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PSYCHOSOCIAL CORRELATES OF REHABILITATION FROM STROKE:

A LONGITUDINAL STUDY

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ABSTRACT

OBJECTIVE. The general aim of this dissertation was to uncover the association between psychosocial factors and rehabilitation outcome after stroke. **METHOD.** A sample of patients with stroke (n=40) and their caregivers (n=36) were assessed at admission to and six months after discharge from rehabilitation hospital, using the following instruments: Structured Clinical Interview for DSM-IV, structured interview based on Diagnostic Criteria for Psychosomatic Research, Symptom Questionnaire, Psychosocial Index, Psychological Well-Being Scales, and Family Assessment Device. 40 subjects from the general population underwent the same psychological assessment. In addition, patients' functional status was measured using the Functional Independence Measure. **RESULTS.** Stroke survivors reported lower education and higher alcohol consumption than controls. No significant differences emerged between the two groups in the prevalence of psychiatric diagnoses or psychosomatic syndromes, however patients reported significantly higher levels of anxiety, depression, somatic symptoms, and lower autonomy than controls. Caregivers reported significantly higher scores in anxiety, depression, and somatic symptoms compared to normative data, while no impairments emerged in psychological well-being and family functioning. At six-month follow-up, in patients a significant decrease in smoking habit and an increase in DSM diagnoses were reported. Both stroke survivors and caregivers showed significant reductions in anxiety, with patients displaying also a decrease in somatic symptoms, an increase in stress and a deterioration in quality of life. Significant deteriorations in several aspects of family functioning was perceived only by patients. An association between patients' functional recovery in the cognitive domain and family behavior control emerged. For caregivers, family functioning significantly predicted hostility and somatic symptoms were associated with family affective involvement. **CONCLUSIONS.** These data highlight the utility in the Italian setting of the adoption of a psychosocial assessment and a family-systems approach in stroke rehabilitation, in order to development interventions properly targeted to the characteristics of patients and their family members.

1. INTRODUCTION

1.1 Stroke: definition and epidemiology

Stroke has been defined by the World Health Organization (WHO; Aho et al., 1980) as a syndrome characterized by “rapidly developing clinical signs of focal (or global) disturbance of cerebral function, lasting more than 24 hours or leading to death, with no apparent cause other than that of vascular origin.” Strokes are subdivided into two major classifications: ischemic and hemorrhagic. The ischemic one takes place as a result of an obstruction within a blood vessel providing blood to the brain, while the hemorrhagic one occurs when a weakened blood vessel ruptures. About 15-20% of strokes are hemorrhagic and 80% ischemic (www.spread.it). Stroke represents the second cause of mortality worldwide and the third cause of mortality in western countries (Carolei et al., 2002). According to the American Heart Association (AHA), each year around 795.000 people have a new or recurrent stroke (ischemic or hemorrhagic). Approximately 610.000 of these are first episodes and 185 000 are recurrent stroke attacks. On average, every 40 seconds, someone in the United States experiences a stroke, and someone dies of one approximately every 4 minutes (Mozaffarian et al., 2015). In Europe, according to the WHO, the number of stroke events is likely to increase from 1.1 million per year in 2000 to more than 1.5 million per year in 2025 merely because of the demographic changes. In most countries rates are usually higher in men than in women and in both genders stroke rates increase exponentially with age (Truelsen et al., 2006). Countries in Eastern Europe, North Asia, Central Africa, and the South Pacific have the highest stroke mortality and stroke burden (Johnston, Mendis, & Mathers, 2009).

In Italy the prevalence of stroke in elderly population (age above 65 years) is about 6.5%, with a higher incidence in men (7.4%) than in women (5.9%) (www.spread.it). The mean age at stroke onset is 74.6±1.1 years, and is higher in women (76.6 years) than in men (72.3 years) (Sacco, Stracci, Cerone, Ricci, & Carolei, 2011). Stroke is a major cause of long-term disability, with 20% of survivors requiring institutional care after 3 months and 15% to 30% being permanently disabled (Goldstein et al., 2011). Around half of all stroke survivors do not recover completely and half of them will need support in activities of daily living (Truelsen et al., 2006), with direct repercussions for patients, families, and health services. Because of the long-term care, rehabilitation, nursing, and lost production, stroke is a disease which is determining an increasing socioeconomic burden in aging populations (Sacco, Marini, Sucapane, & Carolei, 2006; Truelsen et al., 2006). Data from 2010 revealed that the estimated cost of stroke was $73.7 billion, including direct and indirect costs, with a mean lifetime cost estimated at $140 048 (Goldstein et al., 2011).

1.2 Risk factors

A large amount of strokes are preventable through population-wide control of modifiable risk factors (Mendis, 2013). Evidence obtained from large epidemiological studies has revealed that the risk factors for stroke were similar in different parts of the world. The knowledge of risk factors helps healthcare providers to be able to estimate a person’s risk for a first stroke, since effective prevention remains the best approach for reducing the burden of stroke. Risk factors (directly increase disease probability or, if absent or removed, reduce disease probability) or risk markers (attribute or exposure associated with increased probability of disease, but relationship is not necessarily causal) for a first stroke have been classified as nonmodifiable, well-documented and modifiable, or less well-documented or potentially modifiable (Goldstein et al., 2006).

1.2.1 *Nonmodifiable risk factors*

- Age: the risk of stroke increases with the age and the risk of ischemic and hemorrhagic stroke doubles for each successive decade after age 55.
- Sex: stroke is more prevalent in men than in women. Anyway, use of oral contraceptives and pregnancy contribute to the increased risk of stroke in young women.
- Low birth weight: stroke mortality rates are higher among people with lower birth weights.
- Race/ethnicity: Blacks and some Hispanic/Latino Americans have a higher incidence of all stroke types and higher mortality rates compared with whites.
- Genetic factors: a positive family history of stroke augments risk of stroke by around 30%. The increased risk of stroke due to a positive family history could be mediated through different mechanisms, including genetic heritability of stroke risk factors, heritage of susceptibility to the effects of such risk factors, familial sharing of environmental and health behaviors, and interaction between genetic and environmental factors (Golstein et al., 2006).

1.2.2 *Well-documented and modifiable risk factors*

For well-documented and modifiable risk factors there is clear, supportive epidemiological evidence and, in addition, there are randomized trials demonstrating evidence of risk reduction with modification (Goldstein et al., 2011).

1.2.2.1 Medical factors

- Hypertension
- Diabetes:
- Atrial fibrillation and certain other cardiac conditions
- Dyslipidemia
- Carotid artery
- Stenosis, sickle cell disease
- Postmenopausal hormone therapy
- Obesity and body fat distribuition

1.2.2.2 Health behaviors

1.2.2.2.1 Cigarette smoking

Tobacco use is the second-leading cause of total deaths and disability (Mozaffarian et al., 2015). Several studies (Manolio, Kronmal, Burke, O'Leary, & Price, 1996; Rodriguez et al., 2002; Wolf, D'Agostino, Belanger, & Kanne, 1991), including a meta-analysis of thirty-two studies (Shinton & Beevers, 1989), provided evidence that cigarette smoking is a potent risk factor for ischemic stroke: for smokers the risk for ischemic stroke is approximately doubled, accounting for other risk factors. A dose response between the number of cigarettes smoked and relative risk was noted, and there was a small increased risk in women compared with men (Shinton & Beevers, 1989). Smoking is related to both ischemic and hemorrhagic stroke, even if data for hemorrhagic stroke are inconclusive. In the United States smoking contributes to 12% to 14% of all stroke deaths (Goldstein et al., 2011). Cigarette smoking may also contribute to strengthen the effects of other stroke risk factors, such as systolic blood pressure, vital exhaustion (unusual fatigue, irritability, and feelings of demoralization), and oral contraceptives, creating a synergic effect (Goldstein et al., 2011). Several studies (Bonita, Duncan, Truelsen, Jackson, & Beaglehole, 1999; He et al., 2008; Iribarren, Darbinian, Klatsky, & Friedman, 2004; Qureshi, Suri, Kirmani, & Divani, 2005; You, Thrift, McNeil, Davis, & Donnan, 1999; Zhang et al., 2005) show that exposure to environmental tobacco smoke (passive cigarette smoke or "secondhand" tobacco smoke) is also a substantial risk factor for stroke. In addition, several studies provide evidence for an association between smoking cessation and reduction in risk of stroke to a level that approaches but does not reach that of those who never smoked (Fagerstrom, 2002; Robbins, Manson, Lee, Satterfield, & Hennekens, 1994; Song & Cho, 2008).

1.2.2.2.2 Diet and Nutrition

A meta-analysis found a strong, inverse relationship between servings of fruits and vegetables and subsequent stroke (He, Nowson, & MacGregor, 2006). Compared with persons who consumed less than 3 servings of fruits and vegetables per day, the relative risk of ischemic stroke was less in those who consumed 3 to 5 servings per day. The dose-response relationship extends into the higher ranges of intake. The effects of several aspects of diet on stroke risk, such as excess salt intake and low potassium intake, are likely mediated through direct effects on bloody pressure (BP), as well as mechanisms that are independent of BP. The associations with a decreased risk of stroke and a low intake of animal protein, saturated fat, and cholesterol have been observed in Asian countries, but such relationships have been less evident in Western countries (Goldstein et al., 2011).

1.2.2.2.3 Physical Inactivity

Physical inactivity is associated with several adverse health effects, other than to the increasing risk of stroke. Persons practicing physical activity have a 25% to 30% lower risk of stroke or death than people with sedentary lifestyle. The association between amount or intensity of physical activity and stroke risk is unclear, but it seems that women benefit more of greater intensity than men. Physical activity may be a protective factor partly because of its role in reducing BP and controlling other risk factors, such as diabetes and overweight. In addition, other biological mechanisms have also been related with physical activity, including a decrease in plasma fibrinogen and platelet activity and an increase in plasma tissue plasminogen activator activity and HDL-cholesterol concentrations (Goldstein et al., 2011).

1.2.2.2.4 Obesity and Body Fat Distribution

A large number of prospective studies have examined the relationship between weight (or measures of adiposity) and incident of stroke. The body mass index [BMI = body weight (in kg) divided by the stature (height, in meters) squared] is the traditional classification of weight status. A BMI between 18.5 and 24.9 is considered normal, a value between 25 and 29.9 is indicative of overweight and a BMI $\geq$30 is indicative of obesity. BMI is highly correlated with waist circumference and other measures of adiposity and several studies have found a direct relationship of BMI with stroke, even when accounting for other cardiovascular risk factors (BP, blood lipids, and diabetes/insulin resistance). A meta-analysis (Prospective Studies Collaboration et al., 2009) showed a nonlinear relationship between BMI and mortality. In the BMI range of 25 to 50 kg/m2, each 5 kg/m2 augment in BMI was related to a 40% increased risk of stroke mortality; in the lower BMI range (15 to 25 kg/m2), there was no association between BMI and stroke mortality, even after excluding smokers. The direct relationship of BMI with stroke frequently was kept in multivariable analyses taking into account other cardiovascular risk factors (BP, blood lipids, and diabetes/insulin resistance). No clinical trial exploring the effects of weight loss on stroke outcomes are present in the literature, anyway weight reduction may decrease stroke risk through the effect on BP (Goldstein et al., 2011).

1.2.3 *Less well-documented or potentially modifiable risk factors*

For less well-documented or potentially modifiable risk factors, the epidemiological evidence is less clear or there is a lack of randomized trials that show decrease of stroke risk with modification (Goldstein et al., 2011).

1.2.3.1 Medical factors

- metabolic syndrome
- use of oral contraceptives
- sleep-disordered breathing
- migraine
- hyperhomocysteinemia
- elevated lipoprotein(a)
- hypercoagulability
- inflammation and infection

1.2.3.2 Health behaviors

1.2.3.2.1 Excessive alcohol consumption

There is strong evidence that excessive consumption of alcohol is a risk factor for all stroke subtypes. Most studies identified a j-shaped association between alcohol use and the risk of total and ischemic stroke: a lower risk was found in light or moderate drinkers (particularly wine consumers) and an elevated risk in heavy drinkers. Anyway, what constitutes ‘moderate’ depends on age, sex, genetic characteristics, coexisting illnesses and other factors, and its benefit on health consequences is uncertain (Tomba, 2012). A linear association was found between alcohol consumption and risk of hemorrhagic stroke. These associations are due to the fact that light to moderate alcohol consumption is associated with superior levels of HDL cholesterol, reduced platelet aggregation, inferior fibrinogen concentrations, and increased insulin sensitivity and glucose metabolism. Heavy alcohol consumption can produce hypertension, hypercoagulability, reduced cerebral blood flow, and increased risk of atrial fibrillation. There are no data demonstrating that the reduction of heavy alcohol consumption decreases risk or that light alcohol consumption is beneficial (Goldstein et al., 2011).

1.2.3.2.2 Drug abuse

Drugs of abuse, including cocaine, amphetamines, and heroin, are associated with increased risk of both ischemic and hemorrhagic stroke. There are no data on the independent risk of stroke associated with specific drugs of abuse and controlled trials demonstrating a reduction in stroke risk with abstinence are lacking (Goldstein et al., 2011).

1.2.4 *Psychosocial risk factors*

1.2.4.1 Depression

Depression is a common condition after stroke but it has been identified as a risk factor for cardiovascular disease and, more recently, for stroke (Williams, 2005). A meta-analysis (Pan, Sun, Okereke, Rexrode, & Hu, 2011) on 28 prospective cohort studies reported a positive association between depression symptoms and risk of stroke, with pooled adjusted Hazard Ratio (HRs) of 1.45 (95% CI: 1.29-1.63), 1.55 (95% CI: 1.25-1.93) and 1.25 (95% CI: 1.11-1.40) for total stroke, fatal stroke and ischemic stroke, respectively. Depression has been linked, other than to increased stroke risk, also to increased stroke mortality (Williams, 2005). A Danish study (Nilsson & Kessing, 2004) demonstrated that stroke risk was increased 22% in older patients previously hospitalized for depressive disorder but not in those hospitalized for mania/bipolar disorder. These data indicate that the increase in stroke risk is specifically related to depression and not to other mental health disorders. The link between depressive symptoms and increased stroke risk is complex and involves biological, psychological, and behavioral factors. On one hand, vascular-specific mechanisms may be involved, such as serotonin-mediated effects on platelets and increased inflammation (interleukin [IL]-6 and IL-1 b influence depression risk and also stroke risk, possibly via enhanced atherosclerosis), but further studies should clarify this relation (Williams, 2005). In addition, behavioral factors and unhealthy lifestyles frequently adopted by depressed patients, such as impaired self-management, limited physical activity, unhealthy diet, smoking, impaired social roles and relationships, less collaborative care with providers, may play a key role in the relationship between depression and vascular disease. Some concern has been raised as to whether these results are related to depression itself or to the use of antidepressant drugs (Bansil, George, Kuklina, & Tong, 2012). Some studies have reported that antidepressant treatment did not modify the association between depressive symptoms and the increased risk of stroke/transient ischemic attack among men and women (Liebetrau, Steen, & Skoog, 2008; Salaycik et al., 2007). On the contrary, the data from a study on postmenopausal women (Smoller et al., 2009), found that antidepressant medication, particularly selective serotonin reuptake inhibitors, augments the risk of stroke by almost 45%.

1.2.4.2 Psychological distress

Only a small amount of studies have investigated the relationship between other psychiatric conditions, such as anxiety disorders, and risk of stroke. Chen, Hu, Lee, & Lin (2010) identified Panic Disorder as an independent risk factor for subsequent stroke diagnosis, after adjusting for patients' sex, age, monthly income, level of urbanization, and comorbid medical disorders. Other studies focused attention on the broad concept of psychological distress which includes a large range of negative emotions such as anxiety, stress, tenseness, and frustration (Hamer, Molloy, & Stamatakis, 2008). Surtees et al. (2008) found that increased psychological distress, measured by a five-item version of the Mental Health Inventory (MHI-5), with one or more items representing anxiety, depression, loss of behavioral/emotional control, and psychological well-being, is associated with elevated stroke risk, while episodic major depressive disorder, as defined by diagnostic criteria of the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV; American Psychiatric Association, 2000), was not associated with incident stroke in this study. In addition, in another study using the General Health Questionnaire (GHQ), Authors found that middle-aged men (45-59 years) who showed greater psychological distress had a higher risk of fatal ischemic stroke (45%), but not nonfatal stroke or transient ischemic attack (May et al., 2002). Other evidence shows that self-perceived psychological stress during the last year or longer, described as feeling tense, irritable, anxious, or as having sleeping difficulties as a result of conditions at home or at work, was associated with higher risk of stroke (Jood, Redfors, Rosengren, Blomstrand, & Jern 2009). Occupational stress associated with job strain, as well, has been found to be associated to a twofold increased risk of stroke (Tsutsumi, Kayaba, Kario, & Ishikawa, 2009). In a systematic review of 26 studies, a significant association between ischemic stroke and alcohol abuse within the preceding 24 hours or within the previous week, anger, heavy eating, negative or positive emotions, sudden posture change in response to a startling event, birthday, and psychological distress (Guiraud, Amor, Mas, & Touze, 2010).

1.2.4.3 Psychological well-being

Besides research examining the unfavorable impact of negative psychological states on health outcomes, recently researchers have started investigating how positive psychological characteristics, such as positive emotional states and psychological well-being, protect against disease and foster healthy behaviors and longevity. Ryff and Singer (1998) proposed the concept of ‘positive human health’, which refers to a comprehensive – holistic consideration of health, where stressors but also positive resources are taken into account. Accordingly, health is maintained by good health habits (i.e. good nutrition, regular physical activity, no smoking, etc.) and by the presence of emotional and psychological well-being (Rafanelli & Ruini, 2012). Studies examining the association between psychological well-being and stroke are scarce. Recently Kim, Sun, Park, & Peterson (2013) examined the relationship between purpose in life and stroke in a nationally representative sample of American adults over the age of 50. Purpose was assessed using a seven-item questionnaire adapted from the Psychological Well-Being Scales (Ryff & Keyes, 1995) and results showed that higher purpose in life was associated with a reduced likelihood of stroke, even after adjusting for several additional covariates including health behaviors, biological, and psychological factors.

1.3 Inpatient Rehabilitation after stroke

An early start of intensive treatment is an important aspect in stroke care and receiving treatment in a dedicated stroke inpatient unit, with specialist staff and services specifically for stroke is associated with reduction in the odds of death or dependency and the need of institutionalization. Early mobilization is associated with improved outcome: stroke patients should be admitted to stroke rehabilitation units as soon as they are medical stable (Teasel et al., 2009). Stroke rehabilitation is a multidimensional process, which is aimed to facilitate restoration of, or adaptation to the loss of, physiological or psychological function when reversal of the underlying pathological process is incomplete. Rehabilitation is designed to improve functional activities and participation in society in order to attain the best possible quality of life. Measuring the progress of recovery is a vital part of the inpatient rehabilitation process. This requires reliable instruments for measuring functional independence, which is the patient's ability to perform daily living activities and effectively, and the cognitive and motor gain obtained after the rehabilitation process. The National Institute for Health and Care Excellence (NICE) underlines that "key aspects of rehabilitation care include multidisciplinary assessment, identification of functional difficulties and their measurement, treatment planning through goal setting, delivery of interventions which may either effect change or support the person in managing persisting change, and evaluation of effectiveness" (NICE Clinical Guideline, 2013). There is strong evidence that greater intensity of therapy results in improved functional outcomes over the short term (4 weeks to 6 months). Younger age has been associated with significantly better stroke recovery (Carod-Artal, Medeiros, Horan, & Braga, 2005; Somerford, Lee, & Yau, 2004). Studies have also showed that extended time delay between onset of stroke and admission to rehabilitation has a negative impact on stroke recovery (Carod-Artal et al., 2005), while there is some divergence in the literature about the influence of the length of stay on recovery outcome in inpatient rehabilitation (Wong, 2011). Social support was associated with faster and more extensive recovery of functional status after stroke (Glass et al., 2000).

Most of the studies found that positive benefits from rehabilitation were not maintained consistently over time. There is strong evidence that functional gains attained through rehabilitation are maintained or improve for up to 1 year. There is also moderate evidence that these same functional outcomes worsen after 5 years (Teasel et al., 2009). In addition, despite the proven benefits of occupational and physical therapies, there is still a subset of patients reporting significant level of functional disability even after a complete physical restoration and relatively little is known about factors that predict the success or failure of rehabilitative care (Palmer & Glass, 2003).

1.4 Psychological complications after stroke

1.4.1 *Depression*

1.4.1.1 Controversies Related to the Diagnosis of Poststroke Depression

Poststroke depression (PSD) is the most common neuropsychiatric consequence of stroke. Nonetheless there is a variation in the prevalence rates found in different studies which is influenced by the type of diagnostic criteria and evaluation instruments used (self-reported vs clinician interview). The commonly accepted standard to formulate a diagnosis of PSD is using structured mental status interviews and defined diagnostic criteria (i.e., DSM-IV), but only few studies have used it (Ayerbe, Ayis, Wolfe, & Rudd, 2013; Robinson, 2003). There is also a debate between the investigators of depression associated with physical illness around the most appropriate method for the diagnosis of depression when some symptoms (e.g., sleep or appetite disturbance) could result from the physical illness (Cohen-Cole and Stoudemire 1987). Four approaches have been considered in to assess depression in medically ill patients: the inclusive approach in which depressive diagnostic symptoms are taken into account regardless of whether they may be related to medical illness (Rifkin et al., 1985); the etiologic approach in which a symptom is counted only if the clinician assumes that it is not the result of the medical illness (Rapp & Vrana, 1989); the substitutive approach in which other psychological symptoms of depression replace the vegetative symptoms (Endicott, 1984); the exclusive approach in which symptoms are eliminated from the diagnostic criteria if they may be a direct physiological consequences of the medical illness or of the medications used to treat it (Bukberg et al., 1984). Two studies have evaluated the utility of those approaches in stroke patients (Federoff et al., 1991; Paradiso et al., 1997). Federoff et al. (1991) studied the effect of using each of the proposed alternative diagnostic methods for poststroke depression using DSM-IV criteria, concluding that the inclusive approach, that means to count symptoms reported by the patients even if there is some doubt that the symptom may be related to the physical illness, has a positive predictive value (88%), specificity (98%), and sensitivity (100%). In this study, during the in-hospital evaluation, 27 patients (18%) met DSM-IV diagnostic criteria for major depression. Using the exclusive approach, excluding for example weight loss and early-morning awakening from DSM-IV diagnostic criteria, of 27 patients with major depression, based on inclusive criteria, only three were excluded. Adapting DSM-IV criteria in acute medical illness setting is therefore probably avoidable (Robinson, 2003). Anyway, research comparing stroke patients with depression with patients with major depression (MD) with no clinical comorbidity found that depressed stroke patients had less compromised mood, suicidal thoughts and anhedonia (Gainotti, Azzoni, & Marra,1999) and less loss of pleasure and lack of interest (da Rocha e Silva et al., 2013) than patients with MD.

1.4.1.2 Prevalence

Pooled data from research performed throughout the world have registered prevalence rates of 19.3% for major depression and 18.5% for minor depression among hospitalized patients and respectively 14.1% and 9.1% among patient in community settings (Robinson, 2003). The prevalence rates for major depression in stroke patients are significantly higher compared to the general population (a 12-month prevalence around 10% to 12%; Natl. Inst. Ment. Health 2012), while are about the same as patients with heart failure (18%–20%) (Whooley & Wong, 2013), other neurologic disorders such as traumatic brain injury (26%; Fedoroff et al 1992) or Parkinson's disease (21%; Starkstein et al 1990). Longitudinal data are scarce. In a meta-analysis of 50 studies, only 8 studies reported the prevalence of depression more than 1 year after stroke, and only 13 studies assessed patients at more than one time point (Ayerbe et al., 2013). The pooled prevalence of depression observed at any time point was 29%, with a prevalence of 28% within a month of stroke, 31% at 1–6 months, 33% at 6 months to 1 year, and 25% at more than 1 year. The pooled prevalence of depression at any time point in population studies was 22% and in hospital or rehabilitation studies 30%. All the longitudinal studies presented a dynamic natural history, with new cases and recovery of depression occurring over time. The proportion of patients recovered from depression in subsequent assessments, and new cases made the overall prevalence of depression stable (Ayerbe et al., 2013). The stability of the prevalence of depression across studies assessing patients at different time points was reported in a previous systematic review (Hackett, Yapa, Parag, & Anderson, 2005) as well. Anyway conflict findings on depressive symptoms over time have been reported, showing little or no change, a decrease over time or an increase (King, Shade-Zeldow, Carlson, Feldman, & Philip, 2002).

1.4.1.3 Pathogenesis

In several studies poststroke depression has been related with left anterior lesion location (Astrom et al 1993; Herrmann and Walesch 1993; Morris et al 1996; Robinson et al 1984; Vataja et al 2001). Anyway a systematic review (Carson et al., 2000) and a subsequent study failed to find a significant association (Gainotti et al., 2001).

1.4.2 *Bipolar Disorder*

There are few empirical studies investigating the onset of bipolar disorder after stroke. Findings from these studies suggest that mania is more likely associated with right hemisphere lesion and subcortical atrophy (Robson, 2003).

1.4.3 *Demoralization*

Demoralization, as a distinct clinical phenomena from depression, characterized by helplessness, hopelessness, giving up and subjective incompetence, emerged in the literature as a highly prevalent syndrome in medical settings (Tecuta, Tomba, Grandi & Fava, 2014). Demoralization, as defined by the DCPR (Fava et al., 1995), was found in subjects with essential hypertension (Rafanelli et al., 2012), a condition common in stroke patients, but it has not yet been investigated in stroke survivors.

