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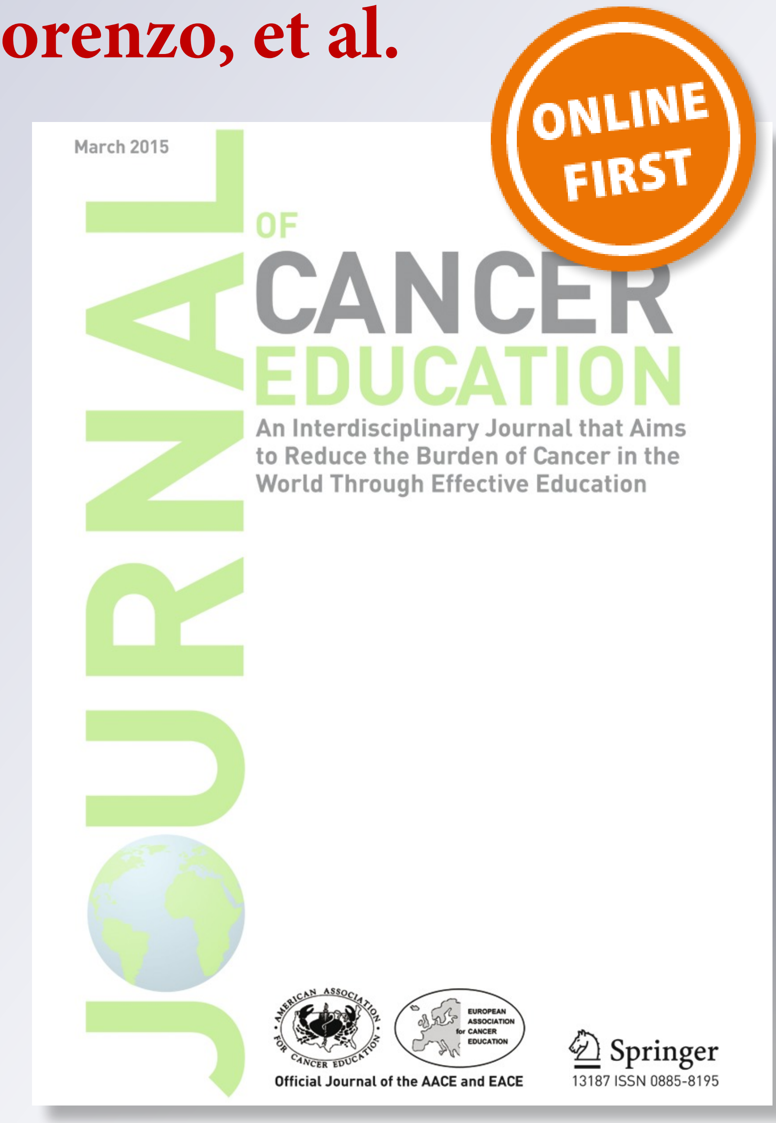

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Nutritional Online Information for Cancer Patients: a Randomized Trial of an Internet Communication Plus Social Media Intervention

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Abstract We hypothesized that cancer patients using an Internet website would show an improvement in the knowledge about healthy eating habits, and this might be enhanced by social media interaction. A 6-month randomized intervention was set up. Eligible subjects were allocated in intervention (IG) and control groups (CG). IG had access to the website, and CG was provided with printed versions. All enrolled participants filled in Nutrition Questionnaire (NQ), Quality of Life Questionnaire (QoL) and Psychological Distress Inventory (PDI), at baseline and after 6 months. The difference between post- vs pre-questionnaires was calculated. Seventy-four subjects (CG 39; IG 35) completed the study. There was an increase in the score after the intervention in both groups for the NQ, even if not statistically significant. Dividing the IG into three categories, no (NI), low (LI) and high interactions (HI), we found a decreased score (improvement) in the CG (−0.2) and in the HI (−1.7), and an increased score (worsening) in the NI (+3.3) (p=NS) analysing the PDI. We found an increased score in the QoL both in CG and IG (adjusted LSMeans +3.5 and +2.8 points, respectively; p=NS). This study represents an example for support cancer patients. Despite the lack of significant effects, critical points and problems encountered may be of interest to researchers and organization working in the cancer setting. Intervention strategies to support patients during the care process are needed in order to attain the full potential of patient-centred care on cancer outcomes.

Keywords Cancer · Internet support · Randomized intervention study · Nutrition · Social media · Quality of Life · Psychological Distress Inventory

Introduction

Numbers of cancer patients are increasing rapidly, due to advances in early detection and treatment [1]. They often experienced multiple and frequently severe late side effects, impaired functional status and complex emotional issues and need supportive and rehabilitative services [2], not routinely supplied by the health services to cope. Following cancer diagnosis, subjects frequently look for a second "virtual" opinion or for additional information on the Internet, and it may overwhelm vulnerable cancer patients with the sheer quantity of often conflicting information [3]. They may require more specific support to make decisions. Recently, Internet applications have shown great potential to provide cancer patients with tailored information and communication for their specific needs [4, 5]. The Internet is a promising medium for facilitating patients empowerment and for encouraging adoption of

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health-promoting behaviours [6, 7]; but a recent meta-analysis concluded that while existing studies on the outcomes of online cancer support show promise for achieving positive effects, there is a need for rigorous design methodology with larger study populations [2].

