Acta Oncologica, 2007; 46: 83–89

informa
healthcare

ORIGINAL ARTICLE

"Between Men": A psychosocial rehabilitation programme for men with prostate cancer

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Abstract

The aim of this study was to evaluate the effect of psychosocial rehabilitation on newly diagnosed prostate cancer patients. The "Between Men" programme consisted of seven weekly sessions of physical training (Phys) alone, information (Info) alone or physical training plus information (PhysInfo). After diagnoses, patients (n = 211) were consecutively included, stratified and randomised to one of four groups: Phys, Info, PhysInfo or standard care control (C). A nurse specialised in urology, an urologist and a physiotherapist performed the interventions. Patients were followed up during one year with mailed standardised questionnaires. It could not be assumed that the "Between Men" programme had any effect on patients' anxiety and depression (HADS). Health-related quality of life (HRQOL) was associated with stage of disease but not with psychosocial intervention. Thus, Physical Function (PF), Role Function (RF) and Fatigue (FA) were inferior among patients with, than without, metastases of prostate cancer both at baseline and at the 12-month follow-up. This randomized study did not demonstrate any significant effect of psychosocial rehabilitation among prostate cancer patients. Considering the low rate (1/2), of included/eligible patients a less complicated design (intervention versus control) would have been preferred in order to increase power.

Prostate cancer, the most frequent form of cancer among men in Sweden [1], has usually an indolent natural history when early detected and localised. However, in some cases local tumour progression and aggressive metastases develop as much as 15 years after cancer diagnosis [2]. Available evidence indicates that surgery (radical prostatectomy), in comparison with watchful waiting (no treatment), reduces frequency of prostate cancer metastases and death caused by that disease [3]. However, there are no randomised studies that compare the effects of radical prostatectomy with either external beam radiotherapy or brachytherapy [4]. Thus, the evidence of radiation therapy in prostate cancer is low [5]. In a non-randomised study, radical prostatectomy does not show any superiority over brachytherapy (curative radiation treatment) regarding time until relapse as indicated by an increase in PSA level [6]. Five years after diagnosis Health-Related Quality of Life (HRQOL) is equal or superior in prostate cancer patients than it is in the population [7]. Nevertheless, the extended treatment side effects persist years after treatment has ended, whereas patients treated by prostatectomy have major erectile dysfunction [7] and urinary incontinence [8] as compared with patients treated by brachytherapy. Watchful waiting could cause difficulties in discharging urine [9].

The only controlled study evaluating psychosocial rehabilitation for prostate cancer involves three interventions: information with discussion, information without discussion and a control group. Both types of information are found to increase patients' knowledge of disease, treatments and side effects. Further, patients who have opportunity to discuss are less troubled by sexual issues than a group of control patients [10]. Other studies are descriptive and comprise information/education [11] or

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(Received 6 April 2006; accepted 30 May 2006)

ISSN 0284-186X print/ISSN 1651-226X online
DOI: 10.1080/02841860600857326

information combined with physical activity [12]. Research suggests that physical activity and exercises are significantly associated with improvements in several aspects of HRQOL, regardless of the participants' age, activity level or health status [13]. Improvements after physical activities are noted in patients with different chronic diseases [14] and levels of pain [15]. From epidemiological studies, it has been found that regular physical activity can reduce the risk for prostate cancer [16]. Physical activity for newly diagnosed prostate cancer patients have been described but not yet evaluated in a preliminary study [17]. Results, from a heterogeneous sample of cancer patients, including men with prostate cancer, indicate that physical training, as part of a psychosocial rehabilitation programme, was highly appreciated by the participants [18].

In conclusion, there are several prostate cancer medical treatments that are associated with extensive side effects, but generic HRQOL among prostate cancer patients is comparable to the population. Psychosocial rehabilitation efforts are mostly published as descriptive studies or correlational research.

The aim of this study was to assess the effect of a psychosocial rehabilitation programme on anxiety and depression and in addition to study HRQOL for different stages of disease. Prostate cancer patients were randomly assigned to one of four groups: Physical training alone (Phys), information alone (Info), physical training plus information (PhysInfo) or a control group (C).

