with a manual at the beginning of the intervention. The manual consisted of a paper book of 164 pages including the topics discussed during the 6 group sessions. The manual also included action plan forms that patients were encouraged to complete. Contents were adapted from the original manual used in the CDSMP,

including figures, photos and practical advice. In addition, a manual for healthcare professionals was provided to support them in conducting group sessions and standardizing the content of the sessions.

Measurements

Patients meeting the inclusion criteria who agreed to participate were enrolled within 2 weeks from admission to rehabilitation units. A physiatrist collected socio-demographic characteristics (age, working status, living, social and family condition) and clinical data (stroke type, onset, risk factors and comorbidity (CIRS- Cumulative Illness Rating Scale).

Primary and secondary outcomes were assessed at T0 (within a week from enrolment), T1 (within a week before inpatient rehabilitation discharge) and T2 (2 months after discharge) (see Table 1).

The primary outcome was self-efficacy on self-management of stroke consequences (the Italian version of the Stroke Self-Efficacy Questionnaire, SSEQ).

Secondary outcomes included physical performance, health related quality of life and depression, measured using the Short Physical Performance Battery (SPPB), the Modified Barthel Index (MBI), the Short-Form Health Survey (SF-12) and the Geriatric Depression Scale (GDS). At T2 the use of health services and physical activity recovery were measured with a semi-structured interview.

Stroke Self-Efficacy Questionnaire (SSEQ)

The SSEQ [21] is a 13-item self-report scale measuring self-efficacy after stroke in specific domains of functioning. The purpose of the SSEQ is to measure the extent to which stroke survivors feel confident about regaining activities lost as a result of their stroke. Each item is rated on a 0-3 scale, where 0 indicates absolutely no confidence and 3 complete confidence about accomplishing the task. The Italian version of SSEQ was recently validated [22] and consists of two factors: activity and self-management, strongly related to independence and recovery after stroke.

Modified Barthel Index (MBI)

The MBI [23] assesses the ability to perform activities of daily living. It is the modified form of the original Barthel Index [24] with 10 items that explore functional and motor abilities. The total score

ranges from 0 to 100. Scores from 0 to 20 indicate total dependence, 21-60 severe dependence, 61-90 moderate dependence, 91-99 slight dependence and 100 total independence.

Short Physical Performance Battery (SPPB)

The SPPB [25] is a widely used instrument measuring lower body function and balance in older adults. It is also useful to predict endurance-based measures of functioning.

Short Form -12 (SF-12)

The SF-12 [26] is a validated and widely used health-related quality of life measure. It consists of 12 items that are aggregated into two summary measures of physical health (PCS) and mental health (MCS), expressed as T-scores (mean=50, SD=10), where higher scores denote a better health-related quality of life.

Geriatric Depression Scale (GDS)

The GDS [27] is used to measure the presence and severity of depression. Scores of 0 to 5 indicate the absence of depression, 6 to 8 mild depression, and \geq 9 moderate to severe depression.

Information on the use of health care services and physical activity recovery was collected with a structured interview two months after discharge.

Statistical analysis

Socio-demographic and clinical characteristics of the experimental group (EG) and the control group (CG) were summarized using absolute frequencies and percentages, mean \pm standard deviation or median and range, as appropriate.

EG and CG were compared using the t-test for continuous variables with a normal distribution, Mann-Whitney test for asymmetric continuous variables and χ^2 -test for categorical variables.

To analyse the trend of self-efficacy, physical disability and quality of life scores over time (T0=baseline, T1=hospital discharge and T2=2 months after hospital discharge), repeated measures mixed models were used. These models are suitable in the presence of missing data. The effects investigated in these analyses were the mean effect of the intervention (EG vs. CG), the time trend of scores regardless of the intervention and the time trend in each group.

Since this study has a quasi-experimental design, a propensity score was used to balance EG and CG on demographic and clinical characteristics. The propensity score was calculated using a logistic regression model, in which the intervention group was the dependent variable and all the characteristics that differed significantly between groups at baseline were the independent variables. The probability of belonging to the intervention group predicted by the model (i.e. the propensity score) was used as a covariate in the mixed models.

We then tested the moderating effect of educational level ($<13/\ge13$ years of study) on outcomes in a mixed model including as main effects time, education and education x group.