1.4.4 *Anxiety disorders*

Anxiety has received substantially less attention relative to other psychological problems that occur after stroke. A meta-analysis (Campbell Burton et al.,2013) indicated that the overall pooled estimate of anxiety disorders assessed by clinical interview was 18% (95% confidence interval 8–29%, I^2= 97%), while the overall frequency of anxiety ‘caseness’ when assessed by rating scale was 25% (95% confidence interval 21–28%, I^2 = 90%). Of the 44 studies included in the review, in 8 clinical diagnoses of anxiety disorders were made in according to DSM criteria (different version) and the others used standardized scales. There was a nonsignificant increase in the prevalence of anxiety over time, with a overall frequency of 20% (95% confidence interval 13–27%, I^2 = 96%) in the acute phase; 23% (95% confidence interval 19–27%, I^2 = 84%) one to five-months after stroke; and 24% (95% confidence interval 19–29%, $I^2 = 89\%$) six-months or more after stroke. Studies that measured different anxiety types found that phobic disorders and GAD were the most common (Sharpe et al., 1990; Burvill et al., 1995; Sagen et al., 2010) and a large number of studies reported comorbidity of anxiety and depression (17–80% of cases) (Campbell Burton et al., 2013). In addition, approximately one-third of patients with poststroke anxiety had a history of prestroke mood or anxiety disorder (Burvill et al., 1995; Leppavuori, Pohjasvaara, Vataja, Kaste, & Erkinjuntti, 2003; Sembi, Tarrier, O'Neill, Burns, & Faragher, 1998). Controlled studies found no difference in anxiety prevalence rates between stroke and nonstroke patients (Burvill et al., 1995; House et al., 1992). Anyway, considering the association with gender, there was a significant difference between female stroke survivors and female controls: in stroke survivors sample 19% of women reported an anxiety disorder, while in community controls 8% of women did. Several studies did not find significant associations between age and anxiety (Campbell Burton, 2013).

1.4.5 *Sexual dysfunctions*

There is a scarcity of research regarding sexual functioning and satisfaction in stroke survivors. Approximately 68% of patients, both male and female, reported decreased activity, and 32% reported a cessation of sexual activity (Sjogren & Fugl-Meyer, 2000). In addition, 42–70% of patients evidenced a decrease of sexual satisfaction post-stroke (Korpelainen, Kauhanen, Kemola, Malinen, & Myllyla, 1998; Kimura, Murata, Shimoda, & Robinson, 2001; Monga, Lawson, & Inglis, 1986), with greater dissatisfaction reported in males than in females and in patients than partners (Korpelainen, Nieminen, & Myllyla, 1999). Post-stroke erectile disorder (ED) was more prevalent among patients with diabetes mellitus and left hemisphere lesion in comparison with patients without diabetes and right hemisphere lesion. Anyway the latter data was not confirmed by other studies (Rosenbaum, Vadas, & Kalichman, 2014).

1.4.6 *Psychotic symptoms*

Two studies identified that only 0.4% and 3.1% of stroke patients had a psychotic disorder and the median time to onset of symptoms was of 6.1 months after stroke. Single psychotic symptoms that do not fulfill criteria for a psychotic disorder seem more common (Hackett, Köhler, O'Brien, & Mead, 2014).

1.4.7 *Abnormal Illness Behavior*

Clark & Smith (1999) found that some stroke survivors are at risk of abnormal illness behavior (AIB), which occurs when the patient maintains illness behavior which is disproportionate to the objective pathology with an inappropriate persistence in the sick role. In this study the percentage of AIB cases increased from admission to hospital (8.3%) to discharge (21.7%), remaining stable at six and twelve months.

1.4.8 *Irritability*

An increase in irritability after stroke has been documented in literature as well. Prevalence estimates for irritability vary from 12% to 53% of patients after stroke (Buijck, Zuidema, Spruit-van Eijk, Geurts, & Koopmans 2012; van Almenkerk, Depla, Smalbrugge, Eefsting, & Hertogh, 2012). Irritability was more frequent than depressive symptoms or apathy (van Almenkerk et al. 2012) and it improved with time (Skånér, Nilsson, Sundquist, Hassler, & Krakau et al., 2007).

1.4.9 *Psychological distress and outcomes after stroke*

An association of poststroke depression (PSD) and increased physical disability, cognitive impairment (House, Dennis, Warlow, Hawton, Molyneaux et al., 1990; Kauhanen et al., 1999; Spalletta et al., 2002), mortality rate (Teasell et al., 2009) and worse rehabilitation outcomes has been found in several investigations. Depression also has a negative effect on social functioning and the quality of life of patients. Findings regarding the relationship between anxiety and clinical outcomes are mixed, with studies reporting a significant negative correlation with activities of daily living and studies finding no association (Campbell Burton et al., 2012). Abnormal illness behavior (AIB) was found to be a strong predictor of functional competence and performance at rehabilitation discharge and both six and twelve months later (Clark & Smith, 1999b).

1.5 Effects of caregiving

The need to reduce the cost of care has provoked several changes in health care systems, including the tendency to promote early discharge of patients. As a result, there is an increasing demand on patients’ family members who have become largely responsible for the management of long-term care and treatment of the patients (Langhorne & Duncan, 2001). Stroke is one of the principal causes of significant long-term disability, with a greater part of patients needing the support of a family caregiver to help them manage physical and cognitive dysfunction (Saban et al., 2010). About 80% of stroke survivors go home after hospital discharge and live for as a minimum of 5 years after the occurrence of the illness (Rosamond et al., 2007). Functional limitations and cognitive impairments subsequent stroke may be permanent and require lifelong caregiver assistance (Saban et al., 2010). A family caregiver can be defined as a relative (partner, adult children, parent or other) who offers assistance to an adult with a chronic or disabling illness such as stroke. This term is generally utilized in the literature to represent family or informal (unpaid) caregivers (Bakas et al., 2014). Providing help to an ill family member is stressful and caregivers frequently experience diverse interrelated individual, interpersonal, and organizational problems in managing stroke-related deficits (Grant et al., 2014). Family caregiver stress is frequently associated with long-term institutionalization of patients, with consequent significant costs to the healthcare system (Bakas et al., 2014; Gaugler, Duval, Anderson, & Kane, 2007; Han & Haley, 1999). Research reports that caregivers feel unsure and unqualified in the caregiving role (Foster et al., 2013). Caregiver distress negatively impact rehabilitation outcomes of patients (Bakas et al., 2014; Han & Haley, 1999) and may lead to social isolation, decrease in quality of life, poorer physical health, and increased risk of mortality for the caregivers (Schulz & Beach, 1999; Teasel et al., 2009). Depression is particularly prevalent in stroke family caregivers (Anderson et al., 1995; Berg et al., 2005; Han & Haley, 1999), with some research reporting higher depression rates in the caregivers than in the survivors for whom they provide care. Prevalence of depression ranged from as low as 34% (Schulz, Tompkins, & Rau, 1988) to as high as 40% to 52% (Anderson, Linto, & Stewart-Wynne, 1995; Draper, Poulos, Cole, Poulos, & Ehrlich, 1992; Silliman, Fletcher, Earp, & Wagner, 1986). Little is known of the changes occurring in caregiver depression and the factors associated with it. Follow-up studies of caregiver depression are rare. Berg et al. (2004) reported that depressive symptoms tend to persist over time. In their study Berg et al. found that 33% during the acute phase and 30% during the follow-up (at 6 and 18 months) of caregivers of patients experiencing their first ischemic stroke showed depressive symptoms, as measured by the Beck Depression Inventory-BDI (Beck et al., 1961). A systematic review (Gaugler,

2010) highlighted that stress, depression, and subjective health measures did not tend to display significant change in longitudinal quantitative studies, although some studies showed increases and/or decreases in distress over time. Investigations of anxiety disorders in caregivers have been more neglected. The few studies available report a high percentage of anxiety symptoms (37-58%) (Beach et al., 2000; Dennis et al., 1998; Wilz & Kalytta, 2008). Wilz and Kalytta (2008) found similar prevalence rates and mean scores of self-rated anxiety symptoms (using the Beck Anxiety Inventory-BAI; Beck et al., 1988) in partners of stroke survivors during patients' admission for rehabilitation and 1 year later.

1.5.1 *Variables associated with caregivers' depression and anxiety*

Several studies examined the association between caregiving outcomes and demographic characteristics of stroke caregivers, including the caregiver's age, income, caregiving duration, and spousal or other relationship with the patient (Han & Haley, 1999). No significant relationship with age was found in two studies (Draper, Poulos, Cole, Poulos, & Ehrlich, 1992; Ross, & Morris, 1988), but in a third one (Schulz, Tompkins, & Rau, 1988) the time interval was critical for the association, because older caregivers were less likely to have depression at 6 to 9 months after stroke but not at 3 to 10 weeks after stroke. No associations with depression have found between caregivers income and caregiving duration (Han & Haley, 1999). However, a study found that caregivers who had higher income were less likely to be depressed at 6 to 9 months after stroke (Shultz et al., 1988). Spouses tended to be more depressed than other caregivers during the acute care phase (Berg et al., 2004), but not during the chronic phase (Han & Haley, 1999). Caregivers' depression has found to be related to patients' greater physical dependency and disability in the acute phase (Anderson et al., 1995; Berg et al., 2004), but not in the chronic phase (Han & Haley, 1999). Stroke survivors' depression (Dennis et al., 1998) and older age (Berg et al., 2004) were also positively associated with caregivers' depression. Of caregiver-related factors, the physical health of the caregiver (Carnwath & Johnson, 1987; Grant, Bartolucci, Elliot, & Giger , 2000; Hodgson, Wood, & Langton-Hewer, 1996), perceived control over the emotions when solving problems (Grant, Elliott, Giger, & Bartolucci, 2001), and availability of social support (Carnwath & Johnson, 1987; Grant et al., 2000) were related to caregiver well-being. Studies examining the relationship between caregivers' anxiety and gender and anxiety and patient's disability were inconsistent. Women scored higher than men on anxiety symptoms at a 6-month follow-up in the study by Dennis et al. (1998) and in that of Wilz and Kalytta (2008). In contrast, the study by Beach et al. (2000) reported no gender differences. An association was found between spouses’ anxiety symptoms and patients’ perceived disability at one year after stroke in Wilz & Kalytta, (2008)' study, while no associations between caregivers' anxiety and patient's degree of disability, cognitive impairment were reported in other studies (Anderson et al., 1995; Dennis et al., 1998; Smith et al., 2004).

1.6 Stroke and family functioning

A large body of research has documented the impact of a family’s functioning on health outcomes, highlighting the importance of introducing the evaluation of patients’ family functioning into clinical judgment (Staccini, Tomba, Grandi & Keitner, 2014). The term “family functioning” refers to the ability of the family to work together as a unit to satisfy the basic needs of its members; it can include capacity to fulfill a function, ability to adapt or capacity to accomplish usual daily activities (Ryan & Keitner, 2009). This concept originates from a family-systems perspective which assumes that the patient and family members are part of a complex integrated system with preexisting styles of communication, roles, patterns of relations and rules. The advent of stroke in a family member may deeply challenge these preexisting patterns and norms which characterized the family system (Palmer & Glass, 2003). Stroke has an acute onset that requires the family more rapid affective and instrumental changes compared to gradual-onset diseases, which, on the contrary, allows for a more protracted period of adjustment (Rolland, 1987). Several studies explored family functioning after stroke. The most widely empirical method of evaluation of family functioning has been with the use of the Family Assessment Device (FAD; Epstein & Bishop,1983), a self-report questionnaire that assesses the six dimensions of the McMaster Model of Family Functioning: problem solving, communication, roles, affective responsiveness, affective involvement and behavior control (see *Table* 1 for a detailed description of the dimensions), and overall level of general family functioning. In Bishop, Epstein, Keitner, Miller & Srinivas (1986)' research, stroke patients and their spouses reported healthy scores on all FAD subscales and did not show significant differences with a control group composed by normal elderly couples. During the acute phase, general family functioning was assessed as healthy, according to cut-off points published by Miller et al. (1985), in 63%-70% of caregivers (Epstein-Lubow, Beevers, Bishop & Miller, 2009; King, Hartke & Houle, 2010). Caregiver overall reported significantly healthier general family functioning than was reported by stroke survivors (Epstein-Lubow et al., 2009). Several reports showed a decreased level of family functioning over time in stroke survivors and their family members (King and colleagues; 2001; 2002). Clark & Smith (1999a) reported significant deterioration in stroke survivors and their spouses, but not in other family members' perception of family functioning, as showed by an evaluation at the time of admission to and discharge from rehabilitation hospital, and after 6 and 12 months after discharge. In this study family members were divided into two groups: spouses of patients and other family members. Deterioration was observed by patients in communication, roles, and general family functioning FAD scales. Similarly, the ratings of spouses suggested deterioration in communication and roles, while there was an improvement in behavior control. The ratings provided by other family members indicated an improvement in roles, affective responsiveness, affective involvement, and behavior control. Evans, Bishop, Matlock, Stranahan & Noonan (1987) reported that traditional *stroke*-outcome predictors, such as age, time since onset, dysphasia, ability for self-care, perceptual neglect, emotional problems, anasognosia, labilty, indifference, and mental status did not significantly contribute in accounting for variance in caregivers' perception of family functioning after at least four months and up to 2 years since stroke onset.

1.6.1 *The impact of family functioning on outcomes in stroke patients*

Successful recommencement of activities of daily living after stroke are also largely dependent on instrumental and emotional support, the majority of which comes from family members. Longitudinal studies indicated that ineffective family functioning is related to negative stroke outcomes. In Clark and Smith (1999b) longitudinal study, superior family functioning predicted better performance in activities of daily living (ADL) and a more active lifestyle at six and twelve months after discharge from rehabilitation program. In the current study global family functioning was a stronger predictor of stroke survivors' ADL performance than the presence of abnormal illness behavior. In particular family functioning influenced not the activities the patient is capable of carrying out (ADL competence), but those that the patient actually does (ADL performance).

Pre-stroke family functioning, evaluated by asking the caregivers to rate FAD items based on how family was perceived during the three months before the stroke, has been shown to be a better predictor of hospital readmission during the year after stroke than typical stroke outcome predictors, such as age, self-care ability and mood (Evans et al., 1987b). Better affective responsiveness was a significant predictor of reduced re-hospitalization time at both six months and one year, while better behavior control was related to more days in hospital at both six months and one year. In the same research, better problem solving and communication significantly predicted, together with patient self-care ability, better family-rated patient adjustment at six months and one year (Evans et al., 1987b). Caregivers' better perception of family functioning five months after patient discharge from a stroke care unit was significantly related to treatment adherence (Evans et al., 1987c). Good adherence to treatment showed a strong and significant relationship with affective involvement, problem solving, communication, and general family functioning. Caregiver’s and patient’s perception of effective family functioning was related to successful home care (Evans, Bishop & Haselkorn, 1991) and greater patient satisfaction with rehabilitation after stroke (Clark & Smith, 1998). Poorer family functioning was related to a more severe level of patients' depression at two year after stroke onset (King et al., 2002).

1.6.2 *The impact of family functioning on outcomes in caregivers of stroke patients*

Few studies examined the relationship between family functioning and caregivers' characteristics and outcomes. In King et al. (2010)' study the perception of family functioning during stroke survivors' hospitalization was related to caregivers' race and type of relationship with patients. In particular, nonwhite and spousal caregivers reported less healthy family functioning. Worse general family functioning has been significantly associated to caregivers' higher unmet needs (King et al., 2010), poorer mental health (Clark et al., 2004) and greater depression (King et al., 2001; Epstein-Lubow et al., 2009).

Table 1. Dimensions of the Mcmaster Model of Family Functioning (Keitner, 2012)

PROBLEM SOLVING (PS)
Problem solving refers to the family's ability to resolve issues so that effective functioning in the family is maintained. A family problem is an issue which threatens the integrity and functional capacity of the family, and which the family has difficulty solving. Family problems are divided into two types: instrumental and affective. Instrumental problems refer to problems of everyday life, such as managing money and obtaining food. Affective problems concern issues of emotion or feeling. Effective families solve most problems efficiently and relatively easily, through various stages of problem solving including identifying a problem, communicating about it with an appropriate person, developing alternatives, deciding on an alternative, acting on that decision and evaluating the process at its conclusion.
COMMUNICATION (CM)
Communication is defined as the way in which the verbal exchange of information occurs within a family. Communication can be affective or instrumental and can be described as clear or masked and direct or indirect. The clear versus masked continuum focuses on whether the content of the message is clearly stated or camouflaged or vague. The direct versus indirect continuum focuses on whether messages go through the appropriate individuals or tend to be deflected to other people. Healthy families tend to communicate in a clear and direct manner in both instrumental and affective areas. In well functioning families, family members feel free to discuss issues with each other, are respectful of differences of opinion, address each other directly, and express their feelings to each other without fear of retribution or misunderstanding.
ROLES (RL)
Role are repetitive patterns of behavior through which family members carry out their family functions, including provision of resources, nurturance and support, sexual gratification, personal development and maintenance and management of the family system. A healthy family is characterized by adequately fulfilled functions, clear allocation, and accountability in place. In an unhealthy family one or more family members are overburdened with family tasks, and accountability and role functions are unclear.
AFFECTIVE RESPONSIVENESS (AR)
Affective responsiveness refers to the capacity of the members to respond to the full spectrum of feelings experienced in emotional life and to the appropriateness of the emotion experienced to the context. This dimension assesses an individual's capacity to a greater extent than do the other family dimensions. It refers to the person's capacity to experience particular kinds of emotions and it is assessed in order to determine whether family members tend to be overcome with feelings or are not sufficiently capable of experiencing them. Families with healthy affective responsiveness have members capable of expressing a full range of emotions, with both a reasonable intensity and for a reasonable duration.
AFFECTIVE INVOLVEMENT (AI)
Affective involvement is the extent to which the family demonstrates interest and applies value to the activities of the individual family members. There is a range of style of involvement, from a total lack of interest in each other at one end to an extreme amount of involvement at the other end. Empathic involvement, which is characterized by family members demonstrating true concern for the interests of others in the family, even though these concerns may be peripheral to their own interests, is the more effective and healthy form.
BEHAVIOR CONTROL (BC)
Behavior control refers to the way in which a family establishes rules about acceptable behaviors relating to physically dangerous situations, situations involving meeting and expressing psychobiological needs and drives, and situations involving socializing behavior between family members and people outside the family. The focus is on the standards or rules that families sets and the amount of latitude they tolerate. There are a variety of styles of behavior control, including rigid behavioral control, flexible behavior control, *laissez-faire* behavior control (where there are no standards or direction), and chaotic behavior control (where standards shift in a random and unpredictable fashion between rigid, flexible and *laissez-faire*. Family members do not know which standards apply at any one time).

2. THE CURRENT STUDY: RATIONALE, AIMS AND HYPOTHESIS

2.1 Rationale of the study

The traditional attitude toward disease and the functional/organic dichotomy were criticized by George Engel in the early sixties. With the advent of the "biopsychosocial model" and the conceptualization of a multifactorial approach of illness (Engel, 1977), it became evident that the patient's functioning as well as his illness can be viewed as a result of interacting mechanisms at cellular, tissue, organismic, interpersonal, and environmental levels. This ecological perspective pays attention to the social environment that surrounds a person's life and considers individual and psychosocial factors that may operate to facilitate, sustain or modify the course of a disease (Fava & Sonino, 2009). Tinetti and Fried (2004) suggested that the goal of treatment should be the attainment of individual goals and the identification and treatment of all modifiable biological and nonbiological factors, according to Engel's biopsychosocial model. Nowadays, psychosomatic medicine may be defined as a comprehensive, interdisciplinary framework with the following aims (Fava & Sonino, 2010):

- The assessment of psychosocial factors affecting individual vulnerability and course and outcome of any type of disease;
- An holistic consideration of patient care in clinical practice;

- The integration of psychological therapies in the prevention, treatment and rehabilitation of medical disease.

It is becoming increasingly clear that we can improve medical care by paying more attention to psychological aspects of medical assessment (Kroenke, 2002). Fava and Sonino (2009) suggested the need for specific assessment in medical setting which take in consideration a number of factors that may influence the vulnerability to and the course and outcome of a medical illness. Specific attention should be paid to the psychosocial correlates and variables of medical disease, including comorbid psychiatric disorders, psychosomatic syndromes, psychological symptoms, quality of life, chronic and acute stress, psychological well-being, and quality of interpersonal relationships and social support (Fava & Sonino, 2009).

Stroke is a leading cause of acquired disability in adults. If secular trends continue it is estimated that there will be 23 million first ever strokes in 2030 (Mathers & Loncar, 2006). Medical advances have caused a decline in stroke-related mortality and changes in healthcare management have led to patients being discharged from hospitals in a shorter time**.** As a result, an estimated 7 million stroke survivors and their families must cope with the residual problems following stroke (Roger et al., 2011). Using a multidisciplinary and integrated approach in the assessment of stroke patients, which includes the evaluation of psychosocial factors that may be significantly associated with the long-term course of the illness, is therefore strongly recommended. This becomes even more important considering that, despite the proven benefits of occupational and physical therapies, relatively little is known about factors that predict the success or failure of rehabilitative care (Palmer & Glass, 2003). Many stroke survivors, despite reaching a considerable physical recovery, do not perform at their level of functional competence. Much of this excess disability, which cannot be accounted for by age or level of impairment, may be due to psychological or social factor (Clark & Smith, 1999). In addition, the disabilities following stroke create significant burdens for caregivers, resulting in lowered quality of life, poor health, social isolation, depression and psychological distress (King et al., 2001). Even though stroke caregivers have to deal with the huge amount of physical, emotional, and financial burden, in literature are reported also positive consequences of caregiving, including satisfaction with their current life and positive feeling about their roles (Han & Haley, 1999; Teasel et al., 2009). Very little is known about the psychosocial variables associated with outcomes in caregivers. The existing literature on stroke patients and their caregivers is characterized by several limitations. First of all, there is a paucity of longitudinal research examining psychosocial adjustment after stroke and the findings regarding change over time are inconsistent: some studies indicated stability and other increases and/or decreases in psychological distress over time (Gaugler, 2010). Second, the majority of studies used self-report instruments, despite the fact that they may not have sufficient reliability in patients who are unaware of their psychological symptoms (Hadidi et al., 2009). The use of observational measures, such as semi-structured interviews, in conjunction with self-reports, would consent to have a more complete picture of patients and caregivers' symptomatology and diagnosis. Third, while the role of depression has been extensively studied both in stroke survivors and their caregivers, other psychosocial variables and correlates that have been seen to be extremely important for their negative consequences on chronic ill patients’ quality of life have been neglected. In particular, no studies examined the prevalence of psychosomatic syndromes, according to the Diagnostic Criteria of Psychosomatic Research (DCPR; Fava et al., 1995). The DCPR were proposed almost 20 years ago by an international group of investigators with the aim of translating psychosocial characteristics observed in various medical diseases in diagnostic criteria, which may entail clinical value. The DCPR have been investigated in several medical and psychiatric populations and in all clinical settings considered, the presence of one or more DCPR diagnoses predicted relevant health-related outcomes (Porcelli & Rafanelli, 2010). In addition, another topic that is still unexplored is the impact of positive psychological characteristics on stroke survivors and caregivers' outcomes. Higher purpose in life was associated with a reduced likelihood of stroke (Kim et al., 2013). Further studies are needed to examine the role of the other dimensions of the multidimensional model of psychological well-being proposed by Carol Ryff (autonomy, positive relations, environmental mastery, personal growth, and self-acceptance) (Ryff, 1989). Finally, even if the stroke outcome research literature suggests that family dynamics impact stroke recovery, there is not uniform agreement yet about what is the relative contribution of the specific aspects of family functioning on outcome, particularly in the acute rehabilitation setting. In addition, no data are available regarding the influence of family dynamics on stroke survivors and their caregivers' outcomes in the Italian setting. In light of these considerations and the identified neglected topics of current literature, a longitudinal research was conducted with the aim to explore psychosocial variables and correlates in hospitalized stroke patients and their family member caregivers. Sensitive and reliable methods were used, including clinical interviews to assess the presence of psychiatric disorders and psychosomatic syndromes, and self-rated instruments to evaluate psychological distress, psychological well-being, and family functioning.

2.2 General and specific aims

The general aim of this research is to uncover the association between psychosocial factors, medical disease onset, and rehabilitation outcome after stroke. The logic behind this study is that the identification of the psychosocial factors associated with the onset of a stroke and those related to unsuccessful outcome would help in the development of innovative prevention and treatment efforts. This research is composed by three studies.

Study 1. A study with a cross-sectional design was performed in order to explore psychosocial variables and correlates in hospitalized patients with stroke and their caregivers.

Specific aims:

1. To compare an Italian sample of hospitalized stroke patients with the general population in the following variables:
   a. lifestyle behaviors (alcohol, coffee, and drug consumption, smoking habits, and body mass index)
   b. presence of psychiatric disorders according to DSM-IV-TR criteria (American Psychiatric Association, 2000)
   c. presence of psychosomatic syndromes according to DCPR (Fava et al., 1995)
   d. the extent of self-rated psychological distress (anxiety, depression, hostility, somatic symptoms, abnormal illness behavior, acute and chronic stress, and perceived quality of life)
   e. the extent of self-rated psychological well-being according to the Ryff's theoretical model (purpose in life, autonomy, positive relations,

    environmental mastery, personal growth, and self-acceptance) (Ryff, 1989)
    f. the perception of family functioning according to the McMaster's theoretical model (roles, communication, affective involvement, affective responsiveness, behavior control, and problem solving) (Esptein et al., 1983).
2. To explore the following psychosocial variables in caregivers:
    a. lifestyles behaviors (alcohol, coffee, and drug consumption, and smoking habits)
    b. presence of psychiatric disorders according to DSM-IV-TR criteria
    c. presence of psychosomatic syndromes according to DCPR
    d. the extent of psychological distress (anxiety, depression, hostility, somatic symptoms, abnormal illness behavior, acute and chronic stress, and perceived quality of life)
    e. the extent of psychological well-being according to the Ryff's theoretical model (purpose in life, autonomy, positive relations, environmental mastery, personal growth, and self-acceptance)
    f. the quality of family functioning according to the McMaster's theoretical model (roles, communication, affective involvement, affective responsiveness, behavior control, and problem solving).
3. To explore the correlations of patients and caregivers' above mentioned psychosocial factors with:
    a. socio-demographic variables
    b. patients' functional status at hospital admission.

Study 2. A longitudinal design study was performed to explore medical and psychosocial variables' change over time for both patients and caregivers.

Specific aims:

1. to explore the longitudinal changes (from admission to, discharge from rehabilitation hospital, and six months after discharge) of stroke survivors' functional status
2. to explore the longitudinal changes (from admission to hospital to six months after discharge) of frequency of lifestyle behaviors and diagnoses (according to DSM and DCPR), and self-rated psychological distress and well-being, in both stroke survivors and their caregivers.

