

# OSTEOPATHIC MANIPULATIVE THERAPY IN CHRONIC IDIOPATHIC CONSTIPATION

## Randomized pilot study



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### INTRODUCTION

Chronic Idiopathic Constipation (CIC) is identified as a gastroenteric functional disfunction, mainly characterized by sporadic not sufficient evacuation, possibly painful. CIC has a very high global incidence, with percentages ranging from 12% to 17% and with a male/female ratio of 1:2,8. The Causes of its manifestation are not completely clear and diagnosis is made through a series of criteria drawn up by an international team of gastroenterologists (Rome criteria III).

### OBJECTIVE

This pilot trial aimed at evaluating the efficacy of Osteopathic Manipulative Therapy (OMTh) in the treatment of chronic idiopathic constipation.

### METHODOLOGY

#### Sample Characteristics and Procedures

A randomized pilot study was performed in a primary osteopathic surgery in Turin, from December 2017 to May 2018.

Recruited both women and men aged 18 years and older with a medical diagnosis of CIC. Mean age of 42,04 (+/-11,75).

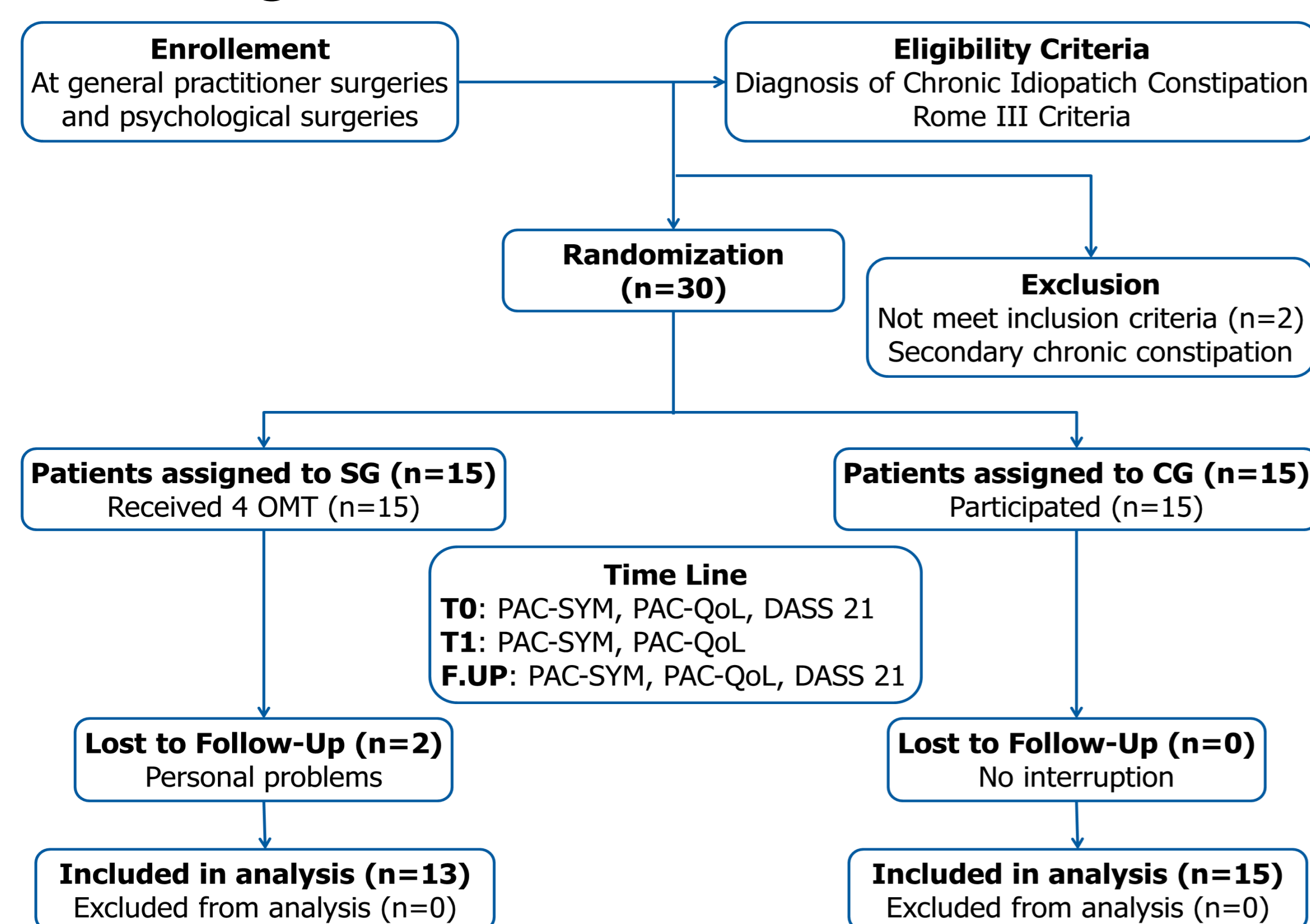
Random allocation to Osteopathic Manipulative Therapy group, the Study Group (SG) and Waiting List group, the Control Group (CG).