Logistic regression models were used to compare the use of health services between the experimental and the control groups in the two months from discharge. Each question of the interview was regressed on group and adjusted for the propensity score and the length of hospital stay.

Lastly, we tested whether adherence to the intervention (attending at least 6 sessions) was associated with better outcomes in the experimental group using a linear regression model and a bootstrap procedure.

The significance level was set at 0.05. All statistical analyses were performed using IBM SPSS, version 25.

Results

Participant characteristics

A total of 185 patients were enrolled, 82 in the EG and 103 in the CG. Fifty-six EG patients (63.4%) and 90 CG patients (87.4%) completed the follow-up at 2 months after discharge (Figure 1).

The baseline characteristics of participants are shown in Table 2. Gender distribution was similar in the two groups, while EG patients were significantly younger (69.3 years) compared to CG (73.7 years) (t-test=-2.5; p=0.013). The median time since admission to the study enrolment was significantly different between EG (18 days) and CG (9 days) (Mann-Whitney Z = -7.662; p <0.001).

Similarly, the median length of hospital stay was longer for EG (40 days) compared to CG (32,5 days) (Mann-Whitney Z = -2.239; p <0.025)

The proportion of haemorrhagic stroke was significantly higher in the experimental group compared to the control group (25.6% vs 11.7%, $\chi^2 = 6.1$; p = 0.014). Furthermore, the experimental group was more likely to have communicative disability than the control group (48.8% vs 18.5%, $\chi^2 = 22.5$, p <0.001) and had a higher CIRS severity index (1.7 vs. 1.5, t-test = 3.7; p <0.001).

Baseline scores on the outcome measures were similar between groups, except for the Short Physical Performance Battery (Mann-Whitney Z=-6.1; p<0.001), which denoted a poorer performance among CG than EG, especially for the balance test. About one fifth of patients in the control and one fourth in the experimental groups had severe depressive symptoms.

Since the two groups showed significant differences in several baseline demographic and clinical characteristics, a propensity score was calculated to balance them on age, gender, days since admission, communicative disability, CIRS severity index and type of stroke. Length of stay was also included in the mixed models to adjust for the different observation time from T0 to T1.

Number of sessions attended

81.7% of EG patients attended at least 6 of the 8 programmed sessions. Specifically, 45.1% of patients participated in at least 5 group sessions and 72% of patients received 2 individual sessions. The large majority of the sessions were attended during hospitalization (86.7%), while the remaining 13.3% were held after discharge.

Time trend of self-efficacy, physical activity and health-related quality of life in the study groups Stroke self-efficacy, measured using the SSEQ total scale, increased by 7.79 points from baseline to discharge (p=0.001) and did not further increase between discharge and T2 (Figure 2). No significant differences were found between EG and CG. A similar trend was found for the SSEQ activity subscale. (Figure 2).

Instead, the SSEQ self-management sub-scale increased by 2.27 points from baseline to discharge (0.021) and the EG had on average significantly lower scores than the CG (-1.75 points; p=0.009). There was a significant interaction between time and group only at T1, because the EC had an improvement during hospitalization phase while the CG had a steady decline (p=0.027). From T1 to T2 and from T0 to T2 there was no significant interaction between time and group (Figure 2).

The physical and mental component scores of quality of life (Figure 3) increased by 4.6 and 7.4 points, respectively, from baseline to discharge (p=0.001; p=0.019). No significant differences were found between groups, however for the mental component the experimental group showed an increasing trend over time while it remained stable in the control group (b=-4.1; p=0.045).

The MBI score increased significantly from T0 to T1 by 49.5 points on average (p<0.001); the intervention group had, on average, significantly higher MBI scores than the control group over time (7.9 points; p=0.048). Moreover, the experimental group showed a more rapid improvement in daily activities from baseline to hospital discharge compared with the control group (b=-7.9; p=0.009). Of note, the EG had a slower increase compared with the control group from discharge to two months (b=6.3; p=0.031) (Figure 3).

The Short Physical Performance Battery score changed significantly from T0 to T2 (2.14 points; p=0.008). The SPPB score in the experimental group was on average 3.78 points higher than that of the control group (p<0.001). There was also an interaction between time and group between T0 and T2 (p=0.017), since the EG had a weaker improvement than CG (Figure 3).

GDS scores did not vary over time. There were no differences between groups and no interaction between group and time (results not reported).

Moderating effect of education

Additional analyses were conducted to investigate whether education was a predictor and/or a moderator of the intervention effect.