Study 3. A study with a longitudinal design was performed to explore change over time in the perception of family functioning of stroke survivors and their caregivers and to verify if and which dimensions of family functioning were significantly associated with outcomes of both samples.

Specific aims:

1. to explore the longitudinal changes (from admission to rehabilitation hospital to six months after discharge) of family functioning in stroke survivors and their caregivers
2. to verify if and which dimensions of patients' perceived family functioning at hospital admission are significant predictors of patients' functional recovery at the end of the rehabilitation process

2. to verify if and which dimensions of caregivers' perceived family functioning at hospital admission are significant predictors of caregivers' psychological distress at six months after discharge.

2.3 Hypothesis Study 1

Based on the available findings from the literature, the hypothesis of the study 1 were the following:

1) It was hypothesized that stroke patients would show, compared to the general population, the following results:
    a. Unhealthy life-style behaviors: higher percentages of people drinking alcohol and smoking, and higher body mass index values
    b. Greater prevalence of psychiatric disorders according to DSM-IV criteria
    c. Greater prevalence of psychosomatic syndromes according to DCPR
    d. Higher psychological distress
    e. Poorer psychological well-being
    f. No differences in family functioning compared to general population
2) It was hypothesized that caregivers of stroke patients would show the following results:
    a. Given the influence of families on health behavior pathways, unhealthy life-style behaviors were expected for caregivers as well
    b. The presence of psychiatric disorders according to DSM-IV criteria
    c. The presence of psychosomatic syndromes according to DCPR
    d. Higher psychological distress compared to normative data from nonclinical populations

   e. Given the lack of data in the literature, no hypothesis was done regarding the extent of psychological well-being
   f. Effective family functioning, according to the established healthy/unhealthy McMaster model cut-offs

3) The following significant relations were hypothesized:
   a. Regarding patients' psychological distress, it was hypothesized: no significant relationship with age and a significant relation with gender, with female reporting higher psychological distress. Given the lack of data in the literature, no hypotheses were done regarding the socio-demographic correlates of patients' psychological well-being and perceived family functioning. Regarding caregivers' psychological distress, significant relations with caregivers' gender and kind of relationship with the patient were expected, with female and partners of patients reporting higher psychological distress. Concerning the association with age, no hypotheses were done, given the inconsistent data in the literature. Regarding family functioning, we also hypothesized a significant relationship with caregivers' kind of relationship with the patient, with partners reporting worse family functioning than other family members.
   b. Significant relations between patients and caregivers' self-rated psychological distress and patients' functional status were expected, with patients with greater disability and caregivers providing care for them reporting higher psychological distress. Given the lack of data in the literature, no hypotheses were done regarding the relation between

patients' functional status and patients and caregivers' psychological well-being and perception of family functioning.

2.4 Hypothesis Study 2

Based on the available findings from the literature, the hypotheses of the study 2 were the following:

1. An improvement in patient's functional status from admission to discharge from rehabilitation hospital and stability in functional status at six-month follow-up
2. Given the inconsistency of the findings in the literature regarding the change over time in psychiatric and psychological symptoms, and the lack of data on lifestyle behaviors and psychological well-being, no hypothesis was done concerning the time trend for these variables.

2.5 Hypothesis Study 3

Based on the available findings from the literature, the hypotheses of the study 3 were the following:

1. A deterioration of patients and caregivers' perception of family functioning from admission to and six month after discharge from hospital
2. A worse perceived quality of family functioning by patients at hospital admission would predict poorer patients' functional recovery at discharge, after adjusting for age. No hypothesis was done regarding the specific dimensions of family functioning predicting functional recovery.
3. Finally, a worse perceived quality of family functioning by caregivers at hospital admission would predict higher caregivers' psychological distress at six months after patients' discharge, after adjusting for age. No hypothesis was done

regarding the specific dimensions of family functioning predicting the extent of psychological distress at follow-up.

3. METHOD

3.1 Participants

Stroke survivors: The sample of stroke survivors included 40 patients who had a hemorrhagic or ischemic stroke and were admitted to the rehabilitation hospital Villa Bellombra in Bologna, Italy, between January 2013 and January 2014. The inclusion criteria for the study were: 1) diagnosis of ischemic or hemorragic stroke, determined on the basis of magnetic resonance imaging (MRI) or computer tomography (CT); 2) first completed stroke; 3) no terminal medical condition. Exclusion criteria included: 1) severe expression or receptive language problems; 2) a score of 21 or less on the Mini-Mental State Examination-MMSE (Folstein, Folstein, & McHugh, 1975), corresponding to moderate/high cognitive impairments which could have influenced patients' participation at the study; 4) non-availability of a primary support person; 5) any previous stroke; 6) non-Italian speakers.

Control group: 40 subjects from the general population matched for stroke patients' socio-demographic variables have been recruited. The inclusion criteria for control sample was a negative history of stroke.

Family member caregivers: The sample of family member caregivers included 36 family members. The principal caregiver, that is the family member most involved in providing assistance with care, have been identified through the amount of hours of assistance give to the sick person. The family member who dedicates the most time to caring for the stroke survivor has been invited to participate in the study.

3.2 Rehabilitation program at Villa Bellombra hospital

Stroke survivors were admitted to the rehabilitation hospital from a stroke unit after the stabilization of their clinical situation (15 days to 1 month after the acute event). The length of hospitalization was 20-30 days. An interdisciplinary team, composed by physicians, nurses, physical therapists, speech-language pathologists, clinical psychologists, and neuropsychologists, provided specialized treatment and care. Patients were scheduled for physical and occupational therapy every day. Cognitive rehabilitation was also part of the treatment. Therapy sessions were individually tailored, with the aim of reaching a set of mutually agreed-upon goals over several weeks. The overall goal of rehabilitation was to help the patient become as independent and self-reliant as possible, with emphasis placed on self-learning and adjustment to disability. Family education and training were integral parts of the rehabilitation process.

3.3 Measures

3.3.1 *Socio-demographic and medical variables*

A questionnaire *ad-hoc* have been created in order to gather socio-demographic information, including sex, age, years of education, marital and employment status, the type of relationship between patient and caregiver (partner/spouse, son/daughter, parent, and others) and whether or not the patient and caregiver were living together. Height and weight were also collected in order to obtain Body Mass Index (BMI) values (weight in kilograms divided by the square of the height in meters). BMI values were also categorized using the World Health Organization (WHO, 1995) cut-off points, as follows: <18.5=underweight, 18.5–24.9=normal, 25–29.9=overweight, ≥30=obese. In addition, the following stroke-related variables have been retrieved from patients' medical records:

- Stroke location (left/right)
- Type of stroke (ischemic/hemorrhagic)
- Number of days from stroke onset
- Comorbid-medical diagnoses
- Scores at the Mini-Mental State Examination (MMSE; Folstein et al., 1975). The MMSE is an observer-rated test composed by 30 items evaluating the following areas: memory, space/time orientation, attention and calculation, verbal fluency, aphasia, and apraxia. A score equal or less than 18 indicates a severe cognitive impairment, a score between 18 and 23 moderate/high cognitive impairments and a score higher than 23 denotes the absence of cognitive impairment. The MMSE was part of the rehabilitation hospital routine admission assessment.

3.3.2 *Observer-rated instruments*

3.3.2.1 Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)-SCID

The Structured Clinical Interview (SCID) for DSM-IV-TR Axis I Disorders (First et al., 1996) is a structured interview for the assessment of the psychiatric disorders according to DSM-IV-TR criteria. The SCID is organized into six independent modules, each corresponding to a major DSM-IV-TR diagnostic class:

- *Mood episodes* (major depressive episode, manic episode, hypo-manic episode, dysthymic disorder, mood disorder due to a general medical condition, and substances-induced mood disorder);

- *Psychotic and associated symptoms* (delusions, hallucinations, disorganized speech and behavior, catatonic behavior, negative symptoms);
- *Psychotic disorders* (paranoid, catatonic, disorganized, indifferentiated, residual schizophrenia; schizophreniform disorder, schizoaffective disorder, delusional disorder, brief psychotic disorder, psychotic disorder due to a general medical condition, and substances-induced psychotic disorder, Not Otherwise Specified-NOS psychotic disorder);
- *Mood disorders* (bipolar disorder, major depressive disorder, minor depressive disorder, NOS mood disorder);
- *Substance use disorders* (alcohol, amphetamine, cannabis, cocaine, hallucinogens, opioids, sedatives, anxiolytics, hypnotics dependence and abuse);
- *Anxiety Disorders* (panic disorder with agoraphobia, agoraphobia without panic disorder, obsessive-compulsive disorder, post-traumatic stress disorder, anxiety due to general medical conditions, substances-induced anxiety, NOS anxiety disorder)
- *Somatoform Disorders* (somatization disorder, undifferentiated somatoform disorder, pain disorder, conversion disorder, body dismorphic disorder, hypochondriasis)
- *Eating Disorders* (Anorexia Nervosa, Bulimia Nervosa, Binge Eating Disorder).
- *Adjustment Disorders*

The specific ratings of the diagnostic criteria are coded as either 1, 2, 3, or ?: 1 indicates that the symptom described in the criterion is clearly absent or that the criterion statement is clearly false; 2, a subthreshold condition that almost meets the threshold for the criterion; 3, that the threshold for the criterion is just met or more than met or that the criterion statement is true; and ?, that there is inadequate information to code the criterion as either 1, 2, or 3. We used the Italian version of the SCID (First et al., 1996; Mazzi et al., 2000).

3.3.2.2 Structured interview for psychosomatic syndromes according to the Diagnostic Criteria for Psychosomatic Research

The interview based on the Diagnostic Criteria for Psychosomatic Research - DCPR (Mangelli, Rafanelli, Porcelli, & Fava, 2007) is a semi-structured interview for the identification of 12 clusters, defined psychosomatic syndromes: four clusters are related to the construct of abnormal illness behavior-AIB (disease phobia, thanatophobia, health anxiety, and illness denial); four clusters are related to the concept of somatization (functional somatic symptoms secondary to psychiatric disorders, persistent somatization, conversion symptoms, and anniversary reaction); the last four clusters are related to psychological dimensions that have been frequently and consistently found in medical patients (alexithymia, type A behavior, irritable mood, and demoralization). *Table* 2 contains a detailed description of the diagnostic criteria for the 12 psychosomatic syndromes. Items of the interview for DCPR are scored through a yes/no response format evaluating the presence of the psychosomatic syndromes in the past 6 or 12 months. The interview has shown excellent interrater reliability, construct validity and predictive validity for psychosocial functioning and treatment outcome (Galeazzi, Ferrari, Mackinnon, & Rigatelli, 2004). For the evaluation of stroke patients, in this research we used a shortened version of the DCPR which did not include the clusters dealing with somatoform disorders as they could determine ‘false-positive’ cases due to the presence of somatic symptoms related to stroke.

Table 2. List of diagnostic criteria for psychosomatic research (Adapted from Porcelli & Rafanelli, 2010)

Syndrome	Diagnostic Criteria
Health anxiety	• A generic worry about illness, concern about pain, and bodily preoccupations (tendency to amplify somatic sensations) of <6 months duration • Worries and fears readily respond to appropriate medical reassurance even though new worries may ensue after some time
Disease phobia	• Persistent unfounded fear of suffering from a specific disease with doubts remaining despite adequate examination and reassurance • Fears tend to manifest themselves in attacks rather than in constant, chronic worries as in hypochondria; panic attacks may be an associated feature • The object of fear does not change with time, and the duration of symptoms exceeds 6 months
Illness denial	• Persistent denial of having a physical disorder and of the need for treatment (eg, lack of compliance, delayed seeking of medical attention for serious and persistent symptoms, counterphobic behavior) as a reaction to the symptoms, signs, diagnosis, or medical treatment of a physical illness • The patient has been provided a lucid and accurate appraisal of the medical situation and management to be followed
Persistent somatization	• Functional medical disorder whose duration exceeds 6 months, causing distress and repeated medical care or resulting in impaired quality of life • Additional symptoms of autonomic arousal (also involving other organ systems) and exaggerated side effects from medical therapy are present, indicating low sensations or pain thresholds and high suggestibility
Functional somatic symptoms secondary to a psychiatric disorder	• Symptoms of autonomic arousal or functional medical disorder causing distress or repeated medical care or resulting in impaired quality of life • Appropriate medical evaluation uncovers no organic pathology to account for the physical complaints • A psychiatric disorder that includes the involved somatic symptoms within its manifestations preceding the onset of functional somatic symptoms
Demoralization	• A state characterized by the patient's consciousness of having failed to meet his or her own expectations (or those of others) or being unable to cope with some pressing problem; the patient experiences feelings of helplessness, hopelessness, or giving up • The feeling state should be prolonged and generalized (at least 1 months in duration)
Irritable mood	• A feeling state characterized by an irritable mood that may be experienced as brief episodes in particular circumstances, or it may be prolonged and generalized; it requires an increased effort of control by the individual or results in irascible verbal or behavioral outbursts • The experience of irritability is always unpleasant for the individual, and overt manifestation lacks the cathartic effect of justified outbursts of anger • The behavior elicits stress-related physiologic responses that precipitate or exacerbate symptoms of a medical condition

Table 2. List of diagnostic criteria for psychosomatic research (Adapted from Porcelli & Rafanelli, 2010)

Syndrome	Diagnostic Criteria
Type A behavior	• At least 5 of the following 9 characteristics should be present: excessive degree of involvement in work and other activities subject to deadlines; steady and pervasive sense of time urgency; display of motor-expressive features (rapid and explosive speech, abrupt body movements, tensing of facial muscles, hand gestures) indicating a sense of being under time pressure; hostility and cynicism; irritable mood; tendency to speed up physical activities; tendency to speed up mental activities; high intensity of desire for achievements and recognition; high competitiveness • The behavior elicits stress-related physiologic responses that precipitate or exacerbate symptoms of a medical condition
Alexithymia	• At least 3 of the following 6 characteristics must be present: inability to use appropriate words to describe emotions; tendency to describe details instead of feelings; lack of a rich fantasy life; thought content associated more with external events than fantasy or emotions; unawareness of the common somatic reactions that accompany the experience of a variety of feelings; occasional but violent and often inappropriate outbursts of affective behavior

3.3.3 *Self-report instruments*

3.3.3.1 Symptom Questionnaire

The Symptom Questionnaire-SQ (Kellner, 1987) is a 92-item self-report for the measurement of psychological distress. Items requires yes/no or true/false answers and yield four principal scales: anxiety, depression, somatic symptoms, and hostility. Each scale can be subdivided into a subscale of symptoms (depressive, anxiety, somatic and hostility symptoms) and well-being subscale (contentment, relaxation, physical well-being and friendliness). Each symptom subscale score may range from 0 to 17, whereas each well-being subscale score may range from 0 to 6. For each scale, higher scores indicate more psychological distress or lower level of well-being. A scale score between 1 and 2 standard deviations above the mean of normal subjects suggests moderate distress and a score above 2 standard deviations suggests substantial or severe distress or psychopathology. The means scores of SQ scales for controls and psychiatric patients have been also published (Fava et al., 1983). The SQ has previously been validated in an Italian population and has been found to be a sensitive instrument to detect changes in clinical trials (Fava et al., 1983). The conventional split-half reliability of the scales in various studies was as follows: anxiety, 0.75 to 0.95 (median, .83); depression, 0.74 to 0.93 (median, .91); somatization, 0.57 to 0.84 (median, .78); hostility, 0.78 to 0.95 (median, .89) (Kellner, 1987).

3.3.3.2 Psychosocial Index

The Psychosocial Index-PSI (Sonino & Fava, 1998) is a 52 items self-rated instrument for the assessment of stress and related psychological distress, abnormal illness behavior, psychological well-being, and quality of life. Since specific questionnaires for the evaluation of psychological distress and well-being were used, an abbreviated version of the PSI, without the items evaluating psychological distress and well-being, was administered. In particular we administered the items evaluating lifestyle behaviors, abnormal illness behavior, stress and perceived quality of life. The part of the PSI consisting of the assessment of lifestyle behaviors includes consumption of alcohol, coffee, drug, and smoking habits. The rating of stress (ranging from 0 to 17) provides an assessment of both recent life events and chronic stress, including daily, work, and interpersonal stress. The rating of abnormal illness behavior (score ranging from 0 to 3) offers an evaluation of the presence of a maladaptive mode of perceiving, experiencing, evaluating and responding to one’s health status, including hypochondriasis and bodily preoccupations. Some questions of the PSI require a yes/no answer, while others are related on a Likert scale from 0 to 3 (from ‘not at all’ to ‘a great deal’). Quality of life is examined, at the end of the questionnaire, through a simple direct question with 5 possible choices (from ‘excellent’ to ‘awful’). The PSI showed excellent inter-rater concordance, with all intraclass correlation coefficients above 0.80 (Sonino & Fava, 1998).

3.3.3.3 Psychological Well-Being Scales

The Psychological Well-Being Scales-PWB (Ryff, 1989), 42-item version, is a self-report questionnaire for the assessment of psychological well-being, according to the six dimensions of Ryff's theoretical model: autonomy, environmental mastery, personal growth, purpose in life, positive relations, and self-acceptance. Individuals respond to various statements and indicate on a 6-point Likert scale ranging from 'strongly disagree' to 'strongly agree'. Responses to negatively formulated items are reversed in the final scoring procedure, so higher scores on each scales indicate greater well-being on that dimension. A description of the different psychological well-being profiles, based on the score to each dimension, is illustrated in *Table* 3. The PWB has previously been validated in an Italian population with satisfactory test–retest reliability (Ruini, Ottolini, Rafanelli, Ryff, & Fava, 2003).

Table 3. Psychological well-being profile based on the PWB scales scores (adapted from Ryff, 1989)

Dimensions	**Definitions**	
	High score	**Low score**
Autonomy	The person is self-determining and independent; able to resist social pressures to think and act in certain ways; regulates behavior from within; evaluates self by personal standards.	The person is concerned about the expectations and evaluations of others; relies on judgments of others to make important decisions; conforms to social pressures to act in certain ways.
Environmental mastery	The person has a sense of mastery and competence in managing the environment; controls complex array of external activities; makes effective use of surrounding opportunities; able to choose or create contexts suitable to personal needs and values.	The person has difficulties in managing everyday affairs; feels unable to change or improve surrounding context; is unaware of surrounding opportunities; lacks sense of control over external world.
Positive relations with others	The person has warm, satisfying, trusting relationships with others; is concerned about the welfare of others; capable of strong empathy, affection, and intimacy; understands give and take of human relationships.	The person has few close, trusting relationships with others; finds it difficult to be warm, open, and concerned about others; is isolated and frustrated in interpersonal relationships; not willing to make compromises to sustain important ties with others.
Personal growth	The person has a feeling of continued development; sees self as growing and expanding; is open to new experiences; has sense of realizing his/her potential; sees improvement in self and behavior over time; is changing in ways that reflect more self-knowledge and effectiveness.	The person has a sense of personal stagnation; lacks sense of improvement or expansion over time; feels bored and uninterested with life; feels unable to develop new attitudes or behaviors.
Purpose in life	The person has goals in life and a sense of directedness; feels there is meaning to present and past life; holds beliefs that give life purpose; has aims and objectives for living.	The person lacks a sense of meaning in life; has few goals or aims, lacks sense of direction; does not see purpose of past life; has no outlook or beliefs that give life meaning.
Self-acceptance	The person possesses a positive attitude toward the self; acknowledges and accepts multiple aspects of self, including good and bad qualities; feels positive about past experiences in life.	The person feels dissatisfied with self; is disappointed with what has happened in past life; is troubled about certain personal qualities; wishes to be different than what he/she is.

3.3.3.4 Family Assessment Device

The Family Assessment Device-FAD (Epstein et al., 1983) is a 60-item self-report designed to measure family members' perceptions of family functioning. It is composed by seven scales: problem solving, communication, roles, affective responsiveness, affective involvement, behavior control and a general functioning scale which evaluates the overall level of family functioning. Subjects rate how well each item depicts their family on a four point scale, ranging from "strongly agree" to "strongly disagree". Lower scores on each scale reveal better family functioning. Healthy/unhealthy cut-off scores have been also published (Miller et al., 1985) in order to facilitate the distinction between functional and dysfunctional family functioning. The cut-off scores were derived after experienced family therapists conducted a comprehensive family evaluation based on the MMFF, rated each dimension as healthy or unhealthy, and matched their clinician assessments with that of the family’s FAD score (Miller et al., 1985). According to those cut-offs, family functioning can be considered as “effective” or “ineffective”. The mean scores of family dimensions for a variety of sample populations (non-patients, medical and psychiatric patients) have been also published (Kabacoff et al., 1990). The FAD has previously been validated in an Italian population with good reliability, internal coherence and good content validity (Grandi, Fabbri, Scortichini, & Bolzani, 2007).

3.3.4 *Functional Independence Measure*

Stroke survivors' functional independence was assessing using the Functional Independence Measure-FIM (Dodds, Martin, Stolov, & Deyo, 1993), which is an instrument aimed to measure physical and cognitive abilities. The FIM is composed by 18 items, of which 13 items evaluate motor tasks (FIM motor scale) and 5 items cognitive tasks (FIM cognitive scale). Each item is scored on a 7-point scale, from 1 (maximum dependence) to 7 (independent without assistance). A rating of less than six indicates the require of supervision or help from another person, while a rating of one indicates that the patient need complete assistance, since the patient is able to perform less than 25% of the task. Three independent FIM scores can be generated by summing item scores: a total score (FIM total: 18 items), a motor score (FIM motor: 13 items), and a cognitive score (FIM cognitive: 5 items). Possible scores range from 18 to 126 for the total score, 13 to 91 for the motor score, and 5 to 35 for the cognitive score, with higher scores indicating more independence. Areas assessed include self-care, sphincters, mobility, communication, and social/cognitive functioning. FIM have widely been used in research on stroke (Heinemann et al., 1993) and it was developed specifically to measure functional outcomes of rehabilitation (Hamilton et al., 1994).

3.4 Procedure

Baseline: During the first week of hospitalization, a clinical psychologist informed stroke survivors of the aims of the study and invited them to participate. The family member who dedicated the most time to caring for the stroke survivor and was more involved in the rehabilitation process has been then identified for each patient. Written informed consent has been obtained from all the patients and caregivers, after explaining the study procedure. Demographic information and stroke-related information have been retrieved from medical records. In the meantime, a control sample from the general population has been recruited by advertisements. All participants (stroke patients, caregivers and controls), during the first week of patients' hospitalization, underwent clinical interviews (SCID and DCPR) by a clinical psychologist and completed self-rating questionnaires (PSI, SQ, PWB, and FAD). The

Independence Measure (FIM) has been administered by physiatrists on admission to and at discharge from hospital, in order to measure patients' functional independence progress after rehabilitation.

Follow-up. Stroke survivors and their caregivers were contacted by phone six months after discharge from hospital for a follow-up assessment by the same clinical psychologist. The same observer and self-rated measures used at baseline were administered. Stroke survivors' functional independence as well was assessed again by the same physiatrists. Follow-up assessments were performed in the most convenient location (eg, Department of Psychology, hospital, home or nursing home).

3.5 Statistical Analysis

All analyses were conducted using the Statistical Package for Social Sciences (SPSS) software 20.0 version. Descriptive statistics were performed to identify and report patients, controls, and caregivers' characteristics, reporting means±SD for continuous variables and percentages for categorical variables. Descriptive statistics were used also to examine the data for outliers and distributional characteristics. Parametric tests were used to examine measures that were normally distributed; non-parametric tests were used to examine measures that were not normally distributed.

3.5.1 *Study 1*

Stroke survivors versus controls. Differences between stroke survivors and controls in categorical socio-demographic variables, lifestyle behaviors and psychiatric (DSM-IV-TR) and psychosomatic (DCPR) diagnoses were tested by Pearson's Chi-Square test or Fisher's exact test. Differences between stroke survivors and controls in continuous socio-demographic variables, BMI, and self-report scales mean scores (SQ, PSI, PWB, and FAD) were tested by independent-samples t-test for variables normally distributed and Mann-Whitney test for those not normally distributed.

Caregivers' characteristics. One sample t-test was used to compare caregivers' SQ scales means scores with normative data. Each FAD score was rated as "healthy" or "unhealthy", using the cut-off scores indicated by the questionnaire's Authors (Miller et al., 1985), in order to detect the proportion of caregivers perceiving unhealthy family functioning.

Associations of patients and caregivers' self-rated psychosocial variables with socio-demographic variables and patients' functional status at hospital admission. Differences between female and male stroke survivors in self-report scales mean scores (SQ, PSI, PWB, and FAD) were tested by independent-samples t-test for variables normally distributed and Mann-Whitney test for continuous variable not normally distributed. Pearson correlation coefficients, for variables normally distributed, and Spearman correlation coefficients for those not normally distributed were used in order to test the relationships between patients' age and SQ, PSI, PWB, FAD scores. Pearson correlation coefficients (or Spearman correlation coefficients) were used also in order to examine the associations between patients' functional independence (FIM cognitive and motor scores at hospital admission) and patients' SQ, PSI, PWB, and FAD scores. For caregivers, Pearson correlation coefficients (or Spearman correlation coefficients) were used in order to test the relationships between caregivers' age and SQ, PSI, PWB, FAD scores. Caregivers were sub-divided according to the relationship to the patient (partners versus adult children versus other relatives) and the living situation (caregivers who lived together with patients versus those who lived apart) and multivariate analyses of variance was performed in order to investigate differences in SQ, PSI, PWB, and FAD scores related to the caregivers' gender, relationship type with the patient, and living situation.

3.5.2 *Study 2.*

Change over time of patients' functional independence and patients and caregivers' lifestyle behaviors, DSM and DCPR diagnoses, psychological distress and well-being. Differences between patients and caregivers who were lost to follow-up with those remaining were tested by Student's t-test for continuous variables normally distributed and Pearson's Chi-Square test or Fisher's exact test for categorical variables. Mann-Whitney test was used for continuous variable not normally distributed. A General Linear Model for Repeated Measures was conducted to compare patients' scores on the FIM at the time of admission to, discharge from hospital, and six months after discharge. To test the modification over time of the categorical variables (lifestyle behaviors, DSM psychiatric diagnoses and DCPR psychosomatic syndromes) in stroke survivors and their caregivers, McNemar’s test has been applied. A General Linear Model for Repeated Measures was also conducted to compare stroke survivors and caregivers' scores on the self-rated questionnaires (SQ, PSI, and PWB) during patients' hospitalization and at follow-up (six months after hospital discharge). Change over time in self-rated scores of patients and caregivers were analyzed separately.