No blinded group because wasn't expected a therapy for the CG.

OMTh was administered by two students for their thesis project.

The SG received four treatments lasting 45 minutes, delivered every 15 days. The CG received no other treatment than the one they were already carrying on.

#### Trial Design



#### Outcome

Patient-Assessment of Constipation Symptoms (PAC-SYM).

Patient-Assessment of Constipation Quality of Life (PAC-QoL).

The patients were also asked to complete the DASS-21 survey, which aims to evaluate the psychological status of the patient.

#### Evaluation Times

The evaluations were carried out at T0 (baseline), at T1 (two months after administrated the first treatment) and at the follow-up (FUP), 4 months from T0.

### DISCUSSION

The evaluations obtained from outcomes and the current literature induce to take into consideration the **centrality of the bio-psychosocial component** in the management of a chronic idiopathic constipation condition. We can state that the **OMTh is partially effective** in reducing the symptomatology and in improving the quality of life linked to constipation in CIC affected patients. In the carrying out of future studies, it could be appropriate a change in study design as well as in its materials and methods. It is possible to conjecture concrete margins of improvement in the efficacy and output of the therapy through a **multidisciplinary intervention** in team with medical specialists in the **gastroenterological area** for an objective diagnostic and monitoring evaluation through instrumental exams and in the **psychological area** for the related comorbidities.

### RESULTS

Per-protocol analysis evidenced statistically significant improvement in the SG towards the CG as for the symptoms (PAC-SYM), as far the quality of life related to constipation (PAC-QoL) at T1.

Furthermore, it has been pointed out a redistribution of the percentages related to DASS-21, in an improving sense, in the comparison T0-FUP.

#### PAC-SYM - QUESTIONNAIRE

Overall Score											
Study Group	Control Group			Difference Between Group	Study Group	Control Group			Difference Between Group	T0-T1	T0 - F.UP
	T0	T1	F.UP			T0	T1	F.UP			
$\bar{x}$ Score	23.85	14.85	20.31	$\bar{x}$ Score	23.40	23.40	23.20	$\bar{x}$ Reduct.	9.0	3.34	
$\bar{x}$ Reduct.	9.00	3.54		$\bar{x}$ Reduct.	0	0.08		IC (95%)	5.04-12.45	0.64-7.32	
IC (95%)	5.47-12.42	0.05-7.13		IC (95%)	-4.33-4.33	-4.33-4.73		p-value	P<0.0001	P=0.11	
p-value	P<0.001	P=0.06		p-value	P=1	P=0.93					

