



ISSN Online: 1949-5005 ISSN Print: 1949-4998

# Quality of Life in Heroin Users Attending Substitution Treatment: A Multicenter Study in Italy

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How to cite this paper: Fiumana, V., Zamboni, L., Mazza, M., Janiri, L., Cibin, M., GICS and Lugoboni, F. (2016) Quality of Life in Heroin Users Attending Substitution Treatment: A Multicenter Study in Italy. *Health*, **8**, 1195-1208. http://dx.doi.org/10.4236/health.2016.812123

Received: June 23, 2016 Accepted: September 4, 2016 Published: September 7, 2016

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#### **Abstract**

Quality of life (QoL) is an important measure to verify the effectiveness of therapy in substance use disorders (SUD). In this cross-sectional, multicenter study QoL has been measured in 1057 heroin dependents attending SerDs ("Servizi per le Dipendenze", Italian National Health System Services for Addictions) and has been correlated with demographic variables and drug treatment. QoL has been measured by using GHQ-12 (12-item General Health Questionnaire), a self-administered questionnaire whose value is inversely correlated with the QoL. The median value of GHQ-12 in the study population was 12 (interquartile range [IQ] 9 - 18): 640 patients (60.6%) scored <15 which relates with a sufficiently good QoL, 257 (24.3%) scored between 15 - 20, and 160 (15.1%) scored >20 points at the GHQ-12, which relates with a bad QoL. Female population showed higher GHQ12 scores when compared to male population (14 [IQ 9 - 19] vs. 12 [IQ 9 - 17], p = 0.03). Similarly, unemployed patients showed higher GHQ12 scores when compared to employed patients (15 [IQ 10 - 20] vs. 12 [IQ 8 - 16], p < 0.00). Unemployment (OR 2.09, CI 95% 1.5 - 3.0, p < 0.00), non-opioid psychopharmacological treatment (OR 1.82, CI 95% 1.3 - 2.6, p = 0.00) and substitution therapy with buprenorphine (OR 0.55, CI 95% 0.3 - 0.8, p = 0.01) were independent predictors of GHQ-12 > 20. Results show that most of patients receiving care for heroin dependence at SerDs have a positive assessment of their quality of life, and that being unemployed and having a dual diagnosis are predictors of poor QoL. Besides, data suggest that assuming buprenorphine could be a protective factor for QoL.

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## **Keywords**

Quality of Life, Heroin Addiction, GHQ-12, Substitution Therapy, Dual Diagnosis

#### 1. Introduction

The ultimate aim of medicine has always been to cure patients. In chronic illnesses, however, complete cure is seldom achievable, and therefore physicians try to maximize life expectancy or at least optimize quality of life (QoL). Monitoring QoL can be an helpful way to measure the effectiveness of therapy [1]. Measuring QoL is considered essential for the evaluation of quality of provided care, rather than the classic methods of complete recovery (and compliance). These new ways of monitoring are necessary in times of limited resources. Substance use disorders (SUD) often adopt the characteristics of chronic illnesses, especially in comorbidity with other mental disorders, by having a fluctuating course of remission and relapse, accompanied by deterioration in labour, social and relational, skills as identified by the DSM V diagnostic criteria [2]. With these patients it is necessary, parallel to conventional therapy, to implement other ways of preserving QoL, for example rehabilitating interventions [3].

QoL is a complex concept, defined by the WHO [4] as "individual's perception of their position in life, in context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns". It is affected by several factors: physical health, psychological state, level of autonomy, social relationships, personal beliefs and relationship with the environment. It has been shown that, above a certain standard of living, QoL is mainly linked to subjective experiences such as self-realization, self-esteem, pleasure, inner harmony, love and freedom [5].