Cancer has a profound impact on subjects' physical functions, and weight loss is a common problem which can evolve into malnutrition [8]. It has been recognized as an important component of adverse outcomes that can lead to serious and potentially lethal complications [9]. Moreover, cancer and its treatments may impair the ability to eat. Symptoms including anorexia, early satiety, changes in taste and smell and disturbances of the gastrointestinal tract are common side effects of cancer treatments [9]. Conversely, cancer patients may experience weight gain during therapy [10] affecting quality of life and the ability to control psychological distress. Moreover, emerging evidence shows that web-based interventions that provide appropriate supportive care and information to patients may supply further relief of symptoms and improve the quality of their lives [11, 12].

A coordinating action of the European Commission aiming to establish one efficient communication for cancer patients and caretaker from clinical researchers, scientists and physicians was launched in 2008 [13]. In the context of this project, we developed a website dedicated to help cancer patients cope with nutritional problems arising during treatment and presenting tips on healthy eating habits. We hypothesized that subjects using the website would have learnt more about healthy eating habits and nutritional problems at the end of a 6-month intervention period compared to a control group who receive the same intervention in the form of a PDF, sent by mail. Furthermore, we hypothesized the use of the website might have a positive effect on symptom distress and quality of life compared with the control group.

Materials and Methods

Study Design

A 6-month randomized intervention study was set up with the aim to evaluate the efficacy of a website (www.supportonutrizionale.it accessed until 15 August 2013) tailored for cancer patients experiencing eating and nutritional problems. Details of the study can be found elsewhere [14]; briefly, it was conducted between June 2011 and January 2013 and it involved cancer patients seeking information about nutritional problems on Internet web sites of the study partners and social network pages: Organisation of European Cancer Institutes (OECI; www.oeci-eeig.org), the Italian Association for cancer patients, their families and friends (Associazione Italiana dei Malati di Cancro (AIMaC); www.aimac.it) and the Italian Federation of Volunteer-Based Cancer Organizations (Federazione italiana delle Associazioni di Volontariato di Oncologia (FAVO); www.favo.it). In addition, printed leaflets have been distributed at the European Institute of Oncology. Inclusion criteria were age >18 years, Italian residency, cancer diagnosis, Internet access and e-mail account over the study period. Because no particular cancer type was identified as study target, we chose to minimize the variability of the study group excluding critical subjects receiving "enteral nutrition", "parenteral nutrition" or palliative care, or reporting a significant weight loss in the last 6 months (≥10 % reduction of usual weight).

Eligible subjects were allocated to one of two study groups using a computer-generated scheme located at TENALEA website [15]: intervention (IG) and control (CG). The first group had the possibility to access the website, which included a series of contents and reports about cancer, nutritional problems and advice to better cope with them (Online Resource 1). Participants could also interact and ask questions to a group of experts established for the study. In addition, some interactive activities were planned for the IG (polls, chat room to talk to the expert). All information published on the website was divided in "baseline contents", "weekly contents" and "in-depth blog examinations". The baseline contents referred to general information about healthy eating habits, diet and lifestyle recommendations to prevent malignancy, cancer and its therapies and nutritional problems occurring during the disease. Weekly contents were about managing eating problems during cancer therapies. In-depth blog examinations referred to specific questions posted on the blog by participants or to insights regarding general nutritional topics.

The control group (CG) did not have the access to the website; they were provided with PDF versions of the contents by e-mail. At the conclusion of the intervention, participants who were assigned to the control group were invited to access to the study website, after the completion of the study questionnaires.

All volunteers gave written consent prior to their inclusion in the study, which was approved by the Independent Ethical Committee of EuroCancerComs.

Measures and Questionnaires

Baseline socio-demographics and clinical variables (site of cancer, year of diagnosis, clinical treatments) were collected from all enrolled subjects. Measures at baseline and at the closure of the intervention were performed using the following study tools.

Internet Website

The website was intended as an exclusive space for the study participants, and it contained a variety of sections and functions. It comprised social media features, such as a discussion forum and a blog, where participants could share opinion and discuss topics. We considered every activity, either a comment or a vote, as a social action and counted them to asses the level of interaction. The usability and accuracy of the content were evaluated by two dieticians and two web developers in order to determine the appropriateness of the website interface.

Nutrition Questionnaire Development and Its Validity

The Nutrition Questionnaire (NQ) is a 20-item self-administered questionnaire. On the basis of a review of scientific literature, it was decided to construct the questionnaire in three main sections on the awareness of lifestyle and healthy eating habits, knowledge on nutritional problems during cancer and on food consumption habits. Questions were generated from existing material and literature [16, 17] and completed with expert advice from three dieticians. Using an initial pool of 25 questions, a review was carried out by a panel of ten researchers and four dieticians to select the items in terms of clarity, accuracy and interpretability. For score construction, each question has four possible answers, assigning a value from 0 to 3. The global score (GS) varies from 0 (worst) to 60 (best). The preliminary instrument has been tested to perform its validity on 45 cancer patients and outpatients at the European Institute of Oncology. We decide to focus NQ validity on items included into "knowledge on nutritional problem during cancer" section, because these 13 questions were more related to the study intervention. We performed an analysis of the pairwise correlation between items, checking for questions enquiring the same topic in slightly different ways (redundancy check). We considered potentially redundant each item which was related to other items with a correlation coefficient >0.6 [18]. We found no redundancy, and no item was excluded. Moreover, we also evaluated a correlation with the corrected total score by subtracting the points of the item from the total. We consider good convergent validity correlation >0.3 [19]. We found a correlation <0.30 in four items, but we decided not to exclude them because it would have resulted in a negligible improvement. Internal reliability was assessed using the Cronbach's alpha. It was 0.70 for both the total score and the score for the "knowledge on nutritional problems during cancer" scale. The final questionnaire used for this study included 20 items and showed an overall adequate validity.