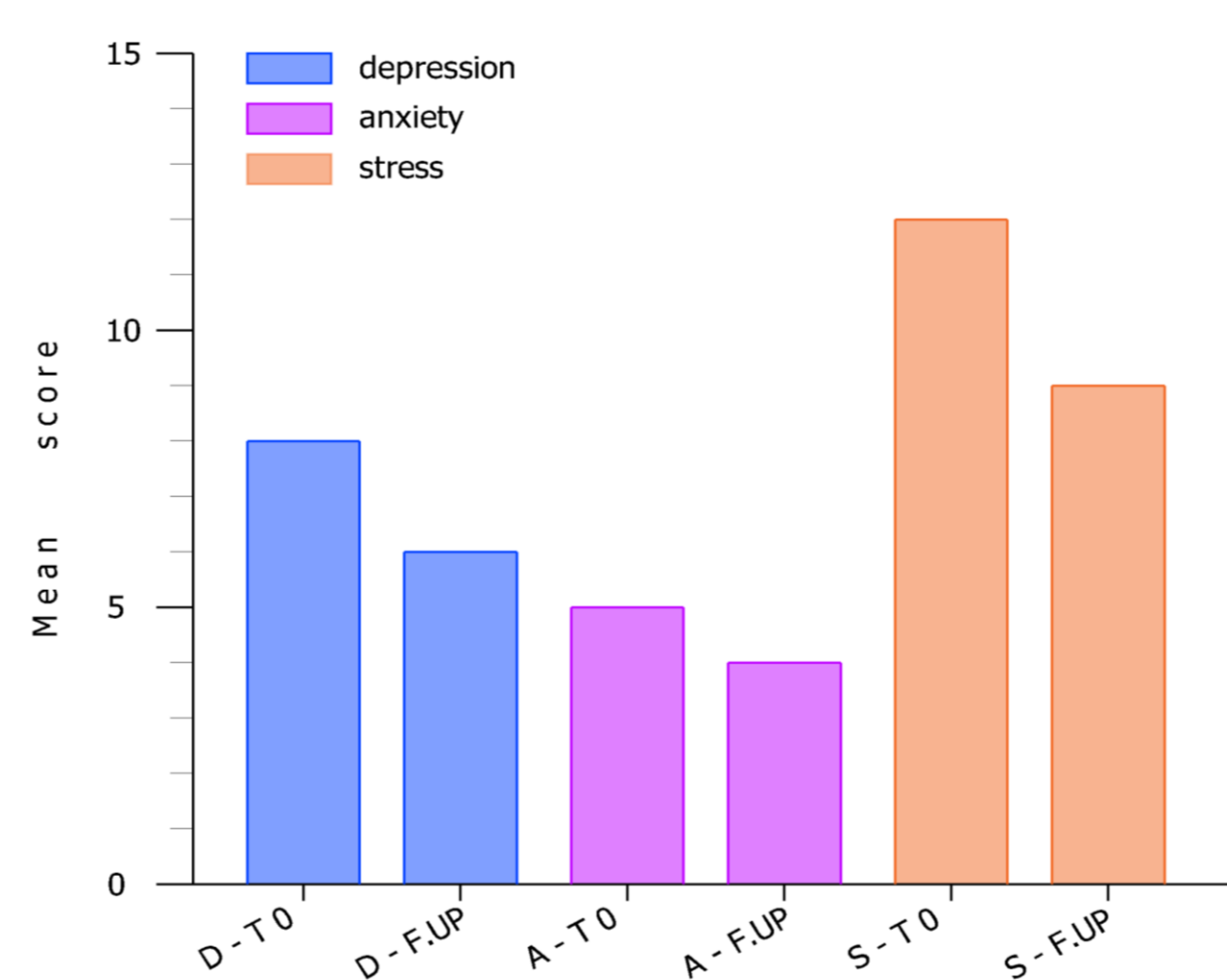
Subscale Symptom Score - $\bar{x}$ (sd)										
Study Group	Control Group			Study Group	Control Group					
	T0	T1	F.UP		T0	T1	F.UP			
Stool Sy.	12.00 (2.20)	7.23 (2.59)	8.85 (1.63)	Stool Sy.	11.60 (3.78)	11.27 (3.39)	10.73 (3.39)			
Abdominal Sy.	8.38 (2.02)	5.00 (1.53)	8.00 (2.31)	Abdominal Sy.	7.87 (2.03)	8.20 (1.90)	8.47 (1.88)			
Rectal Sy.	3.46 (2.18)	2.62 (1.56)	3.46 (1.81)	Rectal Sy.	3.93 (2.05)	3.93 (1.62)	4.00 (1.81)			

#### PAC-QoL - QUESTIONNAIRE

Overall Score											
Study Group	Control Group			Difference Between Group	Study Group	Control Group			Difference Between Group	T0-T1	T0 - F.UP
	T0	T1	F.UP			T0	T1	F.UP			
$\bar{x}$ Score	64.23	42.00	47.54	$\bar{x}$ Score	62.07	62.13	62.47	$\bar{x}$ Reduct.	22.13	17,09	
$\bar{x}$ Reduct.	22.23	16.69		$\bar{x}$ Reduct.	-0.06	-0.4		IC (95%)	13.06-31.19	7.21-26.18	
IC (95%)	11.91-32.54	5.85-27.52		IC (95%)	-7.69-7.57	-7.86-7.06		p-value	P<0.0001	P=0.09	
p-value	P=0.0003	P=0.0059		p-value	P=0.98	P=0.91					

Subscale Symptom Score - $\bar{x}$ (sd)										
Study Group	Control Group			Study Group	Control Group					
	T0	T1	F.UP		T0	T1	F.UP			
Physical Di.	10.00 (1.91)	6.31 (1.75)	8.23 (1.74)	Physical Di.	9.73 (1.91)	9.93 (1.62)	9.67 (1.88)			
Psychosocial Di.	13.08 (4.42)	9.00 (4.83)	9.92 (5.33)	Psychosocial Di.	13.00 (3.25)	12.40 (2.67)	12.60 (2.56)			
Wor. and Con.	25.77 (5.78)	17.38 (6.24)	19.23 (6.52)	Wor. and Con.	23.93 (5.85)	24.33 (5.46)	24.80 (5.06)			
Satisfaction	15.38 (3.52)	9.31 (2.53)	10.15 (3.36)	Satisfaction	15.40 (2.75)	15.47 (2.83)	15.40 (2.59)			

#### DASS-21 - STUDY GROUP



#### DASS-21 - CONTROL GROUP