3.5.3 *Study 3*

Change over time in family functioning. Change over time in the FAD scores of patients and their caregivers were analyzed by means of General Linear Model for Repeated Measures 2x2. The dichotomous variable “group” (patients group *versus* caregivers group) has been considered as within-subjects factor because, in addition to the main effect for time, we were also interested in discovering if there was a significant interaction effect "time*group". Mauchly’s sphericity test was used to test the assumption of sphericity in

Repeated Measures. In addition, each FAD score was rated as "healthy" or "unhealthy", using the cut-off scores indicated by the questionnaire's Authors (Miller et al., 1985), in order to detect the proportions of stroke survivors and caregivers perceiving unhealthy family functioning at hospital admission and at six months after discharge.

Predictors of patients' functional independence gain. Hierarchical multiple regression analysis was used to determine if and which dimensions of family functioning were significant predictors of patients' functional independence change at the end of the rehabilitation process, controlling for the possible effect of age. In addition, the correlations between predictor variables were examined for multicollinearity. Multivariate analysis was conducted of the determinants of two patients outcomes: cognitive FIM score gain (cognitive FIM score difference between admission and discharge divided for admission cognitive FIM score) and motor FIM score gain (motor FIM score difference between admission and discharge divided for admission motor FIM score). As the specified outcomes were known to vary with age, independent variables were tested in a hierarchical manner in order to determine whether family functioning contributed to additional variance beyond that explained by age; the first level contained patients' age and the second level contained FAD scales scores of patients at hospital admission.

Predictors of caregivers' psychological distress at six months after discharge. Multiple regression analysis was conducted of the determinants of four caregivers outcomes at six-month follow-up: SQ total anxiety, SQ total depression, SQ total hostility, and SQ total somatic symptoms scores. In addition, the correlations between predictor variables were examined for multicollinearity. As the specified outcomes were known to vary with age, independent variables were tested in a hierarchical manner in order to determine whether family functioning contributed to additional variance beyond that explained by age and SQ scores at hospital admission; the first level contained caregivers' age and SQ scores of caregivers at hospital admission, the second level contained FAD scales scores of caregivers at hospital admission.

4. RESULTS

4.1 Participants characteristics

4.1.1 *Socio-demographic and medical characteristics of stroke survivors*

Baseline. The sample of stroke survivors (n=40) ranged in age from 30 to 87, with a mean age of 71.8±12.5. 21 (52.5 %) survivors were male and 19 (47.5%) were female, 20 (50%) were married, 10 (25%) widower, 7 (17.5%) single, and 3 (7.5%) were divorced or separated; the majority of patients were retired (n=33; 82.5%). 30 (78.9%) survivors had ischemic stroke, 6 (15.8%) hemorrhagic, and 2 (5.3%) both types; 26 (66.7%) had a right-sided lesion location, 11 (28.2%) left-sided, and in 2 (5.1%) patients the lesion location was bilateral. The medium time from stroke onset was 18.55±4.05 days. Stroke survivors mean scores at the Mini Mental State Examination was 26.57±2.73, with a minimum score of 22 and a maximum score of 30.

Follow-up. At follow-up (months post stroke, M=9±2.25), 27 (67.5%) stroke survivors remained in the study. Of the 13 (32.5%) patients who did not take part to the follow-up assessment, 2 patients had died, 8 refused to participate, 2 had moved to a different city, and 1 patient was untraceable. Of the 27 stroke survivors remained in the study, 2 (7.4%) had a relapse. In comparing patients who were lost to follow-up with those remaining, two significant statistical differences were found. Drop-outs presented significantly superior length of education in years [M=11.27±4.51 vs. M= 7.86±4.05; $t_{(37)=}$2.23, p=0.03] and significantly lower functional independence [Functional

Independence Measure total score M=80.92±24.1 vs. M=95.52±16.2; $t_{(37)=}$2.22, p=0.032; FIM motor score M=23.42±10 vs. M=31.2±9.34; $t_{(37)=}$2.35, p=0.024] at the end of the rehabilitation. Of the 27 stroke survivors remained in the study, 17 (60.7%) were male and 11 (39.3%) were female, with a mean age of 72.14±10.97.

4.1.2 *Socio-demographic characteristics of controls*

The age of controls (n=40) ranged from 60 to 89, with a mean age of 68.9±7.4. 24 (60 %) were female and 16 (40%) male, 22 (55%) were married, 10 (25%) divorced or separated, 4 (10%) single, and 4 (10%) widower; the majority of controls were retired (n=33; 82.5%).

4.1.3 *Socio-demographic characteristics of caregivers*

Baseline. During their relative's hospitalization, 40 caregivers were recruited. After receiving a description of the study, 36 caregivers agreed to participate, 3 declined and 1 was too ill to take part of the study. Of the 36 caregivers included in the study at baseline, 21 (58.3%) were female and 15 (41,7%) male. The age ranged from 39 to 77, with a mean age of 58.8±9. 16 (44.4%) were adult children, 14 (38.9%) partners or spouses, and 6 (16.7%) other relatives. 21 (58.3%) caregivers were living with patients and 15 (41.7%) were living apart; 16 (44.4 %) were married, 11 (30.6%) single, 7 (19.4%) divorced or separated, and 2 (5.6%) widower. The length of education ranged from 5 to 18 years, with a mean length of 13.82±4.45. The majority of caregivers were employed (n=21; 58.3%), 11 (30,6%) were retired, 3 (8.3%) homemakers and 1 (2.8%) unemployed.

Follow-up. At follow-up, 24 (66,7%) caregivers remained in the study. 2 caregivers were not assessed because of the recent patients' death, 8 caregivers refused to participate, 1 caregivers had moved to a different city, and 1 caregiver was untraceable.

There were no statistical differences between who completed the study and those who dropped-out. Of the 24 caregivers who took part to the follow-up assessment, 11 (45.8%) were male and 13 (54.2%) were male, with a mean age of 59.48±9.09.

4.2 Study 1. Psychosocial correlates and variables in an Italian sample of hospitalized stroke survivors and their caregivers.

4.2.1 *Stroke survivors versus controls: comparisons of socio-demographic variables*

The socio-demographic characteristics of patients and controls are shown in *Table* 4. The two groups were not significantly different in age or gender composition. There were no significant differences in the other socio-demographic variables, except for length of education in years which was superior in controls (M=12.27±2.78) than in patients [M=8.82±4.41; $t(64.73)=3.96$, $p \leq 0.001$].

Table 4. Socio-demographic characteristics of stroke patients and controls

	Stroke Patients (*n*=40)	**Controls (*n*=40)**		
			T	***p***
Age (mean ± SD)	71.08 ± 12.43	68.95 ± 7.43	1.24	*ns*
Education (mean±SD)	8.82 ± 4.41	12.27±2.78	3.96	≤0.001
			χ2	***p***
Sex (% male)	52.5	40	1.26	*ns*
Marital Status (%)			7.25	*ns*
Single	17.5	10		
Married	50	55		
Separated/Divorced	7.5	25		
Widower	25	10		
Occupation (%)			2.34	*ns*
Employed	7.5	10		
Unemployed	5	-		
Homemaker	5	7.5		
Retired	82.5	82.5		

ns=not significant

4.2.2 *Stroke survivors versus control: comparisons of lifestyle behaviors*

Graph 1 shows the frequencies of each lifestyle behaviors of patients and controls. The two groups showed significant statistical differences only in alcohol consumption [$\chi 2_{(1,N=78)}$=10.37, p ≤ 0.001]. 55.3% of stroke patients reported current alcohol use, while 20% of controls did. No significant statistical differences were found between the two groups in the other lifestyle variables, such as coffee consumption (84.2% patients *vs* 92.5% controls), drug use (5.3% patients vs 0% controls), currently smoking (30.8% patients *vs* 15% controls), and past smoking habit (44.7% patients *vs* 28.6% controls). *Table* 5 displays the mean values of the body mass index (BMI) and the percentages of stroke survivors and controls with BMI values categorized as underweight (<18.5), normal (18.5–24.9), overweight (25–29.9), and obese (≥30). No statistical differences between stroke survivors and controls have found in BMI.

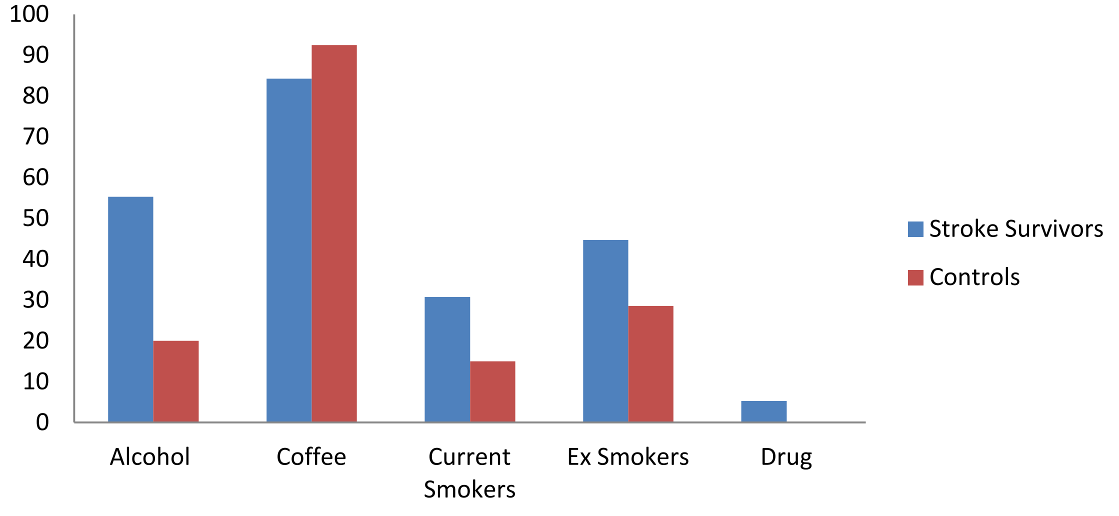

Graph 1. Frequencies of lifestyle behaviors (%)

Table 5. Stroke patients and controls characteristic according to body mass index

	Stroke Patients (*n*=40)	**Controls (*n*=40)**		
	Mean ± SD	**Mean ± SD**	***T***	***p***
BMI	25.08 ± 4.23	26.75 ± 5.03	1.29	*ns*
			χ2	***p***
Classification according to BMI (%)			1.97	*ns*
Underweight (BMI<18.5)	9.1	2.9		
Normal (BMI=18.5–24.9)	40.9	32.4		
Overweight (BMI=25–29.9)	31.8	47.1		
Obese (BMI≥30)	18.2	17.6		

ns=not significant

4.2.3 *Stroke survivors versus controls: comparisons of psychiatric diagnoses and psychosomatic syndromes*

Tables 6 and 7 and *Graphs* 2 and 3 show the frequencies of psychiatric diagnoses and psychosomatic syndromes in patients and controls. Of the 40 stroke survivors, 15 (37.5%) met criteria for at least one DSM diagnosis, specifically mood disorders (n=10, 25%; major depression n=1, 2.5%; minor depression n=7, 17.5%; dysthimia n=1, 2.5%; cyclothimia n=1, 2.5%), anxiety disorders (n= 7, 17.5%; generalized anxiety disorder n=4, 10%; social phobia n=2; 5%; agoraphobia n=1, 2.5%; panic disorder n=1, 2.5%; specific phobia n=1; 2.5%; obsessive compulsive disorder n=1; 2.5%), eating disorders (n=1; 2.5%) and alcohol abuse (n=1; 2.5%). With regard to DCPR, 18 (45%) stroke survivors presented symptoms meeting the criteria for at least one DCPR diagnosis, with 9 patients (22.5%) reporting demoralization, 5 (12.5%) illness denial, 4 (10.5%) irritable mood, 3 (7.5%) alexithymia, 2 (5%) type A behavior, and 1 (2.5%) health anxiety. Of the 40 controls, 9 (22.5%) met criteria for at least one DSM diagnosis, specifically mood disorders (n=5, 12.5%; major depression n=1, 2.5%; minor depression n=3, 7.5%; dysthymia n=1, 2.5%) and anxiety disorders (n=8, 20%; generalized anxiety disorder n=2, 5%; agoraphobia n=1, 2.5%; panic disorder n=2, 5%; specific phobia, n=2; 2.5%; obsessive compulsive disorder n=1; 2.5%). With regard to the DCPR, 17 (42.5%) controls met criteria for at least one DCPR diagnosis, specifically irritable mood (n=6, 15%), alexithymia (n=5; 12.5%), demoralization (n=4, 10%), type A behavior (n=1; 2.5%), and health anxiety (n=1, 2.5%). No significant statistical differences were found between the two groups in specific psychiatric diagnoses or psychosomatic syndromes.

Graph 2. Frequencies of DSM diagnoses for stroke survivors and controls (%)

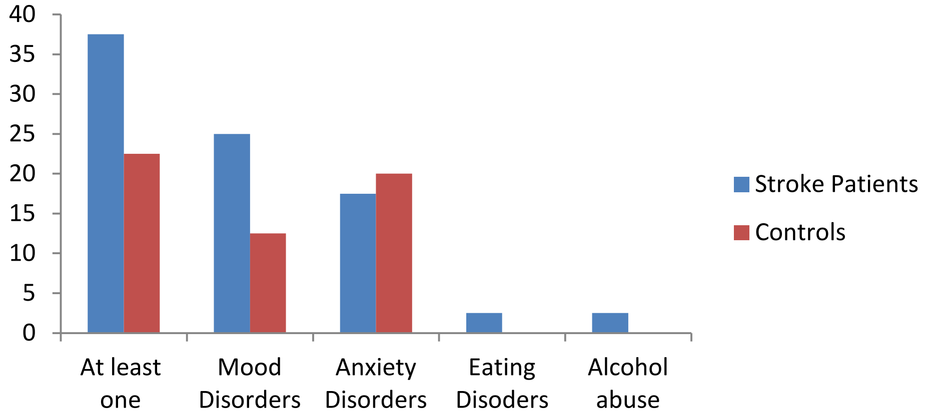


Table 6. Psychiatric diagnoses according to DSM-IV-TR in stroke patients and controls

	Stroke Patients (*n*=40)	**Controls (*n*=40)**		
	n (%)	*n* (%)	*χ2*	*p*
At least one DSM diagnosis	15 (37.5)	9 (22.5)	3.37	*ns*
Mood Disorders	10 (25)	5 (12.5)	3.09	*ns*
Major Depression	1 (2.5)	1 (2.5)	0.00	*ns*
Minor Depression	7 (17.5)	3 (7.5)	1.83	*ns*
Dysthimia	1 (2.5)	1 (2.5)	0.00	*ns*
Cyclothimia	1 (2.5)	-	1.01	*ns*
Anxiety Disorders	7 (17.5)	8 (20)	0.08	*ns*
GAD	4 (10)	2 (5)	0.72	*ns*
Social Phobia	2 (5)	-	2.05	*ns*
Agoraphobia	1 (2.5)	1 (2.5)	0.00	*ns*
Panic Disorder	1 (2.5)	2 (5)	0.35	*ns*
Specific Phobia	1 (2.5)	2 (2.5)	0.35	*ns*
OCD	1 (2.5)	1 (2.5)	0.00	*ns*
Eating Disoders	1 (2.5)	**-**	1.01	*ns*
Alcohol abuse	1 (2.5)	-	1.01	*ns*

ns= not significant

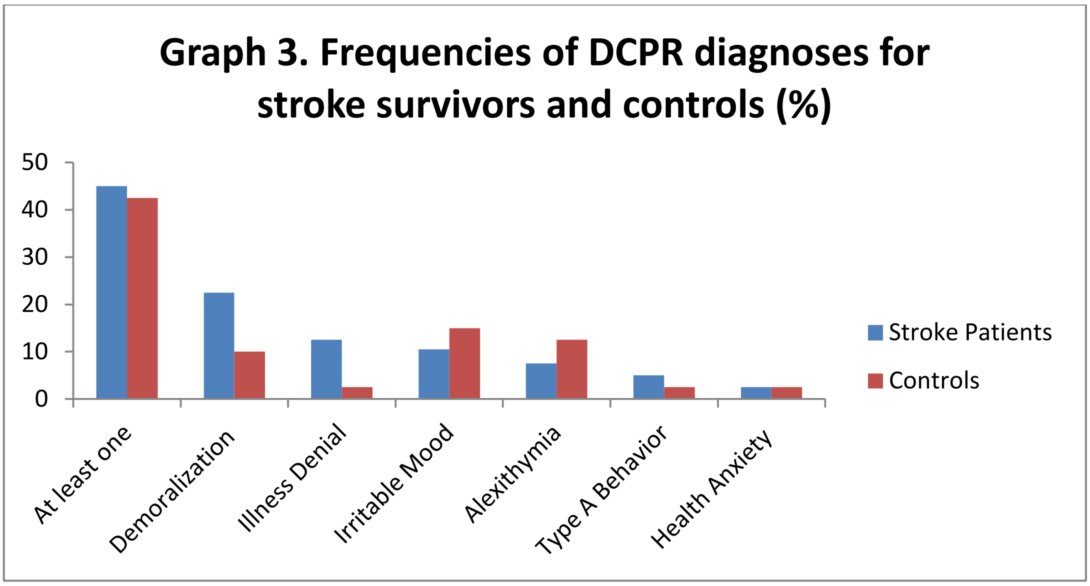

Graph 3. Frequencies of DCPR diagnoses for stroke survivors and controls (%)

Table 7. Psychosomatic syndromes according to DCPR in stroke patients and controls

	Stroke Patients (*n*=40)	**Controls (*n*=40)**		
	***n* (%)**	***n* (%)**	***χ2***	***p***
At least one DCPR diagnosis	18 (45)	17 (42.5)	0.51	*ns*
Demoralization	9 (22.5)	4 (10)	2.23	*ns*
Illness Denial	5 (12.5)	1 (2.5)	0.00	*ns*
Irritable Mood	4 (10.5)	6 (15)	0.46	*ns*
Alexithymia	3 (7.5)	5 (12.5)	0.57	*ns*
Type A Behavior	2 (5)	1 (2.5)	0.35	*ns*
Health Anxiety	1 (2.5)	1 (2.5)	0.00	*ns*

ns= not significant

4.2.4 *Stroke survivors versus controls: comparisons of self-rated scales*

Tables 8, 9, 10, and 11 display means values for patients and controls on each of the Symptom Questionnaire (SQ), Psychosocial Index (PSI), Psychological Well-Being (PWB), and Family Assessment Device (FAD) scales.

4.2.4.1 Symptom Questionnaire

Table 8 displays means values for patients and controls on each of the SQ scales. Significant statistical differences between patients and controls were found in all SQ scales and subscales, with the exception of hostility (total scale and subscale), relaxation, and friendliness subscales. Patients reported significantly higher levels of anxiety [total scale and subscale, respectively $t_{(78)}=3.89$, $p \leq 0.001$ and U=1208, $p \leq 0.001$], depression [total scale and subscale, respectively $t_{(78)}=4.72$, $p \leq 0.001$ and U=1254, $p \leq 0.001$] and somatic symptoms [total scale and subscale, respectively $t_{(78)}=3.71$, $p \leq 0.001$ and $t_{(78)}=3.69$, $p \leq 0.001$] and lower contentment [U=1051, $p=0.014$] and physical well-being [$t_{(78)}=2.08$, $p=0.041$] than controls.

Table8. Symptom Questionnaire mean scores for stroke survivors and controls

	Stroke survivors (*n*=40)	**Controls (*n*=40)**		
Scales/Subscales	**Means±DS**	***Means±DS***	***T/U***	***p***
Anxiety	7.21±4.69	3.38±3.36	1208	≤0.001
Depression	5.72±3.26	2.70±3.01	1254	≤0.001
Somatic symptoms	6.41±3.61	3.73 ±3.74	3.69	≤0.001
Hostility	4.17±4.47	2.70±3.01	1.76	*ns*
Relaxation	2.03±1.66	1.85±1.95	1.11	*ns*
Contentment	3.69±2.03	2.68±2.04	1051	0.014
Physical well-being	3.38±1.67	2.93±1.46	2.08	0.041
Friendliness	.59±1.02	.55±.749	1.42	*ns*
Total anxiety	9.24±5.52	5.23±4.76	3.90	≤0.0001
Total depression	9.92±4.09	5.38±4.52	4.72	≤0.0001
Total somatic symptoms	10.52± 4.59	6.65±4.75	3.71	≤0.0001
Total hostility	5.18±5.17	3.25±3.43	1.96	*ns*

ns= not significant

4.2.4.2 Psychosocial Index

Table 9 displays means values for patients and controls on the PSI stress, abnormal illness behavior, and quality of life scales. No significant statistical differences between patients and controls were found.

Table 9. Psychosocial Index mean scores for stroke survivors and controls

	Stroke survivors (*n*=40)	**Controls (*n*=40)**		
Scales	**Means±DS**	**Means±DS**	***T/U***	***p***
Abnormal Illness Behavior	0.48±0,75	0.33±0.47	832.5	*ns*
Stress	2.40±1,96	2.35±1.85	765.5	*ns*
Quality of life	2.38±1.06	2.53±0.60	0.78	*ns*

ns= not significant

4.2.4.3 Psychological Well-Being Scales

Table 10 displays means values for patients and controls on each of the PWB scales. Significant statistical differences between patients and controls were found only in the autonomy dimension, in which patients reported significantly lower scores (M=31.47±5.68) than controls [M=34.4±5.53; $t_{(76)}$=2.3, p=0.024].

Table 10. Psychological Well-Being scales mean scores for stroke survivors and controls

	Stroke survivors (*n*=40)	**Controls (*n*=40)**		
Scales	**Means±DS**	**Means±DS**	***T***	***p***
Autonomy	31.47±5.684	34.4±5.528	2,30	0.024
Environmental Mastery	31.05±5.604	32.23±4.46	-1,02	*ns*
Personal Growth	26.32±6.531	25.58±6.05	-1,58	*ns*
Positive Relations	31.05±6.885	32.73±.5.97	-1,15	*ns*
Purpose in Life	24.11±5.908	26.35±6.62	-1,58	*ns*
Self-Acceptance	29.42±6.233	30.13±7.31	-0,46	*ns*

ns= not significant

4.2.4.4 Family Assessment Device

Table 11 displays means values for patients and controls on each of the FAD scales. No significant statistical differences between patients and controls were found in any of the FAD scales.

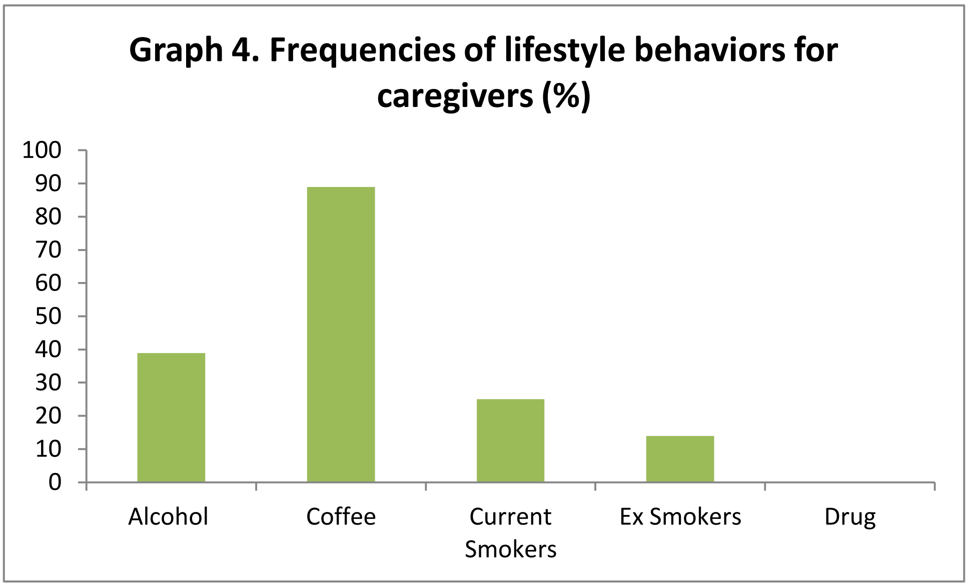
Table 11. Family Assessment Device mean scores for stroke survivors and controls

	Stroke survivors (*n*=40)	**Controls (*n*=40)**		
Scales	**Means±DS**	**Means±DS**	***T/U***	***p***
Problem Solving	1.64±0.49	1.70 ±0.46	0.85	*ns*
Communication	1.92±0.42	1.93 ±0.43	0.22	*ns*
Roles	1.83±0.44	2.02±0.41	570.5	*ns*
Affective Responsiveness	1.98±0.59	1.92±0.51	0.06	*ns*
Affective Involvement	2.10±0.46	2.00±0.59	0.09	ns
Behavior Control	1.86±0.39	1.85±0.41	0.05	*ns*
General Functioning	1.77±0.46	1.87±0.41	0.32	*ns*

ns= not significant

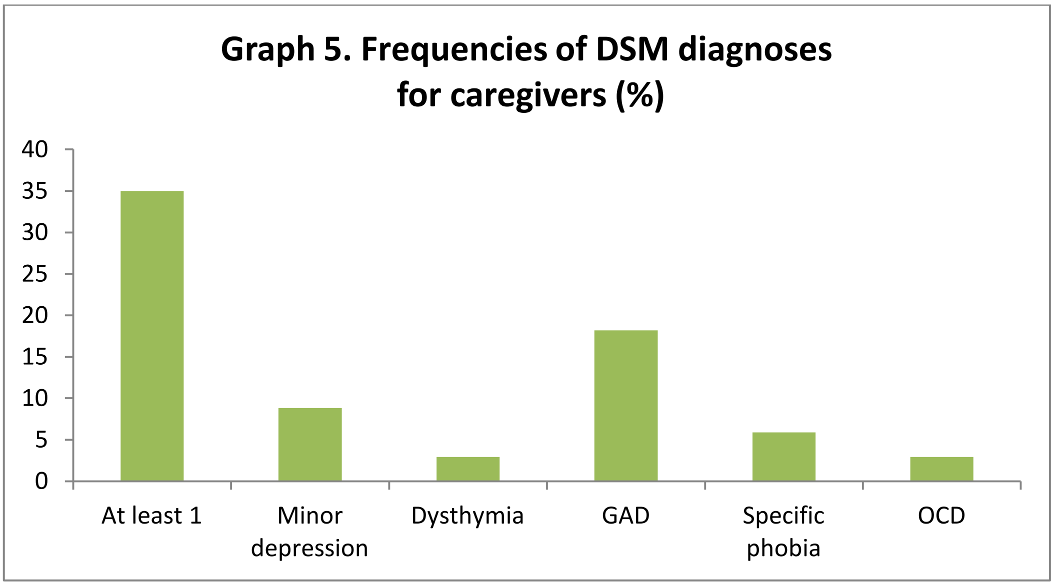
4.2.5 *Lifestyle behaviors in caregivers: smoking habit, alcohol, coffee, and drug consumption*

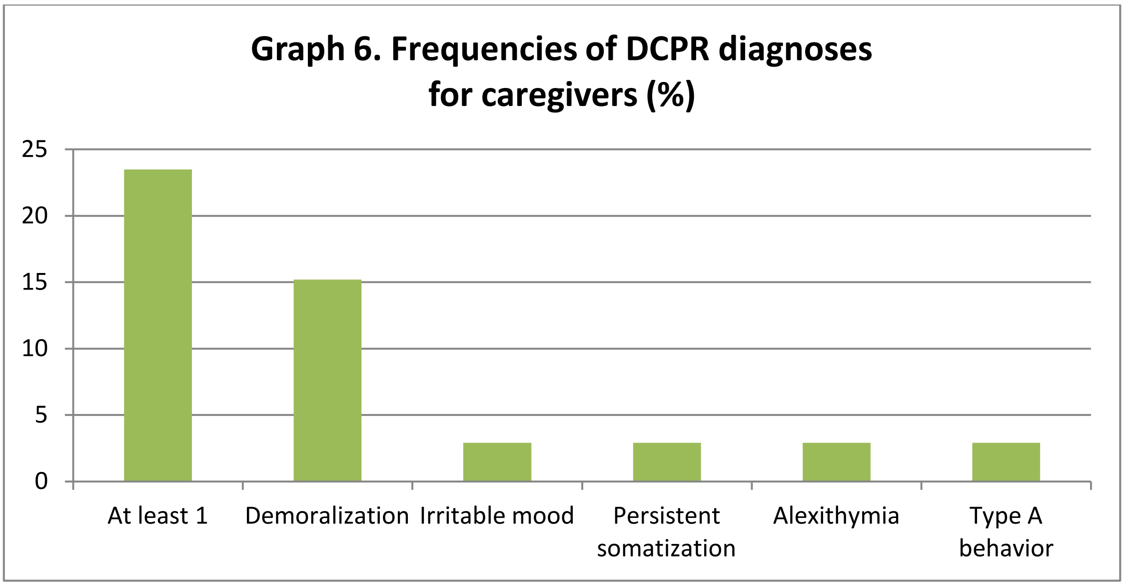
Graph 4 shows the frequencies of each lifestyle behaviors of caregivers. Of the 34 caregivers, 22 (61.1%) did not drink alcohol, while 14 (38.9%) did; 32 (88.9%) consumed coffee; 9 (25%) caregivers were currently smokers, while 5 (13.9%) reported past smoking habit; none of the caregivers reported drug use.