Quality of Life and Psychological Distress Inventory

Quality of life (QoL) was assessed using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire [20]. QoL scores range from 0 (worst) to 100 (best) for the functional and global health status (GHS) parameters and from 0 (best) to 100 (worst) for symptom parameters. A five-point difference in QoL scores is considered the minimum clinically significant difference [21].

Psychological Distress Inventory (PDI) is a 13-item self-administered questionnaire to measure anxiety and depression [22] in cancer patients. Respondents are asked to indicate which of the five options comes closest to describing how they have been feeling in the past week. GS vary from 13 (no distress) to 65 (high level of distress), and a score over 35 is indicative of clinically significant distress [23].

Statistical Analysis

Sample Size Calculation

Our primary objective was based on determining whether the change in "level of knowledge" differed between the IG and the CG. Assuming a standard deviation (SD) equal to 10 and a type I error rate of α=5 %, 105 subjects per group would have achieved 80 % power to detect a difference between the null hypothesis that both groups would have experienced no knowledge improvement between baseline and 6-month questionnaire and the alternative hypothesis that the mean knowledge improvement about nutritional issues of intervention group would have been equal to 4 (10 % improvement than the basal value). Although we assumed the distribution was normal, the sample size calculation was planned to test the primary outcome also by means of the non-parametric (Mann–Whitney–Wilcoxon) test. Assuming a 20 % dropout rate due to withdrawal, to get a sample of 210 evaluable subjects with both pre- and post-questionnaire, we should have randomized 252 subjects.

Statistical Methods

The descriptive statistics were used to characterize the sample with regard to socio-economic and clinical characteristics. Categorical data were expressed as numbers and percentages, while continuous data were presented as mean and standard deviation, median and range. Although this was a randomized trial, we adopted the usual statistical test, Pearson's chi-square for categorical variables and Wilcoxon's test for the continuousness, to compare baseline (subject, tumor and treatment) characteristics. The difference between post- vs pre-questionnaire was calculated within randomized group for each scale and then compared between groups; results were shown in terms of mean and standard deviations, median and interquartile range. A primary analysis was performed through the non-parametric Wilcoxon's test for the comparison of the randomized groups (change in score over time between IG and CG); a secondary analysis was carried out through the Kruskal–Wallis test for the comparison among more than

Table 1 Socio-demographics and clinical characteristics of two study groups (control and intervention groups) at baseline

Characteristics	Randomization group		
	Controls (*N*=61)	Intervention (*N*=64)	*p*[a]
Gender			
M	7 (11.5 %)	14 (21.9 %)	0.12
F	54 (88.5 %)	50 (78.1 %)	
Age (years),			
Mean (SD)	48.4 (9.2)	51.5 (11.4)	0.14[b]
Median (min-max)	47 (30-73)	50.5 (30-73)	
Level of education			
<High school	6 (9.8 %)	10 (15.6 %)	0.50
High School	27 (44.3 %)	30 (46.9 %)	
>High School	28 (45.9 %)	24 (37.5 %)	
Marital status			
Single	8 (13.1 %)	14 (21.9 %)	0.60
Living with partner	5 (8.2 %)	3 (4.7 %)	
Married	39 (63.9 %)	35 (54.7 %)	
Divorced	8 (13.1 %)	11 (17.2 %)	
Widow/widowed	1 (1.6 %)	1 (1.6 %)	
BMI[c] (categories)			
Underweight (<18.5)	4 (6.6 %)	6 (9.4 %)	0.84
Normal Weight (18.5–24.9)	37 (60.7 %)	36 (56.2 %)	
Overweight (25–29.9)	17 (27.9 %)	17 (26.6 %)	
Obese (≥30)	3 (4.9 %)	5 (7.8 %)	
BMI[c]			
Mean (SD)	23.9 (4.0)	24.2 (4.4)	0.69[b]
Median (min-max)	23.4 (17.6-41.0)	24.0 (16.8-40.8)	
Weight loss			
No	53 (86.9 %)	48 (75.0 %)	0.09
Yes	8 (13.1 %)	16 (25.0 %)	
Tumor site			
Breast	44 (72.1 %)	33 (51.6 %)	0.06
Gastrointestinal	10 (16.4 %)	10 (15.6 %)	
Gynaecologic	1 (1.6 %)	7 (10.9 %)	
Lung	2 (3.3 %)	4 (6.3 %)	
Others	4 (6.6 %)	10 (15.6 %)	
Years since diagnosis			
>4 years	6 (9.8 %)	6 (9.4 %)	0.49
2–4 years	10 (16.4 %)	16 (25.0 %)	
<2 years	45 (73.8 %)	42 (65.6 %)	
Clinical information			
Treated with chemotherapy	32 (52.5 %)	31 (48.4 %)	0.65
Treated with radiotherapy	11 (18.0 %)	6 (9.4 %)	0.16
Treated with hormonotherapy	11 (18.0 %)	16 (25.0 %)	0.34
Treated with other	6 (9.8 %)	4 (6.3 %)	0.46
Surgery	43 (70.5 %)	46 (71.9 %)	0.86
Geographical area			
North	36 (59.0 %)	34 (53.1 %)	0.77
Centre	9 (14.7 %)	12 (18.7 %)	
South+islands	16 (26.2 %)	18 (28.2 %)	