Specific research questions can be raised: 1. Does physical training reduce depression among men with prostate cancer? 2. Does a large amount of information about prostate cancer and its treatments reduce anxiety, as defined by HADS, among men with a newly diagnosed prostate cancer? 3. Is there a synergetic effect of physical training and information on prostate cancer patients' quality of life and psychological distress? 4. Are there differences in HRQOL between patients with and without prostate cancer metastases at baseline and at the 12-month follow-up?

Material and methods

Patients and procedure

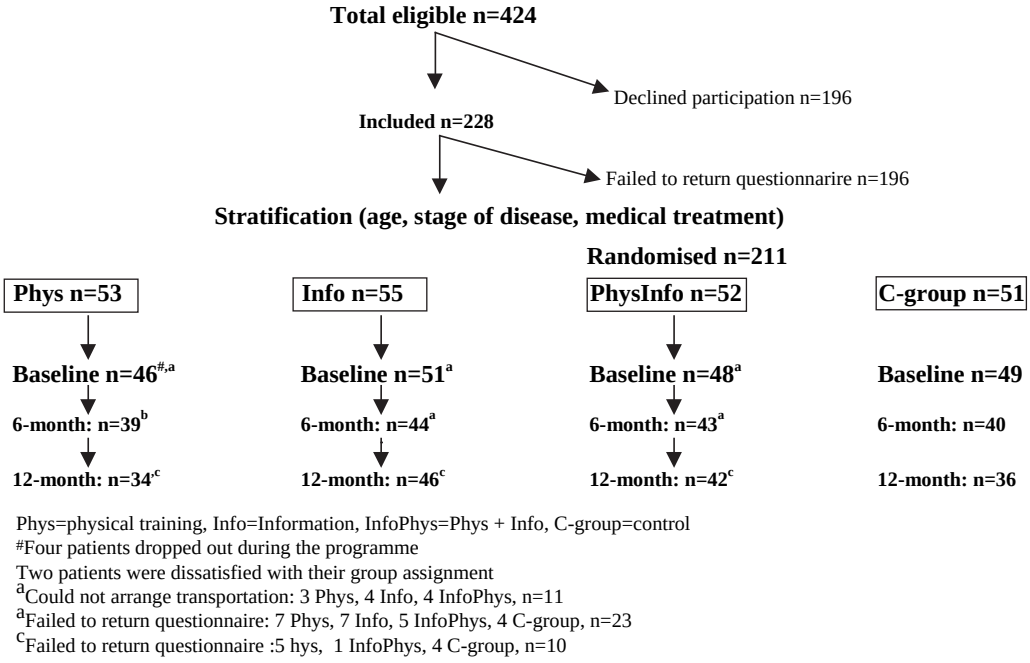
Within six months after diagnosis prostate cancer patients (n = 211), were consecutively included in the "Between Men" programme at the university hospital in Uppsala, Sweden. Patients were excluded if they had another cancer diagnosis, participated in other studies, were patients in other care programmes, had severe hearing or vision impairment, were not Swedish speaking, or were physically or mentally disabled.

A nurse specialised in urology contacted eligible patients (n = 424), identified by their histopathology reports, by telephone, informed them about the "Between Men" programme and then invited them to participate. About half of the patients (n = 228) accepted inclusion, but 17 failed to return pre test questionnaires, because they found them to be too extensive to complete, and therefore they were not included in the study. Subsequently, after previous stratification on stage of disease, curative treatment and age, the Regional Oncological Centre randomised patients to Phys, Info, PhysInfo or C (Figure 1). When patients were informed about the group assignment, some patients dropped out (n = 23) (Figure 1) and in addition some questionnaires were not returned at the 6- and 12-month follow-ups (n = 23 and n = 19, respectively). Thus, the final sample included 158 patients (Figure 1). Questionnaires (described below) were mailed at inclusion two weeks after intervention and at 6- and 12-month follow-ups, with two reminders if needed. The study was approved by the Research Ethics Committee at the Faculty of Medicine, Uppsala University.

