

432/fibrinogen gel, did not survive for more than 3 years, although they were subsequently treated with chemotherapy or radiation therapy. The other 4 cases of primary carcinomas (cases 3, 4, 5 and 10) and 8 of the recurrent carcinomas (cases 6–9, 11–14), which were unaffected by OK-432, were also treated with surgery and/or palliative chemotherapy plus radiation therapy after local injection of OK-432/fibrinogen gel. It is difficult to assess the clinical benefit of applications of OK-432/fibrinogen gel because of the small number of patients and the short observation time in this trial. However, it is relatively easy to apply multiple, local treatments to tumours existing in the head and neck in comparison with tumours of other organs. In this respect, a multi-institutional collaborative study would clarify the clinical applicability of local administration of OK-432/fibrinogen gel to head and neck carcinomas.

1. Okamoto H, Shoin S, Koshimura S, *et al.* Studies on the anticancer and streptolysin-forming abilities of hemolytic streptococci. *Jpn J Microbiol* 1967, **11**, 326–336.
2. Nio Y, Zigelboim J, Bonavida B, *et al.* Sensitivity of fresh and cultured ovarian tumor cells to tumor necrosis factor, interferon- α 2 and OK-432. *Cancer Immunol Immunother* 1988, **27**, 246–254.
3. Talmadge J, Herberman RB. The preclinical screening laboratory;

evaluation of immunomodulatory and therapeutical properties of biological response modifiers. *Cancer Treat Rep* 1986, **70**, 171–182.

4. Uchida A, Hoshino T. Clinical studies on cell-mediated immunity in patients with malignant disease: I. Effect of immunotherapy with OK-432 on lymphocyte subpopulation and phytohemagglutinin responsiveness *in vitro*. *Cancer* 1980, **53**, 478–483.
5. Yamamura Y, Yasue M, Nakazono H, *et al.* A controlled study of surgical adjuvant chemoimmunotherapy with FT-207 and OK-432 for advanced stomach cancer: fourth study. Clinical application of OK-432 for control of cancer. *Excerpta Med* 1986, **80**, 5397–5401.
6. Toge T, Kuninobu H, Yamaguchi Y, *et al.* The clinical efficacy of intratumoral OK-432 administration in advanced cancer patients. *Jpn J Surg* 1988, **18**, 668–674.
7. Tsujitani S, Okamura T, Bab H, *et al.* Endoscopic intratumoral injection of OK-432 and Langerhans' cells in patients with gastric carcinoma. *Cancer* 1988, **61**, 1749–1753.
8. Monden T, Morimoto H, Shimano T, *et al.* Use of fibrinogen to enhance the anti-tumor effect of OK-432. *Cancer* 1992, **69**, 636–642.
9. Shimokawara I, Imamura M, Yamanaka N, *et al.* Identification of lymphocyte subpopulations in human breast cancer tissue and its significance. *Cancer* 1982, **49**, 1456–1464.
10. Saito M, Nanjo M, Aonuma E, *et al.* Activated macrophages are responsible for the tumor inhibitory effect in mice receiving intravenous injection of OK-432. *Int J Cancer* 1984, **33**, 271–276.
11. Uchida A, Micksche M. Lysis of fresh tumor cells by autologous peripheral blood and pleural effusion lymphocytes activated by OK-432. *J Natl Cancer Inst* 1983, **71**, 673–680.
12. Christmas SE, Meager A, Moore M. Studies of the enhancement of natural cytotoxicity by the streptococcal immunopotentiator OK-432. *Int J Immunopharmacol* 1986, **8**, 83–89.



Pergamon

European Journal of Cancer Vol. 30A, No. 12, pp. 1744–1751, 1994
Copyright © 1994 Elsevier Science Ltd
Printed in Great Britain. All rights reserved
0959-8049/94 \$7.00+0.00

0959-8049(94)00330-0

One-year follow-up of the 'Starting Again' Group Rehabilitation Programme for Cancer Patients

G. Berglund, C. Bolund, U.-L. Gustafsson and P.-O. Sjöden

In a randomised prospective study, a brief structured rehabilitation programme, 'Starting Again', was evaluated over a follow-up year. 98 patients were assigned to the programme, and 101 to the control condition. The 11, 2-h sessions emphasised physical training, information and coping skills. Patients in the programme improved significantly more than the controls with respect to appraisal of having received sufficient information, physical training, physical strength and fighting spirit. Results indicate improvement with respect to the three areas focused on in the 'Starting Again' programme: physical training, information and coping skills training.

Key words: rehabilitation, group, randomisation, coping, patient information, physical training, long-term follow-up

Eur J Cancer, Vol. 30A, No. 12, pp. 1744–1751, 1994

INTRODUCTION

SEVERAL REVIEWS of psychosocial intervention studies with cancer patients have been published during the last decade [1–4]. Watson [3] carefully and methodically reviewed work published before 1983. Telch and Telch [2] critically examined efforts to promote coping with cancer, and Mathieson

and Stam [1] scrutinised the relevance of psychosocial interventions for cancer patients. In the most recent review, Andersen [4] made a distinction between psychological interventions for low, moderate and high risk morbidity patients. This distinction is potentially important for the evaluation of interventions, since the rate of spontaneous recovery may vary

with risk for psychosocial morbidity [4]. Several studies [5–7] have reported a positive relationship between extent of disease and/or medical treatment and higher risk for psychological morbidity.

