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Correlates of Complementary and Alternative Medicine (CAM) Use by Cancer Patients in Chandigarh

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ABSTRACT

Introduction: The recent increase in the interest of CAM can be attributed to technological, economic, cultural and social trends. The present study aimed at exploring the correlates of CAM usage by cancer patients in Chandigarh.

Methods: Present hospital based cross sectional study was conducted among cancer patients attending Radiotherapy Outpatient Department (OPD) of a Government Medical College and Hospital (GMCH). A total of 1,117 were included. Statistical methods like normal test of proportions, Chi square ($\chi 2$) test, and logistic regression analysis for estimation of risk factors of CAM use were applied using SPSS 16 software package.

Results: Among 214 new patients 120(56.1%) were using CAM as compared to 312(34.6%) among 903 patient who revisited the GMCH. Maximum CAM use was reported among aged 36-49 years (40.9%). Non-Hindu responders were found to be at significantly higher risk of CAM use ($P< 0.03$). Among 432 users, 162 (37.5%) were of the opinion that allopathy was better than CAM.

Conclusions: The high utilization of CAM among cancer patients urge need of conducting further in depth epidemiological studies to evaluate the efficacy of various CAM therapies in use for cancer with active participation from CAM providers/healers to attain some logical conclusions.

Keywords: Alternative Therapy Complementary and Alternative Medicine (CAM); Conventional Medicine; Holistic Approach, India.

INTRODUCTION

Complementary and Alternative Medicine (CAM)is a group of diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine. CAM is any medical system, practice, or product that is not thought of as standard care. Standard medical care is care that is based on scientific evidence. For cancer, it includes chemotherapy, radiation, biological therapy, and surgery. CAM is defined as "diagnosis, treatment and/or prevention which complements mainstream medicine by contributing to a common whole, by satisfying a demand not met by orthodoxy or by diversifying the conceptual frameworks of medicine"[1]. The American National Centre for Complementary and Alternative Medicine (NCCAM)[2], cites examples including Naturopathy, Chiropractic Medicine, Herbalism, Traditional Chinese Medicine, Other Traditional Medicines, Ayurveda, Meditation, Yoga, biofeedback, Hypnosis, Homeopathy, Acupuncture, and Nutritional-based Therapies, Touch Therapies, Siddha, Colour Therapy, Aroma Therapy, Chiropractic Therapy, Reiki, Acupuncture, Unani, Yoga, Massage in addition to a range of other practices. Complementary and alternative medicine (CAM) is generally used to refer to a range of non-indigenous, unorthodox practices including homeopathy, natu-

ropathy, herbalism etc[3]. Medical professionals divide CAM into two main categories; Complementary therapy is nonstandard cancer treatment that is used alongside traditional treatment, while alternative therapy is nonstandard treatment used in place of traditional methods/ standard medical treatments.

The recent increase in the interest and growth CAM can be attributed to many reasons including technological, economic, cultural and social trends. Its growth is also fueled by the rising dissatisfaction with the traditional health care and delivery of medicine. Additionally, the internet access to alternative medicine can also be attributed to increased use of CAM. The number of patients seeking alternate and herbal therapy is growing exponentially[4]. It has been estimated that two-thirds of the world's population seek health care from sources other than conventional biomedicine[5]. Natural medicines are considered to be in great demand because of their efficacy, safety and lesser side effects. Increased side effects of drugs, lack of curative treatment for several chronic diseases, high cost of new drugs, microbial resistance and emerging diseases are some reasons for renewed public interest in complementary and alternative medicines[6]. The present study aims at exploring the correlates of CAM usage the by cancer patients attending GMCH Chandigarh, a tertiary health care facility providing health care to patients from several states, and also to investigate their misunderstandings/ misconceptions using a multi-factorial approach.

MATERIALS AND METHODS

The study was conducted at Outpatient Department (OPD) Government Medical College and Hospital (GMCH), a tertiary healthcare facility in Chandigarh (UT), North India, during June 2012 to May 2014 to investigate CAM usage patterns among cancer patients and also to explore opinions of cancer patients. Cancer patients attending Radiotherapy of GMCH satisfying following inclusion criterion were included in the study:

Inclusion Criterion: Patients with confirmed diagnosis of any type of cancer irrespective of age, gender, site and staging of cancer approaching for allopathic treatment at the studied health facility for the first time willing to participate in the study were included. Close relatives of patients accompanying the patient also served as respondents to provide information regarding patient under some circumstances wherein patient was not in the condition to give the information.