A moderation effect of educational level on the SSEQ activity subscale was, in fact, found among patients with a higher educational level. The SSEQ activity scores were significantly higher in EG compared with CG, while no difference was found among patients with a lower educational level (Figure 4). This suggests that the intervention is beneficial for patients with a higher level of education.

Similarly, a moderation effect of education was found for the Barthel score. Among participants with a higher educational level the Barthel score was 17.3 points higher in the experimental group than in the control group (p=0.005; CI [5.40; 29.11]), while among participants with **a** lower educational level, the Barthel score did not differ between the two groups (Figure 4).

Furthermore, education was a positive predictor of SPPB and GDS, regardless of the intervention. Specifically, in patients with more than 13 years of education the SPPB score was 3.6 points higher (p=0.006; CI [1.06; 6.11]) and the GDS score 2.3 points lower (p=0.009; CI [-3.94; -0.56]) compared with patients with <13 years of education.

Use of health care services and physical activity recovery

Table 3 shows the absolute and percentage frequencies of health services use and physical activity maintenance in the two months from discharge in the two study groups.

Two items of the "use of health care services and physical activity maintenance" interview differed significantly between the EG and the CG in the multiple logistic regression models, adjusted for the propensity score and the length of hospital stay.

The first was the item "able to do regular exercise" (adjusted-OR=2.93; 95% CI [1.15-7.46]) and the second item was "contacted GP after discharge" (adjusted-OR=8.85; 95% CI [1.52-51.56]), indicating that the EG was more likely to do regular exercise and to contact the GP after discharge than the CG.

Discussion and conclusions

In this paper, we investigated the efficacy of the Look After Yourself (LAY) structured self-management program adapted from the Stanford Chronic Disease Self-Management Program (CDSMP) for stroke survivors vs. usual care during the early rehabilitation phase.

Like CDSMP, LAY is based on self-efficacy theory and is designed to enhance personal efficacy on self-management activities with the use of specific techniques that include information and education towards healthy life styles, emotions and symptoms management, action planning, problem-solving and relaxation activities.

Overall, self-efficacy in the experimental group was not significantly higher than the control group, and both groups improved over time. It cannot be excluded, though, that the patients in the control group and the healthcare professionals of usual care may have changed their behavior due to their participation in the study. This is known as the Hawthorne effect, which consists in the non-specific effect of being included in a trial [28]. On the other hand, supporting patients on self-management activities is already expected in usual care practices and this could have affected the magnitude of the results.

On the other hand, we found that self-efficacy in self-management (SSEQ sub-scale) improved during the hospital stay and declined after discharge in the experimental group, while in the usual care group scores declined throughout the whole study period. Furthermore, activities of daily living (MBI) and the mental health-related quality of life (MH SF-12) showed a more rapid improvement in the experimental group than in the control group from baseline to discharge. After discharge, MBI and MH SF-12 scores remained stable.

These results indicate that the effects of the intervention on activities of daily living and mental health persisted in the two months after discharge, during which the patient is faced with the practical and psychological challenges linked to his/her condition.

To our knowledge our study was one of the few to recruit patients in the post-acute hospital phase. In line with a recent systematic review [29], the LAY intervention incorporates the key features of group self-management programs: increasing knowledge, collaboration and/or communication, accessing resources, goal setting, and problem solving. However, it did not include peer supporters within the group sessions to facilitate experience sharing, social comparison, vicarious learning and motivation. This may partially limit the comparison with existing studies.

In Fryer's systematic review (2016), the timing of interventions varied from one month to one year or more after the acute phase, and the settings for the intervention were all community, home, or outpatient-based.

In Warner's systematic review (2015), out of the nine studies included investigating the effectiveness of stroke self-management programs on functioning and participation outcomes, only three studies were conducted in rehabilitation units. In Byers' study [30], the intervention was delivered in the hospital at the time of discharge by healthcare professionals and consisted of a single session (verbal and written education).

In Folden's quasi-experimental study [31], the guided decision-making intervention was delivered in stroke rehabilitation patients and consisted of four individual sessions (1-2 h, once a week). Sessions were supported by the use of a written guidebook, a guide to achieve goals related to problems that arise after stroke.

In Nir's study [32] the intervention consisted of a written guidebook and 12 consecutive weekly meetings performed in a geriatric rehabilitation department with stroke survivors (after an average of 13 days in an acute setting).

