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A comprehensive herbal combination (Life Spice Vital) and self reported effects on cancer related symptoms and wellbeing, a pilot study

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Abstract:

Background: Cancer is a public health problem where patients are using a variety of complementary- alternative therapies, often not well researched.
Aim: The aim of the study was to evaluate whether the Life Spice Vital herbal combination influenced well- being and cancer related symptoms.
Methods: Open label pilot study of three month duration, with participation of 84 subjects, mean age was 57,5 y (range 24-82 y) with a mean time since diagnosis of 54 months (range 3-209 months). There were 54 women (64,3%) and 30 men , with 34,2% smokers, reflecting the high prevalence of smoking in Denmark. Metastasis were previously diagnosed in 43 (51,2 %). Cancer diagnosis represented 27 different types.
Findings: 40-60 % reported improvements in their condition over the 12 week period, with respect to energy (p= 0,0002), physical performance (p=0,0005), sleep (p=0,002), overall digestive function (p= 0,003), breath (p= 0,05), mood (p=0,01),appetite (p=0,002), courage/spirits (p=0,002), weight loss (p=0,006), and mobility (p=0,05).
Interpretation: Intake of a comprehensive herbal- botanical combination, improved well being and relieved cancer related symptoms systematically in this open pilot study, thus being of potential relevance for relieving symptoms associated with cancer or its treatment, and help maintain or improve well being in cancer patients

Introduction

Cancer is a major public health problem where treatment results are insufficient in many cases. Patients are increasingly often seeking complementary - alternative therapies as part of coping with cancer. Among the general population in Europe the use of alternative therapies vary between 18 % in Holland over 37% in Denmark to approx 70% in Germany and Belgium (Damkier 2000), although the numbers are not directly comparable due to variations in definitions. In the US, use have increased from 33,8 % in 1990 to 42,1 % in 1997 (Eisenberg 1998). Among cancer patients in different countries current or earlier use of alternative therapies/ medicine vary between 7 and 72 % (Damkier 2000, Sparber 2000, Verhoef 1999, Chrystal 2003) and the most recent Danish study, based on questionnaires from 769 (1992) and 483 (1995) patients with response rates of 97 % and 94 % respectively, 45 % used some kind of alternative remedies and 11-13 % had seen a therapist (Damkier 2000). In the US, a recent survey revealed that 63% of cancer patients enrolled in clinical trials at the National Institutes of Health used at least one complementary or alternative therapy – with an average of two therapies per person (Richardson 2000).

The most frequent reason for using alternative therapies was a wish to strengthen general well-being in 66 % and the second most frequent was to treat the cancer disease, 24 % (Damkier 2000).

Herbal/ botanical remedies are among the widely used CAM- therapies (Damkier 2000, Eisenberg 1998), both among the general population and in cancer patients. Despite fairly extensive series of laboratory studies, detailing many biological effects of botanical agents, few clinical trials have been completed to evaluate effect and safety (Cohen 2002). Herbal /botanical agents possess complex biological activities that could affect several aspects of carcinogenesis, such as cell growth, proliferation, differentiation, apoptosis, host- tumour interactions and immune function (Cohen 2002).

Life Spice Vital is a newly developed herbal combination, consisting of 31 different herbs, all approved for human use by the Danish Veterinary and Food Administration. Each herb is thus present in small amounts, similar to the well studied Swiss Padma 28© , although the two preparations are very different in composition. It was originally developed as a general broad-

spectrum support for digestion, organ functions, "blood cleansing" and energy. The inventor had worked with herbs for many years, mainly for external application in skin creams and lotions based on European tradition as described by both folk- medical tradition and modern analytical science re. biological effects of various botanical components. She attended an American Indian pow-wow in Massachusets and met an elderly Indian woman, who taught her principles for combining herbs for achieving synergistic effects superior to what can be achieved by simple mixtures.
The woman remains anonymous and it is not known what tribe or clan she came from, however the principles taught is that no matter what health problem, body function or other aspect one wish to treat it is necessary to find herbs from the three elements: fire, air and water and connect them to Mother Earth as this will create a stronger harmony and synergy in the function of the combination, compared to single herbs or simple mixtures of the same herbs.
The Indian woman did not reveal any specific recipes for various problems. Each tribe, clan or family may have somewhat different principles or cultural tradition for the use of herbs and it has not been possible to find material describing a similar principle – only descriptions of traditional use of single herbs (www.cherokee.org/culture).
The inventor then worked for 4 years, applying the principles to a variety of recipes for a variety of problems, guided both by traditional folk- knowledge and information about biological effects of components in herbs and in 1998 the Life Spice Vital herbal combination had found its current form.
Family, friends and a handful of CAM therapists tried the combination for both human and veterinary use and reported about more energy, better physical performance, some cases of remission of malignant tumours and "longer than expected" residual life time in patients with end-stage malignant diseases. These early experiences were uncontrolled and unsystematic, but apparently quite concordant and called for a systematic acquisition of data in a pilot study. The aim of the study was to evaluate whether the LSV herbal combination influenced well- being and cancer related symptoms, describe possible side effects and describe the proportion of subjects experiencing an eventual effect, necessary for a power calculation in a subsequent randomised, controlled study.