The most salient points of criticism of existing studies, raised in the reviews, are that: there is confusion about the theoretical framework; the types of psychosocial support are insufficiently described; there is a failure to report statistical analysis in enough detail; therapy and assessment are very often carried out by the same person; evaluation methods vary, thereby complicating the comparison of results between studies, and long-term effectiveness is rarely reported.

Very few randomised studies of psychosocial group interventions for cancer patients include follow-ups. However, these are discussed below, with regard to the distinction proposed by Andersen [4] between interventions for low, moderate and high risk groups.

Only one study of patients having a low risk for psychosocial morbidity has been reported [8], which was a randomised study of a brief intervention, focusing on health education, problem-solving skills, stress management and social support for malignant melanoma patients. Assessments were made immediately after the intervention and at 6 months [8]. When patients had been informed of group assignment, 25% of the control group withdrew and the base-line values of several outcome measures differed significantly. After intervention, the intervention group used more active-behavioural coping as compared with the controls. With respect to affective states, the controls reported more lack of vigour than the intervention group. At the 6-month follow-up, differences in coping were maintained, were more pronounced and extended to active-cognitive coping. In addition, depression decreased further in the intervention group.

There are two studies of interventions for moderate risk patients. Cain and co-workers [9] obtained an 83% response rate at the 6-month follow-up. Thematic counselling (individually or in a group) was found to be superior to no counselling in this randomised study. However, the study comprised a small number of patients, and the most powerful statistical methods were not employed. The intervention programme focused on information about cancer and strategies for health promotion, such as progressive relaxation, diet and exercise. Telch and Telch [10] performed a randomised study comparing group coping skills instruction with supportive group therapy. The former was superior to the latter at postintervention with respect to psychological adjustment. The design included a 3-month follow-up, data from which were not reported, since 40% of the patients were unavailable.

Three studies have been performed with high risk patients. Ferlic and colleagues [11] is referred to by Telch and co-workers [2] as a randomised study, while the authors say that patients were "assigned to the treatment group . . . balanced for age, sex and education" (p. 762). A follow-up questionnaire was mailed at 6 months, but the return rate was insufficient and the data were not reported. Spiegel and co-workers evaluated the outcome of a supportive group activity in a randomised, prospective study for women with metastatic

carcinoma [12, 13]. This study is referred to by Watson [3] as a matched design, although the original publication indicates randomisation. The support groups ran for 1 year, and assessments were made every fourth month during that year. The Spiegel studies concern a long-term intervention but no follow-up.

Thus until now, no long-term (1 year) randomised evaluation of a relatively time-limited group intervention for cancer patients exists. A reasonable hypothesis is that thematic counselling is more effective than no counselling [9], and that coping skills training is more effective than support group therapy [10]. In addition, altering coping strategies in a positive and active direction might improve affective states, even long-term [8].

The 'Starting Again' (SA) group is an 11-session programme run for 7 weeks with an emphasis on information, physical training and coping skills training. The programme has been described in detail elsewhere [14, 15]. The present study employs a randomised, prospective design. There were five data collection points: before and after the intervention and at 3-, 6- and 12-months follow-up. Short-term results from pre-, post-intervention and 3-month assessments have been presented elsewhere [15]. They indicate a level of physical training and strength significantly higher than before the intervention in the SA group participants compared with controls; SA patients' appraisal of having received sufficient information increased significantly; frequency of sleeping problems diminished in the SA group and changes of the psychological 'Fighting Spirit' response to cancer favoured the SA group [15].

Previous research supports the conclusion that after a structured programme, cancer patients show at least short-term improvements with respect to many variables [9–11, 14–19]. The main aim of the present study was to investigate the development of short-term programme gains over a follow-up period of 1 year.

MATERIALS AND METHODS

Design

A prospective, randomised control group design was utilised. Patients were informed about the 'Starting Again' (SA) programme, and about the randomisation process by the nurse responsible for the groups. They were then asked to fill out the base-line questionnaires. Patients who accepted were randomised to the SA programme or to a control condition. Efron's method for randomisation of small samples was used [20]. At the randomisation of each individual patient, group sizes were forced towards equality by proportionately increasing the probability of assignment to the smaller group. Postmeasure questionnaires and those at the 3-, 6- and 12-month follow-ups were mailed to patients, who were to return them by mail. If necessary, they were reminded three times.

The control group was divided into two subgroups: one third received a single information session ($n = 36$), consisting of the oncologist and dietitian information packages included in the SA programme, and two thirds received no intervention ($n = 65$).

