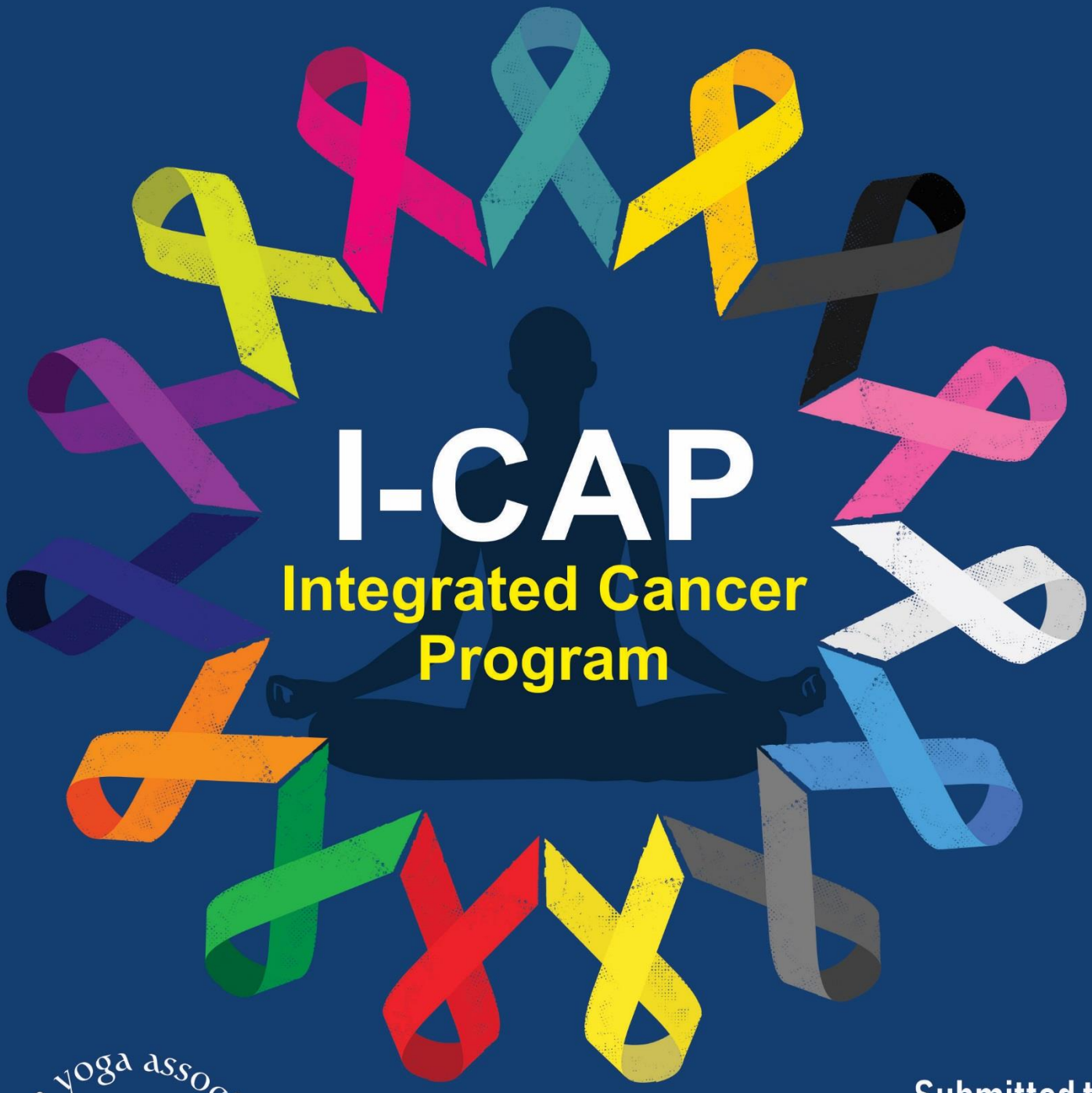
Proposal on
INTEGRATIVE CANCER PROJECT (ICAP)