[a] Pearson's chi-square

[b] Wilcoxon's test

[c] BMI calculated as weight in kilograms divided by the square of height in metres

two groups. Any other comparison was performed by the *t* test, Wilcoxon's test or Kruskal–Wallis test depending on the violation of the normality assumption and the number of groups to be compared. Least square means (SE) were also presented, for the differences over time, which take into account baseline unbalances.

Results

During the study period, 447 subjects filled in the inclusion criteria form on the website. Due to the large number of non-eligible subjects and dropouts over the study period (56 and 13 %, respectively), and despite a 6-month prolongation of the time of enrolment, we were not able to reach the planned sample size. Reasons for ineligibility were mainly due to significant weight loss (28 %), receiving palliative care (23 %) and lack of e-mail address (16 %) (Online Resource 2). One hundred and thirty-eight subjects (31 %) were finally randomized in the two study groups as shown in the participation flowchart (Online Resource 3). One hundred and twenty-five subjects were included into the study, and randomization allocated 64 and 61 subjects to the IG and CG groups, respectively. Demographic and clinical characteristics of participants

Table 2 Comparison between 6-month and baseline data for participants who completed both pre- and post-Nutrition Questionnaire (*N*=74)

Characteristics	Controls (*N*=39)		Intervention (*N*=35)					
			No interaction		Low interactions		High interactions	
	N=39		*N*=11		*N*=10		*N*=14	
	Baseline	6-month	Baseline	6-month	Baseline	6-month	Baseline	6-month
Diet								
Global score (all items)[a]								
Mean (SD)	42.4 (8.2)	49.8 (6.3)	42.5 (11.2)	46.3 (8.5)	41.2 (8.8)	46.3 (6.0)	44.7 (8.9)	52.6 (5.2)
Median (Q1–Q3)	42 (36–50)	51 (47–53)	43 (35–49)	48 (46–50)	44 (37–48)	46 (42–51)	48.5 (37–50)	54.5 (51–56)
Change (6m–baseline)[b, c]								
Mean (SD)	7.4 (8.3)		3.7 (9.5)		5.1 (6.2)		7.9 (6.5)	
Median (Q1–Q3)	7 (1, 13)		2 (−1, 7)		4.5 (0, 7)		7 (3, 8)	
Lifestyle and healthy eating… (items 1–3)								
Mean (SD)	7.8 (1.3)	8.3 (0.9)	7.8 (1.1)	8.0 (0.8)	7.1 (1.4)	7.5 (1.2)	7.9 (1.1)	8.2 (0.8)
Median (Q1–Q3)	8 (8–9)	8 (8–9)	8 (7–9)	8 (8–8)	8 (6–8)	8 (7–8)	8 (8–9)	8 (8–9)
Change (6m–baseline)								
Mean (SD)	0.5 (1.3)		0.2 (1.0)		0.4 (1.8)		0.3 (1.4)	
Median (Q1–Q3)	0 (0, 1)		0 (0, 0)		0.5 (0, 2)		0 (0, 0)	
Nutrition and cancer knowl… (items 4–16)								
Mean (SD)	25.3 (7.5)	31.8 (4.8)	25.5 (9.7)	29.1 (8.3)	24.8 (8.2)	28.6 (4.8)	27.4 (9.0)	34.3 (5.1)
Median (Q1–Q3)	26 (20–32)	33 (30–34)	29 (17–32)	31 (27–33)	26 (21–31)	28.5 (25–32)	31 (18–34)	35.5 (32–39)
Change (6m–baseline)[d]								
Mean (SD)	6.5 (7.8)		3.5 (8.9)		3.8 (6.5)		6.9 (6.7)	
Median (Q1–Q3)	6 (0, 11)		2 (−2, 8)		3 (−2, 6)		5 (2, 9)	
Food habits (items 17–20)								
Mean (SD)	9.3 (1.7)	9.7 (1.9)	9.2 (1.8)	9.2 (2.0)	9.3 (2.1)	10.2 (1.6)	9.4 (1.3)	10.1 (1.3)
Median (Q1–Q3)	10 (8–10)	10 (9–11)	10 (9–10)	10 (8–10)	10 (9–11)	11 (9–11)	10 (8–10)	10 (9–11)
Change (6m–baseline)								
Mean (SD)	0.4 (1.9)		0.0 (1.6)		0.9 (1.4)		0.7 (1.4)	
Median (Q1–Q3)	0 (0, 2)		0 (−1, 1)		1 (0, 1)		0.5 (0, 1)	

Positive values of change represent improvement over time; negative values represent worsening. All tests were performed by the Kruskal–Wallis test