Patients

Inclusion criteria were age below 75 years, curative treatment for a primary tumour and inclusion within 2 months after post-operative treatment with radio- or chemotherapy.

98 patients were randomised to the SA programme and 101 to the control condition. Table 1 illustrates response rates and reasons for non-response for all assessments. 73 other patients declined participation, but agreed to complete the question-

Correspondence to G. Berglund.

G. Berglund, C. Bolund and U.-L. Gustafsson are at the Psychosocial Unit, Radiumhemmet, Karolinska Hospital, S-104 01 Stockholm; and P.-O. Sjöden is at the Centre for Caring Sciences, Uppsala University, Glunten, S-751 83 Uppsala, Sweden.

Revised 27 June 1994; accepted 26 July 1994.

Table 1. Response rates, non-responders (cumulative) and reasons for not responding (recurrence/death and other) in the SA and control groups at all assessments

	Base-line		Postmeasure				3 months				6 months				12 months			
	n	%	n	%	R/D*	Other	n	%	R/D	Other	n	%	R/D	Other	n	%	R/D	Other
SA	98	(100)	90	(92)	0/0	8	90	(92)	1/0	7	88	(90)	2/1	7	87	(89)	4/2	5
Control	101	(100)	98	(97)	2/0	1	93	(92)	2/0	6	91	(90)	5/0	5	89	(88)	5/2	5

*R/D, recurrence/death.

naires. The most frequent reasons for non-participation were no perceived need for an intervention, no interest in the group model, competing activities, long distances to the hospital and dislike of the randomisation procedure. 20 patients declined both participation and monitoring. The non-participants had lower problem levels than the participants [21].

There were no differences with respect to background variables between the SA and the control groups [17]. 80% in both groups were breast cancer patients, 7–8% had ovarian cancers and the rest represented a variety of cancer diagnoses. The typical patient was a woman, 52–53 years of age with a primary breast tumour. She had terminated post-operative radiation, was married or lived with a man and had two children who had left home. Her profession was secretarial or office work.

The 'Starting Again' programme

The programme has been described fully elsewhere [14, 15]. It emphasised physical training, information and coping skills training. Eleven sessions were held in 7 weeks. The mean absenteeism among participants was one session. This represents a variation of the number of participants per session between 3 and 7 (mean 4.9). During the first 4 weeks, patients met twice a week, once for information and once for physical training. The last 3 weeks were devoted to one session of coping skills training each week. An oncology nurse, specialised in psychosocial issues conducted the groups during all sessions. She was mostly accompanied by a specialist of the theme dealt with at each session.

Physical training. The sessions included exercises to increase mobility, muscle strength, general fitness and relaxation in the form of progressive muscle relaxation or deep relaxation with positive images. Patients were given instructions for progressive relaxation at home.

Information. Four themes were considered: the effects on the disease of curative and adjuvant treatments, appropriate diet and the relation between diet and health, crises and development through crises [22] and alternative treatments.

Coping skills. Role plays were employed for returning to work situations, such as how to handle peculiar attitudes towards cancer, meeting people asking too much or too little, and problem situations at the hospital when returning for control visits. One session was devoted to anxiety, and how to handle it with different coping strategies (relaxation, distraction, cognitive techniques).

Outcome measures

A full description of the outcome measures has been previously published [14, 15]. Besides demographic variables, the follow-

ing outcome variables were included: work status, sick leave, patients' appraisal of having received sufficient information, physical strength and activity (21 items in six subscales: physical strength, physical training, tiredness, body image, pain and global health), a shortened HAD-scale (Ref. 23.; 5 anxiety and 6 depressive items, Cronbach alpha for pre- and postanxiety scores were 0.79 and 0.81 and for depression scores 0.76 and 0.81), quality of life, activities at home and in the community (Sjödén, 1983, unpublished), physical symptoms from breast cancer (frequency and burden), communication with staff items selected from Heinrich and colleagues [24] and the Mental adjustment to cancer (MAC)-scale [25].

Factor analysis of base-line data from the symptom list permitted a reduction of the 20 items (frequency) to six subscales [14, 15]. Oblique varimax rotation was applied and factor loadings > 0.45 and interitem correlations of > 0.35 were required. Subscales were (1) worry (three items: anxiousness, worry for health, sleeping problems); (2) aversions (four items: nausea, food aversions, smell aversions, vomiting); (3) mixed symptoms A (five items: fatigue, decreased stamina, joint problems, pain, infections); (4) mixed symptoms B (two items: weight problems, hair loss); (5) surgery effects (two items: problems with operation scar, problems with appearance changes); and (6) cognitive effects (two items: memory problems, concentration problems). Because of the different contents, two items were not included in the subscales, though factor loadings were above 0.45. Those were sexual problems and mucous membrane disturbances.