Studies on QoL in addiction disorders are scarce. In particular studies on QoL in heroin dependent people (HDP) have mainly taken into account the stabilizing and normalizing role of substitution therapy, in most cases by methadone, but also buprenorphine. Important factors have been investigated, such as risk of overdose, the impact of HIV and hepatitis, risk of imprisonment, the co-use of other drugs and treatment compliance [6]-[14]. In these studies opiate dependents showed low QoL compared with the general population and patients with various medical illnesses and, generally, participation in substitution treatment had positive effect on individual QoL [15]. Some socio-demographic variables appear to correlate positively with QoL. Legal job, for example, is one of the most successful ways to increase self esteem [16]. Clearly, employment turned out to be an important element in experiencing a good QoL, by reducing economical difficulties and expanding the sense of personal fulfillment and social integration. Also one's own marital satisfaction is a sizeable and significant correlate of life satisfaction, momentary happiness, health and well-being [17] [18]. In studies regarding QoL in relation to residence (urban or rural, urban or suburban), small towns seem to favor a better quality of life [19] [20].

Studies on QoL have often focused on the elderly population suffering from other

chronic diseases. Literature about SUD and QoL offers conflicting opinions [21]-[27]. In this study QoL has been measured in heroin dependents attending SerDs ("Servizi per le Dipendenze", Italian National Health System Services for Addictions) and has been correlated with demographic variables and drug treatment, in order to identify subgroups that most benefit from different interventions and to improve clinical practices. Primary aim of the study was to investigate QoL in patients attending SerDs for heroin dependence and correlate results with demographic variables and drug treatment (substitution therapy and non opioid psychiatric drugs). Secondary aim of the study was to observe any difference in the QoL in patients attending Urban or Suburban SerDs.

#### SerDs

SerDs (Servizi per le Dipendenze, National Italian Health System Services for Addictions) are the Italian National Health System Services dedicated to care, prevention and rehabilitation of both substance and behavioral addictions. Individuals with occasional and sporadic abuse are normally better served in primary care and are not included in the SerDs. SerDs are spread throughout the country and have an homogeneous organization and intervention models. Access and all offered services are free. Each SerD provides personalized treatments based on individual characteristics and on the type of dependence. Treatments include: opioid substitution therapy (such as buprenorphine or methadone), health care for diseases related to drug use (e.g. HIV and viral hepatitis), mental health care for dual diagnosis, non-opioid psychopharmacological treatment. SerDs also provide the main psychosocial treatments and other rehabilitative interventions; they provide visibility for vacancies and collaborate with Therapeutic Communities and 12-Steps groups (Alcoholics Anonymous, Narcotics Anonymous, Gamblers Anonymous). In these centers no specific criteria or regulations were established concerning the duration of the various therapies. To use substitution therapy is necessary for the patient to test positive for heroin at a drug test and to present with a history of heroin addiction.

## 2. Materials and Methods

#### 2.1. Study Design

In this cross-sectional, multicenter study data were drawn from a cohort of 1057 patients attending 21 SerDs in the North of Italy. Data were collected from July to September 2014. All subjects had a history of varying severity of heroin dependence, used in different ways depending on the case (injected or smoked). No other specific inclusion or exclusion criterion was considered. A trained nurse delivered the questionnaires and data sheets to participating patients, in order to optimize patients' privacy and spontaneity, as nurses are less involved in therapy compared to doctors and psychologists. All patients provided written informed consent before beginning any study activities. The protocol was approved by the local Ethical Review Board. The average participation rate in the study was 68% and 9% of completed questionnaires

were excluded from the sudy because illegible or incomplete.

## 2.2. GHQ-12

The GHQ-12 (General Health Questionnaire 12-item) was used to assess overall health. GHQ-12 is a questionnaire developed during the 70s [28] [29] to identify two main problem categories: inability to function normally and the presence of new stress factors. The GHQ-12 is a widely used screening test to measure QoL from a psychosocial point of view. The validated Italian version [30] [31] of the questionnaire was used in the present study. The GHQ-12 determines, through 12 questions, whether the subject has recently (*i.e.* in the last four weeks) experienced particular symptoms or behaviours. Each item is scored on a four-point Likert scale ("less than usual" (0 points), "no more than usual" (1 point), "a little more than usual" (2 points), and "much more than usual" (3 points)). The sum of all values leads to a total score, which goes from 0 to 36 points. Patients scoring <15 show no discomfort. Patients with scores ≥15 were considered "cases on the GHQ-12", *i.e.* with a probability of more than 80% of experiencing psychosocial malaise [28]. Patients exceeding 20 points on the questionnaire were classified as suffering from a severe psychosocial disorder.