Submitted by
COMMITTEE ON AYUSH AND INTEGRATIVE ONCOLOGY,
STANDING RESEARCH COMMITTEE, INDIAN YOGA ASSOCIATION



indian yoga association
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Submitted to
MINISTRY OF HEALTH AND FAMILY WELFARE
GOVERNMENT OF INDIA
NEW DELHI

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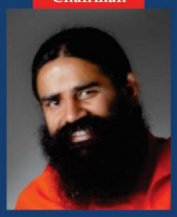

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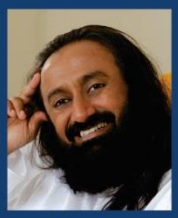

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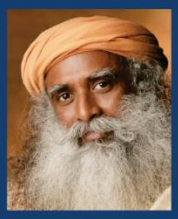

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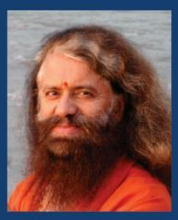

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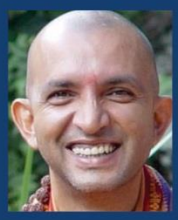

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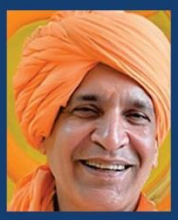

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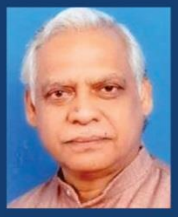

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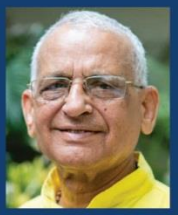

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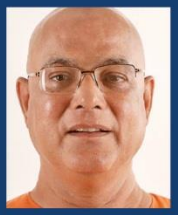

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INDIAN YOGA ASSOCIATION
A self-regulatory Body of Yoga Organisations of India
68, Ashok Road,
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Executive Members

Dr Nagaratna Raghuram	Navdeep Rinwa	Dr Manoj Nesari	Dr Rajkumar Manchanda	Dr Dhiman K S	Dr Ramaswamy	Dr Rath G K	Dr Rajesh Grover	Dr Ravi Mehrotra	Dr Raghavendra Rao	Dr Naveen Salins

Other Members

	Dr Vishal Rao, Senior Consultant, Head and Neck Surgeon, Healthcare Global Enterprises Ltd., Bangalore International Advisor, WHO Tobacco Free Initiatives
	Dr Kumaraswamy, Head, Dept. of Radiation Oncology, Healthcare Global Enterprises Ltd., Bangalore

	Dr Nita Nair, Associate professor, Dept of surgical Oncology, Tata Memorial Hospital, Mumbai
	Dr Raghavendra Ramanjalu, MD Director, RELIEF Foundation drragraj1@gmail.com
	Prof Dr Linge Gowda Director KMIO drlingegowda@yahoo.com
	Dr Narendra Bhatt Hon. Research Director & Adjunct Prof., BVU College of Ayurveda, Pune; National Professor & Visiting Scientist, Haffkine Research Institute, Mumbai; President, IASTAM – India. drnsbhatt@gmail.com, admin@iastamindia.org
	Dr Juhi Gupta CCRH sanjanhvi@yahoo.co.in
	Dr Sunil Dhiliwal MD (Ayu), PhD (Palliative care) dr.sunil.dhiliwal@gmail.com
	Dr BR Senthil Kumar CCRS- Chennai senthilkumarbr@gmail.com
	Dr Arul Amuthan Dept. of Pharmacology, Melaka Manipal Medical College, Team leader, Center for Integrative Medicine and Research, Manipal University dramuthanmd@gmail.com
	Dr VetriVendan vetriyoga@gmail.com
	Dr JLN Shastry Dabur j.sastry@mail.dabur
	Dr Sushma Bhatnagar HOD, Dept of palliative care sushmabhatnagar1@gmail.com
	Dr BR Ramakrishna Principal, Sushrutha Ayurvedic medical college and Hospital, SVYASA University campus, Jigani, Bangalore
	Dr. E. Hemanth Raj, MS., M.Ch., Ph.D., Chairman of Surgical Oncology, Cancer Institute, Adyar, Chennai, sog@cancerinstitutewia.org, 9840014505
	Dr Shivaraman BS, CCRS – Coimbatore, herbsiddha@gmail.com
	Sri Ravi Tumuluri, Coordinator, SVYASA