4.2.6 *Psychiatric diagnoses and psychosomatic syndromes prevalence in caregivers*

Graphs 5 and 6 show the frequencies of DSM and DCPR diagnoses in caregivers. Of the 36 caregivers, 12 (35.3%) met criteria for at least one DSM diagnosis, specifically mood disorders (n=4, 11.8%; minor depression n=3, 8.8%; dysthymia n=1, 2.9%) and anxiety disorders (n=9, 27.3%; generalized anxiety disorder n=6, 18.2%; specific phobia n=2, 5.9%; obsessive compulsive disorder n=1; 2.9%). In addition, 6 (17.6%) caregivers reported a history of previous depressive disorder. With regard to DCPR, 8 (23.5%) caregivers presented symptoms meeting the criteria for at least one DCPR diagnosis, with 5 (15.2%) caregivers reporting demoralization, 1 (2.9%) irritable mood, 1 (2.9%) persistent somatization, 1 (2.9%) alexithymia, and 1 (2.9%) type A behavior.





4.2.7 *Caregivers' psychological distress compared to normative data*

Scores at each Symptom Questionnaire total scales for caregivers are set out in *Table* 10, alongside comparison data of a group of healthy controls reported by Fava & Rafanelli (1998). Results from one sample t-test demonstrate that caregivers reported significantly higher scores in anxiety [$t(34)=6.31$, $p \leq 0.000$], depression [$t(34)=7.63$, $p \leq 0.000$], and somatic symptoms [$t(34)=3.03$, $p \leq 0.005$], compared to normative data. No significant differences were found in hostility SQ scale [$t(34)=1.01$, $p=0.318$]. Mean, maximum and minimum scores for caregivers at abnormal illness behavior, stress and quality of life scales of the Psychosocial Index are presented in *Table* 11, alongside possible scores range. Responses regarding abnormal illness behavior and stress tended to be placed toward the lower end of the range, indicating the lack of significant problems in these areas, whereas those related to quality of life were located in the middle of the range.

Table 10. SQ scores in caregivers during patient's rehabilitation compared to normative data

	Caregivers (N=36)	Controls (N=50)		
Scales	**Mean±SD**	**Mean±SD**	***T***	***p***
Total Anxiety	8,89±4,72	3.84±3.87	6.32	≤0.001
Total Depression	7,83±4,08	2.56±2.87	7.63	≤0.001
Total Somatic Symptoms	7,23±5,35	4.49±4.14	3.03	0.005
Total Hostility	4,49±3,43	3.90±3.79	1.01	*ns*

ns= not significant

Table 11. Psychosocial Index mean scores in caregivers (n=36)

Scales	Possible range	Min-Max	Mean±SD
Stress	0-17	0-9	3.69±2.26
Abnormal Illness Behavior	0-1	0-1	0.37±0.49
Quality of Life	0-4	0-4	2.17±1.01

4.2.8 *Caregivers' psychological well-being*

Mean, maximum, and minimum scores for caregivers at Psychological Well-Being Scales are presented in *Table* 12, alongside possible scores range. Responses tended to be placed toward the higher end of the measurement scale, denoting the lack of impairment in psychological well-being.

Table 12. Psychological Well-Being Scales mean scores in caregivers (n=36)

Scales	Possible range	Min-Max	Mean±SD
Autonomy	7-42	18-42	30.82±6.94
Environmental Mastery	7-42	13-42	30.26±6.84
Personal Growth	7-42	18-42	31.21±6.68
Positive Relations	7-42	20-42	32.85±6.68
Purpose in Life	7-42	11-38	29.85±5.61
Self-Acceptance	7-42	14-42	30.38±7.15

4.2.9 *Caregivers' rating of family functioning*

Table 13 shows the cut-off values (Miller et al., 1985) of the seven scales of the Family Assessment Device, the maximum and minimum scores and mean values presented by caregivers, and the percentage of caregivers which scores felt in the unhealthy range for each dimensions (i.e., equal to or above cutoff). In general, caregivers average scores did not exceed the cut-offs on any FAD scales, with the exception of behavior control.

In addition, according to FAD cut-offs, behavior control was the dimension more frequently rated as unhealthy (48.5%). 42.4% of the family informants also reported problematic functioning for the affective involvement dimension, while 33.3% reported problematic functioning for communication, followed by general functioning (30.3%), roles (24.2%), affective responsiveness (24.2%) and problem solving (12.1%).

Table 13. Family Assessment Device scores in caregivers (n=36)

Scales	**Cut-offs**	Min-Max	**Mean±SD**	**% Above cut-offs**
Problem Solving	2.2	0.5-2.83	1.64±0.50	12.1
Communication	2.2	1.11-3.22	1.93±0.56	33.3
Roles	2.3	1.18-3.45	2.08±0.58	24.2
Affective Responsiveness	2.2	1.00-3.33	1.84±0.59	24.2
Affective Involvement	2.1	1.29-4.71	2.00±0.70	42.4
Behavior Control	1.9	1.22-2.89	1.96±0.48	48.5
General Functioning	2.0	1.00-3.00	1.78±0.51	30.3

4.2.10 *Socio-demographic correlates of patients and caregivers' psychological distress, well-being, and perceived family functioning.*

Stroke survivors did not show significant correlations between age and mean scores at SQ, PSI and FAD scales. Patients' age was significantly positively correlated only with PWB self-acceptance scale (r=0.41; p=0.01), meaning that older stroke survivors showed higher self-acceptance than younger one. No significant relationships were found between caregiver's age and SQ, PSI, and PWB scores, while a significant negative correlation with FAD problem solving (r=-0.35, p=0.044) emerged. This result indicates that older caregivers had a more positive perception of the family’s ability to resolve problems. Stroke patients showed significant sex differences regarding SQ anxiety [total scale and subscale, respectively $t_{(38)}$=2.43, p=0.02 and $t_{(38)}$=2.17, p=0.04] and somatic symptoms [total scale and subscale, respectively $t_{(38)}$=2.76, p=0.01 and $t_{(38)}$=2.35, p=0.02], with female patients reporting higher scores. Significant gender differences were reported also in PWB autonomy [$t_{(38)}$=0.68, p=0.02], personal growth

[$t_{(38)}$=0.30, p=0.01] and self-acceptance [$t_{(38)}$=0.67, p=0.01] scales, with female presenting lower psychological well-being. No significant differences in mean scores of FAD scales emerged between female and male patients. In caregivers, no significant sex differences in mean scores of SQ, PSI, and FAD scales were found, while significant differences on the PWB personal growth with regard to gender [$F_{(1,32)}$=6.728; p=0.014] were reported, with females showing higher scores (M=33.50±6.70) compared to males (M=27.93±5.30). Significant differences on the PWB self-acceptance with regard to the living situation [$F_{(1,32)}$=6.610; p=0.019] and the type of relationship of the caregiver to the patient were found [$F_{(2,31)}$=6.544; p=0.004], with caregivers living with the patients reporting higher self-acceptance scores (M=32.89±6.23) compared to those living apart (M=27.20±7.13) and partners presenting significantly higher self-acceptance scores (M=35.15±5.10) than adult children (M=26.80±6.42), as indicated by Bonferroni procedure.

4.2.11 *Relations between patients' functional status and patients and caregivers' psychological distress, well-being, and perceived family functioning.*

In stroke patients, significant negative correlations were found between FIM cognitive score at hospital admission and SQ anxiety (total scale and subscale, respectively r=-0.40, p=0.013 and r=-0.46, p=0.003), depression (total scale and subscale, respectively r=-0.43, p=0.006 and r=-0.50, p=0.001), and somatic symptoms (total scale and subscale, respectively r=-0.42, p=0.006 and r=-0.50, p=0.001). In the same vein, significant negative correlations were found between FIM motor score at hospital admission and SQ anxiety (total scale and subscale, respectively r=-0.33, p=0.04 and r=-0.42, p=0.007), depression (total scale and subscale, respectively r=-0.33, p=0.04 and r=-0.37, p=0.019), and somatic symptoms (total scale and subscale, respectively *r*=-0.46, *p*=0.003 and *r*=-0.53, *p*≤0.001). Lower FIM cognitive score was also significantly associated with lower quality of life (*r*=0.34, *p*=0.033). No significant correlations between FIM cognitive and motor scores and PWB scales were found. On the contrary, patients reported several significant correlations between FIM cognitive and motor scores and FAD scales. Particularly, FIM cognitive and motor scores at hospital admission negatively correlated with FAD communication (respectively *r*=-0.42, *p*=0.009 and *r*=-0.41, *p*=0.011) and FAD affective responsiveness (respectively *r*=-0.53, *p*=0.001 and *r*=-0.37, *p*≤0.022) scores. FIM cognitive scores were also significantly associated with FAD affective involvement (*r*=-0.59, *p*≤0.001) and FAD behavior control (*r*=-0.39, *p*=0.016) patients' ratings.

In caregivers, no significant relationships were found between patient's FIM scores at hospital admission and caregivers' SQ, PSI, and PWB scores. A significant positive correlation between patients' cognitive FIM score at hospital admission and caregivers' FAD behavior control (*r*=0.38, *p*=0.33) emerged, indicating that caregivers of patients with higher cognitive functioning reported more problems in behavior control.

4.3 Study 2. Change over time in psychosocial variables and correlates for stroke survivors and their caregivers

4.3.1 *Change over time in patients' functional recovery: Functional Independence Measure*

General Linear Model for Repeated Measures was conducted to compare patients' scores on the Functional Independence Measure at admission to rehabilitation, discharge, and 6 months after discharge. A significant increase over time in total

[$F_{(2,24)}$=129,41, p≤0,001], motor [$F_{(2,24)}$=117,36, p≤0,001] and cognitive FIM scores [$F_{(2,24)}$=16,57, p≤0,001] was found. Subsequent post-hoc comparisons using the Bonferroni procedure indicated that FIM scores changes were significant between admission and discharge and between admission and six months after. No significant differences have found between discharge and six months after discharge, indicating a stability of functional independence over time after discharge. The means of FIM scores at different time points are presented in *Table* 14.

Tab. 14. Patients' FIM mean scores for admission, discharge, and 6-month follow-up

	Admission	**Discharge**	**6-month follow-up**
	Mean±SD	**Mean±SD**	**Mean±SD**
FIM total	62.26±18.36	89.05±24.56	102.30±23.05
FIM Cognitive	25.62±5.40	28.00±6.13	29.67±5.68
FIM Motor	36.64±14.23	61.05±19.35	72.48±20.21

4.3.2 *Change in lifestyle behaviors*

There were not significant modifications in lifestyle behaviors for patients and caregivers. The only exception was the number of stroke survivors who smoked, which significantly decreased from admission to hospital to six months after discharge (33.3% vs 7.4%; p=0.016): of the 9 patients smoking at hospital admission, only 2 were still smoking at six months after discharge (*Table* 15).

Table 15. Change over time of smoking habit in patients

Six months after discharge	**Hospital admission**	
	no	yes
no	18	7
yes	0	2

p=0.016

4.3.3 *Change over time in DSM-IV-TR psychiatric diagnoses and DCPR psychosomatic syndromes*

With regards to psychiatric diagnoses according to DSM-IV-TR, *Tables* 17, 18, 19, and 20 show their frequencies among stroke survivors and caregivers at hospital admission and at 6 months after discharge. The stroke survivors group displayed a significant increase of psychiatric diagnoses according to DSM-IV-TR, which number rose to from 9 (33.3%) to 15 (55.6%) from admission to rehabilitation program at six months from discharge (*p*=0.03) (*Table* 16). An increase in mood disorders, from 5 (18.5%) to 10 (37%), with slight increase of cases of major and minor depressive disorder, has been recorded without reaching statistical significance. In the same vein the decrease recorded in anxiety disorders, from 6 (22.2%) to 4 (14.8%), was statistically insignificant. In particular there was a reduction of one case each for generalized anxiety disorder, panic disorder, agoraphobia and social phobia, with a new case of specific phobia. The only case of alcohol abuse registered at hospital admission did not reach criteria for the disorder at 6 months after discharge. A new case of psychotic disorder has been recorded at 6-month follow-up. No changes of the diagnoses' frequencies have been observed for eating disorders and obsessive compulsive disorder. Stroke survivors displayed an increase in psychosomatic syndromes according to DCPR, which number rose from 11 (40.7%) to 16 (59.3 %) from admission to rehabilitation program at six months from discharge. However, this data did not reach statistical significance. The increase was more evident in demoralization, which rose from 6 (22.6%) to 10 (37). A new case of irritable mood was recorded, while there was a decrease in illness denial and type A behavior, without reaching statistical significance. The caregivers group displayed a non-significant reduction in psychiatric diagnoses according to DSM-IV-TR, which number decrease from 9 (37.5) to 8 (33.3) from patients' admission to rehabilitation program at six months after discharge. A non-significant increase in mood disorders (from 12.5% to 16.7%) was recorded, with one new case of major depressive disorder and one new case of minor depression. No changes in frequencies of anxiety disorders were found: a new case of panic disorder compensated a decrease of previous anxiety disorders cases. Caregivers displayed a non-significant increase in psychosomatic syndromes according to DCPR, which number rose from 7 (29.2%) to 10 (41.7%) from patients' admission to rehabilitation program at six months after discharge. Two new cases of irritable mood and one new case of demoralization were recorded. However these data did not reach statistical significance.

Table 16. Change over time of at least one DSM diagnosis in patients

Six months after discharge	**Hospital admission**	
	No	**yes**
No	12	0
Yes	6	9

p=0.03

Table 17. Psychiatric diagnoses according to DSM-IV-TR in stroke patients assessed at both baseline and follow-up

	Hospital admission (*n*=27)	**Six months after discharge (*n*=27)**	
	***n* (%)**	***n* (%)**	***p***
At least one DSM diagnosis	9 (33.3)	15 (55.6)	0.03
Mood Disorders	5 (18.5)	10 (37)	*ns*
Major Depression	-	3 (7.5)	*ns*
Minor Depression	4 (14.8)	6 (15)	*ns*
Dysthimia	1 (3.7)	1 (2.5)	*ns*
Cyclothimia	-	-	*ns*
Anxiety Disorders	6 (22.2)	4 (14.8)	*ns*
GAD	3 (11.1)	2 (7.4)	*ns*
Agoraphobia	1 (3.7)	-	*ns*
Panic Disorder	1 (3.7)	-	*ns*
Social Phobia	2 (7.4)	1 (3.7)	*ns*
Specific Phobia	1 (3.7)	2 (2.5)	*ns*
OCD	1 (3.7)	1 (3.7)	*ns*
Eating Disoders	1 (3.7)	1 (3.7)	*ns*
Alcohol abuse	1 (3.7)	-	*ns*
Psychotic Disorders	-	1 (3.7)	*ns*

ns= not significant

Table 18. Psychosomatic syndromes according to DCPR in stroke patients assessed at both baseline and follow-up

	Hospital admission (*n*=27)	**Six months after discharge (*n*=27)**	
	***n* (%)**	***n* (%)**	***p***
At least one DCPR diagnosis	11 (40.7)	16 (59.3)	*ns*
Demoralization	6 (22.6)	10 (37)	*ns*
Illness Denial	3 (11.1)	-	*ns*
Irritable Mood	3 (11.1)	4 (14.8)	*ns*
Alexithymia	1 (3.7)	1 (3.7)	*ns*
Type A Behavior	2 (7.4)	-	*ns*
Health Anxiety	-	-	*ns*

ns= not significant

Table 19. Psychiatric diagnoses according to DSM-IV-TR in caregivers assessed at both baseline and follow-up

	Hospital admission (*n*=23)	**Six months after discharge (*n*=23)**	
	***n* (%)**	***n* (%)**	***p***
At least one DSM diagnosis	9 (37.5)	8 (33.3)	*ns*
Mood Disorders	3 (12.5)	4 (16.7)	*ns*
Major Depression	-	1 (4.2)	*ns*
Minor Depression	2 (8.3)	3 (12.5)	*ns*
Dysthimia	1 (4.2)	1 (4.2)	*ns*
Anxiety Disorders	6 (25)	6 (25)	*ns*
GAD	4 (16.7)	4 (16.7)	*ns*
Panic Disorder	-	1 (4.2)	*ns*
OCD	1 (4.2)	1 (4.2)	*ns*

ns= not significant

Table 20. Psychosomatic syndromes according to DCPR in caregivers assessed at both baseline and follow-up

	Hospital admission (*n*=23)	**Six months after discharge (*n*=23)**	
	***n* (%)**	***n* (%)**	***p***
At least one DCPR diagnosis	7 (29.2)	10 (41.7)	*ns*
Demoralization	4 (16.7)	5 (20.8)	*ns*
Irritable Mood	1 (4.2)	3 (12.5)	*ns*
Alexithymia	1 (4.2)	1 (4.2)	*ns*
Type A Behavior	1 (4.2)	1 (4.2)	*ns*
Persistent Somatization	1 (4.2)	1 (4.2)	*ns*

ns= not significant

4.3.4 *Change over time in psychological distress: Symptom Questionnaire and Psychosocial Index*

Change over time in the SQ and the PSI scales of patients and their family members were analyzed separately (see *Tables* 21, 22, 23, 24). Repeated measures analysis of variance for the four Symptom Questionnaire total scales indicated that there had been significant variation over time in the ratings of both patients and caregivers. Particularly patients showed significant reductions in anxiety [total scale and subscale, respectively $F_{(1,28)}=8.62$, $p\leq 0.01$ and $F_{(1,28)}=8.17$, $p\leq 0.01$] and somatic symptoms [total scale and subscale, respectively $F_{(1,28)}=4.99$, $p\leq 0.05$ and $F_{(1,28)}=7.14$, $p\leq 0.05$], while depression (total scale and subscale), hostility (total scale and subscale), and all the other SQ subscales did not decrease significantly from admission to hospital to six months after discharge. Caregivers as well displayed significant reductions in anxiety total scale [$F_{(1,22)}=7.30$, $p\leq 0.05$], together with a significant decrease in relaxation [$F_{(1,22)}=7.59$, $p\leq 0.05$] and contentment [$F_{(1,22)}=17.07$, $p\leq 0.001$] subscales. For depression (total scale and subscale), somatic symptoms (total scale and subscale), and hostility (total scale and subscale), and the other SQ subscales there was not a significant effect for time.

Regarding the changes in the PSI scores, the patients ratings indicated a significant increase in stress [$F_{(1,28)}=20.49$, $p\leq 0.001$] and a deterioration in quality of life [$F_{(1,28)}=10.79$, $p\leq 0.005$], while abnormal illness behavior remained stable over time. For caregivers, on the contrary, there was not a significant change over time in any of the PSI scales.

Table 21. SQ mean scores for stroke survivors at hospital admission and 6 months after discharge

	Hospital admission	6-month follow-up		
Scales	**Means±DS**	**Means±DS**	***F***	***p***
Anxiety	7.21±4.69	4.97±3.91	8.17	0.008
Depression	5.72±3.26	5.52±3.47	0.11	*ns*
Somatic symptoms	6.41±3.61	4.79±3.67	7.14	0.012
Hostility	4.17±4.47	4.72±4.10	0.92	*ns*
Relaxation	2.03±1.66	1.72±1.65	1.08	*ns*
Contentment	3.69±2.04	3.17±1.98	2.06	*ns*
Physical well-being	3.38±1.67	3.31±1.81	0.03	*ns*
Friendliness	0.59±1.02	0.97± 1.68	1.64	*ns*
Total anxiety	9.24±5.52	6.69±3.82	8.62	0.007
Total depression	9.92±4.09	8.89±4.31	0.88	*ns*
Total somatic symptoms	10.52± 4.59	8.26±4.76	4.99	0.034
Total hostility	5.18±5.17	5.67±4.26	2.73	*ns*

ns= not significant

Table 22. SQ mean scores for caregivers at hospital admission and 6 months after discharge

	Hospital admission	6-month follow-up		
Scales/Subscales	**Means±DS**	**Means±DS**	***F***	***p***
Anxiety	6,17±3,55	5,26±3,80	2.57	*ns*
Depression	4,35±3,28	4,43±4,54	0.18	*ns*
Somatic symptoms	4,39±4,25	5,04±4,65	1.35	*ns*
Hostility	3,70±3,14	4,35±3,51	1.17	*ns*
Relaxation	2,83±1,92	2,09±1,90	7.59	0,012
Contentment	3,61±1,56	1,96±2,06	17.07	≤0,001
Physical well-being	3,04±1,92	2,91±2,04	0.93	*ns*
Friendliness	1,13±1,10	0,91±0,95	0.86	*ns*
Total anxiety	9,00±4,86	7,13±5,44	7.30	0,01
Total depression	7,96±4,08	6,39±5,83	3.74	*ns*
Total somatic symptoms	7,43±5,58	8,00±6,04	0.53	*ns*
Total hostility	4,83±3,52	5,26± 4,02	0.54	*ns*

ns= not significant

Table 23. PSI mean scores for stroke survivors at hospital admission and 6 months after discharge

	Hospital Admission	6 months after discharge		
Scales	**Means±DS**	**Means±DS**	***F***	***p***
Abnormal Illness Behavior	0.48±0,75	0.34±0.11	0.52	*ns*
Stress	2.41±2,18	3.93±2.15	20.49	≤0.001
Quality of Life	2.52±0.99	1.76±1.24	10.79	0.003

ns= not significant

Table 24. PSI mean scores for caregivers at hospital admission and 6 months after discharge

	Hospital Admission	6 months after discharge		
Scales	**Means±DS**	**Means±DS**	***F***	***p***
Stress	3.57±1.95	3.04±1.49	1.25	*ns*
Abnormal Illness Behavior	0.30±0.47	0.52±0.59	2.00	*ns*
Quality of Life	2.22±0.85	2.30±0.97	0.19	*ns*

ns= not significant

4.3.5 *Change over time in psychological well-being: Psychological Well-Being scales*

Change over time in the Psychological Well-Being scales scores of patients and their family members were analyzed separately. Repeated measures analysis of variance for the six PWB dimensions indicated no significant variation over time in any scales for both patients and caregivers (see *Tables* 25 and 26).