Our results concerning the efficacy of the LAY intervention on patients' perception of their self-care abilities are consistent with Folden et al. (1993) and support the use of a written guidebook as a companion to the psychoeducation sessions. With regards functional outcomes, our findings

concerning activities of daily living and mental health are consistent with Nir et al. (2004). These authors found early effects of the intervention on functional status, health behaviors and depression, while improvements in self-perception of health and self-esteem took place 3 months later.

In order to identify specific subgroups of patients most responsive to the intervention, we investigated the role of education as a moderator of the intervention effect on outcomes. We found that the educational level moderated the intervention effect on the activity subscale of SSEQ and MBI. These results suggest that patients with higher educational levels (≥ 13 years) benefit more from the intervention than from usual care, while no similar benefit is found among those with a lower education (< 13 years).

Moreover, higher education predicted higher self-efficacy on the activity sub-scale score, higher levels on the ability to perform activities of daily living, physical recovery and lower levels of depression regardless of the intervention.

Concerning access to community services, after adjusting for the severity of patient's clinical condition, the experimental group was 2.9 times more likely to do regular exercise and 8.9 times more likely to contact the general practitioner after discharge than the control group. These findings should be interpreted with caution, given the large variability of estimates that results in large confidence intervals.

Our results should be interpreted keeping in mind some important limitations. The quasi-experimental study design has intrinsic limitations compared to a randomized clinical trial. We sought to address the imbalance of the characteristics of the two study groups using an analytical strategy based on propensity scores.

Anticipating psychoeducational interventions in post-acute settings can provide patients with the necessary skills, motivation and self-confidence needed to self-manage their condition. However, because the early post-acute phase of stroke is a critical period, it is likely to affect compliance with the program.

In our study less than one half (45.1%) of patients participated in at least 5 of the 6 group sessions delivered during the hospital stay and after discharge. We argue that the participation rate could be increased by involving patients, families, healthcare professionals and charities in the co-design and implementation of interventions supporting self-management in stroke survivors.

Conclusion

Our study showed the efficacy of a structured self-management intervention for stroke survivors in terms of self-efficacy improvement in self-management, mental component of quality of life and ability to perform activities of daily living during the hospital phase. Nevertheless, the improvement of self-efficacy in self-management declined in the two months after discharge, suggesting that some booster psychoeducational sessions could be planned in the community setting to support patients after discharge.

Practical implications

Offering structured educational interventions based on active problem-solving and individual goal setting may improve self-management skills in stroke survivors.

Moreover, since patients with a higher educational level had better outcomes and benefited more from the intervention than patients with lower education, future research should take into account these disparities, and alternative appropriate interventions should be sought when needed for specific patient subgroups.

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E.C., S.F., and R.B. collected the data; R.M. and L.D. carried out the literature review and wrote the first draft of the paper; M.I. conducted the statistical analyses; M.P.F., P.R., M.T., S.F., S.C., R.B., M.A.A., M.D., D.P. contributed to the paper writing, the data interpretation, and provided intellectual content. All the authors approved the final version of the paper.

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Data availability statements

The data sets generated and/or analysed during this study are available from the corresponding author on reasonable request.

Declaration of conflicting interests

The authors declare that they have no conflict of interest.



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Table 1 - Assessment at baseline (T0), discharge (T1) and two months after discharge (T2).

Variables investigated	Measurements			T2
Self-efficacy	SSEQ	X	X	X
Disability	MBI	X	X	X
Quality of life	SF-12	X	X	X
Physical performance	SPPB	X	X	X
Depression	GDS	X	X	X
Use of health care services and physical activity recovery	Semi-structured interview to patient			X



Table 2 – Demographic and clinical characteristics at baseline (N = 185).

