

## Randomized controlled clinical trial on the efficacy of team play football on schizophrenic patients: a pilot study

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### Abstract

*The physical activity is an important aspect of good health for everyone; it is even more important for psychiatric patients who usually live an unhealthy lifestyle. The aim of this study was to investigate the effects of football practice on the self-reported health quality of life (SRHQL) and Wellbeing in schizophrenic subjects. A randomized controlled clinical trial was conducted to assess the effectiveness of the Psychosocial Rehabilitation Program performed by Daily Center Mazzacurati, Department of Mental Health Roma/D, for psychotic subjects that included weekly football activities for a period of 9 months. The results show that the model proved effective in the experimental group (SG) as regards the psychopathological dimensions, which are significantly improved (Median(IQR): 31(16) versus 53(18);  $p=0.001$ ); in particular the negative symptomatology has been reduced, and this result is hardly achieved with the drug therapy (17(7) versus 25(15);  $p=0.003$ ). This study increases the awareness of following this approach and improving the extension and the confirmation of the results achieved.*

**Keywords:** Schizophrenia, psychosocial rehabilitation, mental illness, sport, football, team play

### Introduction

Paranoid schizophrenia represents the most common of the many sub-types of the debilitating mental illnesses known collectively as schizophrenia. People with schizophrenia show chronic and disabling disorders and heterogeneous clinical aspects at the long term.

One of the most commonly studied predictors of the outcome of schizophrenia is the social function. This parameter plays an important role in a recovery oriented approach. The aim of this approach to mental health service delivery is to support people to build and maintain a meaningful and satisfying quality of life and personal identity [1,2].

The social dysfunctions that characterized the schizophrenia are usually present not only in the social

context, but also at work, at school, and in daily relationships.

The Diagnostic and Statistical Manual of Mental Disorders (DSM V) underlines the social /occupational dysfunction is associated to the non-awareness of the disease. In these patients the low level of insight denotes low level of social abilities and work performances in the rehabilitation programs [3]. Approximately 50 percent of individuals with schizophrenia have impaired awareness of their own illness [4].

Such individuals do not realize that they are sick, and they will, therefore, usually not accept treatment voluntarily and have major odds of hospitalization. The lack of awareness of illness in individuals with schizophrenia is the most common reason why they do not take their medication [5]. Therefore the insight factor

represents a reliable parameter to evaluate the adherence to the rehabilitation programs or to the therapy. The low level of insight is also associated to higher level of gravity of positive symptoms and negative symptoms independently how long the disease was diagnosed.

In a recent review Osatuke et al. [6] have described seven models of the etiology of poor insight. Each model is not mutually exclusive in comparison to the other ones. One model considers that the absence of insight as a symptom of cognitive dysfunction (eg. conceptual disorganization, neurocognitive impairment,) or as an attempt to avoid or ward off negative connotations of the illness (eg. stigmatizing stereotypes). Metacognition refers to the Theory of Mind definition (ToM): refers to the cognitive capacity to attribute mental states to self and others [7].

The occurrence and the persistence of the pathology are hypothesized to be due to meta-cognitive difficulties [8]. Indeed the metacognitive deficit have an impact on social functioning, community integration and quality of life [9, 10].

To develop appropriate psychosocial rehabilitation programs to deal with these deficits, we could use the most recent acquisitions in the neurological field, in particular had become apparent that the temporal lobe also contains a special type of neurons, called Mirror Neurons for their unique quality of firing both during the execution of a movement of the hand or mouth, both during the simple observation of the same movement performed by another person.

The discovery of mirror neurons in humans has offered an explanation of how the ability to imitate the actions of others can be evolved in the ability to simulate the mental states of others [11].

However, as Frith and Frith [12, 13] have pointed out concerning the ToM, to represent actions for a purpose is not enough, but it is also necessary to distinguish between behaviours generated by oneself or by others. The ability to simulate the mental states of others does not necessarily involve conscious reflection, but can be easily restored to a level of consciousness. Conscious reflection on one's own and others' mental states implies computational resources that go beyond the ability to simulate or imitate the action. The inferior parietal cortex is the neurological structure for this purpose. The right inferior parietal cortex seems to be important for the conscious representation of the others' mental states, whereas the left inferior parietal cortex may be involved in the representation of one's own mental states [14].