1) Introduction

2) The world has seen significant improvements in the quality of cancer care over the last decade, though it remains one of the most dreaded ailments, which instantly triggers a situation where the shadow of death becomes a constant companion. The risk, of course, has been mitigated significantly with the advancement of care programs and medical technology, the most critical factor however being timely discovery and optimal treatment. Still the debilitating impact of a cancer incidence is catastrophic, not only to the patient but in the collective psyche of his near and to dear ones, given its financial, emotional and social implications.

The context of cancer care in India is characterized by high incidence, late detection, and lack of access to quality affordable care to majority of the populace and hence high mortality. It is agonising to observe high percentage of late detections, owing to issues of access, affordability and awareness, given that both the cost and success of treatment is favourably skewed towards earlier detection in a significant manner. Added to this is the anguish of the family that has to negotiate with the reality of losing their loved one, while knowing that it is a travesty, not tragedy, of destiny. Further, it is of great concern to observe increasing deterioration of the key risk factors that contribute to the sickness, viz. use of alcohol/tobacco, obesity, environmental pollution etc. It is imperative for the stakeholders of Indian healthcare to address this growing menace before it becomes a national catastrophe. Improving Awareness, Affordability and Access to Care in Indian Cancer Patients is the need of the hour and this committee proposes the following strategies to address this.

1. Primary prevention: Increasing awareness and education of major cancers in India (Breast, Cervix and Head and Neck) among the population and reduce the risk factors that cause them.
2. Tobacco cessation program: To evaluate AYUSH approaches like yoga , Ayurveda, siddha and homeopathy for tobacco deaddiction
3. Tobacco control policy: To work with farmers in using alternate crops instead of tobacco. To develop a whitepaper with inputs from experts on the same and facilitate its implementation. Also, to evaluate alternatives to Nicotine that causes addiction.
4. RCT on Yoga in Cancer directed treatment: To evaluate the cost-effectiveness and efficacy of yoga in patients with breast, cervix and head and neck cancer undergoing conventional cancer directed treatment.
5. Five Pilot studies on each of the AYUSH systems on symptom management in cancer patients

6. Integrated Palliative Care Training of AYUSH doctors: To improve palliative care workforce in the country as less than 0.4% of cancer patients have access to palliative care. To impart palliative care training to AYUSH doctors and enable integrated palliative care across the country. To develop manuals of palliative care in each of the AYUSH systems of medicine.
7. To set up a center for excellence on Yoga in Oncology : To further evaluate and understand the mechanism of action interventions of yoga in cancer patients

Meetings Held

Name of the Meeting	Meeting of AYUSH in Oncology
Date of the Meeting	24th August 2017
Place of the Meeting	SVYASA, Jigani, Bangalore
Presided by	Dr H R Nagendra
Secretary / Convenor	Dr Ishwar N Acharya
Persons Attending the Meeting	Dr Nagarathna Raghuram, Dr Raghavendra Rao, Dr Ravi Mehrotra, Dr Rajesh K Grover, Dr Ramesh Bilimagga, Dr Kumara Swamy, Dr Vinoda Kochupillai, Dr Vishal Rao, Dr Navin Salins, Dr Nita Nair, Dr Ravi Nayar, Dr Narendra Bhatt, Dr Ramakrishna BR, Dr Vetri Vendan,
Persons in Absentia	Dr Bharath Agarwal, Dr LorenzoCohen, Dr Kashinath, Dr Sen Pathak, Dr Rajendra Badwe, Dr Ajaikumar, Dr Gopinath KS, Dr Manoj Nesari.