Characteristics	Experimental Group (n=82) N(%)or	Control Group (n=103) N(%)or	Test; p
Gender	mean ± DS	mean ± DS	, <u>F</u>
Male	43 (52.4%)	60 (58.3%)	0.62; 0.429
Female	39 (47.6%)	43 (41.7%)	0.02, 0.42)
	69.3 ± 12.2	73.7 ± 11.4	-2.501; 0.013
Age Age groups	09.3 ± 12.2	/3./ ± 11. 4	5.124; 0.024
< 65 years	27 (32.9%)	19 (18.4%)	3.124, 0.024
≥ 65 years	55 (67.1%)	84 (81.6%)	
Educational level	33 (07.170)	04 (01.070)	2.763; 0.096
<13 years	64 (78.0%)	69 (67.0%)	2.703, 0.090
≥13 years	18 (22.0%)	34 (33.0%)	
≥13 years Living alone	16 (22.0%)	34 (33.0%)	2.00; 0.157
Yes	25 (30.5%)	22 (21.4%)	2.00, 0.137
No	57 (69.5%)	81 (78.6%)	
Internal barriers	37 (09.3%)	01 (70.0%)	0.016; 0.898
	<i>EE (CT</i> 10/)	70 (69 00/)	0.016; 0.898
No Vac	55 (67.1%)	70 (68.0%)	
Yes	27 (32.9%)	33 (32.9%)	0.215 0.574
External barriers	26 (42 00)	41 (20 00)	0.315; 0.574
No	36 (43.9%)	41 (39.8%)	
Yes	46 (56.1%)	62 (60.2%)	
Days since admission (median, range)	18 (6-44)	9 (2-43)	-7.662; <0.001
Length of stay (median, range)	40 (13-119)	32.5 (6-89)	-2.239; 0.025
ctus type			6.070; 0.014
Hemorrhagic	21 (25.6%)	12 (11.7%)	
Ischemic	61 (74.4%)	91 (88.3%)	
Communicative disability			22.505; < 0.001
None	42 (51.2%)	84 (81.6%)	
Mild	34 (41.5%)	12 (11.7%)	
Moderate	6 (7.3%)	7 (6.8%)	
CIRS			
Severity Index	1.7 ± 0.3	1.5 ± 0.3	3.725; <0.001
Comorbidity index	3.1 ± 1.5	2.7 ± 1.4	1.579; 0.116
MMSE	25.3 ± 3.3	25.3 ± 4.2	-0.075; 0.940
AMCE			0.006.0.027
MMSE groups	29 (35.4%)	35 (35.9%)	0.006; 0.937
<24 points	29 (33.4%)	33 (33.9%)	
≥24 points	53 (64.6%)	66 (64.1%)	
_21 points	33 (04.070)	00 (01.170)	
SSEQ	21.0 ± 8.7	23.2 ± 9.6	-1.625; 0.106
BIM	35.3 ± 21.5	36.4 ± 19.7	-0.377; 0.707
SPPB (median, range)	4 (0-12)	0 (0-9)	-6.147; <0.001
Balance	2 (0-4)	0 (0-4)	0.117, \0.001
Sit-standing	1 (0-4)	0 (0-4)	
Walk	1 (0-4)	0 (0-3)	
Walk SF-12	1 (0-4)	0 (0-3)	
	25 8 ± 6 0	35 5 ± 9 0	0.248. 0.905
PCS MCS	35.8 ± 6.9	35.5 ± 8.9	0.248; 0.805
MCS	44.1 ± 11.3	44.8 ± 11.8	-0.405; 0.686
GDS	7.2 ± 1.9	6.9 ± 2.0	0.828; 0.409
GDS groups	17 (01 50()	07 (06 00/)	1.170; 0.557
None	17 (21.5%)	27 (26.2%)	
Mild-moderate	41 (51.9%)	55 (53.4%)	
Severe	21 (26.6%)	21 (20.4%)	

Abbreviations: BIM= Barthel Index Modified; CIRS= Cumulative Illness Rating Scale; GDS= Geriatric Depression Scale; MCS=Mental Component Score; MMSE=Mini-Mental State Examination; PCS=Physical Component Score; SF12=Short Form health survey; SPPB= Short Physical Performance Battery; SSEQ= Stroke Self-Efficacy Questionnaire.

Table 3 - Use of health care services and physical activity maintenance investigated with semi-structured interview at 2-month after hospital discharge.