[a] *p* value for the baseline comparison (four groups)=0.65

[b] *p* value on change (four groups)=0.45

[c] *p* value on change (three IG subgroups)=0.33

[d] *p* value on change (four groups)=0.51

at baseline are detailed in Table 1. There were more females, 88.5 %, in the control group and 78.1 % in the intervention group, with a mean age of 48.4±9.2 years (CG) and 51.5±11.4 years (IG). They were married, with a high school level of education and on average had a normal weight. The most common tumor site was breast cancer (72.1 % for CG, 51.6 % for IG), and subjects were mainly newly diagnosed (<2 years from diagnosis) with cancer (73.8 % for CG, 65.6 % for IG), undergone surgery and were treated with chemotherapy. More than 50 % of patients came from the Northern Italy with no difference between groups (59.0 % for CG, 53.1 % for IG). Over the study period, numerous contents were published (see Online Resource 1) such as Baseline and Weekly contents and in-depth blog examinations available in the Blog section. The IG (64 subjects) actively participated to the discussion forum, blog and content interaction, posting 97 messages or comments and voting 196 discussions or articles, resulting in a total of 293 social actions.

After the six-month intervention, only 74 subjects completed the final assessment (Online Resource 3) filling in the three post-study questionnaires: 39 in the CG and 35 in the IG. A primary analysis, based on change in score over time for two groups, showed no statistically significant differences between IG and CG (data not shown). For the secondary analysis, we divided the IG into three subgroups depending on the website activities: no interaction (NI) (*n*=11; 31 %), subjects with less than five activities, low interaction (LI) (*n*=10; 29 %) and subjects with more than five activities, high interaction (HI) (*n*=14; 40 %).

Table 2 presents the results of the NQ. Considering all subjects (IG and CG), there was a statistically significant increase over time in the GS after the intervention (baseline vs 6-month; +6.6, $p<0.0001$, data not shown), with no significant difference between CG and all sub-groups of IG (CG +7.4; IG NI +3.7; IG LI +5.1; IG HI +7.9; $p=0.45$). As expected, the observed improvement over time was largely attributable to the “nutrition and cancer knowledge” section (baseline vs 6-month; +5.7, $p<0.0001$, data not shown), though no statistically significant difference was detected between groups (CG +6.5; IG NI +3.5; IG LI +3.8; IG HI +6.9; $p=0.51$). On the contrary, changes over time attributable to “lifestyle and healthy eating” and “food habits” sections were totally negligible (+0.4 and +0.5, respectively, data not shown) with no significant difference between groups.

Table 3 Comparison between 6-month and baseline data for participants who completed both pre- and post-Psychological Distress Inventory (PDI) and Quality of Life (QoL) Questionnaires (*N*=74)

Characteristics	Controls (*N*=39)		Intervention (*N*=35)					
			No interaction		Low interactions		High interactions	
	N=39		*N*=11		*N*=10		*N*=14	
	Baseline	6-month	Baseline	6-month	Baseline	6-month	Baseline	6-month
PDI[a]								
Global score								
Mean (SD)[b]	32.8 (8.9)	32.6 (8.2)	29.7 (7.4)	33.0 (8.1)	30.4 (8.2)	32.3 (10.7)	33.7 (6.1)	32.0 (7.7)
Median (Q1–Q3)	33 (26–38)	31 (26–40)	28 (26–35)	31 (26–35)	28 (24–40)	28 (25–40)	32.5 (30–39)	54.5 (27–37)
Change (6m–baseline)[c]								
Mean (SD)	−0.20 (5.5)		3.3 (6.8)		1.9 (10.7)		−1.7 (4.8)	
Median (Q1–Q3)	0 (−5, 4)		2 (−1, 6)		1 (−4, 7)		−1.5 (−5, 1)	
QoL (GHS)[d]								
Global score								
Mean (SD)[e]	56.0 (20.7)	60.9 (18.8)	59.1 (26.5)	57.6 (22.8)	64.2 (16.7)	64.2 (19.7)	63.1 (18.7)	67.3 (22.0)
Median (Q1–Q3)	58.3 (41.7–66.7)	66.7 (50.0–75.0)	66.7 (58.3–75.0)	58.3 (50.3–75.0)	62.5 (50.0–75.0)	62.5 (50.0–75.0)	66.7 (58.3–75.0)	75.0 (50.0–83.3)
Change (6m–baseline)[f]								
Mean (SD)	4.9 (19.8)		−1.5 (27.1)		0 (18.4)		4.2 (15.9)	
Median (Q1–Q3)	0 (−8.3, 25)		−8.3 (−16.7, 8.3)		1 (−8.3, 16.7)		4.2 (−8.3, 16.7)	

PDI Psychological Distress Inventory, *QoL–GHS* quality of life–global health status

[a] Positive values represent PDI worsening over time; negative values represent PDI improvements over time

[b] *p* value on comparing the baseline, 0.44

[c] *p* value on comparison of the delta, 0.28

[d] Positive changes represents improvements, negative changes represent deterioration of QoL over time

[e] *p* value on comparing the baseline, 0.39

[f] *p* value for comparison of the changes over time, 0.42

The calculated mean PDI global score at baseline was 32.8 and 31.5, respectively, for the CG and IG, and comparison between baseline and 6-month scores for PDI in the CG and subgroups of IG is shown in Table 3. We found a decreased PDI global score (improvement) in the CG (−0.2), and in the HI of IG (−1.7), whereas we found an increased PDI score (worsening) in the IG NI (+3.3) (Table 3 and Online Resource 6). However these changes were not significantly different between groups (p=0.28).