Resolutions of the Meeting

<u>Screening and primary prevention</u>

1. Screening and primary prevention to be done based on National cancer screening framework document. Dr Ravi from NICPR will provide the document
2. Training to be done based on ECHO program (NICPR) training modules prepared to be shared and facilitated by NICPR
3. Training of SDM personnel (1200 subjects) to be roped in training for screening imparted to them by NICPR
4. Screening for 1.8 lakh population screened in SDM program to be done again with a new checklist and mobile app. Patients who are suspicious to be sent to nearest cancer centre for further diagnosis. Basic screening and POI mapper to be used.
5. National cancer grid to be involved for further diagnosis and treatment
6. To evaluate the risk based screening tool in population
7. Training of AYUSH doctors in screening. Fellowship in preventive oncology from NICPR- Duration and structure of course to be brought out
8. Training of local resources for screening by master trainers. Training of master trainers to be done.
9. Pilot studies on GDV, Naditarangini, Iris Diagnosis and other diagnostic methods such as urine examination in siddha to be correlated in validation studies using PETCT in cancer and non-cancer patients. Proposals to be written for individual investigations

<u>Randomized controlled Trial</u>

1. It was decided to do 3 randomized controlled trials 1. Breast Cancer 2. Ca cervix and 3. Head and Neck cancer in patients undergoing adjuvant / primary radiotherapy. This would be conducted across 20 centres. Detailed protocols of these studies with study centres, investigators and budget to be prepared.
2. Dr Nita Nair expressed reservations as Breast / radiotherapy was already done. She proposed a long-term study with follow-up. However, HRN emphasised that the protocol needs to be implemented and done within one year and hence the design.
3. Dr Arun Gupta, Clinical Head DABUR suggested that Clinical trials should be done with global standards, with proper monitoring, using CRM, Database etc. The studies

should be done in consonance with ICH GCP guidelines with ethics committee approval.

4. The studies will be submitted to the National and international advisory committee for suggestions and critique
5. HCG centres, AIIMS, DSCI, and TMH will presently be involved as active participating centres in these RCTs.
6. A Translational component may be added for these studies based on suggestions by investigators
7. Dr Vinoda kochupillai suggested mechanism of action studies
8. Dr Raghavendra Suggested that CCRYN may set up one Centre of Excellence in yoga and oncology (at HCG KR Rd, Bangalore) and 3 joint collaborating centres (DSCI,TMH, AIIMS)

<u>Palliative care training</u>

1. Dr Naveen Salins emphasised on palliative care training for AYUSH doctors.
2. A fellowship or certification in palliative care training to be given for AYUSH doctors.
3. These AYUSH doctors will undergo training via distance education with compulsory internship for 1 month in a tertiary cancer care hospital in department of palliative medicine
4. Modalities of course curriculum, fellowship certification etc. to be worked out
5. AYUSH handbook module for palliative care to also be developed
6. Government permission for AYUSH doctors to prescribe morphine and its derivatives
7. Ayurvedic preparations equivalent to morphine and cannabis to be researched
8. Effects of ayurvedic formulations in palliative care to be researched before implementation. Low cost intervention approaches to be given preference.

<u>General</u>

1. International advisory board to be identified among the delegates to ICC
2. National advisory board to be formulated
3. Preliminary invites to be sent to new members after finalization of advisory board by the committee
4. To form sub committees and leaders for Primary prevention and Screening, palliative care &Training, Randomized controlled studies, Mechanism of action studies/ Translational research
5. To evaluate role of yoga in tobacco deaddiction. Dr VishalRao and Dr Raghavendra to look at its feasibility
6. It was decided to Have Dr Manjunath NK, from SVYASA and Dr Vadiraja HS from CCRYN as members. Dr Vinoda suggested Dr Nisha of AOL for 8yurveda

<u>Following manuals to be prepared and approved by Committee</u>

1. Cancer Screening framework document: Dr Ravi Mehrotra
2. Palliative care Handbook: Dr Navin Salins

3. AYUSH Hand book for palliative care : Dr Nagarathna, Dr Ishwar, Dr Raghavendra, Dr Vadiraj, , Dr Narendra Bhat, Dr Ramakrishna BR, Dr SashiBhushan/ Shastry, Dr Naveen Salins (Training Manual)