The studies on the Mirror Neurons demonstrate that the prefrontal cortex and the Broca's area of the human brain are activated when people do some activities or observe someone doing them. In addition, there is an overlap of neural areas (shared representations) in parts of the prefrontal and parietal cortex in the following cases:

- 1) When making an intentional action;
- 2) When observing another person performing an intentional action;
- 3) When imagining himself or another person performing that action;
- 4) When preparing to imitate the action of someone else.

According to Gallese [15], these unconscious mechanisms represent the embodied simulation: "The motor system is activated as if we were doing the same action we are observing". The embodied simulation is the neural substrate of empathy and the understanding of the minds of others and it is the base for the construction of social identity. These findings suggest the need to develop psychosocial rehabilitation group models, which aim to increase self-awareness, developing treatment programs that focus on social cognition and ToM [16]. The physical activity is an important aspect of good health for everybody; it is even more important for psychiatric patients who usually live an unhealthy lifestyle [17, 18].

The aim of this clinical trial is to analyze the effects of one year soccer training program on social function, quality of life (QoL), awareness of illness, relationship between insight and self-reflectiveness, physical activities and psychopathological dimensions in psychiatric patients with a diagnosis of schizophrenia.

## Materials and methods

### Study framework

This randomized controlled trial was designed to compare two different interventions:

- The sport intervention (SG) consists in 9 months of soccer activities in addition to the normal activities decided by LHU (ie., carpentry activities). The sport activities included:

- 90 minutes per week, including training and match, managed by qualified coach and psychiatric operator. The protocol applied was "Allenamento fisico e tecnico nel calcio per pazienti schizofrenici [19];
- 60 minutes per week of discussion and Round table with a psychiatric operator.

- The control group (CG) performed the normal activities decided by LHU.

Consenting subjects were randomly assigned in a 1:1 ratio to control or SG group using a computer-based random number generator algorithm.

### Patient Eligibility and Follow-Up

Patients were enrolled for the study if they met all of the following inclusion criteria:

- Subjects with schizophrenia spectrum personality;
- Subject with diagnosis of schizophrenia and/or schizoaffective disorders based on DSM V criteria;

Table 1. Baseline characteristics of the two group studied.

Variables at baseline	SPORT group SG	CONTROL group CG	p-value*
	N=19	N=14	
	Median (IQR)	Median (IQR)	
Age (years)	34 (8)	34 (10)	0.928
<b>SF-36</b> Physical Activity AF	75 (35)	72.5 (26)	0.986
physical functioning RF	25 (85)	50 (63)	0.152
bodily pain DF	61 (32)	68 (32)	0.760
general health perceptions SG	52 (11)	55 (28)	0.733
vitality VT	50 (5)	45 (33)	0.577
social role functioning AS	50 (5)	50 (44)	0.553
emotional role functioning RE	33 (85)	33 (36)	0.815
mental health SM	52 (12)	54 (19)	0.928
<b>BCIS</b> self-reflectiveness	13 (4)	14 (7)	0.970
self-certainty	9 (5)	9 (7)	0.970
Tot BCIS	4 (6)	4 (8)	0.762
<b>VGF</b>	51 (5)	51 (13)	0.065
<b>PANSS</b> Positive Syndrome	13 (8)	15 (13)	0.358
Negative Syndrome	21 (14)	25 (10)	0.152
General PSICOPAT	<b>39 (11)</b>	<b>50 (24)</b>	<b>0.004</b>
Total	<b>72 (27)</b>	<b>96.5 (23)</b>	<b>0.010</b>
<b>CGIs</b>	4 (1)	4.5 (1)	0.900

\*p value Wilcoxon signed ranks test. Bold p<0.05

• patients without any other disorder in comorbidity (ie., intellectual disability, epilepsy, substance abuse, affective psychoses);

• subjects were recruited in the Departments of the Local Health Unit (LHU) of Rome, Latium;

• Subjects that haven't followed a physical activities rehabilitation program.

#### Outcomes

A combination of five tools were adopted to measure the effectiveness of the intervention.

1. Short Form-36 questionnaire was used to assess the health-related quality of life. This comprehensive only 36 questions yields an 8-scale health profile as well as summary measures of health-related quality of life. High score corresponds to high level of quality of life;

2. The Beck Cognitive Insight Scale [20] was administered to evaluate patients' self-report of their ability to detect and correct misinterpretation;

3. The Global Assessment of Functioning (GAF) consider psychological, social, and occupational functioning on a hypothetical continuum of mental

Table 2. Characteristic of the two groups studied nine months later.