Table 25. Psychological Well-Being scales mean scores for stroke survivors at hospital admission and 6 months after discharge

	Hospital admission	6 months after discharge		
Scales	**Means±DS**	**Means±DS**	***F***	***p***
Autonomy	32.19±5.47	34.15±6.08	2.61	*ns*
Environmental Mastery	30.85±6.45	29.46±6.19	0.94	*ns*
Personal Growth	26.54±6.81	26.35±6.14	0.01	*ns*
Positive Relations	30.62±7.32	31.81±6.52	1.21	*ns*
Purpose in Life	24.19±5.47	22.92±5.99	0.99	*ns*
Self-Acceptance	30.46±6.54	30.31±6.03	0.03	*ns*

ns= not significant

Table 26. Psychological Well-Being scales mean scores for caregivers at hospital admission and 6 months after discharge

	Hospital admission	6 months after discharge		
Scales	**Means±DS**	**Means±DS**	***F***	***p***
Autonomy	30.22±7.17	32.13±6.08	2.35	*ns*
Environmental Mastery	30.17±7.15	28.57±5.56	1.61	*ns*
Personal Growth	31.09±7.22	31.43±6.53	0.10	*ns*
Positive Relations	33.00±6.84	33.22±5.15	0.26	*ns*
Purpose in Life	28.83±6.14	28.39±5.97	0.11	*ns*
Self-Acceptance	30.09±7.46	28.96±9.46	0.46	*ns*

ns= not significant

4.4 Study 3. Family functioning: change over time and its role in predicting patients and caregivers outcomes.

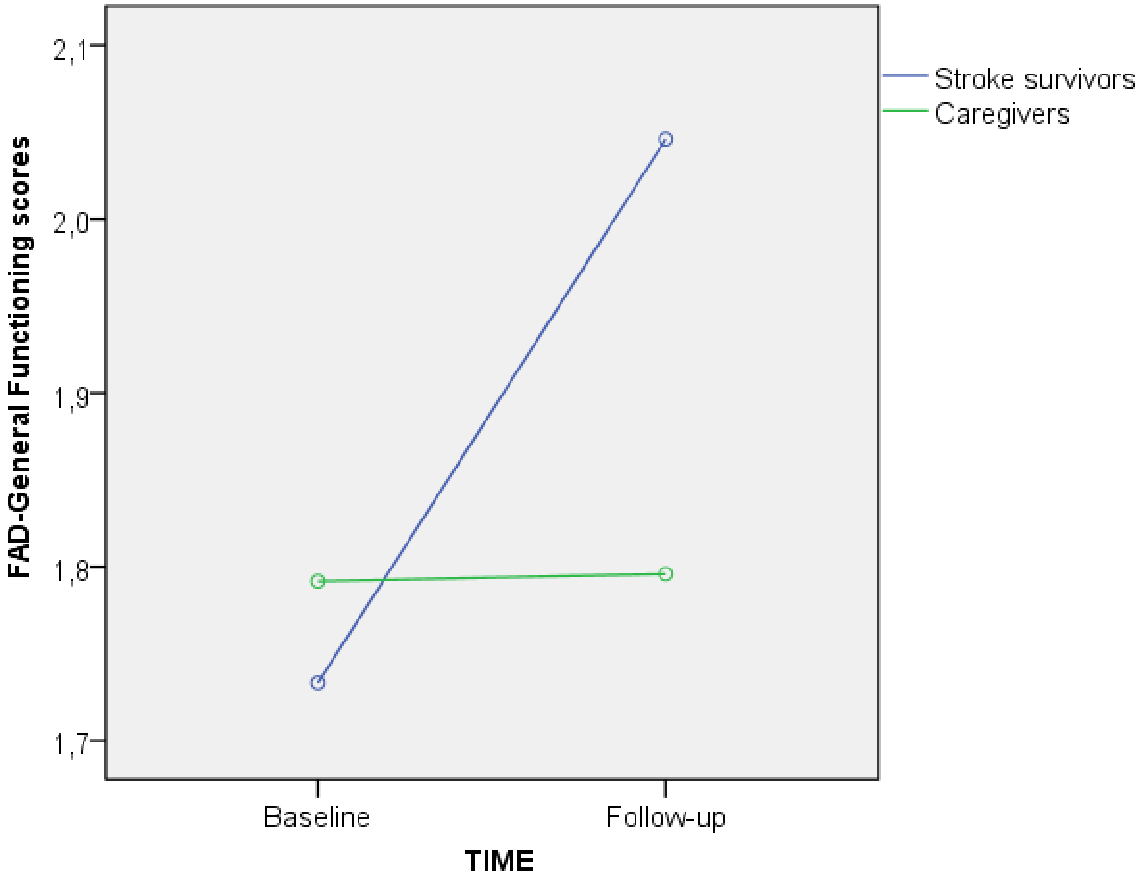
4.4.1 *Change over time in perception of family functioning for stroke survivors and their caregivers*

Change over time in the FAD scores of patients and their caregivers were analyzed by means of General Linear Model for Repeated Measures. The dichotomous variable “group” (patients group *versus* caregivers group) has been considered as within-subjects factor because, in addition to the main effect for time, we were also interested to discover if there was a significant interaction effect "time*group". There was a statistically significant main effect for "time" for the FAD general functioning scale [$F_{(1,19)=}$4.84, p=0.04], indicating a deterioration in general family functioning over time. The main effect for "group" [$F_{(1,19)=}$0.53, p=0.47] and the interaction effect "time*group" [$F_{(1,19)=}$2.70, p=0.11] did not reach statistical significance for this scale

(*Graph* 8). For roles [$F_{(1,18)=}$12.3, p=0.003], behavior control [$F_{(1,18)=}$13.72, p=0.00], communication [$F_{(1,18)=}$4.58, p=0.04], and affective involvement scales [$F_{(1,18)=}$7.82, p=0.01], the results revealed statistical significance for "time*group" interaction, while the main effect for "time" [roles: $F_{(1,18)=}$2.78, p=0.11; behavior control: $F_{(1,18)=}$0.15, p=0.70; communication: $F_{(1,18)=}$0.42, p=0.53; affective involvement: $F_{(1,18)=}$1.07, p=0.37] and that for "group" [roles: $F_{(1,18)=}$0.04, p=0.84; behavior control: $F_{(1,18)=}$0.12, p=0.73; communication: $F_{(1,18)=}$0.09, p=0.77; affective involvement scales: $F_{(1,18)=}$0.78, p=0.12] were not significant. There was a significant difference in the effect of time on these dimensions for patients and family members. Specifically stroke survivors showed a deterioration in roles, behavior control, communication, and affective involvement over the time, as indicated by the higher scores at 6-month follow-up compared to baseline, while family members reported a stability over time (*Graphs* 9, 10, 11, 12). With regard to the problem solving and affective responsiveness scales, the main effect of "time"[problem solving: $F_{(1,18)}$=0.15, p=0.70; affective responsiveness $F_{(1,18)=}$0.8, p=0.78], "group"[problem solving: $F_{(1,18)}$=0.48, p=0.49; affective responsiveness $F_{(1,18)=}$0.48, p=0.83], and "time*group" interaction [problem solving: $F_{(1,18)}$=0.40, p=0.53; affective responsiveness $F_{(1,18)=}$2.22, p=0.15] did not reach statistical significance (*Graphs* 13 and 14). *Table* 27 shows FAD mean scores for patients and caregivers at hospital admission and at six months after discharge.

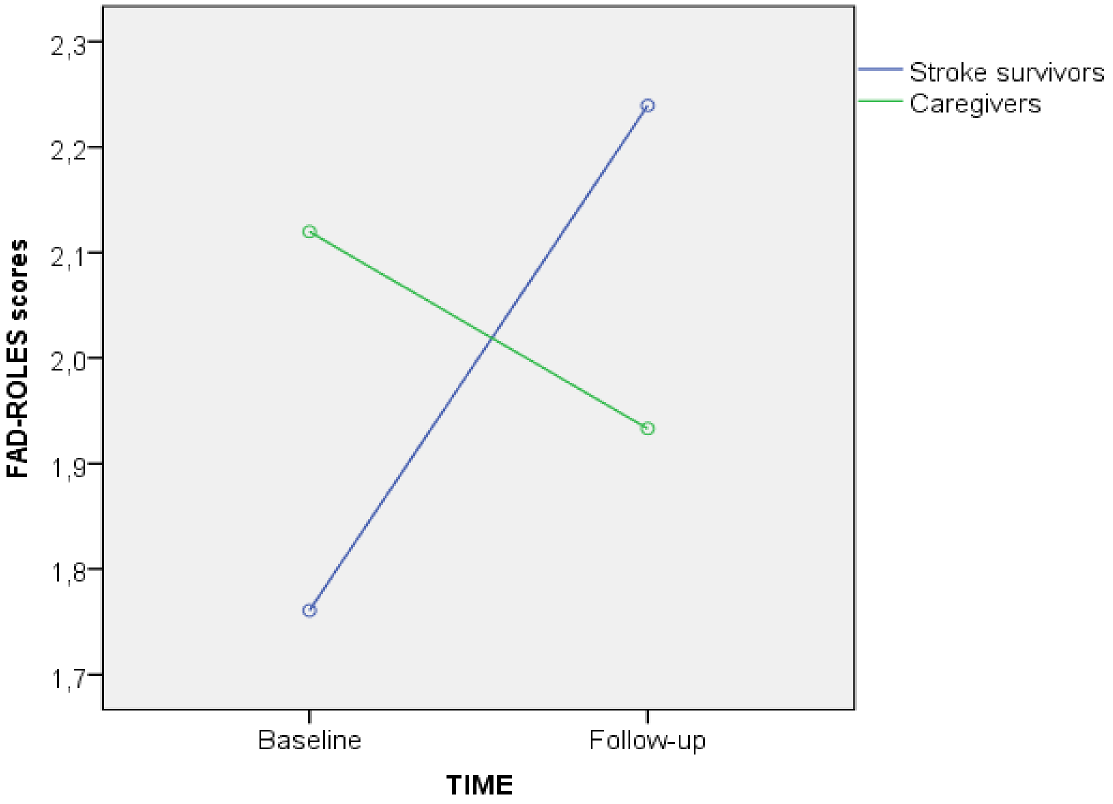
Table 27. Family Assessment Device mean scores±SD for stroke survivors and caregivers

	Hospital admission	6 months after discharge	Hospital Admission	6 months after discharge
	Stroke survivors (n=27)		Caregivers (n=23)	
Scales	**Mean±SD**	**Mean±SD**	**Mean±SD**	**Mean±SD**
General Functioning	1.73±0.50	2.05±0.56	1.79±0.51	1.80±0.54
Roles	1.76±0.43	2.34±0.67	2.12±0.72	1.93±0.62
Behavior Control	1.81±0.32	2.09±0.67	2.02±0.53	1.79±0.49
Communication	1.87± 0.39	2.05±0.46	1.96±0.55	1.89±0.38
Affective Involvement	1.86±0.38	2.42±0.98	2.17±0.85	1.84±0.43
Problem Solving	1.60±0.51	1.57±0.74	1.61±0.47	1.75±0.50
Affective Responsiveness	1.87±0.50	2.06±0.75	2.00±0.56	1.87±0.45

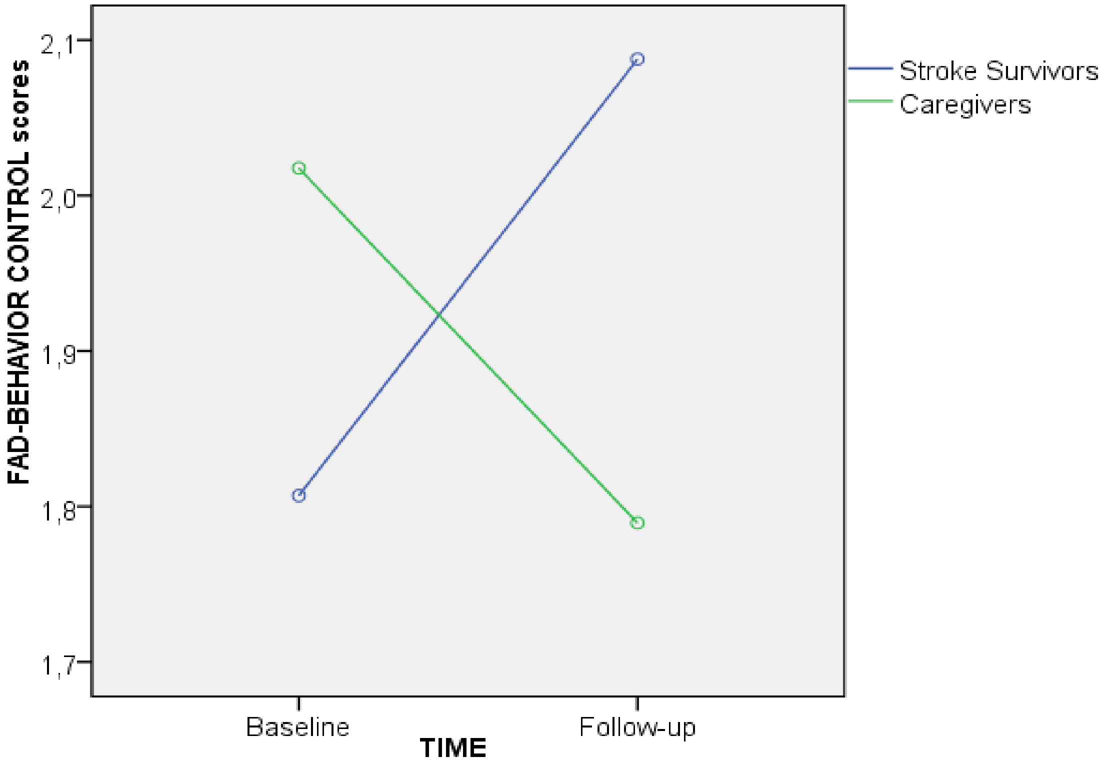


Graph 8. Change over time of FAD General Functioning

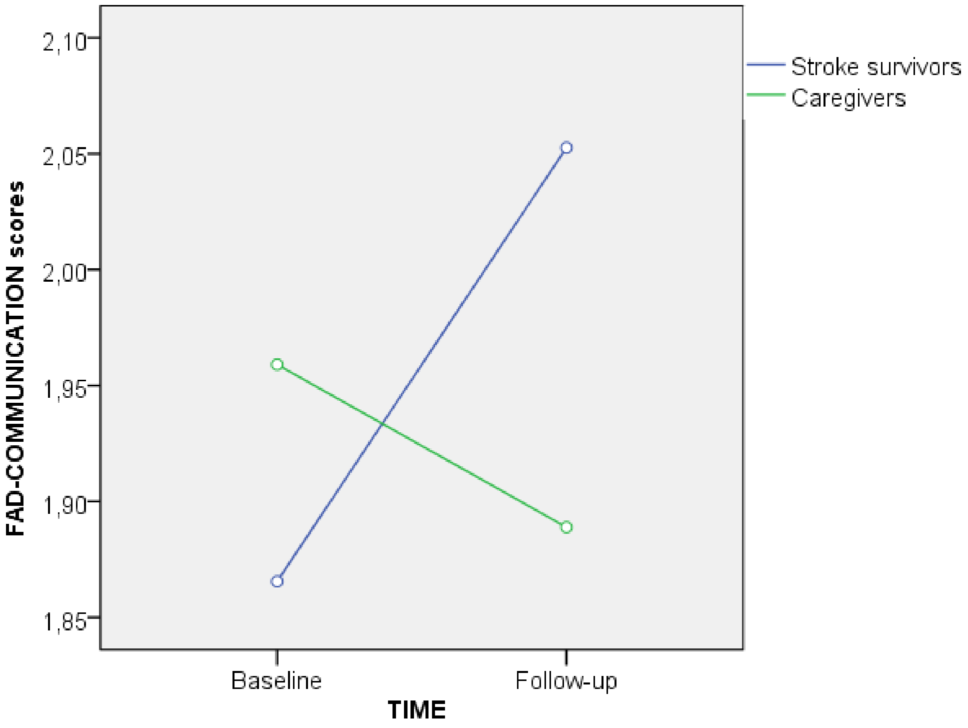
Graph 9. Change over time of FAD Roles



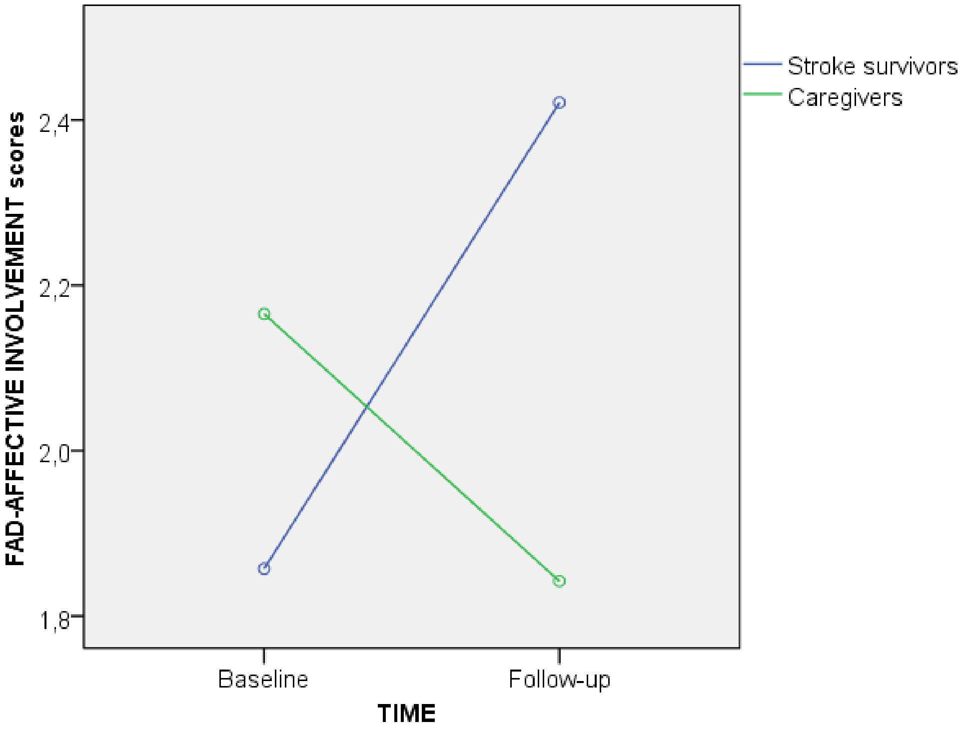
Graph 10. Change over time of FAD Behavior Control



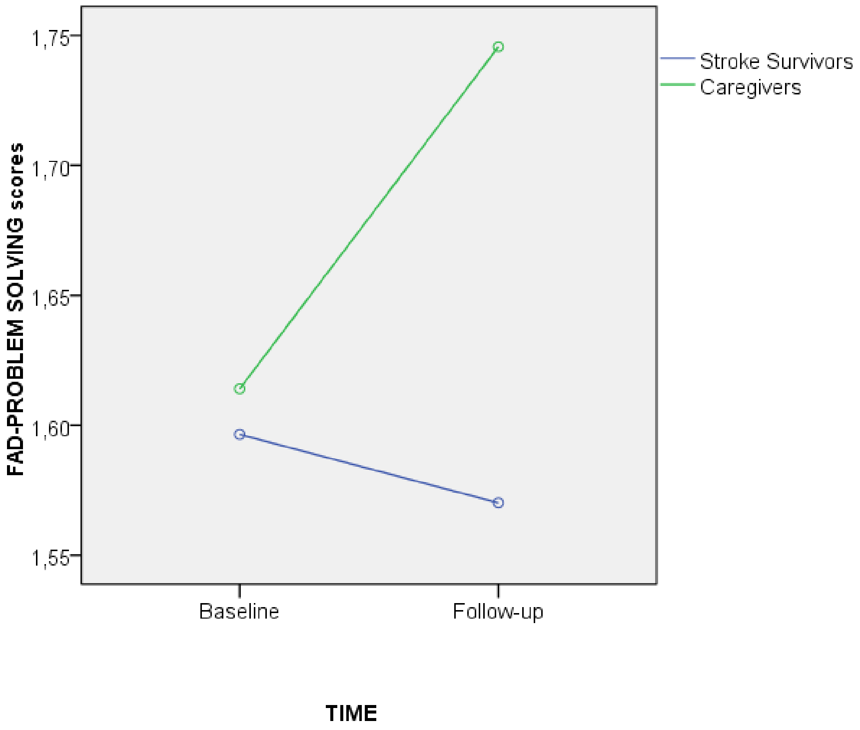
Graph 11. Change over time of FAD Communication



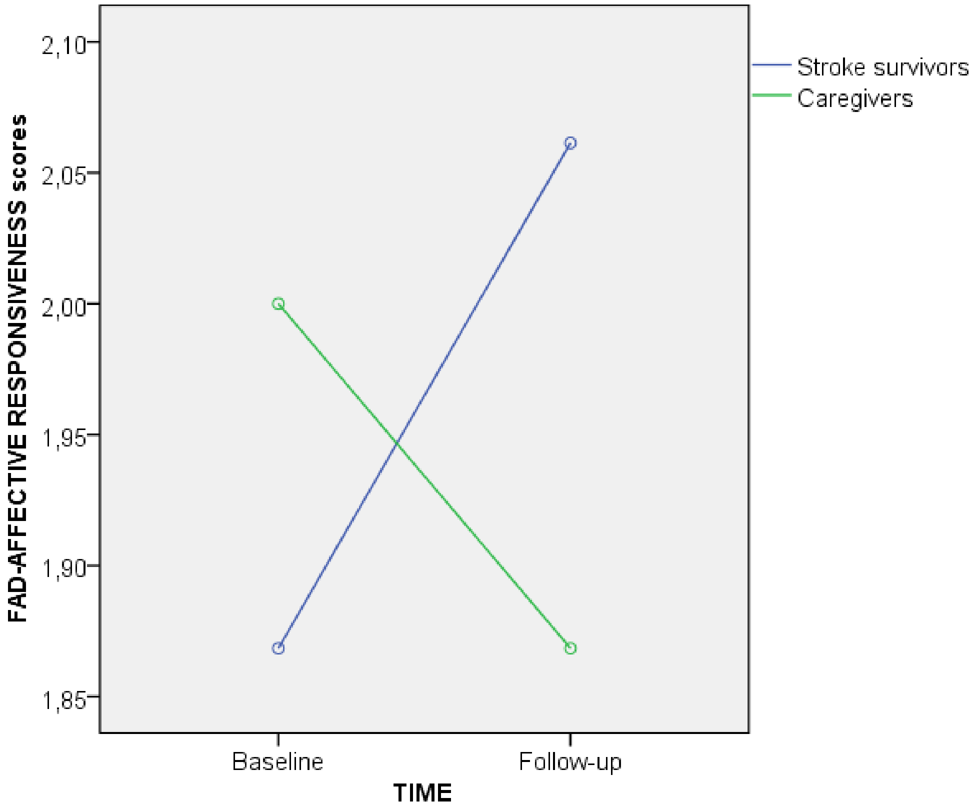
Graph 12. Change over time of FAD Affective Involvement



Graph 13. Change over time of FAD Problem Solving

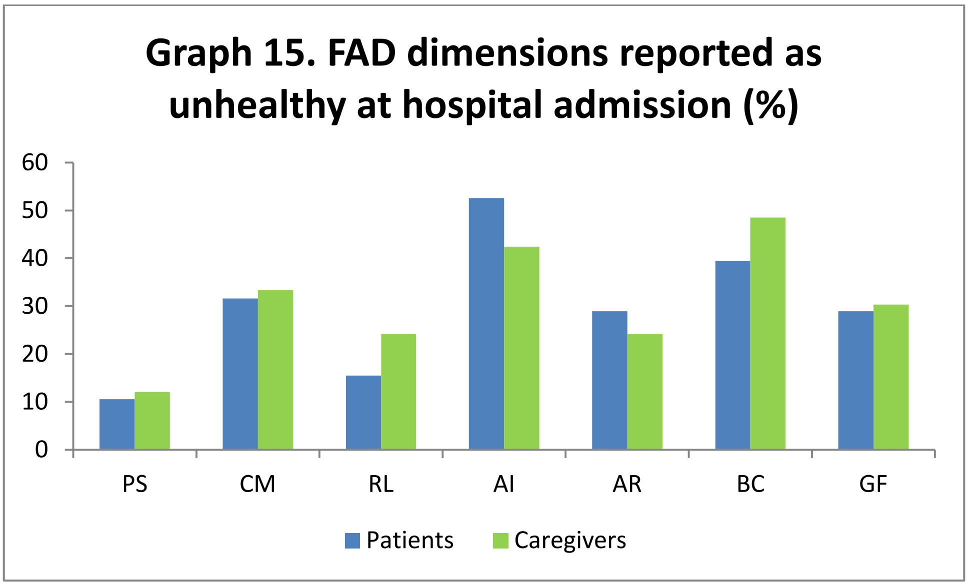


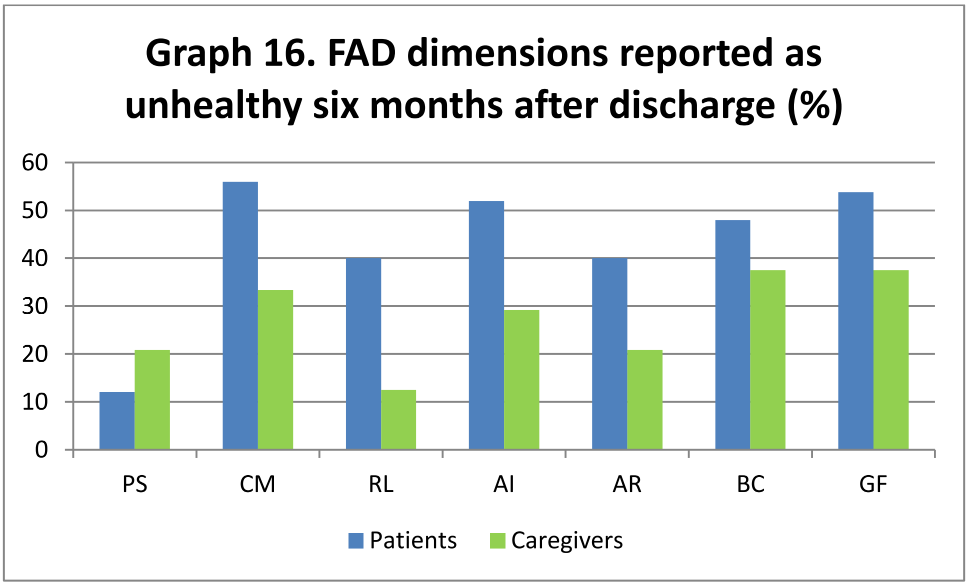
Graph 14. Change over time of FAD Affective Responsiveness



4.4.2 *Ineffective dimensions according to FAD cut-off scores*

At hospital admission, according to FAD cut-offs (Miller et al., 1985), unhealthy (i.e., equal to or above cutoff) affective involvement scores were reported by 52.6% of stroke survivors, followed by behavior control (which was rated as unhealthy by 39.5 % of them), and communication problems (reported by 31.6% of patients). Affective responsiveness and general functioning were rated as unhealthy by 28.9 % of patients, while roles and problem solving were dysfunctional for 15.5% and 10.5% of patients respectively. Six months after discharge, the frequencies of family dimensions rated as unhealthy by patients rose for all FAD scales: problem solving (12%), roles (40%), communication (56%), behavior control (48%), affective responsiveness (40%), and general functioning (53.8%). Only the frequencies of unhealthy affective involvement scores remained the same (52%). At patients' hospital admission, 48.5% of caregivers reported unhealthy scores in behavior control. 42.4% of the family informants also reported problematic functioning for the affective involvement dimension and 33.3% of them reported problematic family functioning for communication, followed by general functioning (30.3%), roles (24.2%), affective responsiveness (24.2%) and problem solving (12.1%). Six months after discharge, an increase in unhealthy ratings for problem solving (20.8%) and general functioning (37.5%) was recorded, while the percentages of caregivers rating communication as unhealthy remained stable (33.3%). Contrary to stroke survivors, the frequencies of family dimensions rated as unhealthy at six-month follow-up by caregivers decreased for the following FAD scales: roles (12.5%), behavior control (37.5%), affective responsiveness (20.8%) , affective involvement (29.2%), and general functioning (53.8%). *Graphs* 15 and 16 report the proportions of stroke survivors and caregivers reported unhealthy FAD scores at hospital admission and six months after discharge.