Exclusion Criterion: Patients not undergoing allopathic treatment for cancer at the health facility or not willing to participate in the study due to any reason were excluded.

Study Design

A cross-sectional study design was adopted among patients of different types of cancer at different stages approaching for allopathic treatment at the health facility.

Sampling Design

A systematic sampling design was adopted to select patients attending the Radiotherapy OPD of the health facility. There were about 40–50 patients attending the OPD every day. Among them only new patients were included in a systematic manner selecting every third patient with a random start every day. Patients revisiting the OPD were excluded while selecting the sample.

Information collected/study variables

Patients suffering from cancer and/or their close family members and healthcare providers served as respondents. They were interviewed to collect information regarding personal and family characteristics, beliefs and practices related with CAM, sources of CAM awareness, perceived reliefs/benefits of CAM use, and positive and negative motivations concerning CAM. Information was collected using interview schedule. Patients were interviewed and in case they were not in the condition of giving information due to any reason, their family members/close relatives accompanying them served as respondents.

Outcomes

Primary outcome measure for this study was reported use of CAM by studied cancer patients undergoing allopathic treatment at their own. Secondary measures included CAM awareness and usage patterns, factors affecting CAM use and perceived reasons and reliefs felt etc.

Optimum Sample Size

Power analysis was done to calculate optimum sample size for the proposed study. Sample size was calculated by using the following formula with approximation for large population:

$n = \frac{Z^2_{1-\frac{\alpha}{2}}(1-P)}{\epsilon^2 P}$ Where, P = anticipated population proportion, 1- α= confidence coefficient, ∈ = relative precision, and Z (.) is the value of standard normal variate.

On the basis of 60% CAM use as primary outcome parameter anticipated on the basis of a pilot survey findings and assuming 95% confidence coefficient and 5% relative precision (not an absolute precision), optimum sample size of 1,024 cancer patients

was obtained. This study covered a sample of 1,117 cancer patients.

Ethical Issues

Ethical Guidelines of ICMR (2006) [10] on human participants were followed. A written informed consent was taken from the patients. Approval from Institutional Ethics Committee was taken for conducting the study.

Statistical Methods

Statistical methods like normal test of proportions, Chisquare (χ^2) test,, and Logistic Regression Analysis for estimation of risk factors of CAM use, analysis of variance (ANOVA) technique, etc., were applied to carry out the data analyses using Statistical Package for Social Sciences (SPSS)-16 software package.

RESULTS

User rates of different CAM therapies were calculated according to patient's characteristics presented in Table -1. Among 214 new patients 120(56.1%) were using CAM as compared to 312(34.6%) among 903 patient who revisited the health facility. CAM user rates among males and females were found to be 39.3% and 38.1% respectively.CAM use was not found to be significantly associated with gender (P=0.70). Maximum CAM use was reported among patients aged 36-49 years (40.9%) followed by those in the age group 50- 59 years (39.2%). CAM use among respondents of low socio economic status was found to be 39.3 % as compared to 39.1% among respondents of high socio- economic status. Among vegetarian patients, 247(36.8%) and among non- vegetarian patients 185(41.6%) were using CAM. There was no significant difference (P>0.10) between CAM Users rates among rural (39.0%) and urban (38.5%) backgrounds. Among illiterate respondents, CAM user rates were found to be 39.0% as compared to 48.4% among graduates. CAM user rate was comparatively higher among respondents having family history of cancer. However the association was found to be non significant (P =0.30).There were 378(39.1%) CAM users among patients aware of disease as compared to 53 (35.6%) among those who were not aware of the disease. CAM use rate was found to be maximum for prostate cancer (56.3%) followed by breast cancer (41.2%).

Patients represented different stages of different types of cancer as shown in Table-2. However, since definitions /criterion of staging of cancer is complex for different types of cancer and relevant stages need site specific cases, the exact distribution of cancer stages of 202 (18.1%) cases could not be ascertained during study.