Following studies to be conducted

1. Correlation of Iris diagnosis with PETCT
2. Correlation of GDV with PET CT
3. Any other diagnostic tests in AYUSH
4. Cam prevalence in cancer: A Nationwide Survey

Following will be the core National committee co-opted in all subcommittees

Dr HR Nagendra, Dr Manoj Nesari, Dr Ishwar N Acharya, Dr Nagarathna, Dr GK Rath, Dr Ravi Mehrotra, Dr Manjunath NK, Dr Raghavendra Rao, Dr Gopinath KS, Dr Navin Salins, Dr Vadiraja HS

Following subcommittees will be formed

Position	Prevention and Screening	Randomized Controlled Trials	Palliative Care	Mechanism of action studies
Chairman	Dr Ravi Mehrotra	Dr GK Rath	Dr Navin Salins	Dr Nagarathna
Secretary	Dr Ishwar N Acharya	Dr Ishwar N Acharya	Dr Ishwar N Acharya	Dr Ishwar N Acharya
Members	Dr Vishal Rao Dr Ramesh Bilimagga Dr Ravi Nayar Dr Narendra Bhatt Dr Vetri Vendan Dr Raghavendra Dr Vadiraja HS Dr Sashi Bhushan Dr RK Grover Dr Rajendra Badwe Dr OP Mathur Dr Bharath Agarwal Dr Kashinath Dr Manoj Nesari Dr Manjunath NK Dr Nagarathna	Dr Raghavendra Dr Manjunath Dr Nita Nair Dr Gopinath KS Dr AjaiKumar Dr Arun Gupta Dr Shastry Dr Vadiraja HS Dr Kumara Swamy Dr Nagarathna Dr Rajendra Badwe Dr SenPathak Dr Manoj Nesari	Dr RK Grover Dr Raghavendra Dr Shashidhar Dr Prasann Shankar Dr Manoj Nesari Dr Nagarathna	Dr Vinoda Kochupillai Dr Raghavendra Dr Vadiraja Dr Kumara Swamy Dr Vishal Rao Dr Ravi Nayar Dr Rajendra Badwe Dr RK Grover Dr Lorenzo Cohen Dr Manoj Nesari Dr Manjunath NK

Proposals in palliative care, mechanisms of action yoga to be invited

Joint collaborating centres

1. To set up joint collaborating centres in Yoga and Naturopathy :Committee will decide on the centres- 4 such centres to be setup with inputs from committee on research
2. Setup Centre of Excellence on Yoga: Committee will decide on the institution.

International Day of Yoga meeting 2017

IDY yoga and oncology meeting to be shifted to 8th-9th November 2017 in 2nd ICC Conference at Clarks Convention Center. Dr HR Nagendra and Dr Ishwar Acharya will coordinate for the same.

Dr H R Nagendra

Name of the Meeting	Sub-Committee meeting of AYUSH in Oncology
Date of the Meeting	28th August 2017
Place of the Meeting	SVYASA, Jor Bagh, New Delhi
Presided by	Chairman of Committee: Dr H R Nagendra Chairman of Sub-Committee: Dr Ravi Mehrotra, NICPR
Secretary / Convenor	Dr Ishwar N Acharya
Persons Attending the Meeting	Dr HR Nagendra, Dr Ishwar N Acharya, Dr Nagarathna, Dr Ravi Mehrotra, Dr Narendra Bhatt, Dr Raghavendra, Dr Vadiraja, Dr Arun Gupta, Dr Sashi Bhushan, Dr Roopa (NICPR- Special Invitee)
Persons in Absentia	Dr Ravi Nayar, Dr Vishal Rao, Dr Ramesh Bilimagga, Dr Vetrivendan, Dr RK Grover, Dr Rajendra Badwe, Dr Bharath Agarwal, Dr Kashinath, Dr Manoj Nesari, Dr Manjunatha NK.