4.4.3 *Predictors of patients' functional independence at discharge from rehabilitation hospital.*

To exclude multicollinearity problems, the correlations between each predictors variables, variance inflation factor (VIF) and tolerance statistics associated with the multiple regression analysis were checked. FAD general functioning scale were removed from multiple regression analysis, since its correlations with the other FAD scales were higher than 0.70 (Tabachnik & Fidell, 2007), except for behavior control and affective involvement. None of the tolerance values were below 0.2 and none of the VIF values were between 5 and 10 (Barbaranelli, 2010). These statistics indicated that there was no cause for concern related to multicollinearity.

4.4.3.1 Predictors of FIM cognitive gain

Taking into account the effect of age, family functioning explained an additional 31.3% of the variance in FIM cognitive gain at discharge. This was not a statistically significant contribution, as indicated by the Sig. F change value (*p*=0.07). The model as whole was not significant [$F_{(7,29)}$=2.02, *p*=0.087]. One dimension of family functioning statistically contributed to the gain in FIM cognitive score: behavior control (beta=0.56, p=0.03). Patients with higher FAD behavior control scores reported higher cognitive functioning gain at discharge. *Table* 28 illustrates the results of the hierarchical multiple regression analysis for patients' FIM cognitive gain.

Table 28. Hierarchical multiple regression analysis predicting patients' FIM cognitive gain

	Step 1			**Step 2**		
Predictor	**B**	**SE B**	**ß**	**B**	**SE B**	**ß**
Age	0.002	0.002	0.117	0.000	0.002	0.031
Problem Solving				-0.015	0.094	-0.282
Communication				-0.039	0.128	-0.080
Roles				-0.059	0.098	-0.134
Affective Responsiveness				0.156	0.094	0.425
Affective Involvement				-0.029	0.117	-0.066
Behavior Control				0.262	0.117	0.558*

Note. Step 1: R^2=0.014, adjusted R^2=0.014; Step 2: R^2=0.327, adjusted R^2=0.165. * $p < 0.05$.

4.4.3.2 Predictors of FIM motor gain

Taking into account the effect of age, family functioning explained an additional 8.5% of the variance in FIM motor gain at discharge. This was not a statistically significant contribution, as indicated by the Sig. F change value (*p*=0.83). The model as whole was not significant [$F_{(7,29)}$=0.56, *p*=0.78]. None of the variables of family functioning statistically contributed to FIM motor gain. *Table* 29 illustrates the results of the hierarchical multiple regression analysis for patients' motor functioning.

Table 29. Hierarchical multiple regression analysis predicting patients' FIM motor gain

	Step 1			**Step 2**		
Predictor	**B**	**SE B**	**ß**	**B**	**SE B**	**ß**
Age	0.007	0.007	0.187	0.007	0.007	0.177
Problem Solving				0.025	0.286	0.023
Communication				0.16	0.39	0.123
Roles				0.116	0.300	0.100
Affective Responsiveness				0.043	0.286	0.044
Affective Involvement				0.122	0.355	0.107
Behavior Control				-0.389	0.356	-0.311

Note. Step 1: R^2=0.35, adjusted R^2=0.008; Step 2: R^2=0.120, adjusted R^2=0.093.

4.4.4 *Predictors of caregivers' psychological distress at six months after discharge*

To exclude multicollinearity problems, the correlations between each predictors variables, variance inflation factor (VIF) and tolerance statistics associated with the multiple regression analysis were checked. FAD general functioning scale was removed from multiple regression analysis, since its correlations with FAD affective responsiveness and communication scales were higher than 0.70 (Tabachnik & Fidell, 2007). None of the tolerance values were below 0.2 and none of the VIF values were between 5 and 10 (Barbaranelli, 2010). These statistics indicated that there was no cause for concern related to multicollinearity.

4.4.4.1 Predictors of caregivers anxiety at six months after discharge

Taking into account the effect of caregivers' age and SQ anxiety scores at hospital admission, family functioning at hospital admission explained an additional 8.6% of the variance in SQ anxiety scores at six months after discharge. This was not a statistically significant contribution, as indicated by the Sig. F change value (*p*=0.27). However, the model as whole was significant [$F_{(8,14)}$=10.70, *p*≤0.000]. None of the dimensions of family functioning statistically contributed to caregivers' anxiety, neither age did. Only caregiver' anxiety significantly at hospital admission predicted anxiety at six months after discharge (beta=0.66, p≤0.000). *Table* 30 illustrates the results of the hierarchical multiple regression analysis for caregivers' anxiety.

Table 30. Hierarchical multiple regression analysis predicting caregivers' SQ anxiety scores at six months after discharge

	Step 1			**Step 2**		
Predictor	**B**	**SE B**	**ß**	**B**	**SE B**	**ß**
Age	-0.159	0.068	-0.266*	-0.113	0.079	-0.19
SQ Anxiety at hospital admission	0.839	0.127	0.75***	0.742	0.148	0.663***
Problem Solving				2.635	1.7	0.225
Communication				0.035	1.81	0.004
Roles				-1.236	1.137	-0.151
Affective Responsiveness				-1.766	1.891	-0.187
Affective Involvement				1.382	1.095	0.203
Behavior Control				3.119	1.61	0.289

Note. Step 1: R^2=0.774***, adjusted R^2=0.751; Step 2: R^2=0.859***, adjusted R^2=0.779. * p < 0.05; *** p < 0.001.

4.4.4.2 Predictors of caregivers depression at six months after discharge

Taking into account the effect of caregivers' age and SQ depression scores at hospital admission, perception of family functioning at hospital admission explained an additional 14.5% of the variance in depression at six months after discharge. This was not a statistically significant contribution, as indicated by the Sig. F change value (*p*=0.22). However, the model as whole was significant [$F_{(8,14)}$=6.42, *p*≤0.001]. None of the dimensions of family functioning statistically contributed to caregivers' depression, neither age did. Only caregivers' depression at hospital admission significantly predicted depression at six months after discharge (beta=0.50, p≤0.01). *Table* 31 illustrates the results of the hierarchical multiple regression analysis for caregivers' depression at six months after discharge.

Table 31. Hierarchical multiple regression analysis predicting caregivers' SQ depression at six months after discharge

	Step 1			**Step 2**		
Predictor	**B**	**SE B**	**ß**	**B**	**SE B**	**ß**
Age	-0.198	0.093	-0.308*	-0.146	0.109	-0.228
SQ Depression at hospital admission	0.902	0.207	0.631***	0.724	0.234	0.507**
Problem Solving				1.543	2.215	0.123
Communication				4.503	2.413	0.439
Roles				-0.916	1.525	-0.104
Affective Involvement				-1.877	2.416	-0.186
Affective Involvement				0.115	1.515	0.016
Behavior Control				-1.891	2.103	-0.164

Note. Step 1: R^2=0.641***, adjusted R^2=0.605; Step 2: R^2=0.786**, adjusted R^2=0.664. * $p \leq 0.05$; ** $p \leq 0.01$; *** $p \leq 0.001$.

4.4.4.3 Predictors of caregivers somatic symptoms at six months after discharge

Taking into account the effect of caregivers' age and SQ somatic symptoms scores at hospital admission, perception of family functioning at hospital admission explained an additional 12.6% of the variance in somatic symptoms at six months after discharge. This was not a statistically significant contribution, as indicated by the Sig. F change value (p=0.46). However, the model as whole was significant [$F_{(8,14)}=4.21$, $p \leq 0.01$]. Among family functioning dimensions, affective involvement significantly predicted somatic symptoms at six months after discharge (beta=0.52, $p \leq 0.05$), together with caregivers' somatic symptoms at hospital admission (beta=0.67, $p \leq 0.005$). *Table* 32 illustrates the results of the hierarchical multiple regression analysis for caregivers' SQ somatic symptoms at six months after discharge.

Table 32. Hierarchical multiple regression analysis predicting caregivers' somatic symptoms six months after discharge

	Step 1			Step 2		
Predictor	**B**	**SE B**	**ß**	**B**	**SE B**	**ß**
Age	-0.146	0.096	-0.220	-0.172	0.122	-0.259
SQ Somatic Symptoms at hospital admission	0.771	0.157	0.713***	0.724	0.186	0.670**
Problem Solving				2.753	2.697	0.212
Communication				-0.383	2.864	-0.036
Roles				0.184	1.823	0.020
Affective Responsiveness				-1.191	2.917	-0.114
Affective Involvement				3.912	1.724	0.517*
Behavior Control				-2.393	2.595	-0.200

Note. Step 1: R^2=0.581***, adjusted R^2=0.539***; Step 2: R^2=0.706**, adjusted R^2=0.538. * p < 0.05; ** p < 0.01; *** p < 0.001.

4.4.4.4 Predictors of caregivers hostility at six months after discharge

Taking into account the effect of caregivers' age and SQ hostility scores at hospital admission, perception of family functioning at hospital admission explained an additional 26.8% of the variance in hostility at six months after discharge. This was a statistically significant contribution, as indicated by the Sig. F change value (*p*=0.033). The model as whole was significant as well [$F_{(8,14)}$=7.32, $p \leq 0.001$]. None of the family functioning dimensions was a better predictor of hostility at six months after discharge. Caregivers' hostility at hospital admission significantly contributed (beta=0.55, $p \leq 0.001$) to hostility at six months after discharge. *Table* 33 illustrates the results of the hierarchical multiple regression analysis for caregivers' hostility.

Table 33. Hierarchical multiple regression analysis predicting caregivers' SQ hostility at six months after discharge

	Step 1			**Step 2**		
Predictor	**B**	**SE B**	**ß**	**B**	**SE B**	**ß**
Age	-0.045	0.067	-0.102	-0.059	0.067	-0.132
SQ Hostility at hospital admission	0.831	0.173	0.727***	0.636	0.151	0.557***
Problem Solving				2.478	1.458	0.286
Communication				-1.464	1.439	-0.207
Roles				0.376	0.986	0.062
Affective Responsiveness				2.525	1.548	0.362
Affective Involvement				1.377	0.947	0.273
Behavior Control				0.585	1.394	0.073

Note. Step 1: R^2=0.539***, adjusted R^2=0.493; Step 2: R^2=0.807***, adjusted R^2=0.697.

* p ≤0.05; ** p ≤0.01; *** p ≤0.001.

5. DISCUSSION

5.1 Discussion results study 1

The first aim of this research was to compare lifestyle behaviors and psychosocial variables and correlates in an Italian sample of stroke survivors with a sample composed by subjects from the general population. The two groups were not significantly different in demographic variables such as sex, age, occupation, and marital status. On the contrary, the length of education in years was significantly superior in controls than in stroke patients. This result supports an association of education with the incidence of stroke, suggesting low educational attainment as a risk factor for stroke. In previous studies as well low education was identified as a risk factor for a cardiovascular event. Siegel et al. (1987) analyzed data from the Systolic Hypertension in the Elderly Program pilot project. A total of 551 men and women 60 years of age and older were prospectively studied. The Authors observed that lower level of education, together with age, history of a cardiovascular event, and cigarette smoking, were significant predictors of a cardiovascular event. Quareshi and colleagues (2003), in a longitudinal study with a mean follow-up period of 15.2±4.6 years, reported that persons with less than 12 years of education were at higher risk for fatal stroke and myocardial infarction (MI), after adjusting for potential confounding factors included age, sex, race/ethnicity, systolic blood pressure, presence of diabetes mellitus, serum cholesterol level, smoking status, body mass index, and socioeconomic status. The relationship between education and risk of stroke and MI was more prominent in persons aged 50 years or less. In Liu et al. (1982) study an inverse relationship was observed between education and blood pressure status. The mechanism by which low education is related to the risk of cardiovascular event, including stroke, is still not clear. The possible link between education and socioeconomic status may in part explain the phenomenon. Persons with lower education may be more likely to have a lower socioeconomic status, which in turn may be related to more obstacles in the access to health care (Moroney et al., 1997). In addition, persons with lower socioeconomic status have increased exposure to a broad range of psychosocial variables predictive of morbidity, including chronic and acute stress in life and work, lack of social support, elevated levels of anger and hostility, low sense of mastery and control (Lantz et al., 1998). In our study, unfortunately, we were unable to obtain data regarding socioeconomic status, which constitutes a limit of the research. Anyway in the previous cited study of Quareshi and colleagues (2003), the relation between education and cardiovascular risk was independent of socioeconomic status. A link between education, income and lifestyle behaviors has also been reported (Lantz et al., 1998). Lifestyle behaviors, such as smoking cigarettes, being overweight, drinking alcoholic beverages, and being physically inactive, are formed during childhood and youth and persist into adulthood (Hinkle et al., 1968). Persons with low education may have less access to preventive medical care (Lantz et al., 1998). Our results contribute to previous studies by providing evidence regarding the association between length of education and risk for developing stroke. Further studies with larger sample are needed to confirm this data and to clarify the mechanisms by which higher educational attainment affects the risk of stroke.

The lifestyle behaviors examined in both stroke survivors and controls were alcohol and coffee consumption, current or past smoking habit, drug use, and body mass index. The literature reports evidence regarding excessive consumption of alcohol, cigarette smoking, drug abuse, and obesity as risk factors for all stroke subtypes (Goldstein et al., 2011). There are no data regarding the consumption of coffee. Results from our study showed that stroke survivors and controls reported similar mean BMI values (25.08 for patients *versus* 26.75 for controls), while a significantly greater percentage of stroke patients drank alcohol compared to control (55.3% versus 20%). The two samples did not significantly differ from each other in coffee consumption, current and past smoking habit, drug use and BMI values. However, it should be noted that, while the percentages of coffee and drug consumption were similar in the two samples (coffee consumption: 84.2% patients *versus* 92.5% controls; drug use: 5.3% patients *versus* 0% controls), the prevalence of stroke survivors currently smoking (30.8%) was twice that found in controls (15%), and the percentage of stroke patients with past smoking habit was higher than controls as well (44.7% versus 28.6%). Our results partly confirmed our initial hypothesis that stroke survivors would present unhealthy lifestyle behaviors and are partly in line with previous research, providing evidence that excessive alcohol consumption and cigarettes smoking are risk factors for developing stroke. On the contrary, the impact of drug abuse and obesity has not been confirmed by our data. Coffee consumption as well was not related to stroke incidence.

The sample of hospitalized stroke patients was also compared with the general population regarding the presence of psychiatric disorders according to DSM-IV-TR criteria and psychosomatic syndromes according to DCPR. A higher prevalence of diagnoses in stroke survivors, compared to controls, was expected. Previous studies showed that the presence of psychiatric diagnoses, especially major depression and anxiety disorders, is associated with the incidence of stroke. House et al. (1991) reported that the prevalence of depression in stroke survivors was twice that found in controls, although this difference was only significant at the 6-month follow-up assessment. The Framingham Study reported that significantly more stroke survivors had a depressive disorder compared with controls matched for age and gender (Kase et al., 1998). Differently, a controlled study (Burvill et al., 1995) found no significant difference in anxiety disorders prevalence rates between stroke survivors and community controls (respectively 11% *versus* 7%). In our study, at the admission to the rehabilitation hospital, 37.5% of stroke survivors met criteria for at least one DSM diagnosis, of which 25% reported mood disorders and 17.5% anxiety disorders. Among mood disorders, minor depression was the most frequently reported (17.5%), while general anxiety disorder (GAD) was (10%) the most common among anxiety disorders. In addition, there was a case of eating disorders (2.5%) and one of alcohol abuse (2.5%). A similar trend was observed in the control group, in which 22.5% of controls met criteria for at least one DSM diagnosis, specifically 12.5% mood disorders and 20% anxiety disorders. In the control group as well, minor depression and GAD were the most common disorders (respectively 7.5% and 5%). No statistical significant differences in DSM diagnoses prevalence rates between stroke survivors and controls were found. However it should be noted that the prevalence of mood disorders in stroke survivors was twice that found in controls. These data confirm the high prevalence of depression in stroke survivors found in previous studies. A meta-analysis (Robinson, 2003) collecting data from research performed throughout the world have registered prevalence rates of 19.3% for major depression and 18.5% for minor depression among hospitalized patients and respectively 14.1% and 9.1% among patient in community settings. In our study the prevalence of major depression was lower (2.5%) compared to that showed in the mentioned meta-analysis, while the frequency of cases of minor depression was similar (17.5%). Our findings confirm also the earlier observation by

Burvill et al. (1995) of the lack of significant differences in anxiety prevalence rates between patients and controls. In addition, the data showing GAD as the most frequent anxiety disorder reported by our stroke patients sample, confirm the findings of previous studies that measured different anxiety types (Campbell-Burton et al., 2013).

Regarding the DCPR diagnoses prevalence rates, 45% of stroke survivors presented symptoms meeting the criteria for at least one DCPR diagnosis. The most common was demoralization (22.5%), followed by illness denial (12.5%), irritable mood (10.5%), alexithymia (7.5%), and Type A behavior (5%). Only 1 patient (2.5%) reported health anxiety. With regard to the control group, 42.5% of controls met criteria for at least one DCPR diagnosis. The more frequent psychosomatic syndrome reported by controls was irritable mood (15%), followed by alexithymia (12.5%), and demoralization (10%). Only one case (2.5%) of type A behavior and one of health anxiety was reported. No significant statistical differences were found between patients and controls in the prevalence rates of DCPR psychosomatic syndromes. Our hypothesis that stroke patients would present significantly higher prevalence rates of DSM and DCPR diagnoses was therefore not confirmed. Anyway the results from our study provide clinically relevant data, showing that almost half (45%) of the patients undergoing rehabilitation after stroke present a DCPR psychosomatic syndrome, while the percentage of DSM diagnoses was lower (37.5%). The DSM-IV diagnosis of minor depression was included in this study and accounted for most of the psychiatric diagnoses (17.5%) in stroke patients. With its exclusion, as common in clinical practice (Rafanelli et al., 2003), the percentages of DSM diagnoses would have been even lower. The results indicate therefore that DCPR criteria are a useful tool for classifying psychological distress in stroke survivors and its use, together with the DSM criteria, is strongly recommended in medical settings. The data regarding our sample of stroke survivors are in line with previous reports in cardiology settings, in which the prevalence of any DCPR diagnosis ranged from 51 to 69%, while that of any DSM diagnosis was 37%. The elevate prevalence of demoralization found in our patients sample confirms its clinical relevance. The DCPR criteria of demoralization include the aspects suggested by Frank (1974), such as the awareness of being unable to cope with a pressing problem or of having failed to meet one's own or others' expectations. Studies using the DCPR interview found substantially higher rates of demoralization in medically ill patients (Tecuta et al., 2014). In our study there were not significant differences in demoralization prevalence rates between stroke patients and controls. However, it should be noted that, as well as for mood disorders, in the stroke survivors group there was a prevalence of demoralization which was twice that reported in controls. In our study 22.5% of stroke survivors reported demoralization, while only 10% of controls did. In addition, the frequency of demoralization in stroke survivors was higher compared to the prevalence of DSM major depression, which was only 2.5%, and of DSM minor depression (17.5%). These findings confirm those of a large study of 809 medical patients, in which the frequency of DCPR demoralization was 30%, whereas the frequency of DSM-IV major depression was only 17% (Mangelli et al., 2005). At the same vein the prevalence of illness denial was higher in stroke survivors (12.5%) than in controls, in which no cases were found. Anyway, the difference did not reach statistical significance. In addition, the prevalence of illness denial in our sample of stroke survivors was slightly higher compared to that found in other medical settings: 3.3% in cardiology (Rafanelli et al., 2003) and 9.5% in oncology (Grassi et al., 2004). On the contrary, the prevalence rates of irritable mood and alexithymia were slightly lower, but still not significantly different, in stroke survivors compared to controls (respectively 10.5% *versus* 15% for irritable mood and 7.5%

versus 12. 5% for alexithymia). These data confirm the previous reports showing that irritable mood is frequent (around 15%) in all medical settings to the same extent as community individuals (Porcelli & Rafanelli, 2010). Additionally, a previous community-based investigation showed that alexithymia is a common condition in the general population (Mangelli et al., 2006). The lack of a significant differences in the prevalence of DSM and DCPR diagnoses between stroke survivors and the general population and the high prevalence of diagnoses in the latter are likely due to the fact that control sample was constituted by an elderly population. The inclusion criteria for controls was negative history of stroke, which do not exclude that some of them had other physical problems different from stroke which may represent in any case risk factors for the development of anxiety, depression and psychosomatic syndromes.

However, according to our hypothesis, stroke survivors reported higher level of psychological distress in self-rated measures. Patients reported significantly higher levels of self-rated anxiety, depression and somatic symptoms at the Symptom Questionnaire (SQ). On the contrary, no differences have found in the levels of Psychosocial Index (PSI) stress, abnormal illness behavior, and quality of life. According to our initial hypothesis, our patients reported significantly higher levels of psychological distress (e.g., anxiety, depression, and somatic symptoms) than controls, but not superior stress, abnormal illness behavior and lower quality of life. These data support those of previous research documenting the significant impact on patient's mental health of the occurrence of a stroke and the difficulties in adjusting to their changed conditions (Campbell Burton et al., 2013). The findings that the self-rated assessment of anxiety and depression was more sensitive than the observer-rated methods in detecting differences between the two groups may be due to the fact that the self-rated methods, (particularly the SQ) have a different time focus (previous months and years in the diagnostic interview; during the previous week in the SQ) (Sonino et al., 2011). In addition, SQ scores, as other self-assessment questionnaires, provide important data for the quantification of a patient's levels of distress. Two patients may both have the same DSM-IV-TR diagnosis or the same medical disease, but they may present very different scores on a rating scale and these differences may affect the clinical course of the illness (Tomba & Bech, 2012). According to our hypothesis, patients also revealed lower positive functioning than controls, but only in one aspect of psychological well-being. Specifically, stroke survivors reported significantly lower autonomy compared to controls. This finding partially confirms previous research. Kim et al. (2013) have similarly found an association between impairment in psychological well-being and stroke onset, but in their study only one dimension of the Ryff's psychological well-being theoretical model (Ryff, 1989) was assessed. Authors showed that lower purpose in life was associated with a higher likelihood of stroke onset. In our study as well patients reported lower purpose in life compared to controls (respectively 24.11 *versus* 26.35), but the PWB dimensions that significantly discriminated between the two groups was only autonomy. This means that subjects who had a stroke tend to be more influenced by other people's judgment and expectations in their choices and that their way to think and act is deeply affected by social pressures.

Finally, another aim of the study was to compare the quality of family functioning in patients with stroke and controls. The two samples did not differ in any dimension of the McMaster Model of Family Functioning. The findings supported therefore our hypothesis and previous reports (Bishop et al., 1983) suggesting a lack of significant differences between the stroke survivors and controls during the acute phase. A possible explanation of this finding may be that the patients' ratings of family functioning after the suddenly onset of a stroke represent an evaluation of how family was perceived during the time before the stroke. We did not expect therefore a more problematic family functioning during the acute inpatient phase. Eventually a deterioration of family functioning might occur when patients return home and the family members need to adjust to patients functional and cognitive changes.

The second aim of this study was to explore lifestyle behaviors and psychosocial variables and correlates in caregivers of stroke patients. Our sample of caregivers was composed mainly by patients' adult children (44.4%) and partners (38.9%). Most of the caregivers were not living with patients at the time of the stroke occurrence (58.3%). The lifestyle behaviors examined in stroke survivors’ caregivers were the same assessed for stroke patients, with the exception of body mass index which we were unable to collect. Therefore the frequencies of alcohol and coffee consumption, current or past smoking habit, and drug use were investigated. All these behaviors that influence our health are indeed strongly influenced by our family context since they are usually developed, maintained, or changed within the family setting. Family members tend to share the same lifestyle behaviors, including similar use of substances (e.g., tobacco, alcohol, and illicit drugs) (Doherty & Campbell, 1988). Parents' lifestyles influence the behaviors adopted by children. For example, adolescents are much more likely to start smoking if either a parent or sibling smokes. Smokers tend to marry other smokers, smoke the same amount of cigarettes as their partners, and try to quit at the same time (Venters, Jacobs, Luepker, Maiman, & Gillum, 1984). In our sample, 38.9% of caregivers drank alcohol, 88.9% drank coffee, 25% were currently smokers, and 13.9% reported past smoking habit; none of the caregivers reported drug use. These findings suggest the presence of more healthy lifestyles behaviors in caregivers compared to patients, as showed by the minor consumption of alcohol and tobacco in caregivers.