Variables nine months later		SPORT group	CONTROL group	p-value*
		N=19	N=14	
		Median (IQR)	Median (IQR)	
<b>SF-36</b>	Physical Activity AF	90 (15)	80 (36)	0.175
	Physical functioning RF	75 (50)	50 (69)	0.140
	Bodily pain DF	74 (32)	64 (30)	0.416
	General health perceptions SG	72 (19)	61 (28)	0.077
	Vitality VT	55 (15)	50 (16)	<b>0.031</b>
	Social role functioning AS	63 (13)	50 (46)	0.130
	Emotional role functioning RE	75 (40)	40.5 (88)	0.201
	Mental health SM	64 (12)	60 (12)	0.364
<b>BCIS</b>	self-reflectiveness	15 (8)	15.5 (5)	0.919
	self-certainty	7 (5)	9 (5)	0.121
	Tot BCIS	7 (6)	6.5 (8)	0.228
<b>VGF</b>		62 (6)	49.5 (11)	<0.001
<b>PANSS</b>	Positive Syndrome	11 (5)	19 (13)	<b>0.035</b>
	Negative Syndrome	17 (7)	25 (15)	<b>0.003</b>
	General PSICOPAT	31 (16)	53 (18)	<b>0.001</b>
	Total	58 (28)	101 (37)	<b>0.001</b>
<b>CGIs</b>		2 (1)	4 (4)	<b>&lt;0.001</b>

\*p value Wilcoxon signed ranks test. Bold p<0.05

health illness. Do not include impairment in functioning due to physical (or environmental) limitations. It is a numeric scale: from 1 to 100. High score referred absent or minimal symptoms.

4. Positive And Negative Schizophrenic Symptoms (PANSS) is a 30-item rating scale that is specifically developed to assess individuals with schizophrenia and is used very widely in research settings. the PANSS is an adaption from earlier psychopathology scales, including the Brief Psychopathology Rating Scale (BPRS) and Psychopathology Rating Scale - PRS [21] is based upon the premises that schizophrenia has two distinct syndromes, a positive and a negative syndrome. The positive syndrome includes those productive features such

as delusions and hallucinations, while the negative syndrome includes those features which are lacking/poorly developed in individuals with schizophrenia, such as social withdrawal and flattened or blunted affect [22].

5. The Clinical Global Impression (CGI) provides an overall clinician-determined summary measure that takes into account all available information, including a knowledge of the patient's history, psychosocial circumstances, symptoms, behavior, and the impact of the symptoms on the patient's ability to function.

#### Follow-Up

The study started in September 2013. All patients

**Table 3. Comparison for the scores before and after in the sport activity intervention group.**

Variables nine months later		Before	After 9 months	p-value*
		SPORTgroup	Sport group	
		N=19	N=19	
		Median (IQR)	Median (IQR)	
<b>SF-36</b>	Physical Activity AF	75 (35)	90 (15)	<b>0.002</b>
	Physical functioning RF	25 (85)	75 (50)	<b>&lt;0.001</b>
	Bodily pain DF	61 (32)	74 (32)	0.245
	General health perceptions SG	52 (11)	72 (19)	<b>0.001</b>
	Vitality VT	50 (5)	55 (15)	<b>0.007</b>
	Social role functioning AS	50 (5)	63 (13)	<b>&lt;0.001</b>
	Emotional role functioning RE	33 (85)	75 (40)	<b>0.001</b>
	Mental health SM	52 (12)	64 (12)	<b>0.001</b>
<b>BCIS</b>	self-reflectiveness	13 (4)	15 (8)	<b>&lt;0.007</b>
	self-certainty	9 (5)	7 (5)	<b>0.001</b>
	Tot BCIS	4 (6)	7 (6)	<b>0.002</b>
<b>VGF</b>		62 (6)	51 (5)	<b>&lt;0.001</b>
<b>PANSS</b>	Positive Syndrome	13 (8)	11 (5)	<b>0.001</b>
	Negative Syndrome	21 (14)	17 (7)	<b>0.001</b>
	General PSICOPAT	<b>39 (11)</b>	31 (16)	<b>&lt;0.001</b>
	Total	<b>72 (27)</b>	58 (28)	<b>&lt;0.001</b>
<b>CGIs</b>		4 (1)	2 (1)	<b>&lt;0.001</b>

\*p-value Wilcoxon signed ranks test. Bold p<0.05

were seen after 9 months (June2014). All participants gave informed consent, and the study had the approval of the institutional review board of the LHU, Roma D.