Table -1 a): User Rates of CAM therapies according to the patient characteristics

Characteristic	Base	CAM Use	
		No (%)	Yes (%)
Nature of patient			
New Patient	214	94 (43.9)	120 (56.1)
Revisit	903	591 (65.4)	312 (34.6)
Referred from			
Govt. hospital	258	166 (64.3)	92(35.7)
Private Hospital	350	219 (62.6)	131(37.4)
Private Practitioner	27	19 (70.4)	8(29.6)
None	482	281(58.3)	201(41.7)
Gender			
Male	501	304(60.7)	197(39.3)
Female	616)	381(61.9)	235(38.1)
		X^2 =0.16	**P=0.7**
Age			
<21	44	30(68.2)	14(31.8)
21-35	93	59(63.4)	34(36.6)
36-49	274	162(59.1)	112(40.9)
50-59	324	197(60.8)	127(39.2)
60 & above	382	237(62.0)	145(38.0)
Mean± SD	51.4±14.3	52.6±12.8	51.5±14.1
Religion			
Hindu	839	515(61.4)	324(38.6)
Muslim	43	21(48.8)	22(51.2)
Sikh	233	148(63.5)	85(36.5)
Christian	02	01(50.0)	01(50.0)
Socio-economic status			
Low	445	270(60.7)	175(39.3)
Middle	301	189(62.8)	112(37.2)
High	371	226(60.9)	145(39.1)
Marital status			
Married	946	563(59.5)	383(40.5)
Unmarried	62	40(64.5)	22(35.5)
Widow/Widower/Divorcee	109	82(75.9)	27(25.0)
Type of family			
Joint	662	367(55.4)	295(44.6)
Nuclear/ Extended	455	318(70.0)	13(30.0)
		X^2 =4.64	**P=0.03**
Dietary habit			
Vegetarian	672	425(63.2)	247(36.8)
Non-Vegetarian	445	260(58.4)	185(41.6)
		X^2 =2.6	**P=0.12**
Occupation			
Housewife	323	323(63.0)	190(37.0)
Unemployed	122	89(73.0)	33(27.0)
Service	109	64(58.7)	45(41.3)
Business	35	18(51.4)	17(48.6)
Laborer	124	70(56.5)	54(43.5)
Skilled Worker	40	26(65.0)	14(35.0)
Agriculture	91	52(57.1)	39(42.9)
Any Other	83	43(51.8)	40(48.2)
Social background			
Rural	721	440(61.0)	281(39.0)
Urban	396	245(61.9)	151(38.1)
Educational status			
Illiterate	387	236(61.0)	151(39.0)
Primary	206	129(62.6)	77(37.4)
Middle	178	121(68.0)	57(32.0)
High School	172	107(62.2)	65(37.8)
Intermediate	50	27(54.0)	23(46.0)
Graduate	64	33(51.6)	31(48.4)
Post Graduate	38	21(55.3)	17(44.7)
Engineer	04	01(25.0)	03(75.0)
Others	18	10(55.6)	8(44.4)
Family history of cancer			
Yes	163	94(57.7)	69(42.3)
No	954	591(61.9)	363(38.1)
		X^2 =1.1	**P=0.3**

Table -1 b): User Rates of CAM therapies according to the patient characteristics

Characteristic	Base	CAM Use	
		No	Yes
Awareness of patient about suffering from cancer			
Yes	967	589(60.9)	378(39.1)
No	149	96(64.4)	53(35.6)
		X^2 =0.7	**P=0.5**
Satisfied with conventional therapy			
Yes	1001	601(60.0)	400(40.0)
No	27	18(66.7)	09(33.3)
Site of cancer			
Brain cancer	12	09(75.0)	03(25.0)
Breast Cancer	204	120(58.8)	84(41.2)
Oral cancer	53	32(60.4)	21(39.6)
Cervical cancer	102	72(70.6)	30(29.4)
Head & neck cancer	114	71(62.3)	43(37.7)
GIT	16	12(75.0)	04(25.0)
Prostate cancer	16	7(43.8)	09(56.3)
Others	600	362(60.3)	238(39.7)
Allopathic Therapy Received(N=140)			
Radiation Therapy only	571	349(61.1)	222(38.9)
Chemotherapy only	711	422(59.4)	289(40.6)
Surgery only	450	277(61.6)	173(38.4)
Others	46	33(71.7)	13(28.3)
Overall	**1117**	**685(61.3)**	**432(38.7)**

Table -2: Distribution of cases by staging of cancer and gender (N=1117)

