








Feasibility, acceptability, and behavioral outcomes of a multimodal intervention for prostate cancer patients: Experience from the MARTINI lifestyle program

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Abstract

Background: Prostate cancer (PCa) is the most frequently diagnosed malignant tumor in men. The potential benefit of a healthy lifestyle contrasts sharply with the observed poor adherence to current international lifestyle guidelines. Thus, well-designed sustainable interventions of aftercare that can be translated into routine practice are highly recommended. The present pilot study aimed to evaluate the feasibility and acceptability of a multimodal lifestyle intervention program in PCa patients after radical prostatectomy (RP).

Methods: In a single-arm study, carried out at the Martini-Klinik of the University Medical Center Hamburg-Eppendorf, Germany, 59 eligible men with locally advanced PCa were recruited within 3–6 months after RP and assigned to a multimodal lifestyle program. The program consisted of 10 weekly 6–7 h course days, with a focus on dietary control, physical activity (per World Cancer Research Fund recommendations) and psychological support. Primary objectives were feasibility, acceptability, completion rate, and safety. In addition, changes in lifestyle, psychological well-being, clinical and laboratory values were assessed. The study was registered in the German Clinical Trials Register (No. DRK S00015288 [MARTINI-Lifestyle-cohort] [www.germanctr.de]).

Results: A high program acceptance was observed. Only three participants (5%) dropped out of the program prematurely. Personal feedback reflected appreciation for participation, personal gain through new knowledge and through the group experience. Without exception, all participants have taken part in follow-up examinations and no adverse events or incidents occurred. In addition, changes in lifestyle habits, clinical parameters and improved quality of life were detected.

These authors contributed equally to this study.

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Conclusion: The MARTINI lifestyle program appears feasible and safe, and acceptance of the multimodal intervention was high among PCa patients. These encouraging results favor conducting a large multicenter trial to implement the program into routine practice and to evaluate the effectiveness of the intervention on survival and quality of life.

KEYWORDS

feasibility, multimodal lifestyle intervention, prostate cancer

1 | INTRODUCTION

Prostate cancer (PCa) is the most frequently diagnosed malignant tumor in men and represents the second most common cause of cancer deaths in Germany.¹ Increasing evidence from epidemiologic and interventional studies suggest that adherence to a healthy lifestyle might not only counteract side effects of current treatments but also improve long-term outcomes in PCa patients. Positive effects on health-related or cancer-specific quality of life, physical function, psychological distress, development of comorbidities, disease progression, and mortality have been reported.²⁻⁶

Numerous studies demonstrate that psychological and social challenges for men after radical prostatectomy (RP) is associated with distress, depression and anxiety, particularly fear of disease progression.⁷⁻⁹ A greater capacity to cope with the physical and psychological posttreatment changes can significantly improve the level of psychological well-being and quality of life.^{10,11} Therefore, several studies highlight the importance of evidence-based intervention supporting the adaptation process for men after prostatectomy.¹²⁻¹⁴

The potential benefit of a healthy lifestyle contrasts sharply with the observed poor adherence to current international lifestyle guidelines. Recent research indicates that only 3 out of 10 recommendations from the World Cancer Research Fund (WCRF) and the American Institute for Cancer Research (AICR) were achieved in the majority of PCa patients scheduled for surgery.¹⁵ Against this background and in light of increased survivorship support, the identification of relevant modifiable lifestyle parameters are of growing interest. However, the few previous combined multimodal randomized controlled trials had several limitations, including very long duration that could not be translated into routine practice, insufficient intensity and sustainability of the lifestyle program or lack of relevant clinical endpoints.

Therefore, the aim of this study was to determine the feasibility of a multimodal lifestyle program from the MARTINI lifestyle cohort. In 12 weekly course days nutritional habits, exercise behavior, and psycho-oncology topics were addressed to evaluate feasibility and acceptability of the program, as well as changes in lifestyle habits, anthropometry and laboratory parameters.

