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Microstyle study: a randomized controlled trial on lifestyle intervention in prostate cancer patients undergoing radiotherapy

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Background

Prostate cancer (PC) is the most frequent neoplasia in men in Italy (19.8% of male tumors). The aim of the Microstyle trial is to improve adherence to a healthy lifestyle in patients undergoing RT. In this work we present the variation in adherence to the Mediterranean Diet (MD) between baseline and the 6th month after intervention and the association between Homa Index and patient characteristics, circulating biomarkers and the psychological questionnaires.

Results

Overall, we enrolled a total of 311 patients from October, 2021 to December 2023. In table 1 are reported patients with data on HOMA Index. Regarding adherence to the MD, comparing the score from baseline to the 6th month, we observed a higher increase in the IG vs CG (Figure 3). Network analysis (Figure 4) shows that greater improvement in the adherence to the MD is correlated with a better erectile functions, and a decrease in total cholesterol and blood glucose levels. Patients living in Naples or with high physical activity have higher adherence to the MD. However, patients with high Homa-Index have lower improvement (Figure 5). Patients living in Naples, with high perfusion and triglycerides or hormonal therapy have higher Homa. Conversely, higher level of physical activity is significantly associated with lower Homa (Figure 6).

Table 1: Baseline characteristics of participants.

	Overall, N = 292[2]	Homa Index < 2.8 N = 157[2]	Homa Index > 2.8 N = 135[2]	p-value[1]
Centre				<0.001
Milan	170 (58%)	108 (69%)	62 (46%)	
Naples	122 (42%)	49 (31%)	73 (54%)	
Arm				0.8
IG	145 (50%)	77 (49%)	68 (50%)	
CG	147 (50%)	80 (51%)	67 (50%)	
Age	72 (67, 77)	73 (67, 77)	71 (67, 76)	0.4
Missing	1	0	1	
BMI				<0.001
<25	134 (46%)	96 (61%)	38 (28%)	
>25	158 (54%)	61 (39%)	97 (72%)	
WHR				0.11
<0.9	10 (3.4%)	8 (5.1%)	2 (1.5%)	
>0.9	282 (97%)	149 (95%)	133 (99%)	
RT				0.046
Exclusive RT	196 (67%)	96 (61%)	100 (74%)	
Salvage RT	68 (23%)	45 (29%)	23 (17%)	
Adjuvant RT	28 (9.6%)	16 (10%)	12 (8.9%)	
Missing	18	13	5	
Hormone Therapy				0.003
No	159 (54%)	98 (62%)	61 (45%)	
Yes	133 (46%)	59 (38%)	74 (55%)	
NCCN 2020 Risk Category				0.069
Low	43 (15%)	24 (15%)	19 (14%)	
Unfavorable Intermediate	73 (25%)	29 (19%)	44 (33%)	
Favorable Intermediate	77 (27%)	45 (29%)	32 (24%)	
High	67 (23%)	42 (27%)	25 (19%)	
Very High	30 (10%)	16 (10%)	14 (10%)	
Missing	2	1	1	

[1] n (%); Median (IQR)
[2] Pearson's Chi-squared test; Fisher's exact test; Wilcoxon rank sum test

Figure 3. Change in MD adherence in the total sample, by arms and centre.

MD ADHERANCE SCORE: BASELINE VS 6th MONTH

Figure 5 Network analysis

Anthropometric measurements
Age: Age
BMI: Body Mass Index
WHR: Waist to Hip Ratio

Biomarkes
ALP: ALP
ALT: ALT
AST: AST
BIG: Blood Glucose
CF: Cardiac Frequency
CHD: Cholesterol HDL
CrL: Cholesterol LDL
CrL: Creatinine Level
Ery: Erythrocytes
Hmt: Hematocrit
Hmg: Hemoglobin
HOM: HOMA Index
Ins: Insulin Level
Lkc: Leukocytes
Prf: Perfusion
Plt: Platelets
PSA: Prostate-Specific Antigen
Tst: Testosterone
TtC: Total Cholesterol
Trg: Triglycerides

Questionnaires
CDM: Mediterranean Diet Change
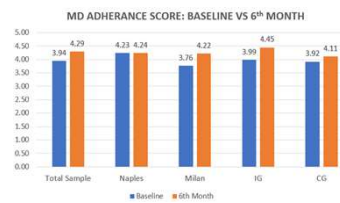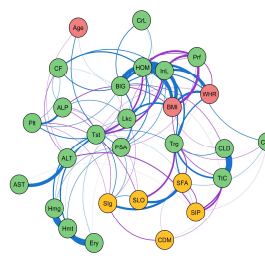SFA: Score FACT-P
Sig: Score IIEF
SIP: Score IPSS
SLO: Score LOT-R

Figure 5. OR for improvement vs worsening of MD adherence

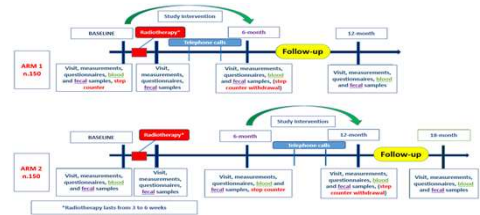**Forest Plot of Odds Ratios: MD Adherence Improvement vs Worsening**

	Odds Ratio	Lower	Upper
Centre Naples vs Milano	1.66	0.98	2.86
Depression Yes vs No	0.38	0.12	1.07
HOMA Index Abnormal vs Normal	0.53	0.31	0.88
IPAQ High vs low	1.75	1.05	2.95

Figure 6. OR for Homa > 2.8

Forest Plot of Odds Ratios: HOMA Index High vs Low

	Odds Ratio	Lower	Upper
IPAQ High vs low	0.6	0.36	0.99
Centre Naples vs Milano	2.56	1.51	4.37
Perfusion Abnormal vs Normal	3.3	1.49	7.63
Triglycerides Abnormal vs Normal	2.45	1.37	4.47
Hormonal Therapy High vs Low	1.81	1.1	3

Method

Figure 1:. IG: intervention group. CG: control group

The Microstyle study is a randomized controlled trial with two parallel arms: intervention group (IG) and control group (CG) (Figure 1).
The Mediterranean Diet Questionnaire (Gnagnarella et al, 2018): a 16-items self-administered questionnaire used to assess adherence to the Mediterranean diet (MD) in the Italian population. Based on the patients' responses, they are classified into three levels of adherence to the Mediterranean diet: low, medium, and high; the International Physical Activity Questionnaire (IPAQ) used to assess physical activity undertaken across a comprehensive set of domains.

Summary/ Highlights

Preliminary results show that the intervention improves MD adherence. Homa-index and the level of physical activity are significantly associated with MD adherence. Physical activity, residence (south vs north of Italy), perfusion, triglycerides, and hormonal therapy are significantly associated with the high Homa-Index.

SCAN ME!

References

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