Questionnaires

The Hospital Anxiety and Depression Scale (HADS). The HADS consists of two subscales: depression (7 items) and anxiety (7 items). Subscale scores range from 0 (no distress) to 21 (maximum distress). The originators of the scale [19] suggested that a score of 7 or less on either subscale indicates a "non-case", 8–10 a "doubtful case" and a score of 11 or more a "case" (i.e. a person characterised by clinically relevant anxiety and depression). In the analyses a score of seven or less was considered a non-case and a score more than seven a case. The validity of the HADS has been demonstrated e.g. among patients with stroke, myocardial infarction and breast cancer [20]. Internal consistency has been reported to be between 0.80 and 0.93 for anxiety and between 0.81 to 0.90 for depression [21].

The EORTC QLQ-C30 version 3.0. This questionnaire (30 items) [22] is cancer specific, multidimensional and includes several subscales of functioning and symptoms. The response format is for the most part made up of four categories (not at all = 1, a little = 2, quite a bit = 3 and very much = 4), but the global quality of life (QLQL) is ranging from "very poor" to "excellent" on a 7-point scale. All subscales and individual item responses are linearly



Phys=physical training, Info=Information, InfoPhys=Phys + Info, C-group=control
#Four patients dropped out during the programme
Two patients were dissatisfied with their group assignment
[a]Could not arrange transportation: 3 Phys, 4 Info, 4 InfoPhys, n=11
[a]Failed to return questionnaire: 7 Phys, 7 Info, 5 InfoPhys, 4 C-group, n=23
[c]Failed to return questionnaire :5 hys, 1 InfoPhys, 4 C-group, n=10

Figure 1. Progress through the various stages of the "Between men" trial.

transformed to a scale of 0 to 100 (see the EORTC guidelines). A higher score represents higher ("better") functioning or a higher number of (or more severe) symptoms. The Between Men study included: 1. all five functional scales: physical = PF, role = RF, emotional = EF, cognitive = CF and social function = SF; 2. a global health status/quality of life scale = QL; and 3. one symptom scale, fatigue = FA. Because chemotherapy treatment was not applied in this patient group, both single items and the pain and nausea/vomiting scales were excluded in the analyses.

The Between Men programme

Each of the three intervention programmes (Phys, Info, and PhysInfo) was made up of seven sessions. Group size varied from three to ten participants. Written folders were used in all programmes.

Physical training (Phys). An experienced physiotherapist led 60-minute physical training sessions followed by a 15-minute coffee break. This programme included light physical training with movement and fitness training, relaxation when lying down and sitting, breathing exercises with non-stressed, slow breathing and exercises of the pelvic floor.

To refresh the patients' memory about the different exercises a booster session was held two months after the conclusion of the training exercises. This session also served to prompt the patients to continue or reinitiate physical training into their daily life. In addition, patients could discuss their current physical activities and other important issues.

Information (Info). A nurse served as the group leader of this programme, which was organised as 60-minute information sessions followed by a 15-minute coffee break. Emphasis was laid on giving the information about prostate cancer, its treatment and potential side effects (e.g., incontinence, impotency), possible effective consequences and how to deal with side effects. However, during the first two sessions, the core issue was reactions to crisis. Furthermore, patients had ample opportunity to discuss their experiences regarding diagnosis and communication with the group leaders and other participants. After this introduction, the next step in the programme was an urologist's lecture on cancer in general, the function of the prostate and prostate cancer disease, methods of diagnosing prostate cancer and available medical treatments. Then, two sessions were dedicated to side effects (such as incontinence and sexual functioning), including solving any problems related to these side effects. Demonstration of products used as incontinence and sexual aids was an essential part of these sessions, which were complemented with information on the availability of these articles and instructions on how to obtain them. To conclude the programme the final session was used to summarise all the preceding

topics, paying particular attention to patients' needs and wishes.

Information plus physical training (PhysInfo). This programme was a combination of the Phys and Info programmes. Patients in this condition were given physical training and then information in the same session. The PhysInfo programme consisted of seven 135-minute sessions.