### 2.3. Statistical Analyses

Continuous variables with skewed distribution are reported as median (1st-3rd quartile), while discrete variables are reported as count and percentages. Mann-Whitney U,  $\chi^2$ , and Fisher exact tests were applied for bivariate analyses when appropriate. All collected variables were tested for bivariate association with GHQ-12 according to the pre-specified cut-offs, and nominally significant covariates (p < 0.05) were simultaneously included into a multivariable logistic regression model to identify independent predictors and to calculate their adjusted odd ratios (ORs) with associated 95% confidence intervals (CI). The Hosmer and Lemeshow goodness-of-fit test was used to assess model calibration. The final regression model included the following variables: age, sex, marital status, employment, SerDs of enrolment, level of education and pharmacological treatment. All tests were two-sided and an alpha level of 0.05 was considered statistically significant.

#### 3. Results and Discussion

## 3.1. Demographics

A total of 1057 patients from 21 SerDs were included in the study. Of these 651 (61.6%) were recruited in urban SerDs and 406 (38.4%) in suburban SerDs. Main characteristics of the patients are summarized in **Table 1**. Median patient age was 38 years (IQ 30 - 46), with 797 (75.4%) males; 66.5% patients were single, 15.8% married, 15.1% separated/divorced, and 2.6% widowed. Level of education was primary school degree in 618 (58.5%), secondary school degree in 411 (38.9%) and bachelor's degree in 28 patients (2.6%). Patients with a regular and legal job were 654 (61.9%), while the remaining were retired, unemployed or students. 413 (39.1%) patients were prescibed non opioid

Table 1. Demographic characteristics.

	Patients (%)	GHQ results*	Age*	Male gender (%)	Employment (%)	Psychoactive therapy (%)	Methadone therapy (%)	Buprenorphine therapy (%)
Udine	21 (2.0)	12 (IQ 10 - 19.5)	46 (40 - 50)	9 (42.9)	13 (61.9)	8 (38.1)	19 (90.5)	1 (4.8)
Bolzano	34 (3.2.)	13.5 (IQ 10 - 13.5)	47 (34 - 52)	15 (44.1)	20 (58.8)	12 (35.3)	22 (64.7)	12 (35.3)
Mantova	29 (2.7)	14 (IQ 9 - 17.0)	40 (33 - 45)	9 (31.0)	23 (79.3)	10 (34.5)	26 (89.7)	1 (3.4)
Monselice	21 (2.0	16 (IQ 9 - 21)	39 (32 - 44)	6 (28.6)	14 (66.7)	10 (47.6)	15 (71.4)	3 (14.3)
Mestre	30 (2.8)	11 (IQ 9 - 17)	43 (35 - 47)	5 (16.7)	15 (50.0)	22 (73.3)	16 (53.3)	7 (23.3)
Treviso	32 (3.0)	14 (IQ 9 - 21)	30 (22 - 41)	10 (31.3)	18 (56.3)	11 (34.4)	25 (78.1)	7 (21.9)
Legnago	51 (4.8)	14 (IQ 10 - 20)	38 (30 - 44)	6 (11.8)	33 (64.7)	27 (52.9)	35 (68.6)	15 (29.4)
Este	62 (5.9)	13 (IQ 10 - 18)	33 (26 - 42)	14 (22.6)	41 (66.1)	23 (37.1)	36 (58.1)	21 (33.9)
Rovigo	71 (6.7)	14 (IQ 10 - 19)	32 (26 - 41)	17 (23.9)	45 (63.4)	23 (32.4)	70 (98.6)	71 (100.0)
Dolo	45 (4.3)	13 (IQ 9 - 17)	33 (26 - 41)	10 (22.2)	26 (57.8)	25 (55.6)	29 (64.4)	14 (31.1)
Oderzo	34 (3.2)	12 (IQ 9 - 15)	34 (27 - 42)	6 (17.6)	25 (73.5)	8 (23.5)	22 (64.7)	10 (29.4)
Villafranca	15 (1.4)	12 (IQ 7 - 17)	32 (27 - 42)	5 (33.3)	10 (66.7)	4 (26.7)	15 (100.0)	15 (100.0)
Verbania	21 (2.0)	12 (IQ 7 - 19)	29 (25 - 44)	4 (19.0)	16 (76.2)	3 (14.3)	14 (66.7)	5 (23.8)
Zevio	56 (5.3)	13 (IQ 10 - 19)	40 (31 - 47)	5 (8.9)	37 (66.1)	23 (41.1)	41 (73.2)	15 (26.8)
Udine bis	77 (7.3)	11 (IQ 8 - 14)	42 (32 - 50)	14 (18.2)	43 (55.8)	32 (41.6)	61 (79.2)	15 (19.5)
Bassano	47 (4.4)	13 (IQ 9 - 17)	40 (32 - 46)	10 (21.3)	27 (57.4)	19 (40.4)	47 (100.0)	47 (100.0)
Rimini	48 (4.5)	11 (IQ 9 - 17)	35 (31 - 45)	13 (27.1)	24 (50.0)	9 (18.8)	42 (87.5)	5 (10.4)
Bologna	83 (7.9)	12 (IQ 8 - 17)	40 (34 - 49)	34 (41.0)	67 (80.7)	25 (30.1)	43 (51.8)	40 (48.2)
Pisogne	24 (2.3)	17 (IQ 11 - 25)	42 (34 - 47)	4 (16.7)	17 (70.8)	7 (29.2)	21 (87.5)	3 (12.5)
Alessandria	161 (15.2)	12 (IQ 8 - 18)	41 (36 - 48)	47 (29.2)	91 (56.5)	72 (44.7)	126 (78.3)	36 (22.4)
Pordenone	95 (9.0)	13 (IQ 10 - 18)	37 (28 - 48)	17 (17.9)	49 (51.6)	40 (42.1)	63 (66.3)	32 (33.7)