#### Statistical analysis

Statistical analysis was performed using SPSS for Windows (Statistical Package for the Social Sciences, Version 19; SPSS, Inc., Chicago, IL, USA).

The categorical data were shown as percentage and continuous data were presented as medians and interquartile ranges (IQR).

The health scales outcomes were examined as continuous variables and analysed using Mann Whitney's not parametric test.

The longitudinal data were compared using Wilcoxon Signed Ranks's test. All significance tests were two-tailed and values of p<0.05 were considered statistically significant.

#### Results

40 patients were eligible: 20 were included in the sports program (SG) and the other 20 patients followed standard treatments (CG). Two patients in the control group had not completed the follow-up. Baseline characteristic were similar between treatment groups (Table 1). There was one significant difference in among groups (p<0.05) concerning Positive and

Negative Syndrome Scale (PANSS) general and total: patients included in the football group showed significantly better score when compared to CG.

Table 2 compares the variables analyzed for patients in groups SG and CG.

Nine months later, the patients in group SG had a significantly higher median vitality (median=55 and IQR=5 vs median=50 and IQR=16;  $p=0.031$ ), significantly lower medians in all PANSS scores (Positive Syndrome  $p=0.035$ ; Negative Syndrome  $p=0.003$ ; General PSICOPAT  $p=0.001$ ; Total  $p=0.001$ ) and CGIs ( $p<0.001$ ).

Concerning the longitudinal analysis to compare before and after the sport team intervention, no significant differences were found in the control group, with the exception of CGIs showed a significant reduction after nine months ( $p=0.022$ ) (data not shown in table).

Whereas the SG group showed significant improvements of the quality of life in accordance with the SF36 scales ( $p<0.05$ ) with the exception for the Bodily pain score ( $p=0.245$ ) (Table 3). Concerning the BCIS significant higher medians for "self-reflectiveness" and "Tot BCIS" were amount after nine months ( $p=0.007$ ;  $p=0.002$ ) and a significant reduction of "self-certainty" was obtained ( $p=0.001$ ).

The VGF median was changed from 51 (IQR=5) to 62 (IQR=6) with a significant level  $p<0.001$ .

The PANSS showed significant higher medians for Positive Syndrome, General PSICOPAT and "Total score" (respectively:  $p=0.001$ ;  $p<0.001$ ;  $p<0.001$ ) and a significant lower median for Negative Syndrome ( $p=0.001$ ). The CGIs median was decreased from 4 (IQR=1) to 2 (IQR=2) with  $p<0.001$ .

## Discussion

One of the main cores of schizophrenic pathology and, more generally, of mental disorders is represented by a serious loss of meaning, produced by an altered structure of subjectivity, understood as generative disorder [23]. Another essential aspect of these diseases

consists of a serious difficulty in interpersonal relationships that require specific interventions designed to improve the intersubjective ability of patients.

These features of psychotic patients are also closely related to a deep impairment of the metacognitive functions, which determines the inability to harmonize their internal states, to modulate the relationships with others and affects the awareness of the disease, thus compromising the social functioning and quality of life.

In summary it is to lead to severe compromise of "Freedom" of the individual to be understood as the ability to determine the paths of their lives.

Based on these theoretical premises has been developed the Model of Sports Psychosocial Rehabilitation, a bottom-up intervention model that tries to integrate the experiences pre-reflective self-awareness produced from the sport with a job-level representations mental, in order to acquire greater awareness of their maladaptive patterns and to the structuring of a stable sense of self-efficacy and self-esteem needed to master their internal states and events of life.

The results show that the model proved statistically effective in the experimental group (SG) as regards the psychopathological dimensions, which are significantly improved; in particular has reduced the negative symptomatology, this result is hardly achieved with the drug therapy.

In addition improved self-awareness, the general state of physical and mental health, social relationships and overall social functioning compared with the control group. Limitations are present in the present study. The sample size is not adequately powered. Moreover, a follow-up period of more extended it would be necessary to evaluate the long-term efficacy of the intervention. The sample from which to extract the participants is not well defined. Finally, the reproducibility of the model has yet to be developed and standardized.

Despite these negative aspects, there is a strong awareness of following this road and that this can be covered by other working groups to replicate and enhance the results achieved.

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