The results for the QoL questionnaire are presented in Table 3 and in Online Resource 4. We found an increased GHS both in CG and IG (adjusted LSMeans +3.5 and +2.8 points, respectively), with no statistical difference between groups (p=0.87). Statistically significant changes were found in the "Role Functioning" scale (Online Resource 4). CG showed a decrease score, while the IG presented an increase over the intervention period, respectively of −6.3 points and +5.1 points adjusted for baseline unbalance (p=0.016). The changes in the other scales and symptoms were not statistically significant.

Discussion and Conclusion

Discussion

This randomized intervention study is one of the first to evaluate the effects of a website to support Italian cancer patients in management of common eating problems during or after cancer treatment. We measured the change in knowledge on nutritional problems during cancer, the level of psychological distress and the quality of life at the end of a 6-month intervention period. We hypothesized a positive effect in cancer patients but our hypotheses were not confirmed. The results show some changes for subjects who completed the intervention, and some trend points were in the positive direction in the more active subjects (IG), compared to the CG, but the changes were not statistically significant.

Several reasons may account for this lack of effect. The major factor was the limited sample size. We planned a larger study population, but we suffered many more non-eligible (56 %) and dropout (28 %) subjects than expected (Online Resource 3), and at the same time, the website engagement was low. Therefore, the final number of subjects included in the analysis was small. However, this issue is consistent with other studies on the use of Internet interventions [2, 4]. Among individuals with chronic disease, the use of the Internet has increased steadily and it seems an important step for health information [24]. But despite this fact, recent data revealed cancer patients had a lower access than the general population [2]. To overcome this aspect, we set up a recruitment not restricted in terms of location, cancer type, treatment and gender to give a realistic reflection of the Italian cancer patients using the Internet. But unexpectedly, we obtained a final sample size that was too small to have enough power to draw any conclusion, with a remarkable prevalence of females with cancer of the breast (Table 1).

Another important aspect to take into consideration is the nature of cancer itself. Cancer is a complex disease, and its treatments may create severe stress situations from depression, anxiety, loneliness, uncertainty and loss of control to fear about cancer recurrence [25]. In our study, cancer type, stage and treatment were self-reported by participants. No access of personal medical records and any face-to-face interaction was planned, and this could have affected our data. Cancer treatments may account for a minimal change or a worsening in outcomes in case of progressive disease. Progressive cancer disease can affect social functioning and performance [22], and screening for psychological distress is recommended in cancer subjects. Depending on tool choice, inclusion criteria and chosen population, the distress prevalence varied between 20 and 40 % in cancer patients showing at least subclinical symptoms of anxiety or depression [26]. In our study population, psychological distress was moderate at baseline (PDI=32.8 in the CG and 31.5 in the IG); only subjects who scored over 35 manifested clinically significant distress (Online Resource 5). The higher improvement rate after the intervention period was found in the HI group, though the results were not statistically significant (Online Resource 6). Web-based interventions providing supportive care and information [11, 12] and treatment of distress are likely to result in higher quality of life, satisfaction with care and better adherence to treatment [27], but a key issue is whether or not distress is actually amenable to treatment and what treatment works best for whom.

The lack of a change in the score may be due to the fact that the support approaches (nutritional tips, recommendations, advice) were insufficient for a positive impact on the QoL or the psychological distress, or the intervention expectancy was too high, or the control group beneficiated for the intervention, though they had no direct access to the website. The contents provided by e-mail were adequate for their needs and knowledge.

Among subjects who completed the final assessment, more than 60 % of the participants reported high levels of satisfaction (*very much* and *quite*) with the intervention, though they asked for more interaction and detailed information. We published contents on the website and sent weekly information by e-mail (see Online Resource 1); we involved a group of experts to answer specific questions and to ensure more engagement of participants in the blog and forum. Probably, the study moderator and the small number of active participants had influenced the value of the forum in general, its appeal and its usefulness as a community of interrelated users. More research is needed to better understand how to tailor support interventions that fit patient personality types and individual preferences.