Statistical methods

Chi-squared tests were applied to category variables and *t*-tests to all continuous background variables. Repeated measures analyses of variance (ANOVA) were applied to all dependent continuous variables when there was no significant between-group (*t*-test) difference at base-line. In the case of significant base-line differences, gain scores were employed. Tukey's [26] HSD-test was employed for *post hoc* between-group differences. For within-group differences, including comparison of more than two means, Scheffé's test was applied as recommended [26]. ANOVA scores are based on those patients who provided data for all points of assessment (SA = 84, C = 85).

RESULTS

Work

There were no significant between-group differences at any time assessed. However, there was a strong effect of time. At the base-line, a mean of 67% (SA = 72%, *n* = 71, C = 63%, *n* = 64) did not work. At the postmeasure, 8–12 weeks later, 29% in both groups were still not working (SA: *n* = 26, C: *n* = 28). For SA and control groups, respectively, the percent-

ages not working were 21 ($n = 19$) and 25 ($n = 23$); 19 ($n = 16$) and 27 ($n = 25$); and 22 ($n = 18$) and 29 ($n = 25$) at 3, 6 and 12 months, respectively. Of those, 9% ($n = 8$) and 12% ($n = 10$) in the SA and control groups were above 65 years of age, which means that 13–17% ($n = 11$ –14) remained unemployed.

Sick leave

There were no significant group differences. At base-line, 70% of the SA participants ($n = 69$) and 56% ($n = 57$) of the controls had some degree of sick leave. Some patients combined half-time sick leave with half-time work. At postmeasure, this number had decreased to 20% in both groups ($n = 18$ and

$n = 20$). Over the year, there was a steady decrease, but at the 1-year follow-up, 11% ($n = 9$ and $n = 9$) were still on sick leave.

Patients' appraisal of having received sufficient information (six items)

There was a significant group by time interaction [$F(4, 167) = 27.08, P = 0.0001$] due to the fact that SA patients considered themselves more satisfied than controls at each point of assessment from postmeasure throughout the follow-up year (Tukey HSD-test, Table 2). Thus, patients in the SA group maintained a significant improvement with respect to satisfaction with information. Testing of within-group differences (base-line ver-

Table 2. Mean values for the SA ($n=77$ –84) and control ($n=78$ –85) groups for dependent variables

Scales	Mean values					ANOVA effects		
	Base-line	Postmeasure	3 months	6 months	12 months	Group \times Time	Time	Group
Information problems								
SA	13.49	8.34	7.90	8.78	8.36	0.0001	0.0001	0.0001
Control	13.05	12.57	13.08	13.05	13.32			
Physical strength problems								
SA	10.93*	8.89	7.88	7.09	7.09			
Control	8.75	8.96	8.26	8.14	8.37			
Gain scores								
SA		-2.04	-3.05	-3.84	-3.84	N.S.	0.005	0.0005
Control		0.21	-0.49	-0.61	-0.38			
Physical training problems								
SA	8.55*	7.74	7.71	7.57	7.55			
Control	7.82	8.11	7.82	7.61	7.71			
Gain scores								
SA		-0.81	-0.84	-0.98	-1.00	N.S.	0.05	0.005
Control		0.29	-0.00	-0.21	-0.11			
Tiredness								
SA	5.35	4.34	3.75	3.51	3.64	N.S.	N.S.	0.005
Control	5.14	4.40	4.06	3.41	3.61			
Body image problems								
SA	5.35	5.23	5.06	4.68	4.76	N.S.	0.001	N.S.
Control	4.90	4.68	4.57	3.90	4.19			
Pain								
SA	1.00	1.08	1.95	1.78	0.92	0.0001	0.0001	0.0001
Control	0.72	0.77	2.99	2.63	0.66			
Global health problems								
SA	2.25	1.96	1.58	1.52	1.78	N.S.	0.0001	N.S.
Control	2.00	1.98	1.69	1.69	1.74			
HAD-Anxiety								
SA	7.12	6.94	4.91	6.22	6.48	N.S.	0.0001	N.S.
Control	7.31	7.17	5.48	6.95	7.11			
HAD-Depressive								
SA	6.69	6.68	6.36	6.33	5.79	N.S.	0.005	N.S.
Control	6.44	7.25	6.87	7.07	6.32			
Problems with quality of life								
SA	2.48	2.50	2.26	2.10	2.29	N.S.	N.S.	N.S.
Control	2.49	2.43	2.28	2.22	2.36			
Activities at home—problems								
SA	11.06	12.14	11.98	11.57	11.04	N.S.	N.S.	N.S.
Control	11.60	11.94	12.37	11.36	11.80			
Activities in the community—problems								
SA	19.07	18.39	18.65	18.79	18.81	N.S.	N.S.	N.S.
Control	19.30	19.28	19.08	18.40	18.83			
Communication with staff								
SA ($n = 43$)	9.16	9.72	9.49	9.51	9.37	N.S.	N.S.	N.S.
Control ($n = 52$)	11.25	11.56	11.25	10.75	10.92			

*Significant group difference ($P < 0.05$), t -test (unpaired, two-tailed); N.S., not significant.

sus each of the postmeasures) confirmed that the SA participants improved significantly from base-line to postmeasure and maintained this improvement over the year, while the control group did not change.