<sup>\*</sup>Expressed as Median (interquartile range).

psychiatric drug treatment for a dual diagnosis. Among these: 49 were taking antidepressants, 252 anxiolytics/hypnotics and 70 more than one drug. 1030 patients were receiving substitution therapy with methadone or buprenorphine for at least 3 months, 788 (74.6%) received substitution therapy with methadone, and 242 (22.9%) with buprenorphine. The 90% of the study group was smoking tobacco.

## 3.2. Quality of Life

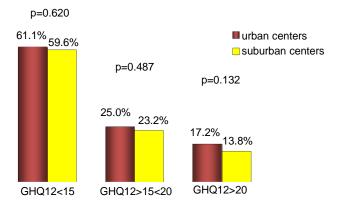
The median value of GHQ-12 in the study population was 12 (interquartile range [IQ] 9 - 18): 640 patients (60.6%) scored <15, 257 (24.3%) scored between 15 - 20, and 160

(15.1%) scored >20 points. The comparison of GHQ-12 excluded significant differences between centers (p = 0.13) but revealed an inhomogeneous distribution of patients with highest GHQ-12 score (ranging from 3.6% to 28.1% of individual SeRDs population, p = 0.02), while percentages of patients with a score <15 (from 41.7% to 76.6%, p = 0.20) and between 15 - 20 (from 6.7% to 34.0%, p = 0.41) were comparable.