The QoL questionnaire was analyzed by comparing means and median between groups through non-parametric tests. In literature, the interpretation of the comparison of QoL questionnaires over time and between groups is reported in several ways. The EORTC scoring manual [28] introduced the "minimal clinically important difference" (MID) suggesting that "The fact that a change is statistically significant does not necessarily imply that it also has clinical significance". Lydick and Epstein [29] proposed two different approaches: the "anchor-based interpretation", which links health-related QoL to known clinically relevant indicator or to patient-determined rating of change, and the "distribution-based interpretation". These approaches were then further developed by Osoba [21] and King [30]. Osoba created a short questionnaire (SQ) to be filled in immediately after the completion of the last QoL questionnaire. Based on the SQ, each subject classified himself/herself and his/her health perception as "improved", "no change" or "deteriorated". Another researcher, Bedard et al. [31], used the "overall health" and the "overall QoL" (questions Q29 and Q30) as "anchor". Subjects were able to rate their overall health status, and changes of two units were used to classify subjects as "improved", "deteriorated" or "no change". For each functional scale/symptom, "mean change over time was calculated for each patient who improved, deteriorated or remained stable". In the present paper, we adopted the approach of Bedard. We found 14.9, 77.0 and 8.1 % of "improved", "no change" and "deteriorated", respectively, which were very close to the percentages reported by Bedard (15.2, 75.2 and 9.5 %, respectively). However, the very small sample size (74 versus 210 subjects) did not allow us to estimated the MID with sufficient reliability (data not shown). However, the single statistically significant result we found on the "role functioning" scale (Online Resource 4) is consistent with the result reported by Bedard [31]. King [30] based the subject stratification on clinical status, since "groups with lower clinical status generally have worse QoL". The grouping was based on performance status, weight loss, toxicity, extent of disease, disease progression and prognosis. Differences between "adjacent" clinical groups were presented. We grouped subjects according to weight loss, but unfortunately, we found 63 out of 74 subjects with no weight loss and all the remaining patients but one with a weight loss <=10 %. Our sample size was too small to allow any kind of patients' sub-grouping based on clinical status.

Considering the strengths of the study, this is, to our knowledge, the first study to evaluate effects of the use of a website to support Italian cancer patients in management on common eating and nutritional problems during cancer treatments. In addition, the use of a randomized design, the recruitment of participants throughout the country as well as a validated tool for content management, social interaction and online questionnaire administration can be considered as major strengths.

Our study had however some limitations. Though reasons for refusal were unknown, we experienced a low participation rate. The web-based approaches can represent the major limiting factor. On-line intervention studies require a larger samples size to allow monitoring and controlling for potential confounders and heterogeneity [32]. Another factor that could have influenced the results or hindered the demonstration of the effect of the intervention is the short intervention time. Published studies are generally limited to 3 to 6 months follow-up period, and this time period might not be sufficient to measure any change in behaviour, knowledge and QoL or psychological distress [2]. In addition, the use of tools such as NQ, PDI and the QoL used as measurement, even if validated instruments, may be not suitable for the online users, and a standardization of instruments for such intervention is recommended to enable comparison across these studies.

Conclusion

This study represents an example of model for communication between cancer patients and researchers involved at different levels in cancer care. This website can help cancer patients experiencing eating and nutritional problems. Patients can ask questions and raise concerns with health-care professionals through this web-based tool. Such tools are unlikely to replace face-to-face patient–practitioner consultation, but it should support and reinforce communication between them. Patient–practitioner relationship may have an important influence on patients' health outcomes and must be taken into account. Despite the lack of significant effects, critical points may be of interest to researchers and organization working with cancer patients. Advancements in health information technologies that support patient are providing new opportunities to involve patients in their care. Patient-centred approach to health care is a key characteristic of quality health care, and nowadays, the need for innovative and sustainable communication models is more important than ever.

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Conflicts of Interest Patrizia Gnagnarella, Alessandro Maria Misotti, Luigi Santoro, Demosthenes Akoumianakis, Laura Del Campo, Francesco De Lorenzo, Claudio Lombardo, Giannis Milolidakis, Richard Sullivan and John Gordon McVie declare that they have no conflict of interest.