Subjects and methods

Subjects

Subjects were recruited in two different ways: through an article in the patient organisation "The Thistles" newsletter (n = 21) and self referred consecutive clients at the alternative practitioners group in a four month period in the summer- autumn 2000, (n = 68). Inclusion criteria were diagnosed malignant disease in adult patients, all types and all stages in an expected treatment stable period. It was aimed at holding other treatments (both alternative and conventional), diet and use of food supplements stable, in the 3 month trial period with LSV, ie LSV were the only new modality added. Subjects with progressive disease who changed treatment in the period (n = 1 and 4, respectively) could continue with LSV, but were excluded from further analysis, thus this report is based on 20 and 64 subjects in the two groups, totalling 84. Subject were informed written and orally and signed informed consent.

The study was approved by the Regional Ethical Committee for Copenhagen and Frederiksberg, Denmark, as part of a general approval for pilot studies in the institute (J. no 07-00-044/02) and The Danish Data Protection Agency (J. no 2002-41-2523).

Research design and treatment
Open- label pilot study, with a before-and after registration of indicators of well being, mood, energy, physical performance and cancer related symptoms: digestive disturbances, tiredness, weight changes, appetite, thirst, sleep, mobility and pain.
Subject were supplemented with 5 tablets of 400 mg active ingredients LSV / d in divided dosages, 2 in the morning, 1 midday and 2 in the evening.

Data collection and measurements
Individual information on diagnosis, disease stage, medical and lifestyle history was obtained for all subjects by interview, aided by semi quantitative questionnaires. Medical information from diagnosing/ controlling hospital were obtained by the patient, ensuring that the cancer diagnosis were correct. Registration of self reported health were recorded on a registration form with predefined classification in six scores : 0= very poor, 1= poor, 2= neither poor nor good, 3 = good, 4 = very good, 5 = remarkably good. This applied for questions about physical performance, mood, sleep, appetite, thirst, digestion, breath, energy, spirits and memory. Questions about cancer related symptoms such as constipation, diarrhoea, weight loss, weight gain, pain, worry, mobility and loneliness were scored as 0 = none, 1 = some, 2 = medium grade, 3 = a lot, 4 = very much, 5 = severely disturbing.
Subjects were seen every four weeks for supply replenishment, control of compliance and consultation about possible side effects. Questionnaires were filled in at start and after 12 weeks. Additionally practitioners kept a systematic diary of events, interview data and other findings not fitting in the questionnaire,(ie telephone consultations) and thus reported their impressions systematically.

Statistical analysis
Statistical analysis were performed with PC SAS, version 8.2 (SAS Institute, Inc. Cary, NC, USA) Descriptive statistics include means and t- test for normally distributed data, medians and non parametric tests for data not normally distributed, frequency counts and chi-square- test .

Changes over time were analysed by subtracting start score from 12 week score and recode the 6 categories to two or three: better and unchanged / worse. To determine if changes over time were more likely to be better than worse McNemars test for paired dichotomous variables were used.

All tests were considered significant at the 5 percent level.

Results
Subjects
The mean age was 57,5 y (range 24-82 y) with a mean time since diagnosis of 54 months (range 3-209 months). There were 54 women (64,3%) and 30 men , with 34,2% smokers, reflecting the high prevalence of smoking in Denmark. Metastasis were previously diagnosed in 43 (51,2 %). Cancer diagnosis represented were 27 different types: Breast cancer 23 (27,4 %), Colon 10 (10,7%),lung 8 (9,5%), malignant melanoma 6 (7,1 %), prostate cancer 5 (6%), esophagus 4 (4,8%), brain 3 (3,6%), two each of rectal-, bladder-, kidney-, ovarian-, pancreatic cancer and myelomatosis. Additional one each of CLL, CML, neck-, skin-, bone-, primary liver-, Non-Hodgkin lymphoma, thyroid-, throat-,occult-, and pleura cancers.
Additional baseline characteristics are shown in table 1, which also demonstrates that the subjects recruited from the alternative practitioners were 6,6 y older (p = 0,03) and had been ill for a longer period (median 58,8 mo vs.. 30,0 mo, p= 0,05), but otherwise the groups were comparable. This