Comparison between urban and suburban centers (*i.e.* patient volume) showed no significant difference in GHQ-12 results with a similar median test value (12 [IQ 9 - 17] vs. 13 [IQ 9 - 19], p = 0.20, respectively). Consistently, the analysis of patient categories according to the pre-specified cut-off values, revealed a comparable proportion of patients with <15 (61.1% vs. 59.6%, p = 0.62), >15 <20 (25.0% vs. 23.2%, p = 0.48) and >20 score (17.2% vs. 13.8%, p = 0.13) in urban centers vs. suburban centers (**Figure 1**). Overall, female population showed higher GHQ-12 scores when compared to males (14 [IQ 9 - 19] vs. 12 [IQ 9 - 17], p = 0.03) with no difference between urban and suburban SerDs (**Figure 2**). Similarly, unemployed patients showed higher GHQ-12 scores when compared to those employed (15 [IQ 10 - 20] vs. 12 [IQ 8 - 16], p < 0.00). The presence of opioid substitution treatment (15 [IQ 11 - 20] vs. 12 [IQ 8 - 17], p < 0.00) and substitution therapy with methadone (13 [IQ 9 - 18] vs. 12 [IQ 8 - 17], p < 0.00) were associated with a significant higher GHQ-12 scores; conversely, patients on treatment with buprenorphine (12 [IQ 8 - 16] vs. 13 [IQ 9 - 18], p = 0.00) showed lower GHQ-12 median values (**Figure 3**).

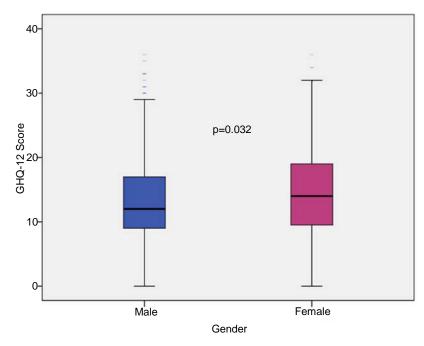
### 3.3. Predictors of Quality of Life

**Table 2** shows the main predictors of GH-Q12 at the adjusted multivariable regression analysis. After adjustment for potential confounding factors, the unemployment (OR 1.91, CI 95% 1.5 - 2.5, p < 0.00), separated/divorced status (OR 1.53, CI 95% 1.1 - 2.2, p = 0.02), psychopharmacological treatment (OR 1.99, CI 95% 1.5 - 2.6, p < 0.00), and substitution therapy with buprenorphine (OR 0.73, CI 95% 0.5 - 1.0, p = 0.05) were independent predictors of GHQ12 >15. When a value >20 was considered as cut-off, the



Comparison among urban vs. non urban centers

**Figure 1.** Distribution of GHQ12 (General Health Questionnaire 12-item) scores in urban and suburban centers.



**Figure 2.** Comparison of GHQ12 (General Health Questionnaire 12-item) score between male and female. The thick black line represent median.

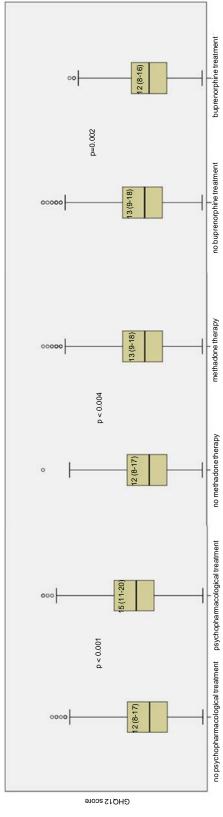
only independent predictors of GHQ12 score were unemployment (OR 2.09, CI 95% 1.5 - 3.0, p < 0.00), psychopharmacological treatment (OR 1.82, CI 95% 1.3 - 2.6, p = 0.00) and substitution therapy with buprenorphine (OR 0.55, CI 95% 0.3 - 0.8, p = 0.01).

The sex distribution was in line with literature [32] [33]. The average age of our sample (38.68 years) confirmed that the Italian rehabilitation center population is aging [34].

The GHQ-12 is preferable over a test like the SF-36 (Short Form 36 Items Health Survey), because the latter is more orientated towards organic conditions [1]. The male subjects showed to have an overall better QoL. In general, females were subjected to a more severe addiction [35] [36], but not for specific opioid dependence [36]. The percentage of tobacco smokers (90% of the sample) is in line with about 82% found in prevoius studies [37].

In our population, being married seems to have a beneficial effect on QoL. Indeed, being separated or divorced was an independent predictor of GHQ-12 >15. We have no data about the extent of marital satisfaction in married patients neither about the level of emotional and sexual satisfaction of single or divorced subjects [17] [18] but our clinical experience shows that many addicts divorced are recognized as guilty of the separation from the spouse, and therefore must pay alimony. This can impact on the economic autonomy of the patient and severely affect their QoL.