References

1. Jemal A, Bray F, Center MM, Ferlay J, Ward E, Forman D (2011) Global cancer statistics. CA Cancer J Clin 61:69–90
2. Hong Y, Pena-Purcell NC, Ory MG (2012) Outcomes of online support and resources for cancer survivors: a systematic literature review. Patient Educ Couns 86:288–296
3. Maddock C, Camporesi S, Lewis I, Ahmad K, Sullivan R (2012) Online information as a decision making aid for cancer patients: recommendations from the Eurocancercoms project. Eur J Cancer (Oxford, England : 1990) 48:1055–1059
4. Ruland CM, Andersen T, Jeneson A, Moore S, Grimsbo GH, Borosund E, Ellison MC (2013) Effects of an internet support system to assist cancer patients in reducing symptom distress: a randomized controlled trial. Cancer Nurs 36:6–17
5. Kuijpers W, Groen WG, Aaronson NK, van Harten WH (2013) A systematic review of web-based interventions for patient empowerment and physical activity in chronic diseases: relevance for cancer survivors. J Med Internet Res 15:e37
6. Leykin Y, Thekdi SM, Shumay DM, Munoz RF, Riba M, Dunn LB (2012) Internet interventions for improving psychological well-being in psycho-oncology: review and recommendations. Psycho-Oncology 21:1016–1025
7. Buriak SE, Potter J (2014) Impact of an online survivorship primer on clinician knowledge and intended practice changes. J Cancer Educ 29:114–121
8. Jacquelin-Ravel N, Pichard C (2012) Clinical nutrition, body composition and oncology: a critical literature review of the synergies. Crit Rev in Oncol Hematol 84:37–46
9. Bozzetti F (2013) Nutritional support of the oncology patient. Crit Rev Oncol Hematol 87:172–200
10. Caan BJ, Kwan ML, Shu XO, Pierce JP, Patterson RE, Nechuta SJ, Poole EM, Kroenke CH, Weltzien EK, Flatt SW, Quesenberry CP Jr, Holmes MD, Chen WY (2012) Weight change and survival after breast cancer in the after breast cancer pooling project. Cancer Epidemiol Biomarkers Prev 21:1260–1271
11. Rock CL, Doyle C, Demark-Wahnefried W, Meyerhardt J, Courneya KS, Schwartz AL, Bandera EV, Hamilton KK, Grant B, McCullough M, Byers T, Gansler T (2012) Nutrition and physical activity guidelines for cancer survivors. CA Cancer J Clin 62: 243–274
12. van Straten A, Cuijpers P, Smits N (2008) Effectiveness of a web-based self-help intervention for symptoms of depression, anxiety, and stress: randomized controlled trial. J Med Internet Res 10:e7
13. McVie J, G (2008) EuroCancerComs funded under the EU FP7 “Science in Society” (Project number: 230548 ed.)
14. Gnagnarella P, Misotti A, Santoro L, Akoumianakis D, Milolidakis G, De Lorenzo F, Lombardo C, Sullivan R, McVie G (2011) A dedicated website for cancer subjects, the nutritional support study: preliminary results. Ecancermedicalscience 5:228
15. Tenalea. Trans European Network for patient randomisation in clinical trials. http://ec.europa.eu/information_society/activities/eten/cf/opdb/cf/project/index.cfm?mode=detail&project_ref=ETEN_NM12#main-content. Accessed June/6 2013
16. Parmenter K, Wardle J (1999) Development of a general nutrition knowledge questionnaire for adults. Eur J Clin Nutr 53:298–308
17. World Cancer Research Fund, Americna Institute for Cancer Research Expert Panel (2007) Food, nutrition, physical activity, and the prevention of cancer: a global perspective. World Cancer Research Fund, Americna Institute for Cancer Research Expert Panel, Whashington
18. Friedman DS, Tielsch JM, Vitale S, Bass EB, Schein OD, Steinberg EP (2002) VF-14 item specific responses in patients undergoing first eye cataract surgery: can the length of the VF-14 be reduced? Br J Ophthalmol 86:885–891
19. Vespasiani G, Nicolucci A, Erle G, Trento M, Miselli V (2002) Validazione del questionario sulla conoscenza del Diabete – GISED 2001. GIDM 22:109–120
20. Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, Filiberti A, Flechtner H, Fleishman SB, de Haes JC (1993) The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. J Natl Cancer Inst 85:365–376
21. Osoba D, Rodrigues G, Myles J, Zee B, Pater J (1998) Interpreting the significance of changes in health-related quality-of-life scores. J Clin Oncol : Off J Am Soc Clin Oncol 16:139–144
22. Morasso G, Costantini M, Baracco G, Borreani C, Capelli M (1996) Assessing psychological distress in cancer patients: validation of a self-administered questionnaire. Oncology 53:295–302
23. Morasso G, Di Leo S, Caruso A, Decensi A, Beccaro M, Berretta L, Bongiorno L, Cosimelli M, Finelli S, Rondanina G, Santoni W, Stigliano V, Costantini M (2010) Evaluation of a screening programme for psychological distress in cancer survivors. Support Care Cancer 18:1545–1552
24. Hesse BW, Hansen D, Finholt T, Munson S, Kellogg W, Thomas JC (2010) Social participation in Health 2.0. Computer 43:45–52
25. Mitchell AJ, Ferguson DW, Gill J, Paul J, Symonds P (2013) Depression and anxiety in long-term cancer survivors compared with spouses and healthy controls: a systematic review and meta-analysis. Lancet Oncol 14:721–732
26. Mitchell AJ, Chan M, Bhatti H, Halton M, Grassi L, Johansen C, Meader N (2011) Prevalence of depression, anxiety, and adjustment disorder in oncological, haematological, and palliative-care settings: a meta-analysis of 94 interview-based studies. Lancet Oncol 12:160–174
27. Graves KD, Arnold SM, Love CL, Kirsh KL, Moore PG, Passik SD (2007) Distress screening in a multidisciplinary lung cancer clinic: prevalence and predictors of clinically significant distress. Lung Cancer (Amsterdam, Netherlands) 55:215–224
28. Fayers PM, Aaronson NK, Bjordal K, Groenvold M, Curran D, Bottomley A (2001) The EORTC QLQ-C30 scoring manual. European Organisation for Research and Treatment of Cancer, Brussels
29. Lydick E, Epstein RS (1993) Interpretation of quality of life changes. Qual Life Res : Int J Qual Life Asp Treat Care Rehab 2:221–226
30. King MT (1996) The interpretation of scores from the EORTC quality of life questionnaire QLQ-C30. Qual Life Res : Int J Qual Life Asp Treat Care Rehab 5:555–567
31. Bedard G, Zeng, L, Zhang L, Lauzon N, Holden L, Tsao M, Danjoux C, Barnes E, Sahgal A, Poon M, Chow E (2014) Minimal important differences in the EORTC QLQ-C30 in patients with advanced cancer. Asia-Pacific J Clin Oncol 10(2):109-17
32. Knijnenburg SL, Kremer LC, Versluys AB, Braam KI, Mud MS, van der Pal HJ, Caron HN, Jaspers MW (2013) Evaluation of a patient information website for childhood cancer survivors. Support Care Cancer 21:919–926