The SA programme was more effective than one information session (mean values for the one-session group: 13.18, 12.11, 12.68, 13.46 and 13.21). There was a significant group by time interaction in the three-group ANOVA [$F(4, 162) = 13.86$, $P = 0.0001$], and Tukey HSD testing showed the SA condition to be superior at every data collection point after intervention. There were no significant changes within the one session group. This group was considered separately only in the above analysis. In all others, all 101 control participants were analysed together.

Physical strength (six items)

The SA and control groups differed significantly with respect to physical strength at base-line [$t(197) = 2.82$, $P < 0.01$], the SA reported more problems. ANOVA based on gain scores showed a main effect of groups [$F(1,164) = 14.74$, $P < 0.0005$] (Table 2) and *post hoc* testing demonstrated significant differences at all points of assessment. Thus, in comparison with the base-line, the SA improved significantly more than the controls. Scheffé's test confirmed a significant improvement in the SA group but not amongst the controls.

Physical training (three items)

Problems with physical training differed significantly between groups at the base-line [$t(195) = 2.66$, $P < 0.01$], the SA group with more problems than the control group. ANOVA of gain scores indicated a significant group difference favouring the SA condition [$F(1,162) = 10.23$, $P < 0.005$] (Table 2). Tukey's HSD test demonstrated that differences between groups were significant at postintervention, at 3 months and at 12 months, but not at the 6-month follow-up. In the SA group, there was a significant difference between base-line and all the remaining assessments, while the control group did not change.

Tiredness (three items)

Tiredness diminished significantly with time [$F(4,167) = 21.15$, $P = 0.0001$], and development was similar in both groups (Table 2).

Body image problems (four items)

In an earlier publication [15], the body image scale was divided into one scale of two items, called body avoidance, and two single items (problems with getting used to body and body acceptance). Using that analysis, body avoidance changed positively in the SA and negatively in the control group from pre- to postmeasure. The data from the follow-up year showed a similar pattern, irrespective of whether the scale was divided or not. Therefore, we chose to present a single scale including all four items. Problems with body image decreased significantly with time [$F(4,156) = 4.67$, $P = 0.001$]. There were no group differences (Table 2).

Pain (three items)

There was a significant group by time interaction [$F(4,170) = 16.52$, $P = 0.0001$] (Table 2). At base-line and postmeasure, there was no significant difference but at the 3 and 6 month follow-ups, the control group suffered significantly more from pain than the SA as confirmed by the Tukey HSD test (Table 2).

Health problems (global assessment) (one item)

Health problems diminished significantly with time [$F(4,169) = 11.46$, $P = 0.0001$] (Table 2) in both groups.

The modified HAD-scale

Anxiety (five items). HAD-anxiety symptoms diminished significantly with time [$F(4,165) = 30.95$, $P < 0.0001$] and, with respect to absolute values, more in the SA than in the control group, although there were no significant between-group differences at any point of assessment (Table 2).

Depressive (six items). Depressive symptoms diminished significantly with time [$F(4,165) = 4.45$, $P = 0.005$]. The SA group improved in absolute values while the control group worsened. At the 12-month follow-up, problems had decreased in both groups. There were no significant between-group differences (Table 2).

Problems with quality of life (two items)

Problems with quality of life were very similar and stable in both groups over time (Table 2).

Problems (=low frequency) with activities at home (nine items)

Activities at home were very frequent during the whole year. Most of them were performed four to six times a week independently of time or group assignment (Table 2).

Problems (=low frequency) with activities in the community (11 items)

Activities in the community did not change over time nor differ between groups.

Communication with staff (11 items)

This variable was not influenced either by time or by the intervention (Table 2). Overall, there were very few problems in patient-staff communication. However, problems in patient-doctor communication were significantly more pronounced than in patient-nurse communication. Throughout, communicating with doctors was significantly more difficult for the control group than for the SA group [$F(4,101) = 4.93$, $P < 0.05$] and decreased significantly with time in both groups [$F(4,101) = 3.44$, $P < 0.01$].

Physical symptoms (frequency and burden)

In general, the physical symptoms related to breast cancer diminished with time, and many of them significantly so. Worry, aversions, mixed symptoms A and B and surgery effects, sexual problems and mucous membrane disturbances diminished significantly with time, while cognitive effects did not (Table 3).