Our study showed that subjects not using any psychopharmacological treatment, and therefore probably not displaying any comorbid mental disorders, had a significantly better QoL than subjects who did. Indeed, psychiatric drug treatment is an independent



**Figure 3.** Comparison of GHQ12 (General Health Questionnaire 12-item) scores according to pharmacological treatment.

**Table 2.** Predictive value of demographic and clinical characteristics in GHQ12 (General Health Questionnaire 12-item) score.

GHQ12 >15						
Unemployment	OR 1.91, CI 95% 1.5 - 2.5	<0.001				
Separated/divorced status	OR 1.53, CI 95% 1.1 - 2.2	0.018				
Psychoactive treatment	OR 1.99, CI 95% 1.5 - 2.6	< 0.001				
Buprenorphine treatment	OR 0.73, CI 95% 0.5 - 1.0	0.05				
GHQ12 >20						
Unemployment	OR 2.09, CI 95% 1.5 - 3.0	<0.001				
Separated/divorced status	OR 0.90, CI 95% 0.3 - 2.8	0.860				
Psychoactive treatment	OR 1.82, CI 95% 1.3 - 2.6	0.001				
Buprenorphine treatment	OR 0.55, CI 95% 0.3 - 0.8	0.013				

predictor of GHQ-12 >15 and of GHQ-12 >20. As concerning dual diagnosis, it is important to keep in mind that addiction and psychiatric disorders influence each other and so they do not just often exist simultaneously, but rather overlap, resulting in new and even more complex mental, relational and existential difficulties [38].

In this study, subjects with substitution therapy (methadone and buprenorphine) showed a QoL below the threshold of suffering. This important result further justifies the replacement therapy rational. Our study also seems to suggest that buprenorphine treatment can lead to the development of a better QoL compared to methadone, as previously reported in literature [15]. Treatment with buprenorphine seem to represent a protective independent predictor of GHQ-12 >15 and of GHQ-12 >20. This could be due to the fact that the buprenorphine is probably better restricted to those patients with mild-moderate dependence [39] and then, perhaps, with a better QoL, whereas methadone can be used with all levels of dependence but especially in the more severe forms.

An interesting result is the effect of having an occupation. The fact that the majority of the population in our sample had a job is in contrast with DSMV criteria n5 [2], but it is in line with other studies from the North-East of Italy, where a significant relation was found between employment and relational skills in heroin dependent patients frequenting SerDs [33] [34] [40]. In our study being unemployed proved to be the most statistically significant predictor for a poor QoL. This may depend on the decrease of self-esteem but also on the lack of economic independence in order to have their own home, eat what they like and be part of the consumer society. Data on these specific items were not collected in our study. However, our clinical experience shows us how those elements are often experienced by patients as elements of suffering. There were no significant differences among people living in province capitals (recruited in urban SerDs) and people from smaller towns (suburban SerDs). This could be due to similar

living standards in the cities where the survey was taken, which are basically all in the same geographical region (North-East Italy).

The finding that an important part (60.5%) of our sample scored a QoL below the threshold of psychological and physical suffering, by other means experiencing an acceptable QoL, is quite surprising as these people are considered extremely afflicted by their condition. Hypotheses to explain these results are numerous, but common roots might be in attending SerDs. These SerDs facilities offer various treatment possibilities. Substitution therapy, according to its therapeutic rationale, has a stabilizing effect heroin dependence, reducing the risk of relapse and hence aid the patient to accomplish a stable planning in labor, relational and social areas. The SerD also offers psycho-therapy, in groups as well as individual, rehabilitation programs, and self-help groups based on the model of the Alcoholics Anonymous. At the light of the above, the visibility for vacancies plays a very important role. These interventions do not only increase patients understanding of their disease and the ability to cope with addiction- derived impulses, but also provide a social environment in a specific setting: taking care of themselves. Further on, the SerDs staffs can act as a mediator in handling other problems, for example by collaborating with other specialists to treat organic or psychiatric conditions.