2 | PATIENTS AND METHODS

2.1 | Design, setting, and participants

This study was a single-arm feasibility study carried out at the Martini-Klinik of the University Medical Center Hamburg-Eppendorf, Germany. Patients after RP with locally advanced PCa (pT3) with an increased risk of biochemical recurrence were invited to participate in the pilot phase. Baseline characteristics of study participants are shown in Table 2. The principal inclusion criteria were sufficient German language skills, surgical treatment of PCa by RP with postoperative non-detectable PSA, no contraindications related to exercise, and engagement in targeted lifestyle behavior at baseline. Exclusion criterion was planned adjuvant radiotherapy. Eligible patients were recruited within 3–6 months after RP by e-mail to participate. The study protocol was approved by the ethics committee of Hamburg (PV5358) and the study was conducted according to the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants. The study was registered in the German Clinical Trials Register [No. DRK S00015288].

2.2 | Data collection

The following data on lifestyle behavior, psychological status and clinical characteristics were collected at baseline (t0) and 11 weeks later after the completion of the program (t1).

2.2.1 | Assessment of laboratory measurements and biomarkers

Venous blood samples for determination of laboratory parameters (e.g., lipid profile, fasting glucose, Vitamin D and selenium) were detected. Lipid profile and glucose levels were measured in clinical routine. Vitamin D levels were determined with the photomultiplier Cobas E411 from Roche, selenium levels were measured by Graphite Furnace Atomic Absorption Spectrometry (GF-AAS).

2.2.2 | Assessment of behavioral changes in terms of nutrition and physical activity

We performed the hand strength with Kern MAP 130K1, the 6-min walking test and over 1 week the accelerometry (Actigraph wGT3X-BT). In addition, the anthropometric values for body-mass-index, body composition (Akern BIA 101) and waist circumference were collected. Assessments included evaluation of dietary habits (Food frequency questionnaire,¹⁶ and a physical activity questionnaire¹⁷).

2.2.3 | Assessment of psychological well-being

Psychological well-being was assessed using standardized measurements: depression via Patient Health Questionnaire (PHQ-9),¹⁸ anxiety via Generalized Anxiety Disorder questionnaire (GAD-7),¹⁹ self-reported perceived stress via German 10-item Perceived Stress Scale (PSS-10),²⁰ fear of progression via short version of the Fear of Progression questionnaire (12 items)^{21,22} and health related quality of life via HRQL-SF-12 questionnaire.²³

2.3 | Intervention program

The multimodal intervention targeted the areas of nutritional behavior, physical activity and psychological issues supported the life change processing. To achieve sustainable changes different strategies were developed to optimize individual physical and mental resilience, to increase healthy life attitudes and coping skills as well as to use social resources. In all sessions we promote an open communication about the individual health related experience, cancer processing confrontation and disease coping. The techniques of motivational interviewing, self-monitoring of individual behavior, goal setting, feedback on the new behavior, and relapse prevention were primarily used.

The integrated concept consists of 10 weekly 6–7 h course days (group size 8–10 participants), 2 additional examination days in week zero and 11. Aim of the nutrition intervention was to improve adherence to the WCRF recommendations in daily life. The exercise program aimed to support the implementation of regular physical activity without much equipment to build up strength and improve endurance. The joint sporting exercises were partly supplemented by teaching the theoretical background. The psychological intervention addressed stress management techniques and relaxation exercises (once a week). Furthermore, the issue of sexuality in partnership and a partner module was integrated (main topics of the multimodal lifestyle intervention program are shown in Table 1).

2.4 | Outcome measurements

Primary outcomes of this pilot study were the feasibility and acceptability based on recruitment, program content, and procedures. For this, we assessed recruitment rate, acceptance and

coordination of the program, motivation of participants, and completion rate. Safety of the intervention was defined as absence of adverse outcomes that could be linked to the lifestyle intervention program, for example, excessive weight loss, eating disorders, extraordinary mental stress within the 12 weeks.

Secondarily, changes in lifestyle habits, anthropometry and laboratory parameters were examined. Here, we estimated changes in the specific areas of the behavioral intervention, psychological wellbeing, performance diagnostic, anthropometry and biomarkers. However, all secondary outcome results were obtained mainly to assess satisfaction with the program content and the feasibility of the procedures. These were not powered to detect differences before and after the intervention.

2.5 | Statistical analysis

Descriptive statistics included frequencies and proportions for categorical variables. Means, medians, and ranges were reported for continuously coded variables. The χ^2 tested the statistical significance in proportions differences. The t-test and Wilcoxon test examined the statistical significance of means and median differences. R software environment for statistical computing and graphics (version 3.4.3) was used for all statistical analyses. All tests were two sided with a level of significance set at $p < 0.05$.