difference did not influence the overall self reported effects of taking the food supplement, thus all subjects are pooled into one group for the analysis and reporting of results. Previous cancer treatment were surgery alone for 28 (33,3%), surgery plus adjuvant chemotherapy and/or radiotherapy for 14 (16,7%),whereas 23 (27,3 %) were inoperable and had chemo/ radiotherapy alone, 11 (13%) had endocrine therapy, 6 (7,1 %) were not offered any treatment and two refused to receive conventional treatment. Most subjects followed routine ambulatory controls in hospital, 80% in the alternative practitioners group vs.. 31,6 % in the "Thistle" group, p = 0,0001.
After 12 weeks had 64 completed (76,1 %), two (2,4%) were lost to follow up and 18 (21,4%) had died, 15 of these due to advanced disease and one each from an infection, a thrombosis and a bleeding episode, respectively, which occurred around time of inclusion and cannot be attributed to the intake of the food supplement. Death were associated with more progressive disease, with metastatic disease in 84,2 % vs.. 52,3% (p=0,02), lower body weight (mean 63,2 kg vs.. 72,2 kg, p=0,04),previous weight change (47,4% vs. 27,6%, p= 0,02), smaller stature (mean 165,8 cm vs. 171,5 cm, p=0,04), whereas no differences were found for age, BMI, smoking, time since primary diagnosis or time since metastasis diagnosis, gender or previously received treatment.

Tolerance and side effects

Participants were requested to call if any unexpected events occurred and intervention was stopped for a few days until complaints had cleared and then restarted to clarify if the complaints was caused by the intervention. Ten cases of temporary loose stools occurred, all of which ceased within 2-3 weeks without discontinuation of the product. One case of stomach ache occurred, with a duration of one week, which cleared without cessation, due to relief from constipation . Terminal patients who died during the study period also tolerated the food supplement well and several called in (either by themselves or relatives) to say goodbye and express that the food supplement had improved their functional status, even in the very end of life.

Self reported effects of the food supplement

Overall 40-60 % reported improvements in their condition over the 12 week period, with respect to energy (p= 0,0002), physical performance (p=0,0005), sleep (p=0,002), overall digestive function (p= 0,003), breath (p= 0,05), mood (p=0,01),appetite (p=0,002), courage/spirits (p=0,002), weight loss (p=0,006), and mobility (p=0,05). Non significant differences were seen for worry, thirst, pain, quality of life, constipation, diarrhoea, loneliness and memory. There were no overall differences between the two groups regarding the self reported symptoms and all subjects were pooled for simplicity and achievement of sufficient statistical power. Table 2 summarizes these findings, demonstrating that the proportion reporting getting worse were in the 8-17 % range, and the proportion reporting being unchanged were in the 30-60 % range , depending on item. No associations were found with regard to gender, smoking status, disease type, stage or previous treatment received.
Stratifying subjects on basis of start score, into those scoring medium or below (scores 0,1,2 in the questionnaire) and those scoring good or above (scores of 3, 4, 5 in the questionnaire), revealed that in the low-scoring group an even larger proportion reported improvement, depending on item, but 70-80 % for mood, appetite, overall digestive function, courage/ spirits, constipation and weight loss and 60-70 % for breath, sleep, energy, optimism, physical performance and diarrhoea. Due to the risk of a "regression towards the mean" – phenomena, these additional findings are reported solely in a descriptive manner and not concluded upon, nevertheless : from a clinical viewpoint it is important to have access to nutritional supplements capable of relieving some of the symptoms and disability related to malignant diseases and treatment of these.

It was beyond the scope of the study to investigate possible tumour regression, as the control of the subjects in the public health care system was of variable content, intervals and quality.