	Experimental Group (N=56)		Control Group (N=90)	
	N (yes)	%	N (yes)	%
Emergency room access	9	16.1	10	11.1
Rehospitalization	5	8.9	8	8.9
Contacted GP after discharge	53	94.6	81	90.0
Communicative difficulty with GP	3	5.4	5	5.6
Contacted the Social worker after discharge	5	8.9	14	15.6
Use of Disabled Transportation services	10	17.9	11	12.2
Contacted charitable organizations after discharge	4	7.1	1	1.1
Rehabilitation after discharge	26	46.4	33	36.7
Rehabilitation problems	2	3.6	2	2.2
Contacted the "Aids services " after discharge	13	23.2	10	11.1
Communicative difficulty with "Aids services"	2	3.6	3	3.3
Able to walk every day	55	98.2	86	95.6
Able to walk outside	50	89.3	81	90.0
Able to do regular exercise	31	55.4	34	37.8
Needed help in arm self-mobilization exercises	12	21.4	25	27.8
Falls	10	17.9	10	11.1

Figure 1 - Flow chart of the quasi-experimental design.

CONSORT 2010 Flow Diagram

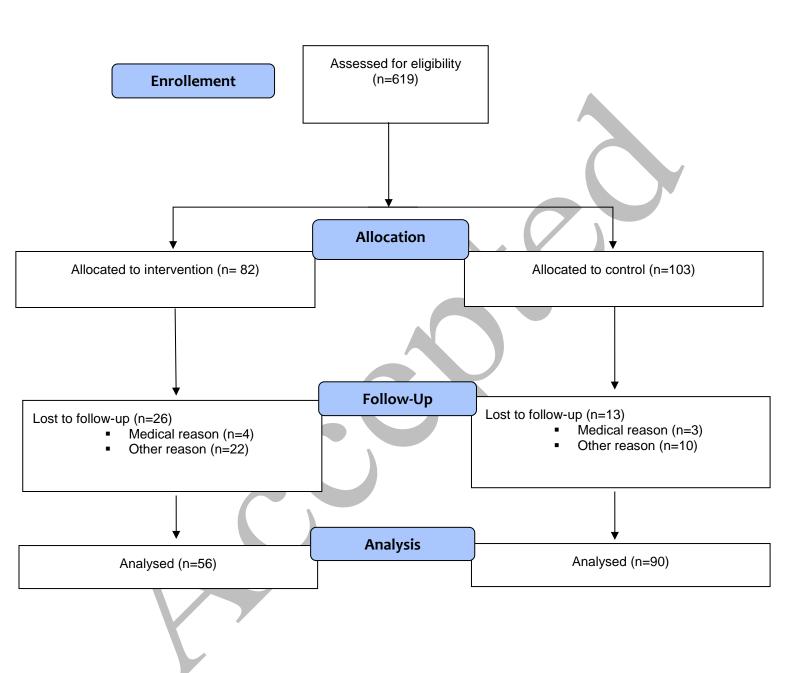


Figure 2. Mean predicted values by group over time for the Stroke Self-Efficacy Questionnaire (SSEQ): total score (1), activity (2) and self-management (3). Solid line= Experimental Group (EG), Dotted line= Control Group (CG).

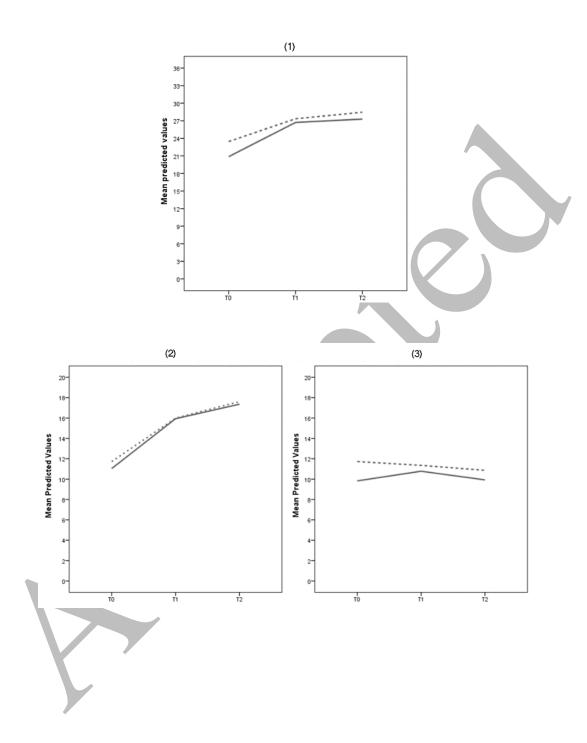


Figure 3. Mean predicted values by group over time for secondary outcomes: MBI (1); SPPB (2); SF-12, Physical (3) and Mental component (4). Solid line= Experimental Group (EG), Dotted line= Control Group (CG).