3 | RESULTS

3.1 | Baseline characteristics

Patients demographic and clinic characteristics are summarized in Table 2. Median age was 64 years. Overall, 72.9% of the patients were overweight (BMI 25–<30 kg/m²) or obese (BMI \geq 30 kg/m²), and 61% were defined as current or former smokers. The median preoperative PSA was 7.3 mg/l. At final pathology, the majority of the patients presented with pathologic stage pT3a (84.7%), Gleason grade group 2–3 (88.2%), and pathologic NO (88.1%) PCa.

3.2 | Feasibility

The actual feasibility study was launched in 2016 with planned 60 participants. Overall, a total of 59 participants have completed the feasibility study. Ten potential participants were found not to meet the inclusion criteria due to acute disease before the start of the intervention (x3) or a rapid PSA recurrence after operation and thus an indication for salvage radiotherapy (x7). Three participants (5%) dropped out of the program prematurely due to displeasure with the program (x1), too long a journey (x1) and the illness of a family member (x1).

All participants have taken part in the follow-up examinations. Based on these results, a high program acceptance could be

TABLE 1 Contents of the multimodal intervention program.

Week	Nutrition	Physical activity	Psychological part
1	WCRF-recommendations overview	Lecture: Why do we need physical activity? Practice: stretching and Qi-Gong-exercises	Health promotion: three-steps-exercise
2	Healthy weight, weight reduction, sugar intake, sugar sweetened beverages	Lecture: Mobility training Practice: Mobility, mobility-exercises, stretching	Stress- und stress management, progressive muscle relaxation (PMR)
3	Fiber rich diet, hunger and satiety	Movement of all large joints until the end position is reached	Pleasure training and mindfulness: rest and enjoy Imagination exercise "feel-good place"
4	Red and processed meat Fish and plant based alternatives	Lecture: muscular fascia Practice: exercises with fascia roll	Relaxation and autogenous training: relax and release
5	Energy density, fat, fatty acid composition	Endurance sport and pulse rate measurement, Walking and simple yoga exercises	Mental training I: developing beneficial attitudes and mindsets Breath exercise
6	Healthy plate concept, portion sizes, self-reflection	Yoga	Mental training II: Problem solving training Body scan exercise
7	Fruits and vegetables	Lecture: Nordic Walking Practice: Nordic Walking	Sexual rehabilitation Exercise the intimacy
8	Secondary plant substances: green tea, broccoli, pomegranate, curcuma	Core stability: simple total body exercises	Importance of social bonding, "communication" and sexuality in the partnership Communication training with partner
9	Evaluation of food records	Rehabilitative training and stability, small jumps	Empathy with yourself, internal communication Imagination "Mindfulness by myself"
10	Conclusions	Development of a training plan	Transfer in the daily life, view into the future Letter for the future, goals for 3 months

Note: Each week, different contents from the fields of nutrition, physical activity and psychological part were presented and discussed by experts from the respective fields.

Abbreviations: PMR, progressive muscle relaxation; WCRF, World Cancer Research Fund.

assumed. Personal feedback after completing the program reflects the appreciation of the participation, the personal gain through new knowledge and through the group experience, but also gratitude for positive physical changes from starting regular physical activity supported by the change in diet. As to safety no adverse events or incidents that could be linked to the intervention program occurred.

3.3 | Behavioral changes

3.3.1 | Nutrition intake

In line with the WCRF recommendations, the intake of vegetable, legumes and fish increased significantly between baseline (t0) and post-intervention (t1), while the consumption of meat, meat products, sugar and confectionery decreased (Table 3). As to fruit, fat and alcohol intake, no changes were detected.

3.3.2 | Physical activity and performance diagnostic

To assess physical fitness before (t0) and after the intervention (t1), various measurements such as 6-min walk test, hand strength, bioimpedance analysis and accelerometry were performed. Only the 6-min walk test showed significant differences (Table 3). The focus of the sports intervention was on teaching different sports without aids in everyday life and less on building up physical endurance and fitness.