This study has its strengths but also certain limitations. The number and the high rate of participants and also the multicenter design are strong points. Quality of life is rarely assessed in opioid substitution treatment because of a bias in the treatment literature towards measuring abstinence outcomes only, which is an inappropriate and unrealistic approach to measuring quality of care for what is now recognized as a chronic and frequently relapsing disease. This study also benefits from being conducted in the real-world context of 21 public opioid use treatment programs providing services in North East Italy. A limitation is the incompleteness of data about cases of dual diagnosis, amount of replacement therapy prescribed to patients, and severity of addiction. These items may therefore be subjected to further and future studies to explore the Qol in HDP and in cases of dual diagnosis. Moreover, the locality where the study took place is generally associated, at least in Italy, with high life standards and with a good welfare. It would be interesting to conduct this same survey in other parts of Italy where living standards are generally lower, for example in the middle and south of the Country. Finally, tough the 68% response rate can be considered considerable, it cannot be excluded that individuals with better quality of life could be over represented among the respondents.

#### 4. Conclusion

The measure of QoL is considered essential in the evaluation of the quality of provided care, rather than the classic methods of compliance and complete recovery. These new ways of monitoring are necessary in times of limited resources. Some socio-demographic variables are independent predictors for a poor QoL for different reasons. Being unemployed can lower self-esteem and create economic problems. Having a psychiatric disorder concomitant to heroin dependence can worsen the complexity of the clinical

picture and increase the suffering of the patient. In our population, both methadone and buprenorphine were associated with a QoL below the threshold of sofference, and buprenorphine performed slightly better. Moreover, the use of buprenorphine appeared to be a protective factor against the development of a worse QoL. The greater percentage (60.5%) of our subjects scored a QoL below the threshold of psychological and physical suffering, by other means was experiencing an acceptable QoL. Hypotheses to explain these results are numerous, but common roots might be found in the fact that in Italy addicted patients have the possibility to attend the SerDs. SerDs centers are able to provide a complete and continuous care in comparison to other healthcare services, promoting patients' health and QoL and guiding treatment providers towards targeted and personalized therapies.

## Acknowledgements

Our thanks go to all SerDs that participated in the study (Udine, Bolzano, Mantova, Monselice, Mestre, Treviso, Legnago, Este, Rovigo, Dolo, Oderzo, Villafranca, Verbania, Zevio, Udine, Bassano, Rimini, Bologna, Pisogne (BS), Alessandria, Pordenone).

We would also acknowledge Coco Walstra, student researcher at VUmc Amsterdam, Holland, for her help in English translation of the paper.

Members of GICS active in collecting data include: Arzillo C, Benigna L, Bersani N, Bersani P, Betti O, Biasin C, Bossi C, Bottazzo A, Bove A, Caccamo E, Cancian S, Cantanchin F, Cantiero D, Canzian G, Cargnelutti D, Casalboni D, Casari R, Casarini R, Cibin M, Civitelli P, Cozzi T, De Cecco L, Del Zotto R, Dellantonio E, Dersini F, Duranti I, Faccini M, Fadelli M, Favero E, Fona B, Fontana N, Franceschini A, Gaiga E, Gardiolo M, Gentile N, Gervino D, Ghezzo N, Giacomin MA, Kashanpour H, Lietta P, Manera E, Manzato E, Mazzo M, Meneghello D, Mihalcea C, Milan E, Montresor M, Moratti E, Morbioli L, Musso D, Musso M, Pani A, Pavani V, Peroni F, Pellachin P, Piazza M, Pieri MC, Prosa D, Pupulin B, Rescigno B, Resentera C, Ricci C, Righetti P, Ripoli MA, Riscica P, Rizza C, Rizzetto V, Rossi A, Rovea A, Ruffato A, Ruzziconi C, Sabbion R, Santo E, Scarzella M, Sembianti N, Simonetto P, Smacchia C, Stellato M, Stimolo C, Suardi L, Vaiana A, Zavan V, Zerbetto E, Zerman M.

#### **Conflict of Interests**

The authors declare no conflict of interests.

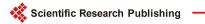
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