Control group. The control group received standard care, i.e. the information and care that was available at that time at the university hospital Akademiska in Uppsala, Sweden Mostly, information included two leaflets; one was locally edited at the hospital and the other by a pharmaceutical manufacturer. Patients had the opportunity to phone a nurse (during a minor period of the study) if they had any question, whereas neither group information nor physical training was available.

Statistical methods

Analyses were based on the intention to treat and primarily ANCOVAs were done to study differences between randomisation groups, changes over time (inclusion, 6- and 12-months follow up) and interactions between group attainment and time. Statistically significant differences were assumed when $p < 0.05$. Pre-intervention assessments were used as covariates to control for baseline differences. When dependent measures were considered sensitive to medical treatments, the independent variable "metastases" was used as a second covariate. Fisher's least significant difference (LSD) procedure was performed to determine group differences ($p < 0.05$) [23]. Secondly, results were analysed by point estimates (means) and 95% confidence intervals [24]. In addition to the analyses of randomisation groups, confidence intervals were estimated for the interventions Phys including Nonphys (Info + C-group) versus Phys (Phys + Physinfo) and Info including Noninfo (Phys + C-group) versus Info (Info + Physinfo). χ^2 tests were used for the nominal data [25].

Results

The randomisation procedure resulted in the following distribution of patients: 53 to the Phys group, 55 to the Info group, 52 to the PhysInfo group and 51 to the C group, thus 105 patients got the opportunity to participate in Phys and 107 in the Info intervention, respectively. Overall, 20% of patients had metastasis, the most frequent curative treatment was radical prostatectomy and the average age of the patients was about 69 years, with a range of 43–86 years. Education was unequally distributed over randomisation groups, $\chi^2 = 25.3$, $df = (12, 1939)$, $p < 0.05$ (Table I).

The proportions of marriage (80%) and retirement (70%) were comparable among the groups.

Overall, the ANCOVAs, including baseline (covariate), 6- and 12-month follow-ups, showed no main effect of the Between Men programme on anxiety or depressive symptoms. In addition, there were no time interactions, therefore, analyses continued with point estimates and 95% confidence intervals.

Table I. Demographic characteristics and medical treatments of patients randomised to the Phys, Info, PhysInfo and C-groups.

	Phys (n = 53) n (%)	Info (n = 55) n (%)	PhysInfo (n = 52) n (%)	C (n = 51) n (%)	Total n (%)
Stratification					
Metastasis at inclusion	11 (21)	11 (20)	10 (19)	10 (20)	42 (20)
Curative treatment	19 (36)	20 (36)	19 (37)	18 (35)	76 (36)
No metastases, no curative treatment	24 (45)	23 (42)	23 (44)	23 (45)	93 (44)
Medical Treatment					
Watchful waiting	16 (30)	21 (39)	22 (42)	17 (33)	76 (36)
Radical prostatectomy	14 (26)	15 (28)	7 (13)	14 (27)	50 (24)
Radiation therapy	5 (9)	6 (12)	9 (17)	1 (2)	21 (10)
Hormonal therapy	14 (26)	11 (20)	13 (25)	12 (24)	52 (24)
Records unavailable	5 (9)	1 (2)	1 (2)	7 (14)	14 (7)
Education*					
Elementary school	24 (52)	16 (30)	19 (39)	12 (26)	71 (37)
Vocational school	9 (20)	11 (21)	13 (27)	8 (17)	41 (21)
Junior secondary school	3 (7)	7 (13)	1 (2)	11 (23)	20 (10)
Higher certificate	3 (7)	7 (13)	1 (2)	3 (6)	14 (7)
University graduation	7 (15)	12 (23)	15 (31)	13 (28)	47 (24)

*There is a significant association between randomisation and education, $\chi^2 = 25.25$ (12, 1939, $p < 0.05$).

Table II. Depression (HADS) by randomisation groups at the 12 months follow-up; means, 95% confidence interval, median and the 90th percentile.