Discussion

A wide variety of food supplements and herbal-botanical remedies are used in the public for dealing with symptoms and disturbances related to malignant diseases, however very few of these have been evaluated scientifically (Hilsden 1999, Richardson 2001, Cassileth 1999). This pilot study is a first attempt to describe the degree and magnitude of effect of a newly developed comprehensive botanical remedy. As a pilot study this work have several shortcomings, first and foremost the lack of a control group. The subjects were fairly ill, 50% had been diagnosed with metastatic disease and a mean time since primary diagnosis of 4,5 y.
As such, a reasonable expectation would be for a general deteroriation in self reported health over time and well being – nevertheless a significant proportion reported improvements on several items, regardless of disease stage, demonstrating a potential for improvement of well being and symptom control in this group of patients. Due to the lack of a control group we have been conservative in estimating the effect by using the McNemar test that omits the unchanged group and test the probability for getting better against that for getting worse. On several items findings were highly significant, thus it is unlikely that they should have occurred at random.
Long term sequelae after oncologic treatment, ie specific such as cardiac or neurologic disability after specific treatment or generalized physical /cognitive disability are not very well studied. The whole field of rehabilitation after cancer treatment have just recently attracted scientific attention (Beck 2003, Teichmann 2002, Seegers 1998, Schwidurski-Maib 1987), thus there is a gap in knowledge about which *other factors* (than disease stage, treatment modality etc) that may facilitate beneficial long- term outcome : survival, disease free survival, quality of life, self reported health status and function. There is a lack of studies describing the natural course of self reported health, cancer related symptoms and function in daily life in patients in a "adjuvant-treatment free" period, as well as for those with late-stage disease, as most studies on these issues have been performed either pre- treatment, during adjuvant therapy or in the very late end of life.

Another shortcoming is the lack of using a validated questionnaire for the assessment of symptoms and parameters of well-being, such as the EORTC QLQ-30 (King 1996, Osoba 1998). It was not possible due to the considerable fee requested for its use, this being a very low- budget study. Furthermore only the specific module for breastcancer had been validated in Denmark at the time of study and there is a lack of reference data for the group in this study, ie the EORTC questionnaire would not have covered the purpose of this study fully, could we have afforded the cost.

The third shortcoming is the lack of measuring other parameters of interest to explain the perceived effects, changes in symptoms and improvement of general wellbeing and energy, ie immune status, inflammatory markers or markers of redox activity.It was not possible due to lack of funding and should be attempted in a subsequent study. A comprehensive combination like LSV can be considered a concentrated supply of a very broad spectrum of secondary plant substances, with a host of possibilities for influencing cellular function at several levels. It will, however, not be feasible to tease out single substances responsible for the observed effects – thus it is necessary in future studies to study the effects of the total product on systems and functions, rather than of the individual components in the combination.

No similar herbal combination have been studied for its ability to improve well being in cancer patients. PC- SPES has been studied for its potential in the treatment of prostate cancer, primarily

with PSA changes as the endpoint. After several trials it was discovered that the product contained synthetic drugs that very well could have contributed to the beneficial clinical outcomes reported (Porterfield 2000, Guns 2002, Blumenthal 2002).
Essiac and Flor- Essence is a herbal combination consisting of four- five herbs that have been in use for + 40 y, with several anecdotal reports on improvement of quality of life and pain alleviation as well as impact on cancer progression. The individual herbs have been studied in the laboratory, which is feasible with a combination with a relatively small number of ingredients. The findings have not been translated to the clinical setting(Tamayo 2000).
Several controlled and mechanistic studies have been performed in China with a variety of herbal combinations used in combination with western-type of cancer treatment, often favoring the combined approach with respect to survival and quality of life (Yang 1999, Yang 2001, Li 2001, Jiang 2001, Liu 2001, Cai 2002, Yang 2003, Li 2003, Kong, 2001, Duan 2002), yet these reports are in chinese and cannot easily be interpreted.

Despite these limitations, the herbal combination under study shows promise for its ability to reduce cancer related symptoms and improve well being in subjects with a variety of malignant diseases in different stages, regardless of previous treatment, gender and age. Further controlled studies are needed.

Conclusion
Intake of a comprehensive herbal- botanical combination, Life Spice Vital improved well being and relieved cancer related symptoms systematically in this open pilot study, thus being of potential relevance for relieving symptoms associated with cancer or its treatment, and help maintain or improve well being in cancer patients . Further controlled studies is warranted to investigate this further as well as to clarify possible biological influences of the product.

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The sponsor and supplier of the study approved the study protocol, but had no role in data analysis, data interpretation or writing of the report.