The MAC-scale

The three MAC-scale variables which diminished significantly with time were *anxious preoccupation* [$F(3,125) = 8.23$, $P = 0.0001$] (ANOVA of gain scores due to significant base-line group difference [$t(145) = 2.25$, $P < 0.05$] (Table 4), in absolute values, the SA group showed more anxious preoccupation than the control group); *fatalistic* [$F(4,127) = 8.55$, $P = 0.0001$] and *hopeless* [$F(4,127) = 3.21$, $P < 0.05$]. *Fighting spirit* was significantly higher in the control group at base-line [$t(145) = 3.65$, $P < 0.0005$]. After intervention, it decreased significantly more in the control group than in the SA group. There was a significant group difference in gain scores [$F(1,130) = 13.39$, $P < 0.0005$] which was confirmed at every data

Table 3. Mean values for the SA (n = 80–84) and control (n = 82–85) groups for physical symptoms grouped in six subscales and two single symptoms

Scale	Mean values					ANOVA effects		
	Base-line	Postmeasure	3 months	6 months	12 months	Group × Time	Time	Groups
Worry (three items)								
SA	3.82	3.29	2.85	1.99	3.13			
Control	3.23	3.20	3.00	1.79	3.02	N.S.	0.0001	N.S.
Aversions (four items)								
SA	1.86	0.51	0.88	0.70	0.79			
Control	1.76	0.90	0.70	0.52	0.74	N.S.	0.0001	N.S.
Mixed symptoms A (five items)								
SA	5.90	5.53	4.64	4.44	4.74			
Control	5.51	5.46	5.24	4.95	4.76	N.S.	0.0001	N.S.
Mixed symptoms B (two items)								
SA	1.20	1.08	0.93	0.91	1.17			
Control	1.14	0.76	0.74	0.79	0.81	N.S.	0.05	N.S.
Surgery effects (two items)								
SA	1.39	1.27	1.15	0.78	0.80			
Control	0.98	0.70	0.54	0.48	0.43	N.S.	0.0001	0.005
Cognitive functioning (two items)								
SA	1.34	1.11	1.15	0.89	1.06			
Control	1.01	1.01	1.22	1.02	1.16	N.S.	N.S.	N.S.
Sexual problems frequency (one item)								
SA	0.70	0.60	0.50	0.49	0.60			
Control	0.61	0.52	0.40	0.39	0.47	N.S.	0.05	N.S.
Mucous membrane disturbances frequency (one item)								
SA	1.09	0.78	0.61	0.64	0.62			
Control	0.89	0.68	0.60	0.50	0.59	N.S.	0.0001	N.S.

N.S., not significant.

Table 4. Mental adjustment to cancer: anxious preoccupation, fighting spirit, fatalistic, helpless and avoidance mean values for the SA group (n = 62–65) and control group (n = 64–67)

Variables	Mean values					ANOVA effects		
	Base-line	Postmeasure	3 months	6 months	12 months	Group × Time	Time	Groups
Anxious preoccupation								
SA	20.75*	18.86	17.79	17.44	17.24			
Control	19.03	17.80	16.91	16.50	16.78			
Gain scores								
SA		-1.89	-2.95	-3.30	-3.51			
Control		-1.23	-2.13	-2.53	-2.25	N.S.	0.0001	N.S.
Fatalistic								
SA	15.41	14.14	13.58	14.19	13.64			
Control	15.48	14.52	14.59	14.52	14.65	N.S.	0.0001	N.S.
Fighting spirit								
SA	45.03*	47.15	45.75	44.09	44.02			
Control	49.91	43.64	43.70	44.03	42.57	N.S.	0.0001	N.S.
Gain scores								
SA		2.12	0.72	-0.94	-1.16			
Control		-6.27	-6.21	-5.88	-7.34	N.S.	N.S.	0.0005
Hopeless								
SA	8.67	7.84	8.02	7.48	7.69			
Control	7.71	7.62	7.39	7.48	7.40	N.S.	0.05	N.S.
Avoidance								
SA	1.40	1.19	1.19	1.26	1.21			
Control	1.43	1.57	1.49	1.51	1.43	N.S.	N.S.	0.05

*Significant group difference ($P < 0.05$), t -test (unpaired, two-tailed); N.S., not significant.

collection point as compared with base-line. The within-group decline was significant for the control group. *Avoidance* did not change over time nor was there any group difference (Table 4).

DISCUSSION

Patients' appraisal of having received sufficient information and of physical strength, physical training and fighting spirit were improved in the SA group compared with the controls during the entire follow-up year. The design permits the conclusion that this is an effect of the 'Starting Again' programme [27].

This is in contrast to the short-term observations, where three scales, that is body avoidance, depression, and avoidance (MAC-scale, one item), differed significantly at postintervention or at 3 months, but were not maintained.

Maintenance of therapeutic gains is a long-standing problem in all forms of psychological interventions. Due to the lack of studies, maintenance problems have not yet been emphasised in studies of cancer patients. However, there is no reason to suppose that interventions for cancer patients differ from other psychological interventions in this respect. Wilson [28], in an up-to-date overview, described research on relapse and its prevention following behavioural and cognitive interventions for a variety of problems. These treatment methods are successful in the short-term in many problem areas, but the factors underlying successful maintenance are still largely unknown. Wilson [28] concluded that research on maintenance still suffers from methodological problems especially low statistical power and conceptual difficulties. The most common forms of relapse prevention are: (1) booster sessions; (2) treatment programmes with relapse prevention strategies integrated into the initial treatment; and (3) procedures that require minimal therapist contact. Each of these have a certain amount of empirical support and should therefore be included in future studies of psychological interventions with cancer patients [29].