Randomization groups	Mean values	95% confidence interval	Median	90th percentile
C-group (n = 39)	3.6	2.4–4.8	3.0	10
Phys (n = 35)	3.0	2.1–4.0	2.0	8
Info (n = 46)	3.1	2.1–4.1	2.5	9
PhysInfo (n = 38)	3.3	2.3–4.3	2.0	8
Totally (n = 158)	3.3		3.0	
Nonphys versus Phys				
NonPhys (n = 85)	3.4	2.6–4.1	3.0	9.4
Phys (n = 73)	3.2	2.5–3.8	2.0	8.0
Noninfo versus info				
Noninfo (n = 74)	3.3	2.6–4.1	3.0	8.5
Info (n = 84)	3.2	2.5–3.9	2.0	8.0

The C-group had comparatively "high", and the Phys group "low", mean value of depression (HADS) at 12 months (Table II). The confidence intervals around the group means were highly overlapping. (Table II). A confidence interval around the (C mean-Phys mean) difference (3.6 − 3.0 = 0.6), included 0, which means that probably there is no difference between means. The 90th percentile is 10 for the C-group and 8 for the Phys group, respectively (Table II). The baseline mean values for depression were Phys = 3.6, Info = 2.9, PhysInfo = 3.4 and the C-group 3.3. Thus the major improvement of depression, from baseline to the 12-month follow-up, was in the Phys-group (−0.6), whereas the C-group slightly deteriorated (+0.3). The comparisons of Nonphys versus Phys and Noninfo versus Info respectively, strengthen the impression of no difference between groups.

At baseline the mean values of anxiety (HADS) were: Phys = 4.5, Info = 3.2, PhysInfo = 4.0 and the C-group = 3.4. All groups improved at the 12-month follow-up, but the Info had minor level of anxiety (2.2), the narrowest confidence interval and low level for the 90th percentile, than the C-, Phys and PhysInfo groups (Table III). However, mean values of the Phys and PhysInfo-groups were higher than the corresponding value of the C-group. The (C-group mean – Info group mean) difference was small and its' confidence interval included 0.

There is no synergetic effect of physical training and information as demonstrated by the PhysInfo values compared with only Phys (Table III) or only Info, respectively (Table IV).

Prostate cancer patients with metastases scored less HRQOL, than patients without metastases, for three subscales; PF, RF and FA, both at baseline and at 12 months (Table II). Generally, with the exception of CF, patients with metastases scored inferior quality of life than men without metastases did (Table II), whereas quality of life for men without metastases were very similar to the matched population.

Discussion

The effect of psychosocial rehabilitation on outcome measures was evaluated in men with prostate cancer, randomised to the Phys, Info, PhysInfo or C-group.

Table III. Anxiety (HADS) by randomisation groups at the 12 months follow-up; means, 95% confidence interval, median and the 90th percentile.

Randomization groups	Mean values	95% confidense interval	Median	90th percentile
C-group (n = 39)	2.6	1.5–3.7	1.0	9.0
Phys (n = 35)	3.5	2.3–4.7	3.0	8.8
Info (n = 46)	2.2	1.4–3.0	1.0	7.0
PhysInfo (n = 39)	3.3	2.2–4.5	2.0	9.0
Totally (n = 159)	2.9		2.0	
Nonphys versus phys				
Nonphys (n = 85)	2.4	1.7–3.0	1.0	7.4
Phys (n = 73)	3.5	2.6–4.3	2.0	8.6
Noninfo versus info				
Noninfo (n = 74)	3.0	2.2–3.8	2.0	9.0
Info (n = 84)	2.8	2.1–3.4	2.0	8.0

Table IV. T-tests of differences, in HRQOL, between patients with or without prostate cancer metastases. Means(SD) for theEORTC QLQ-C30 functional scales, QL and FA at baseline and at the 12-month follow-up. In the right column the corresponding values, for an age-matched population sample, are presented.