3.3.3 | Psychological well-being

The analysis of psychological factors (Table 3) show several significant differences in pre-post-values (t0 vs. t1). The results show conclusively that the intervention was associated with less fear of disease progression and perceived stress feelings. Furthermore, the values of physical capability were increased, which are a main part of quality of life.

TABLE 2 Baseline demographic and clinical characteristics.

Variable	Characteristics (n = 59)	
Age at surgery (year)	Median (IQR)	64 (59–68)
Waist circumference (cm)	Median (IQR)	101 (96–108)
Body mass index, n (%)	Median (IQR)	26.03 (24–28)
Smoking status, n (%)	Ex-smokers	33 (55.9)
	Smokers	3 (5.1)
	Nonsmokers	23 (39)
Preoperative prostate-specific antigen (µg/l)	Median (IQR)	7.3 (5–12)
Pathologic T stage, n (%)	pT3a	50 (84.7)
	pT3b	9 (15.3)
Pathologic N stage, n (%)	N0	52 (88.1)
	N1	6 (10.2)
	NX	1 (1.7)
Pathologic Gleason Grade Group, n (%)	1	0
	2	44 (74.6)
	3	8 (13.6)
	4	2 (3.4)
	5	5 (8.5)
Surgical margin status, n (%)	neg R0	51 (86.4)
	pos R1	8 (13.6)

3.4 | Anthropometry and biomarkers

In contrast to the BMI, waist circumference significantly decreased after the intervention (Table 3). In addition, positive changes with regard to selenium and fasting glucose levels as well as total cholesterol were observed.

4 | DISCUSSION

Sustainable patient tailored lifestyle interventions focused on aftercare for PCa patients undergoing RP are highly recommended. The results of our pilot study clearly demonstrate the feasibility, high acceptance rate and safety of the multimodal MARTINI lifestyle intervention program. Personal feedback reflected appreciation for participation, personal gain through new knowledge and through the group experience. Almost all patients completed the study and no adverse events or incidents occurred. In addition, changes in lifestyle habits, clinical parameters and improved quality of life were detected.

Previous studies have shown that lifestyle factors can have a positive impact on the progression of PCa.^{24,25} In particular low physical activity and nicotine abuse appear to be associated with

TABLE 3 Changes of nutrition intake, physical activity and performance diagnostic, psychological well-being and anthropometry and biomarkers before (t0) and after (t1) the intervention.

n = 59		Median (IQR)	p Value
Vegetable (g/day)	t0	115 (94–154)	0.002
	t1	143.8 (114–205)	
Legumes (g/day)	t0	3.9 (3–7)	0.006
	t1	6.2 (3–9)	
Fruits (g/day)	t0	191.2 (124–304)	0.490
	t1	172.6 (128–308)	
Meat and meat products (g/day)	t0	125.3 (76–167)	0.001
	t1	90.5 (57–134)	
Fish and shellfish (g/day)	t0	35.4 (15–40)	0.001
	t1	36.7 (19–41)	
Fat (g/day)	t0	39.8 (30–53)	0.246
	t1	45.1 (33–58)	
Sugar and confectionery (g/day)	t0	41.6 (24–62)	0.007
	t1	30.5 (17–49)	
Alcoholic beverages (g/day)	t0	277 (101–543)	0.831
	t1	315.3 (151–490)	
Cereals and cereal products (g/day)	t0	191.8 (153–314)	0.093
	t1	191.7 (136–255)	
Waist circumference (cm)	t0	101 (96–108)	<0.001
	t1	97 (94–106)	
Accelerometry (Steps/week)	t0	91.930 (78.844–102.571)	0.9
	t1	83.493.5 (75.0375–103.714)	
6 min-walking-test (20 m)	t0	560.2 (516–609)	<0.001
	t1	630 (595–645)	
max. hand strength right (kg)	t0	42.1 (37.6–48.7)	0.3
	t1	43 (38.5–46.9)	
max. hand strength left (kg)	t0	39.5 (33.8–45.3)	0.4
	t1	39.5 (34.6–43.9)	
BIA phase angle (°)	t0	5.8 (5.3–6.4)	0.3
	t1	5.9 (5.4–6.2)	
Body mass index (kg/m ²)	t0	26.03 (24.5–28.2)	0.4
	t1	25.41 (24.05–27.65)	
Depression (PHQ-9)	t0	4.29 (1–6)	0.29
	t1	4.02 (1–5)	
Anxiety (GAD-7)	t0	4.03 (1–5)	0.08
	t1	3.75 (1–5)	
Progressive of fear (PoF)	t0	24.20 (16–28)	<0.001
	t1	21.15 (13–23)	