In a recent review, Andersen [4] stated that the spontaneous recovery with respect to psychosocial morbidity is so high in low risk patients that it is difficult for an intervention to achieve superior results. This is not the case in moderate and high risk groups. The present study included low risk patients (defined by the high response rate at the 1-year follow-up) and, according to Andersen [4], large improvements as compared to controls should not have been anticipated. However, a few dependent variables did improve as a result of the intervention. Of 27 dependent variables, 19 improved significantly with time, and of those, four had significantly better improvement in the SA group than in the controls. The control group did not have better improvement than the SA group with respect to any dependent measure.

One weakness of the present study is the use of the modified HAD instead of the whole scale. At the time when our decision was made to modify the scale, no studies of the HAD-scale were published. We were advised to omit three items said to have the lowest correlations with the scale as a whole. In fact, these items are the ones with the highest factor loadings [30]. There is no reason to assume that the results would have been very different if the entire scale had been used. Alpha coefficients for the Swedish version of the HAD exceed 0.80 when each of the items is excluded individually (Brandberg, personal communication). In addition, alpha values for the present HAD scales were approximately 0.80, which is acceptable. Over the follow-up year, the modified HAD scale failed to show any group differences or significant group by time interactions. However, at

postmeasure [15], there was a significant difference between groups. The SA patients did not increase their level of depressive symptoms as the control group did.

It cannot be excluded that the modification of the HAD-scale resulted in a less sensitive measure. However, there may be other reasons for the lack of anxiety changes. One is that patients' satisfaction with information does not strongly influence the level of anxiety. Another possibility is that a reduction of anxiety requires more specific and extensive interventions [18] than those used in the present study.

In conclusion, the 'Starting Again' programme seems to be successful with respect to patients' appraisal of having received sufficient information, fighting spirit, physical strength and physical training as late as 1 year after treatment termination. This is encouraging since the effects of time-limited interventions tend to diminish with time. To increase the effect of physical exercise, we could have had more of them (overlearning) and also a maintenance programme. The effects of the information programme with respect to patients' appraisal of having received sufficient information is promising, but this feeling of being better informed did not lead to a decrease of anxiety or depressive symptoms. With a more extensive programme, containing more coping skills training and home assignments, that goal may be attainable.

- Mathieson CM, Stam HJ. What good is psychotherapy when I am ill? Psychosocial problems and interventions with cancer patients. In Cooper CC, Watson M, eds. *Cancer and Stress: Psychological, Biological and Coping Studies*. Chichester, Wiley, 1991, 171-196.
- Telch C, Telch M. Psychological approaches for enhancing coping among cancer patients: a review. *Clin Psychol Rev* 1985, 5, 325-344.
- Watson M. Psychosocial intervention with cancer patients: a review. *Psychol Med* 1983, 13, 839-846.
- Andersen BL. Psychological interventions for cancer patients to enhance the quality of life. *J Consult Clin Psychol* 1992, 60, 552-568.
- de Haes JCJM, Van Oostrom MA, Welvaart K. The effect of radical and conserving surgery on quality of life of early breast cancer patients. *Eur J Surg Oncol* 1986, 12, 337-342.
- Cassileth BR, Lusk EJ, Tenaglia AN. Patients' perceptions of the cosmetic impact of melanoma resection. *Plast Reconstr Surg* 1983, 71, 73-75.
- Andersen BL, Anderson B, de Prose C. Controlled prospective longitudinal study of women with cancer: I. Sexual functioning outcomes. *J Consult Clin Psychol* 1989, 57, 683-693.
- Fawzy FI, Fawzy NW, Kemeny ME, Elashoff R, Morton D. A structured psychiatric intervention for cancer patients. *Arch Gen Psychiat* 1990, 47, 720-725.
- Cain EN, Kohorn EI, Quinlan DM, Latimer K, Schwartz PE. Psychosocial benefits of a cancer support group. *Cancer* 1986, 57, 183-189.
- Telch C, Telch M. Group coping skills instruction and supportive group therapy for cancer patients: a comparison of strategies. *J Consult Clin Psychol* 1986, 54, 802-808.
- Ferlic M, Goldman A, Kennedy BJ. Group counseling in adult patients with advanced cancer. *Cancer* 1979, 43, 760-766.
- Spiegel D, Bloom JR. Group therapy and hypnosis reduce metastatic breast carcinoma. *Psychosom Med* 1983, 45, 333-339.
- Spiegel D, Bloom JR, Yalom I. Group support for patients with metastatic cancer. *Arch Gen Psychiat* 1981, 38, 527-533.
- Berglund G, Gustafsson U-L, Bolund C, Sjöden P-O. Starting again—a comparison study of a group rehabilitation program for cancer patients. *Acta Oncol* 1993, 32, 15-21.
- Berglund G, Gustafsson U-L, Bolund C, Sjöden P-O. A randomized study of a rehabilitation program for cancer patients: the 'starting again' group. *Psycho Oncol* 1994, 3, 109-120.
- Blake SM. Group psychotherapy with breast cancer patients: a controlled trial. Unpublished MSc thesis: Department of Psychiatry, University of Manchester, 1983.
- Bloom JR, Ross RD, Burnell G. The effect of social support on