	Patients with metastases at baseline (n = 39)	Patients without metastases at baseline (n = 150)	t-value	Patients with metastases at 12 months n = 29	Patients Without metastases at 12 months n = 130	t-value	Aged-matched population n = 158
PF	73.3 (23.8)	84.6 (18.3)	3.2*	78.2 (22,5)	87.8 (16.9)	2.6*	85.9 (19.6)
RF	72.6 (33.0)	83.7 (25.7)	2.2*	75.0 (30.3)	85.7 (24.8)	1.98*	84.9 (26.6)
CF	83.8 (21.1)	83.9 (18.6)	ns	85.1 (23.3)	83.8 (19.5)	ns	86.6 (16.5)
EF	81.2 (18.9)	83.6 (19.7)	ns	81.6 (20.1)	87.8 (18.0)	ns	86.6 (18.1)
SF	80.3 (22.6)	84.0 (22.1)	ns	77.0 (23,7)	83.5 (23.7)	ns	89.9 (19.8)
Glob QoL	68.6 (20.4)	75.4 (38.0)	ns	66.7 (23.4)	73.3 (21.9)	ns	77.0 (22.1)
FA	33.9 (27.8)	22.9 (22.2)	−2.6*	28.7 (25.3)	22.9 (22.2)	−2.3*	19.9 (21.7)

*$p < 0.05$.

It could not be assumed that, the interventions had any effect on anxiety or depressive symptoms. HRQOL did not change by intervention or time; rather metastases were an important, independent variable when considering quality of life.

Ineffective intervention could be a reason for no effect on outcome measures. However, the Between Men interventions were conducted by professionals in their corresponding branches. Instructions of Phys were executed by a physiotherapist with long experience with cancer patients and side effects of cancer treatment. A nurse expert in urology and an experienced urologist/oncologist held the Info programme. As we reported earlier [26], participants highly appreciated both the Info and the Phys interventions, but if they would have to opt for one of them today, the majority would chose the combination PhysInfo or Info alone but not Phys alone. However, seven sessions of physical training might have been insufficient to obtain any important change of outcome. Another possible explanation, of no effect of the Between men program, is that also men in the C-group presumably performed physical training and/or obtained information, which diminished control over these independent variables. Another hypothesis is that, two programs in one session (PhysInfo) might have been stressful and consequently caused no synergetic effect on outcome measures. Perhaps an intervention aiming at diet change (like increasing intake of vitamin E, selenium and fat fish, reducing calcium and red meat) and concurrent increase of high physical activity [27].

We expected physical training to be effective against depression and information against anxiety. Existing data showed the expected directions of changes but the confidence intervals were too overlapping. With sufficient power these research questions could have been properly answered. Instead, in addition to relatively small randomisation groups at the beginning, 20% of the patients dropped out during the first year of the study, which resulted in decreasing power at each assessment period. Furthermore, the factorial design included four groups in all analyses, making comparisons more complicated. Particularly, the presence of PhysInfo, which aimed at studying the synergetic effects of physical training and information, made comparisons difficult. Obviously, it would have been easier to evaluate one type of intervention instead of two types and their combination. Thus, the absence of any effect on outcome measures might be due to both low power and a complicated design. Another reason for lack of effect may be the heterogeneity of the patient sample, which stratification, by stage of disease, curative treatment and age, was aimed to control for. However the consequences of this method might have been an unbalance of confounders, for example with a variation in percentage of men having undergone radiation therapy (17% in the PhysInfo-group and 2% in the C-group) and the level of education (Table I).

Patients' values on all outcome measures at baseline increased the risk of a floor or ceiling effect [23], would have been more successful which implies small possibilities of change. The EORTC and the HADS questionnaires are frequently used in scientific papers and considered adequate outcome measures. However, an outcome measure of patients' knowledge, about cancer disease, cancer treatments and side-effects, could perhaps have added valuable comprehension to the study, as "knowledge" is affected by information in Lepore's [10] study.

To conclude, this study could not find any difference between psychosocial rehabilitation and no intervention. The major recommendations for future research are smaller studies including homogeneous patient groups, simple designs (interventions and control), and high power.

Acknowledgements

This study was made possible by a grant from the Swedish Cancer Society, Stockholm, Sweden.

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