Stage of the disease at diagnosis	Male (N=501)	Female (N=616)	Total (N=1117)
1A	2 (0.4)	3 (0.5)	5 (0.4)
1B	1 (0.2)	6 (1)	7 (0.6)
1B2	0 (0)	1 (0.2)	1 (0.1)
1C	0 (0)	5 (0.8)	5 (0.4)
1st	71 (14.2)	92 (14.9)	163 (14.6)
2A	5 (1)	12 (1.9)	17 (1.5)
2B	5 (1)	27 (4.4)	32 (2.9)
2C	1 (0.2)	1 (0.2)	2 (0.2)
2nd	83 (16.6)	102 (16.6)	185 (16.6)
3A	5 (1)	7 (1.1)	12 (1.1)
3B	5 (1)	39 (6.3)	44 (3.9)
3C	0 (0)	1 (0.2)	1 (0.1)
3D	1 (0.2)	0 (0)	1 (0.1)
3rd	126 (25.1)	100 (16.2)	226 (20.2)
4A	7 (1.4)	4 (0.6)	11 (1)
4B	5 (1)	2 (0.3)	7 (0.6)
4th	95 (19)	82 (13.3)	177 (15.8)
Advanced	2 (0.4)	0 (0)	2 (0.2)
T1N0M0	1 (0.2)	0 (0)	1 (0.1)
T1N2Mx	0 (0)	1 (0.2)	1 (0.1)
T2N0M0	1 (0.2)	0 (0)	1 (0.1)
T2N1Mx	0 (0)	1 (0.2)	1 (0.1)
T3M2M0	1 (0.2)	0 (0)	1 (0.1)
T3N0M0	3 (0.6)	2 (0.3)	5 (0.4)
T3N0Mx	0 (0)	1 (0.2)	1 (0.1)
T3N2aMx	2 (0.4)	0 (0)	2 (0.2)
T4N0M0	0 (0)	1 (0.2)	1 (0.1)
T4N1M0	0 (0)	1 (0.2)	1 (0.1)
T4N2cMx	1 (0.2)	0 (0)	1 (0.1)
T4NxM1	0 (0)	1 (0.2)	1 (0.1)
Unspecified	78 (15.6)	124 (20.2)	202 (18.1)

Respondents who were not of Hindu religion were found to be at significantly higher risk of CAM use (P< 0.03) on the basis of logistic regression analysis. Whereas, CAM use among cancer patients was not influenced by factors like Age, Socio Economic Status, Social Background, Dietary habits, Marital status, Type of family, Literacy status and Family history of disease etc. CAM use was found prevalent irrespective of these Socio-Demographic characteristics of patients (Table -3).

The sources of awareness regarding Ayurvedic therapy included relatives/ family members: 154(16.2%), friends: 91(9.5%) and doctors: 45(4.7%). There were 205(18.9%) respondents who were aware of Unani treatment. Only 34(3.1%) were aware of Siddha treatment. Also, 825(76.3%) respondents were aware of homeopathic treatment and reported source of awareness included doctors: 91(11.0%), relatives/ family members: 87 (10.5%). There were 246 (22.7%) respondents who were aware of naturopathy/herbal treatment, 242 (22.4%) respondents who were aware of acupuncture. Awareness of spiritual therapy was found among 462 (42.7%).Among all 1117 surveyed patients, 432 (38.7%) patients including 197 (39.3%) among males and 235 (38.1%) among females were using different CAM therapies. CAM users were asked regarding relief felt after CAM use. Among all users, 109 (25.2%) felt no relief and remaining 323 (74.8%) reported feeling of some relief. There were 109(25.2%) respondents didn't felt any type of relief with these therapies (Table -4).

Reasons of using CAM therapies reported by users were mainly advice of family members or friends (23.1%) followed by self desire (16.7%), whereas, by 60.0% patients no reason of CAM use could be specified. About 72% patients reported that they were not having any prior knowledge of CAM therapies which they used. Only in about 23% cases, CAM therapies were provided by professional practitioners or their staff and in majority of cases the providers were not specified by respondents (Table -5).CAM users were asked to give their views on comparison of CAM with allopathic treatment. Among all 432 users, 162 (37.5%) patients were of the opinion that allopathy was better than use of CAM. Only 77 (17.8%) patients reported to have faith in CAM therapies. Considerable numbers of patients having faith have not specified the therapy (Table -6).