- patient adjustment after breast surgery. *Patient Counselling and Health Education* 1978, Autumn, 50–59.
18. Heinrich RL, Schag CC. Stress and activity management: group treatment for cancer patients and spouses. *J Consult Clin Psychol* 1985, 53, 439–446.
 19. Johnson J. The effects of a patient education course on persons with a chronic illness. *Cancer Nurs* 1985, 5, 117–123.
 20. Hjelm-Karlsson K. Using biased coin designs for randomization in health care research. *Western J Nurs Res* 1991, 13, 284–287.
 21. Berglund G, Gustafsson U-L, Bolund C, Sjöden P-O. Is the wish to participate in a cancer rehabilitation program an indicator of the need? Comparisons of participants and non-participants in a randomized study. *Psycho Oncol* (accepted for publication).
 22. Cullberg J. *Kris och utveckling*. Stockholm, Natur och Kultur, 1975.
 23. Zigmond A, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983, 67, 361–370.
 24. Heinrich RL, Schag CC, Ganz PA. Living with cancer: the cancer inventory of problem situations. *J Clin Psychol* 1984, 40, 972–980.
 25. Greer S, Watson M. Mental adjustment to cancer: its measurement and prognostic importance. *Cancer Surv* 1987, 6, 439–453.
 26. Kirk RE. *Experimental Design: Procedures for the Behavioural Sciences*. Belmont, Brooks/Cole Publishing Company, 1986.
 27. Kazdin AE. *Research Design in Clinical Psychology*. New York, Harper & Row, 1980.
 28. Wilson PH. Relapse prevention: conceptual and methodological issues. In Wilson P, ed. *Principles and Practice of Relapse Prevention*. New York, Guilford, 1992.
 29. Marlatt GA, Gordon JR. *Relapse Prevention: Maintenance Strategies in the Treatment of Addictive Behaviours*. New York, Guilford, 1985.
 30. Moorey S, Greer S, Watson M, et al. The factor structure and factor stability of the Hospital Anxiety and Depression Scale in patients with cancer. *Br J Psychiatry* 1991, 158, 255–259.

Acknowledgement—This study was supported by a grant from the Swedish Cancer Foundation.



Pergamon

European Journal of Cancer Vol. 30A, No. 12, pp. 1751–1756, 1994
Copyright © 1994 Elsevier Science Ltd
Printed in Great Britain. All rights reserved
0959-8049/94 \$7.00 + 0.00

0959-8049(94)E0163-X

A Classification After Radical Cystectomy of Patients With Bladder Cancer Associated With Schistosomiasis

M. Rafla, A.S. Ibrahim, A.J. Valleron and J.Y. Mary

The aim of this study was to classify the bilharzial bladder cancer patients after radical cystectomy into several prognostic strata with increasing risk of recurrence. 310 patients through the period 1977–1983 at the National Cancer Institute of Cairo were systematically analysed for 12 variables evaluated after radical cystectomy. Eight factors were shown to have a significant influence on the recurrence-free survival curve after radical cystectomy namely: tumour stage, size, grade and location in the bladder, lymph node involvement, metastasis, renal insufficiency and urinary diversion. Using the proportional hazard model, five factors were significantly related to a lower recurrence-free survival, one major prognostic factor, tumour grade (G2 or G3) (relative risk estimate of 5.5), and four minor prognostic factors (relative risk estimates around 2), namely tumour diameter greater than 5 cm, anterior or trigonal location of the tumour, tumour stage (T3 or T4) and presence of renal insufficiency before surgery. Four prognostic strata have been defined in relation to the presence of these prognostic factors. This classification was validated on a second sample of 122 patients by comparing for each prognostic stratum, the recurrence-free survival curve observed on this sample and the corresponding predicted curve by Cox model. No statistically significant difference could be detected. This classification of bladder cancer patients appears to be adequate for bilharzial bladder cancer patients after radical cystectomy, at least in the conditions they presented and were treated for at the NIC in Cairo.

Keywords: bladder cancer, schistosomiasis, radical cystectomy, prognosis, recurrence, classification
Eur J Cancer, Vol. 30A, No. 12, pp. 1751–1756, 1994

INTRODUCTION

BLADDER CANCER occurs with high frequency in some parts of Africa and the Middle East. It is a major health problem in Egypt since it represents approximately 20% of the total cancer incidence. It is the most frequent cancer in males and the second most common neoplasm (after breast cancer) in females [1]. This

cancer is almost always associated with schistosomiasis. The most common treatment in Egypt is radical cystectomy with urinary diversion [2]. Recurrence after surgery occurs locally in the pelvis and 90.6% of the recurrences occur during the first postoperative year [3].

In a previous study [4], we determined five prognostic factors