Contributors
June Bach Pedersen wrote the protocol with contributions from Eva Lydeking-Olsen and Stig Gerdes. Stig Gerdes and the 18 alternative practitioners : Amy Birck, Pia Bjerrum, Inger Christensen, Inger B Gressbakken, Pia Hansen, Sigurd Hauge, Margith Mogensen, Eva M hlhausen, Hanne T Møller, Henning Mørkeberg, Grete Nielsen, Inge Petersen, Randi V Petersen, Kirsten Pille, Inge Rheinländer, Elke Simmelhack, Mette Stauning, Anett Norup Syberg investigated subjects and June Bach Pedersen was responsible for data-collection as coordinator for the group. E Lydeking-Olsen performed statistical analysis and wrote the report with contributions from Stig Gerdes and June Bach Pedersen.

Conflict of interest statement:
None of the authors are affiliated with Life Spice Productions.

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Table 1. **Baseline characteristics for participants in 12 week pilot study with Life Spice Vital**

Group	**All** (n=84)	**Therapists group** (n=64)	**Thistles group** (n=20)
Age (y) a)	57,5 ± 11,9	59,1 ± 11,2 *	52,5 ± 12,9 *
Height (cm) a)	169,9 ± 9,6	169,4 ± 9,3	171,7 ± 10,8
weight (kg) a)	70,3 ± 16,3	69,9 ± 16,3	71,5 ± 16,3
Time since primary diagnosis(mo.) b)	54 ± 3-209	58,5 (42-174) **	30,0 (3-209) **
Time from diagn to metastasis (mo.) b)	24,3 (0-120)	24,3	25
Female, n (%)	54 (64,3)	43 (67,2)	11 (55,0)
Smokers, n (%)	28 (34,2)	21 (32,8)	7 (38,9)
Proportion with prior weight change > 10 %, n (%)	29 (34,5)	27 (42,1)*	2 (10,5)*
Metastasis, n (%)			
None	41 (48,8)	33 (51,6)	8 (40,0)
Local regrowth	2 (2,4)	2 (3,1)	0 (0)
Regional lymph nodes	8 (9,5)	5 (7,8)	3 (15,0)
Distant	33 (39,3)	24 (37,5)	9 (45,0)

a) Mean (SD) b) Median (range) * p = 0,03 ** p = 0,05

Table 2 **Self reported effects on wellbeing and cancer related symptoms after 12 weeks intake of Life Spice Vital, n= 64**

Wellbeing:	n	**Worse, n (%)**	**Unchanged, n (%)**	**Better, n (%)**	**p- value***
Energy	61	7 (11.5)	18 (29.5)	36 (59.0)	0.0002
Physical performance	62	5 (8.1)	23 (37.1)	34 (54.8)	0.0005
Mood	64	11 (17.2)	23 (35.9)	30 (46.9)	0.001
QoL	64	6 (9.4)	38 (59.4)	20 (31.3)	0.14
Courage/spirits	64	8 (12.5)	33 (51.6)	23 (35.9)	0.002
Cancer related symptoms:					
Digestion, overall function	63	8 (12.7)	24 (38.1)	31 (49.2)	0.003
Constipation	64	10 (15.6)	37 (57.8)	17 (26.6)	0.49
Diarrhoea	64	10 (15.6)	38 (59.4)	16 (25.0)	0.1
Appetite	64	6 (9.4)	27 (42.2)	31 (48.4)	0.002
Sleep	64	8 (12.5)	22 (34.4)	34 (53.1)	0.002
Breath	63	11 (17.5)	26 (41.3)	26 (41.3)	0.05
Mobility	64	11 (17.2)	34 (53.1)	19 (29.8)	0.05
Thirst	63	7 (11.1)	31 (49.2)	25 (39.7)	0.16
Pain	63	10 (15.9)	28 (44.4)	24 (38.1)	0.25

*McNemars test for paired dichotomous data

Table 3. Proportion with self reported improvement at 12 weeks, stratified after start score*

	Start score ≤ medium		*Start score > medium*	
Cancer related symptoms:	Improved, n	%	Improved, n	%
Weight loss	19	79.2	0	0
Constipation	17	77.3	0	0
Courage/spirits	13	76.4	10	21.3
Digestion, overall function	17	73.9	14	35.9
Appetite	17	73.9	14	34.2
Mood	19	73.1	11	29
Diarrhoea	16	69.6	0	0
Physical performance	25	62.5	9	40.1
Energy	21	60	15	57.7
Optimism	18	66.7	3	8.3
Worry	11	30.5	14	66.7
QoL	15	40.5	4	10.3
Sleep	18	64.3	16	44.4
Breath	14	60.9	12	30
Mobility	18	37.5	0	0
Thirst	13	56.6	12	30
Pain	24	58.5	0	0

* Due to the risk of regression towards the mean, p -values have been omitted - from a clinical viewpoint, however, a stratified reporting seem valuable.