DISCUSSION

The present study concluded that there was high degree of awareness and practice of CAM among cancer patients irrespective of their socio demographic characteristics, type of cancer, etc. Overall CAM use was found to be 38.7%. The prevalence of CAM use was lower than that reported in the U.S. (53.7%) or Australia (64%) and Japan (44.6%).[11, 12]

Table -3: Logistic Regression analysis of risk factors of CAM use:

Risk Factor	Regression Coefficient (β)	Odds Ratio Exp (β)	95% CI for Odds Ratio		P- Value
			Lower Limit	Upper Limit	
Age (above 49 years)	-0.46	0.95	0.43	2.11	0.91
Low SES	-0.57	0.57	0.27	1.20	0.14
Gender (Male)	0.33	1.38	0.61	3.14	0.43
Background (rural/slum)	0.08	1.08	0.49	2.39	0.84
Religion (Hindu)	-1.12	0.32	0.12	0.89	0.03
Marital Status (Married)	-0.40	0.67	0.24	1.89	0.45
Dietary Habit (Veg.)	0.09	1.09	0.52	2.29	0.80
Type of family (joint)	0.24	1.27	0.58	2.75	0.55
Literacy (illiterate)	-0.31	0.73	0.34	1.58	0.43
Having family history of cancer	0.28	1.32	0.49	3.56	0.54
Constant	1.21	3.6			

Table-4 (a): Respondents by source of awareness of different CAM therapies

CAM therapy and source	No. (%)
Ayurvedic treatment (N= 952)	
Relative/family member	154 (16.2)
Doctors	45 (4.7)
Friend	91 (9.5)
Any other	662 (69.5)
Unani (N=205)	
Relative/family member	16 (7.8)
Doctors	14 (6.8)
Friend	23 (11.2)
Any other	152 (74.1)
Siddha treatment (N =34)	
Relative/ family member	1 (2.9)
Doctors	2 (5.9)
Friend	1 (2.9)
Any other	30 (88.2)
Homeopathic treatment (N=825)	
Relative/ family member	87 (10.5)
Doctors	91 (11)
Friend	77 (9.3)
Any other	570 (69.1)
Naturopathy/ herbal treatment (N=246)	
Relative/ family member	25 (10.2)
Doctors	8 (3.3)
Friend	31 (12.6)
Any other	182 (74)
Acupuncture/ acupressure (N=242)	
Relative/ family member	19 (7.9)
Doctors	13 (5.4)
Friend	33 (13.6)
Any other	177 (73.1)
Psychological therapy/ counseling (N=98)	
Relative/ family member	2 (2)
Doctors	9 (9.2)
Friend	8 (8.2)
Any other	79 (80.6)
Spiritual therapy/prayer & faith healing (N=462)	
Relative/ family member	45 (9.7)
Doctors	4 (0.9)
Friend	32 (6.9)
Any other	381 (82.5)
Laughter therapy (N=345)	
Relative/ family member	8 (2.3)
Doctors	13 (3.8)
Friend	17 (4.9)
Any other	307 (89)
Physiotherapy (N=124)	
Relative/ family member	16 (12.9)
Doctors	29 (23.4)
Friend	7 (5.6)
Any other	72 (58.1)

With regard to CAM use pattern in the Asian countries very few studies are available but prevalence seems to be higher than the western countries.The prevalence of CAM use ranged from 54% to 61% in Turkey, 64% in Malaysia and 93.4% in China.[12,13] This higher usage could be due to different definitions of CAM, differences in the size and nature of the study population and different geographic settings.[13]

In this study, sources of information reported by cancer patients about CAM were diversified included family members, friends/relatives, health care providers Moschen et al[14].,reported the similar findings to this study, patients commonly received information from family members or friends who are usually involved in the decisions to make dietary changes or CAM use.

CAM use among Cancer patients were not influenced by factors like age, gender, socio economic status, social background, dietary habits, Religion, marital status, type of family, literacy status and family history of disease etc. in the present study. There were more males (39.3%) than females (38.2%) among the CAM users. The use of CAM was not affected by age, marital status, and level of education, religious affiliation, or socioeconomic status. However the level of education found to be significantly influence the use of CAM among cancer patients in the study in Malaysia[15] .The type of CAM therapies vary, depending on age, level of income, level of education, and perceived cause and prognosis of the disease. The use of CAM in industrialized nations is more common among females; young adults/middle aged individuals, members of higher socioeconomic classes, and persons with higher levels of education[16,17,18].