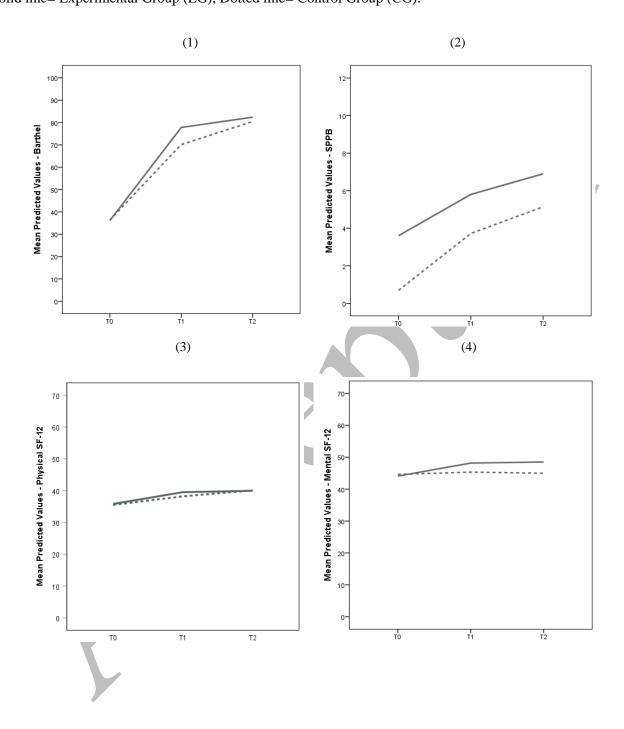


Figure 4. Mean scores of the SSEQ activity sub-scale (1) and MBI (2) between groups and educational level.

Dark grey= experimental group, Light grey= control group.

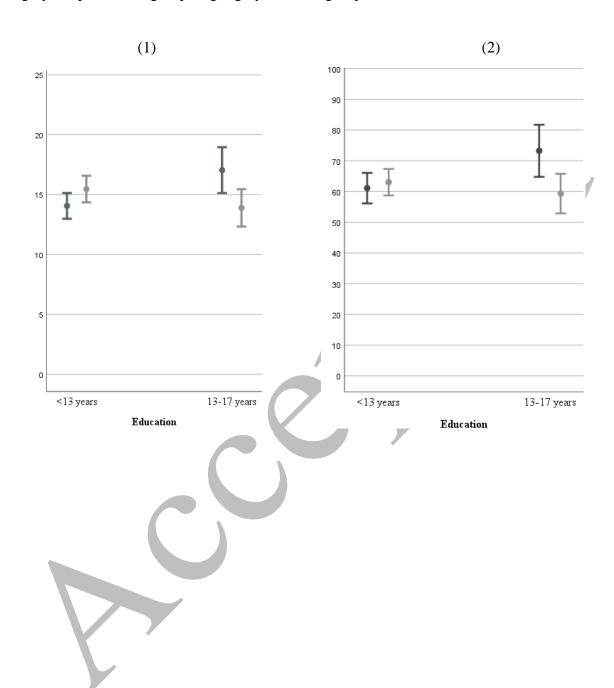


Figure 5. Summary description of LAY intervention sessions

SESSIONS	TOPICS	METHODS
GROUP 1st	Stroke Risk factors Rehabilitation	Education on prevalence, symptoms, causes, course and management of a stroke.
INDIVIDUAL 1st	Self-management activities	Goal setting and Action planning
GROUP 2 nd	Self-management activities Emotions and symptoms management	Action planning restitution, problem-solving, relaxation techniques.
GROUP 3 rd	Self-management activities Sleep quality Communication skills	Relaxation techniques, action planning restitution, problem- solving, communication strategies to request help.
GROUP 4 th	Drugs and symptoms management	Action planning restitution, problem-solving, relaxation techniques.
INDIVIDUAL 2 nd	Risk and prevention of falls	Rising from a fall and balance exercises
GROUP 5 th	Falls prevention Healthy eating	Action planning restitution, problem-solving, education about healthy eating habits.
GROUP 6 th	Exercises and physical activity Availability of the community services Looking back and planning the future	Education on the importance of physical activity and strategies to find the time to integrate exercise in the weekly routine, action planning restitution and problem-solving.

Group sessions: 10-12 stroke survivors and their caregivers

Individual sessions: one-to-one