(Continues)

TABLE 3 (Continued)

n = 59		Median (IQR)	p Value
Perceived stress (PSS)	t0	21.16 (15–25)	<0.001
	t1	20.20 (13–22)	
Quality of Life (SF-12)			
Physical domain	t0	46.00 (37.1–54.8)	<0.01
	t1	50.31 (36.2–55.3)	
Mental domain	t0	51.18 (43.6–57.8)	0.06
	t1	53.10 (35.5–57.4)	
Selenium (µg/L)	t0	83 (74–97)	<0.001
	t1	101.5 (90–121)	
Vit.D (µg/L)	t0	27.8 (20–36)	0.4
	t1	28.9 (22–35)	
LDL (mg/dL)	t0	118 (94–136)	0.07
	t1	115 (84–129)	
HDL (mg/dL)	t0	56 (47–62)	0.8
	t1	54 (45–68)	
Triglyceride (mg/dL)	t0	140 (97–194)	0.8
	t1	120 (93–157)	
Total cholesterol (mg/dL)	t0	200.5 (177–224)	0.04
	t1	193 (163–215)	
Uric acid (mg/dL)	t0	5.8 (4.8–6.8)	0.9
	t1	5.7 (5.0–6.1)	
Fasting glucose (mg/dL)	t0	92 (82–100)	0.007
	t1	80 (75–99)	

an unfavorable outcome.²⁶ The data for other factors is less clear and occasionally contradictory.²⁷ For example, studies on obesity showed a significant association with more aggressive tumors, but did not show a worse clinical outcome. Overall, a plant-based diet with whole grain products and a low proportion of saturated fatty acids appears to have the greatest significant positive impact clinically.^{28,29}

The potential benefit of a healthy lifestyle contrasts sharply with the observed poor adherence to current international lifestyle guidelines. One of our earlier studies¹⁵ showed that the lifestyle lived by patients with PCa deviates significantly from the recommendations of the WCRF. Recommendations on sustainable changes in lifestyle factors such as diet, physical activity and stress experience therefore seem necessary. However, if these are delivered solely through verbal education or as information flyers, this does not seem to lead to sustainable lifestyle changes. In contrast, interventions with regular active participation, which enables these changes to be internalized and learned, show significantly better and sustainable results.³⁰ In our study, participants were recruited by mail and the process was quick and unproblematic. Adherence to the course was

very high and the participants showed a high level of satisfaction with the contents and processes of the program.

The limitations of the presented lifestyle intervention are certainly the small number of participants, which limits the ability to reliably statistically evaluate the self-report and the measurement results with regard to the effectiveness of the intervention. In addition, as a pilot feasibility study, patients were not randomized, so it was not possible to compare with a control group. Another limitation is the single center implementation, as participation was not possible for patients who had long commutes. The effort of a day program with an interprofessional team is challenging in terms of time and personnel in the organization and financing and is certainly a critical point in the transferability of the program to other centers. The use and benefit of web-based programs was also not investigated in the feasibility study and could certainly be included in follow-up studies.

However, due to the proven feasibility of the study with high adherence of participants to the program and the positive changes in the course of the intervention, multicenter randomized studies with a higher number of participants are planned.

5 | CONCLUSION

Our pilot study of lifestyle intervention for locally advanced PCa was feasible, safe, sustainable, and showed high participant acceptance. Multicenter randomized follow-up studies should also investigate the potential impact on tumor progression and comorbidity.

AUTHORS CONTRIBUTION

Thederan: Main author of writing and responsible for implementation of nutritional intervention. **Pott and Krueger:** Statistics and implementation of psychology intervention. **Chandrasekar:** writing and corrections. **Tennstedt:** statistical analysis. **Knipper:** Statistical analysis. **Heinzer:** Implementation of urological intervention. **Schulz:** Creation of sport intervention. **Makarova and Zyriax:** Statistical analysis, writing and corrections.

DATA AVAILABILITY STATEMENT

Data are not available to other researchers because they are from a institutional database of patients providing routinely collected data.

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