The present study rejected the usual assumption that CAM therapies are inexpensive. The cost of the therapy was within the reach of many cancer patients belonging to the underprivileged segment of the society, contributing to its immense popularity in Kolkata[19].

Table-4 (b): Respondents by source of awareness of different CAM therapies:

CAM therapy and source	No. (%)
Yoga/Meditation(N=966)	
Relative/ family member	50 (5.2)
Doctors	14 (1.4)
Friend	23 (2.4)
Any other	879 (91)
Any other(Specify) (N=78)	
Relative/ family member	2 (2.6)
Doctors	0 (0)
Friend	6 (7.7)
Any other	70 (89.7)
Any prior knowledge about the treatment therapies adopted (N=432)	
Yes	122 (28.2)
No	310 (71.8)
CAM use (N=1117)	
Yes	432 (38.7)
No	685 (61.3)
Relief felt after using any CAM therapy (N=432)	
No relief	109 (25.2)
Gives relaxation to mind	4 (0.9)
Improve physical health	2 (0.5)
Felt relief	15 (3.5)

Table- 5: Gender wise respondents by perceived reason of CAM use and source of CAM therapy:

	Male (%)	Female (%)	Total (%)
Reason for using CAM (N=432)			
On advice of family or friends	52 (26.4)	48 (20.4)	100 (23.1)
Self desire	37 (18.8)	35 (14.9)	72 (16.7)
Recommended by a physician	0 (0)	1 (0.4)	1 (0.2)
Any other	108 (54.8)	151 (64.3)	259 (60)
Complementary therapy provided by (N=432)			
General Practitioners (GP)	16 (8.1)	8 (3.4)	24 (5.6)
Health staff	32 (16.2)	21 (8.9)	53 (12.3)
Private professional therapist	6 (3)	13 (5.5)	19 (4.4)
Private professional clinic	2 (1)	4 (1.7)	6 (1.4)
Private Non-professional	15 (7.6)	6 (2.6)	21 (4.9)
Professional therapists	3 (1.5)	0 (0)	3 (0.7)
Any Other (Specify)	123 (62.4)	183 (77.9)	306 (70.8)

Table-6: Opinion of CAM users regarding allopathic treatment and CAM therapies (N=432)

Comparison of CAM with the allopathic treatment (N=432)	N (%)
Allopathic is better than CAM	162 (37.5)
No Relief/ Not effective	29 (6.7)
CAM gives good relief	10 (2.3)
CAM causes side effects	10 (2.3)
Both medicines are equally effective	10 (2.3)
CAM takes long time to relief	19 (4.4)
Mostly CAM doctors are fake	2 (0.5)
CAM is not acceptable by family members	4 (0.9)
Hard to manage	1 (0.2)
CAM works from roots	2 (0.5)
CAM Gives hope for life	1 (0.2)
CAM makes our mind strong	2 (0.5)
Allopathic medicines are very heavy doses	1 (0.2)
Don't know	2 (0.5)
Faith in any of the above therapies	
Yes	77 (17.8)
No	331 (76.6)
No Response	24 (5.6)

A study conducted in Ontario, Canada, compared the characteristics of CAM users and CAM nonusers concluded that the exact reasons for the popularity of CAM are complex, varying with time, space and also from therapy to therapy which is in agreement with present study[20].

The main weakness of present study is that it is a hospital based survey; thereby excluding patients who have abandoned conventional treatment completely or never used it at all. Moreover, it does not represent CAM use in the community.

CONCLUSIONS AND SUGGESTIONS

The high utilization of CAM among cancer patients and nondisclosure proportions suggests prioritizing research investigating reasons to use CAM and efficacy / safety of CAM use. There is an urgent need of conducting further in depth epidemiological studies to evaluate the efficacy of various CAM therapies in use for cancer with active participation from CAM providers/healers to attain some logical conclusions. Need for holistic approach for care of cancer patients in Indian set-up should also be considered due to deep rooted faith in some alternative therapies.

Compliance with Ethical Standards: The study has maintained its compliance with the Ethical Standards**.**

Funding: This study was not funded by any grant.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all individual participants included in the study.

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