Regarding the prevalence rates of psychiatric diagnoses according to DSM-IV-TR, 35.3% of caregivers met criteria for at least one DSM diagnosis. Anxiety disorders were recorded in 27.3% of caregivers, with general anxiety disorder being the more frequent (18.2%). Mood disorders were diagnosed in 11.8% of caregivers and minor depression was the more prevalent (8.8%). With regard to psychosomatic syndromes, 23.5% of caregivers presented symptoms meeting the criteria for at least one DCPR diagnosis, with demoralization being the most frequent (15.2%). These finding support our hypothesis regarding the presence of high psychological distress in caregivers. Coherently with the existing literature, the psychiatric disorders more frequently found in caregivers were mood and anxiety disorders, even if in our study the prevalence rates were slightly lower of those reported in previous research. The few studies available reported indeed a percentage of anxiety symptoms ranging from 37 to 58% (Beach et al., 2000; Dennis et al., 1998; Wilz & Kalytta, 2008) and a percentage of depression ranging from 34 to 52% (Anderson, Linto, & Stewart-Wynne, 1995; Draper, Poulos, Cole, Poulos, & Ehrlich, 1992; Schulz, Tompkins, & Rau, 1988; Silliman, Fletcher, Earp, & Wagner, 1986). The presence of high psychological distress in caregivers was also confirmed by the scores obtained at the Symptom Questionnaire. Caregivers reported significant higher scores compared to normative data in anxiety, depression, and somatic symptoms. Differently, caregivers showed no impairment in psychological well-being according to Ryff's theoretical model. These data confirm that the presence of psychological distress, which was reported by caregivers in our study, does not necessarily imply the lack of positive psychological characteristics. As suggested by Ryff and colleagues (2006), well-being and ill-being are distinct domains of mental functioning.

The data regarding perceived family functioning, according to Family Assessment Device cut-offs, showed that 30.3% of caregivers reported problematic general family functioning. In our sample, in addition, a relevant amount of caregivers reported problems regarding behavior control in the family. This dimension was the one more frequently rated as unhealthy (48.5%), while problem solving was rated as unhealthy only by a small amount of caregivers (12.1%). The data of our study are in line with previous reports (Epstein-Lubow et al., 2009; King et al., 2010) which reported that almost one third of stroke survivors’ caregivers perceived problematic family functioning. In our research, in particular, caregivers showed more difficulties in the area of behavior control which is the way in which a family establishes rules about acceptable behaviors relating to several kind of situation, including physically dangerous situations and those involving meeting and expressing psychobiological needs and socialization.

Another aim of the study was to explore the socio-demographic correlates of caregivers' and patients' self-rated psychological distress, well-being and family functioning. According to our hypotheses, for stroke patients a significant relation with gender and psychological distress and well-being was found, with female reporting significantly higher psychological distress (e.g., anxiety and somatic symptoms) and lower well-being (e.g., autonomy, personal growth and self-acceptance). Regarding the association with age, no significant relation with psychological distress emerged, while older stroke survivors showed higher self-acceptance, and a more positive perception of family roles and problem solving. Our data on psychological distress are coherent with those of the literature regarding anxiety in the elderly. Several studies identified socio-demographic variables, such as female gender, as a risk factor for both anxiety symptoms and disorders in the elderly (Vink et al., 2008). With respect to the age, our data confirm those of previous studies reporting no significant relations between psychological distress and increasing age (Vinks et al., 2008). The data regarding psychological well-being as well are coherent with previous studies in which personal growth and self-acceptance were found more impaired in women compared to men (Ruini et al., 2003), while the data showing that older stroke survivors reported higher self-acceptance compared to younger patients are in contrast with previous findings in which the PWB dimension of self-acceptance was not significantly related with age (Ruini et al., 2003; Ryff, 1989). For caregivers, contrary to what was expected, no associations with gender were found for psychological distress and any of the dimensions of psychological well-being, except for personal growth which was higher in female compared to male. Interestingly, in stroke patients the relation between gender and personal growth was the opposite. In addition, patients' partners and those living with them reported higher PWB self-acceptance compared to patients' adult children and those living apart. No significant associations between the type of relation with the patient and the living situation and caregivers' perception of family functioning were found, contrary to our hypothesis. At the same vein, no associations were reported between age and caregivers' psychological distress and well-being, while a significant negative correlation with FAD problem solving suggested that older caregivers had a better perception of the family ability to solve problems effectively.

Finally, the last aim of this study was to explore the relations of caregivers' and patients' self-rated psychological distress, well-being and family functioning with patients' functional status at hospital admission. Stroke patients with a lower functional status at hospital admission, both in the cognitive and the motor domains, showed higher self-rated anxiety, depression, and somatic symptoms. More impairment in cognitive status was also associated with patients' lower quality of life. Our data confirm our hypothesis that patients’ psychological distress has a significant relation to their functional status and support previous studies which reported trends for more dependent patients to have a higher risk of depression and anxiety (Langhorne et al., 2000). No associations between patients' functional status and psychological well-being were reported, while several dimensions of family functioning were associated with it. Particularly, patients with higher impairment at hospital admission in both motor and cognitive status showed also a negative perception of family communication and affective responsiveness. Lower patients' cognitive status was also associated with a poorer affective involvement and more problems in behavior control. These data support a relevant relation between patients’ level of independency at hospital admission and family functioning. Possible interpretations of these results could be on one hand that the severity of the illness might have negatively affect patients perception of family’s functioning and, on the other hand, that problematic family functioning may have negatively impacted the functional independence of patients. From a clinical point of view, these data suggest the utility of the assessment of patient’s family dynamics, especially for those with higher impairment in functional independence.

Contrary to our hypothesis, no significant correlations were found between patients' functional status and caregivers' psychological distress and well-being, while caregivers of patients with higher cognitive status reported more problems in FAD behavior control. Interestingly, the significant relation between behavior control and cognitive status was also reported in patients. Given the number of non-significant correlations and their magnitude, there was little evidence to support our hypothesis that the level of patients’ functional independence has a meaningful relationship to caregivers’ psychological distress and well-being at hospital admission. These findings are in contrast to previous research on stroke reporting that caregivers' depression was related to patients' greater physical dependency and disability in the acute phase (Anderson et al., 1995; Berg et al., 2004), but are similar to the study of Kreutzer, Gervasio & Camplair (1994) who found that injury severity was only marginally related to the distress of caregivers of patients with traumatic brain injury.

5.2 Discussion results study 2

The study 2 had a longitudinal design with the dual aim of exploring the longitudinal modification of stroke survivors' functional status and the longitudinal change of the psychosocial variables and correlates in both stroke survivors and their caregivers. The psychological and psychosomatic data of this second study refer to patients and caregivers who were assessed in both occasions: at admission to rehabilitation hospital and six months after discharge. Specifically, at six-month follow-up 27 (67.5%) stroke survivors and 24 (66.7%) caregivers remained in the research.

The first aim of this study was to explore the longitudinal change from admission to, discharge from rehabilitation hospital, and six months after discharge of stroke survivors' functional status. Our hypothesis of an improvement in patient's functional status from admission to discharge from rehabilitation hospital and stability in functional status at six-month follow-up was confirmed. As expected, there was a significant improvement in patients' functional independence, both in the cognitive and motor domain at the discharge from hospital, indicating the efficacy of the rehabilitation treatment. After six months from discharge, patients' level of functional independence did not significantly change from discharge, indicating stability over time of the effects of the rehabilitation treatment.

The second aim of this study was to explore the longitudinal change from admission to hospital to six months after discharge of frequency of lifestyle behaviors and diagnoses (according to DSM and DCPR), and self-rated psychological distress and well-being, in both stroke survivors and their caregivers. Given the inconsistency of the findings in the literature regarding the change over time in psychiatric and psychological symptoms, and the lack of data on long term lifestyle behaviors and psychological well-being, no hypotheses were done concerning the time trend for these variables.

The lifestyle behaviors examined in both stroke survivors and controls were alcohol and coffee consumption, current or past smoking habit, and drug use. In addition, body mass index was calculated for stroke survivors only. At six months after discharge, the only significant change in lifestyle behaviors was found for stroke survivors. A significant decrease in the percentage of subjects smoking cigarettes was reported. This result is very relevant, given the importance of smoking abstinence in preventing stroke relapse (Goldstein et al., 2011). Anyway it should be noted that any smoking cessation program was provided neither during the rehabilitation treatment nor after. There is therefore a risk that smoking abstinence after discharge may be a temporary reaction associated with the fear and anxiety provoked by the recent occurrence of the stroke. Since sustained smoking cessation is difficult to achieve, participation in programs to facilitate smoking cessation should be strongly recommended for patients who were smoking at the time of stroke onset, in order to help them to stop smoking permanently. Effective behavioral and pharmacological treatments for nicotine dependence are available and the combination of counseling and medications is more effective than either therapy alone (Goldstein et al., 2011). Caregivers should be involved in this program as well, given the proven strong influence of family members in smoking habit. Smokers in fact are much less likely to successfully quit smoking if their partner smokes or is critical of their attempts to quit (Coppotelli & Orleans, 1985).

Regarding the change over time of the prevalence of diagnoses according to DSM-IV-TR, there was a significant increase only in stroke patients but not in caregivers. Six months after discharge from hospital, the cases of patients with at least one DSM diagnosis significantly rose from 33.3% to 55.6%. From a clinical point of view, it is worth paying attention to an increase over time in the frequencies of mood disorders in patients (from 18.5% to 37%), even if it was not statistically significant. At the same vein, in both patients and caregivers was observed a slight increase of cases with at least one DCPR diagnosis, even if in any of them this change reached statistical significance, In stroke patients, cases with at least one DCPR diagnosis rose from 40.7% to 59.3%; in caregivers DCPR cases increased from 29.2% to 41.7%. In stroke patients, demoralization and irritable mood cases rose from hospital admission to six months after discharge (respectively from 22.6% to 37% and from 11.1% to 14.8%). In caregivers the most evident increment was in the frequencies of irritable mood, which rose from 4.2% to 12.5%, and there was a new case of demoralization. The significant increase over time of frequency of cases with at least one diagnosis according to DSM-IV-TR in stroke survivors confirm the findings of some previous studies reporting that the prevalence of psychological disorders is higher in the chronic stage (< 6 months post stroke), compared to the acute and sub-acute phases of illness (Langhorne, 2000). The results of our study in particular showed an increase in depressive symptoms, as stressed by the increment in mood disorders and demoralization cases. For caregivers, on the contrary, our findings lead to the conclusion of a stability over time, especially in the prevalence rates of DSM diagnoses. These findings support the results of a systematic review (Gaugler, 2010) which underlined that depression in caregivers of stroke patients did not tend to demonstrate any significant change in longitudinal quantitative studies. Wilz and Kalytta (2008), as well, reported similar prevalence rates and average sum scores of anxiety symptoms (using the Beck Anxiety Inventory-BAI; Beck et al., 1988) in spouses of stroke patients during patients' admission for rehabilitation and 1 year later. Concerning the change in frequency of DCPR psychosomatic syndromes in caregivers from hospital admission to six months after discharge, noteworthy, even if not statistically significant, is the increase of irritable mood. This result is consistent whit the report of Williams (1993), which found that 40% of caregivers reported high hostility and anger. The DCPR concept of irritable mood is largely based on the work of Snaith and Taylor (1985). Irritable mood is defined as a feeling state that requires an increased effort of control over temper by the individual or results in irascible verbal or behavioral outbursts. It may be experienced as brief and isolated episodes, in particular circumstances, or it may be prolonged and generalized. Research showed that everyday stresses may elicit irritable mood (Fava, 1987). Delivering care to stroke patients represents an increase both in responsibility and in the number of hours spent with patients. These tasks are additional to the usual daily workload, which may include household maintenance and working outside the home (Williams, 1993). Moreover, many caregivers feel uncertain and unprepared in the caregiving role (Foster et al., 2013). All these factors may certainly explain the increase in irritable mood cases found in our study.

Regarding to the change over time of self-rated psychological distress, stroke survivors and their caregivers reported a similar trend over time. Specifically, a significant decrease in anxiety symptoms, as measured by the Symptom Questionnaire (SQ), was observed in both samples from admission to hospital to six months after discharge. In stroke survivors, in addition, there was a significant reduction over time in

SQ somatic symptoms, an increase in Psychosocial Index (PSI) stress and a significant deterioration of PSI quality of life. On the contrary SQ depression, SQ hostility, and PSI abnormal illness behavior did not change over time in both groups. Caregivers did not show any changes in PSI stress, abnormal illness behavior and quality of life. It should be noted, that the stability of self-rated depressive symptoms, which levels were significantly high at hospital admission, denotes the permanence of a substantial psychological distress at six months after discharge for both stroke survivors and caregivers. Overall, the findings of our study regarding both observed and self-rated psychological distress suggested that anxiety symptoms, both in stroke patients and their caregivers, are more frequent during the acute phase of the illness and tend to decrease over time, while depressive symptoms tend to persist even after months from the onset of stroke. In addition, six months after hospital discharge, 37% of stroke survivors and 20.8% of caregivers presented demoralization, meaning that more the one-third of patients and one-fifth of family members experienced feelings of helplessness, or hopelessness or giving up. This condition for both patients and caregivers was often related to the disappointment with the extent of recovery achieved by stroke survivors and with a strong sense of being unable to cope with the sudden and permanent changes produced by the onset of the illness and with the management of stroke-related deficits. These findings suggest on one hand the need for the medical staff to improve communication strategies during the rehabilitation process, in order to encourage realistic expectations of recovery (Grant et al., 2014), and in another hand the need for adequate care for stroke survivors and caregivers even after the acute phase. Most patients and caregivers reported indeed a strong feeling of social isolation and loneliness after the return home from the rehabilitation hospital (Grant et al., 2014).

With regard to the modification over time (from hospital admission to six months after discharge) of psychological well-being (PWB), no significant changes were reported neither for patients nor for caregivers. These results were unexpected, especially for patients. Stroke often results in a loss of functional independence, which has potentially destructive implications for the stroke survivor’s perception of competence and may deeply alter the social role functioning as well as physical abilities (Palmer & Glass, 2003). We would expect that the onset of a stroke would weaken the subject's sense of environmental mastery, autonomy, and positive relations. Anyway, previous research on general population showed that the Psychological Well-Being scales score tend to be stable over time (Ryff, 1989; Ruini et al., 2003). Rafanelli et al. (2004) suggested that PWB scales measure an attitude toward optimal functioning, raising the issue of the collocation of the questionnaire within the state-trait continuum. The dimensions theorized by Ryff are a mixture of state and trait elements and consequently they do not necessarily present fluctuations in the short term. A possible explanation of the lack of a modification over time in patients and caregivers psychological well-being could be therefore that six months is not enough time to provoke significant changes of these aspects. However, in our study patients reported a decrease of PSI quality of life which is in contrast with the lack of modification in psychological well-being. Anyway, given the proven influence of psychological well-being in the recovery process of various diseases and in longevity (Rafanelli & Ruini, 2012), an assessment of psychological well-being, other than distress, is strongly recommended both in stroke survivors and their caregivers.

5.3 Discussion results study 3

The general aim of study 3 was to explore change over time in the perception of family functioning of stroke survivors and their caregivers and to verify if and which dimensions of family functioning are significantly associated with outcomes of both samples. The advent of stroke in a family member may deeply challenge the preexisting patterns and norms which characterized the family system (Palmer & Glass, 2003). Stroke has an acute onset that requires the family more rapid affective and instrumental changes compared to gradual-onset diseases, which, on the contrary, allows for a more protracted period of adjustment (Rolland, 1987). Longitudinal change in family functioning is important to assess because, as Clark & Smith (1999) suggested, the majority of alterations from prestroke family functioning occurs after the hospital discharge.

The first aim of this study was therefore to verify any changes in family functioning from patients' admission to hospital to six months after discharge. The findings from our study partly confirmed our hypothesis to find a deterioration over time of the perception of family functioning of both patients and their caregivers. A significant decline over time in family functioning was perceived exclusively by the patients. Specifically stroke survivors showed a deterioration in roles, behavior control, communication, and affective involvement over the time, as indicated by the higher FAD scores at 6 months after discharge compared to hospital admission, while family members reported stability over time for these dimensions. Problem solving and affective responsiveness did not significantly vary over time for both patients and caregivers. This means that only patients perceived an increment in the problems related to role definitions, probably due to a difficulty to adapt to new roles and responsibility by the family members, an increase in the rigidity of behavior control, and a deterioration in the clarity and directness of communication in the family. Our data in part confirm the reports of the previous study by Clark and Smith (1999a) in which significant deterioration in patients' perception of communication, roles, and general family functioning was reported as well. In our research, however, patients reported a deterioration also in behavior control and affective involvement. Our findings of a stability over time of the perception of family functioning by caregivers show differences with those of Clark and Smith (1999a). The Authors reported a deterioration in the spouses' perception of communication and roles, and an improvement in behavior control. Anyway in Clark and Smith's study, the sample of family members was divided into two groups: spouses of patients and other family members. The change over time in family functioning was dissimilar according to the different function covered by the family members: improvements in roles, affective responsiveness, affective involvement, and behavior control were recorded in the ratings provided only by the family members who were not the spouses. A limit of our study is that we did not investigate if the longitudinal trends in family functioning vary according to the caregivers' type of relation with the patient (partner or other kind of family member). Therefore the heterogeneity among caregivers' relationship with the patient in our sample (which was composed prevalently by partners and adult children) may have influenced the findings, and the subdivision of the sample in partners and other family members may have lead to different results. Caregivers often reveal interpersonal issues related to the changes in their relationships with stroke survivors due to the stroke-related deficits. A partner may be more effected by these modifications and report more social isolation compared to an adult child, who may have in turn the support of his or her partner in coping with the illness. After stroke, the reciprocal relationship for couples may be deeply challenged by intimacy issues and sexuality problems (Grant et al., 2014). In addition, given the high mean age of our sample, partners may have themselves medical problems which may affect family functioning as well. Another explanation of our findings could also be that patients' changes in roles and activities in the family due to the stroke-related deficits impact more deeply their perception of family functioning. As suggested by Keitner et al. (1987) in a study of patients with major depression, the tendency of patients to perceive the family more negatively may reflect a more general sense of hopelessness and helplessness. Our sample of stroke patients reported a substantial prevalence of mood disorders and demoralization. An explanation based on Becks' theory of the role of cognitive distortion in depression (Beck, 1976) may be that stroke-related problems lead the patients to view their family functioning in a even more negative way. On the other hand a different explanation may be that the patients are accurate in their perceptions, while the other family members may underestimate the degree of family problems and deterioration in family functioning (Keitner et al., 1987).

The third aim of this study was to verify if and which dimensions of patients' perceived family functioning at hospital admission were significant predictors of patients' functional recovery at the end of the rehabilitation process. The findings of our study reported that family functioning did not contributed significantly to the variance of patients' functional recovery at the end of the rehabilitation. Anyway, a significant relation between patients' recovery in the area of cognitive functioning and perceived affective involvement and behavior control was found. In particular patients that perceived a more rigid behavioral control reported a higher gain in cognitive status, which includes social cognition and communication, such as visual and auditory comprehension, vocal and non-vocal expression, memory, problem solving, and social interaction. This finding support those of a previous study by Evans et al., (1987b), who reported that a worse perception of behavior control was related to a decreased risk of rehospitalization following stroke. These data suggest therefore that stroke patients may benefit from a strong behavior control, while a more flexible style of control, which usual is judged the more effective, may not be beneficial for them (Evans et al., 1987b). Finally, none of the family function dimensions were significantly related to patients' motor recovery.

The last aim of this study was to verify if and which aspects of caregivers' perceived family functioning at patients' hospital admission were significant predictors of caregivers' psychological distress at six months after discharge. None of the family dimensions predicted the level of caregivers anxiety and depression at six-months follow-up; only the degree of anxiety and depression reported by caregivers at hospital admission were significant predictors of respectively anxiety and depression at six months after discharge form hospital. Therefore our findings did not replicate those of previous reports, in which worse family functioning were significantly associated with greater caregivers’ depression (King et al., 2001; Epstein-Lubow et al., 2009). Family functioning did not contributed significantly neither to the variance of caregivers somatic symptoms six months after discharge, which was highly explained by caregivers' age and somatic symptoms at hospital admission. Anyway, a significant relation with affective involvement was found. In particular caregivers who reported a better affective involvement at hospital admission reported more somatic symptoms at six months after discharge. This means that the benefits of greater family affective involvement are not absolute in general terms. As suggested by Reiss et al. (1986), family members dealing with illness or disability often feel closer to each other and may increase the frequency of their interactions. Anyway, if this pattern becomes a preoccupation, caregivers may focus too much attention on patients, with a consequent lack of time for themselves away from the caregiving situation. Caregivers should therefore be encouraged to enhance patients’ independence by consenting to them to do as much of their own care as possible (Grant et al., 2014). Finally, family functioning significantly contributes in explaining the variance in hostility at six months after discharge; anyway none of the McMaster dimensions were significantly related to hostility. This means that the perception of family functioning in general plays a relevant role in the level of irritability and anger reported by family members six months after their ill family members' discharge. This data is clinically relevant, considering that caregivers at six months after discharge showed an increment in the frequencies of irritable mood, albeit not statistical significant.

Overall these data are consistent with and provide additional support to previous investigations of family functioning during and after stroke rehabilitation. The deterioration of perceived family functioning by stroke survivors and the impact of family functioning in stroke survivors and caregivers outcomes highlight the clinical utility of a comprehensive assessment of family dynamic during patients’ rehabilitation treatment. This assessment is important in order to understand patients and caregivers’ family resources and offer a better care. On the basis of this assessment, clinicians should develop a highly individualized case management plan to help patients and caregivers attain skills and services necessary to facilitate a successful post-discharge transition (Grant et al., 2014). As Clark and Smith (1999a) suggested, patients and their caregivers should be advised during the time in rehabilitation that family problems may arise as they try to adapt to their changed circumstances. Families should be therefore encouraged to seek help in case of need.

5.4 LIMITS OF THE RESEARCH

The results from this research must be interpreted taking into account its limits, first of all the low samples size, the lost of subjects at follow-up, and the lack of a control group for caregivers. Because of these limitations, the findings may not be generalized to other populations of Italian stroke survivors and caregivers. Future research should therefore include adequate samples, with controls for caregivers as well. A further limit, as already mentioned, was the inability to obtain data regarding socioeconomic status of patients and caregivers. Several limitations were related to the assessment of lifestyle behaviors, first of all that we did not take into account the assessment of physical exercise. Given that physical inactivity is a risk factor for stroke, its consideration may be worthy of attention in this clinical population. Second, since previous studies suggested that moderate consumption of alcohol may not be problematic or even reduce the risk of stroke, a further limit of our research is that the quantity and the type of alcohol consumed by the patients, caregivers and controls were not examined. A third limit is that we were unable to collect subjects' weight before the occurrence of stroke. Therefore the data regarding the lack of differences between stroke survivors and controls in BMI values may be due to the fact that patients had lost weight during the acute phase. In addition in stroke survivors sample there was a case of eating disorder, specifically anorexia nervosa, which could have significantly affected the mean BMI values of the sample. Regarding the assessment of family functioning, an important limit is that the Family Assessment Device has been administered only to the patient and the principal caregivers. However, a complete evaluation of family dynamics should include perspectives from all family members. A recommendation for future research is to examine the usefulness of combining information of family functioning from different informants besides to principal caregivers. In addition, taking in account the limits of any self-report instrument, another important indication may be to add observational measures for the evaluation of family functioning, such as a semi-structured interview. Having a clinician's rating will consent to compare the diverse perspectives and to have a more complete picture of the family's problems and strengths (Keitner, 2012).

5.5 CONCLUSION AND CLINICAL IMPLICATIONS

Despite the above mentioned limitations, the results of our research are relevant especially for their implications in terms of implementation of interventions. One of the major strength of this research is its longitudinal design. Studies with follow-ups are rare in stroke survivors and their caregivers, and cross-sectional studies offer an incomplete view of recovery (Clark & Smith, 1999a) and psychosocial adjustment after stroke. In addition, the majority of previous studies focused particularly on the role of depression both in stroke survivors and their caregivers, while other psychosocial variables (that have been seen to be extremely important for their negative consequences on chronic ill patients' quality of life) were often neglected. To our knowledge this is the first study investigating psychological well-being and the frequencies of DCPR psychosomatic syndromes in stroke survivors and their caregivers. In addition, this is the first study examining the impact of family functioning on patients and caregivers' outcome after stroke in the Italian setting.

Findings from this research suggest that a complete assessment of patients and family members lifestyle behaviors is strongly recommended. Behavioral modification of all modifiable risk factors should be one of the aims of rehabilitation programs, other than physical and cognitive training. An integration of psycho-educational intervention aimed to the modification of unhealthy risk factors with the use of strategies based on a motivational approach should therefore implemented by clinicians during or following the acute rehabilitation treatment. The involvement of patient’s family members, given their influence on lifestyle behaviors, is also crucial. The data of our research suggest the clinical value of the evaluation of specific psychological and psychosomatic aspects, supporting the integration of DSM and DCPR criteria for assessing psychological distress in stroke survivors and their caregivers. As observed, while 37.5% of the patients presented symptoms indicating a psychiatric diagnosis according to the DSM-IV, a higher percentage of patients (45%) met the criteria for a DCPR syndrome. These percentages rose at six months after discharge, both for patients and caregivers. This indicates that the DCPR identified psychosocial dimensions related to stroke and caregivers that would have not been detected by the use of DSM-IV criteria alone. The data of this research confirm also the value of using both observer and self-rated multidimensional instruments in the clinical evaluation, given the incremental utility associated with the use of both. In our study, for example, self-rated instruments were more sensitive than the observer-rated methods in discriminating between stroke patients and controls and in detecting change over. Differently, the integration of the assessment of negative psychological states with an evaluation of positive psychological characteristics was less useful in this clinical population. No significant impairments in psychological well-being were found for stroke survivors and their caregivers neither at hospital admission nor at six months after discharge. The only exception was the dimension of autonomy, which was significantly lower in patients than controls. This suggests that psychosocial interventions aimed at increasing psychological well-being, other than reducing psychological distress, may not be indicated for stroke patients and their caregivers. Finally, the findings regarding the deterioration of perceived family functioning over time by stroke survivors and the impact of family dynamics on patients' cognitive status and caregivers' somatic symptoms and irritability, highlight the clinical utility of an assessment of family dynamic during and after patients rehabilitation treatment. Family counseling should be therefore offered to families, in order to prevent the possible deterioration of family functioning after the advent of stroke. However, even without a specific family intervention, which could be difficult to put in place during patients' rehabilitation, a good family assessment can be therapeutic in and of itself (Keitner, 2012).

Improving the assessment of psychosocial variables and correlates in patients and their caregivers should be a priority during stroke rehabilitation. An integrated and comprehensive assessment is indeed essential to ensure an intervention properly targeted to the characteristics of stroke patients and their caregivers and to provide the best possible treatment outcome. Data from this research indicate that both patients and caregivers experience considerable psychological distress. The development of adequate care is therefore of primary importance to assure the best possible quality of life for both the caregiver and the care-receiver.

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