Resolutions of the Meeting

1. The meeting began with a prayer and presentation of the nationwide study on prediabetes and diabetes prevention undertaken by SVYASA by Dr Nagarathna. Dr Nagarathna appraised that 1.78-lakh population was screened across 68 districts and demographic data and tobacco data were already available. She said that they had complete data and cooperation in almost 40 districts and these districts could be selected for the program.
2. Dr Raghavendra presented on the screening and primary prevention for Cancers of Breast, Cervix, and oral cavity. It was decided to rope in ANM and AYUSH doctors for the assessment. This was planned to be done in the 40 districts identified. Dr Ravi suggested that we do not involve ASHA workers as they are overburdened and previous experience with them has failed.
3. D Ravi Mehrotra shared the lancet study and screening framework document released last year by their department. It was decided to adopt these strategies for Indian context. Dr Ravi Mehrotra appraised the team of the large Govt. program being conducted across 109 districts for 80% population coverage in screening over next three years. They plan to train and rope in AYUSH doctors in rural areas. It was observed that our program was similar to the initiative that was already launched by the ministry.
4. Instead of repeating this exercise, specific tangible questions should be posed was what come out of subsequent discussion. Dr Raghavendra suggested a pre and post measure to look at tobacco deaddiction. Dr Ravi suggested, Urinary/salivary cotinine could be done as a field test costing Rs.60 per test using a strip. This test reveals

presence or absence of cotinine in urine. Another is a Breath analyser that costs Rs.25000 in the market.

5. It was decided to do the study on Yoga and lifestyle based deaddiction for tobacco, alcohol and areca nut users in the population already screened for diabetes study. This will be a primary prevention study as smoking and alcohol constitutes ~50% of preventable cancers.
6. The population will be rescreened with more details on tobacco and demographics. Population will be randomized / self-selected to cases and controls depending on their motivation. Their motivation for quitting will also be assessed at baseline apart from tobacco and alcohol usage and Urinary/salivary cotinine. They will undergo 9 days of intense classes in their village on cessation. They will also have weekly contact classes for next 6 months. They will then be assessed again for tobacco, alcohol and areca-nut usage and urinary/ salivary cotinine levels.
7. Dr HR Nagendra suggested having Brahma Kumaris to participate, as they are very committed and good in counselling and have tobacco cessation and lifestyle as their goals. Dr HR Nagendra will talk to them and see if they would participate and work out logistics of the same. They can be involved in the study as lifestyle counsellors and motivators.
8. Suggestions were put to integrated medicines from Ayurveda, Unani and homeopathy for primary prevention. Dr Ravi and Raghavendra suggested that without hard evidence, using them in large setting is not feasible and hence it was decided that the team would come up with preventable strategies that can be pilot tested in small trials.
9. The suggestion to involve AYUSH medical colleges was also welcome, However their commitment and zeal to depute interns and doctors to rural areas and adoption of villages needs to be seen.
10. It was decided to get a statisticians help in assessing the sample size for the study.
11. So following action points were formulated:
    a) To draft a project proposal on tobacco deaddiction circulate to members
    b) To have NICPR share the cancer screening training module for AYUSH doctors
    c) NICPR to share the study details and budget for the nationwide cancer prevention study (109 districts)
    d) To develop training schedules for training AYUSH doctors and volunteers
    e) To identify yoga volunteers.
    f) To Identify personnel, team leaders for the study
    g) To evolve a budget plan and action plan for the study.
    h) To develop IEC materials for anti-tobacco campaign and ECHO Training for AYUSH doctors.
12. This section of the project should be ready by September 20th 2017.
13. Integrative oncology centre for cancer screening.

Dr Ravi Mehrotra and Dr HR Nagendra

Name of the Meeting	Meeting of AYUSH in Oncology
Date of the Meeting	7th, 8th and 9th November 2017

Place of the Meeting	SVYASA, Jigani, Bangalore (7th November) Clarks Convention Center (8th & 9th Novmber)
Presided By	Dr H R Nagendra
Secretary / Convenor	Dr Ishwar N Acharya
Persons Attending the Meeting	Dr HR Nagendra, Dr Manoj Nesari, Dr R Nagarathna, Dr Raghavendra, Dr Vinoda Kochupillai, Dr Naveen Salins, Dr Rajesh Grover, Dr Kumaraswamy, Dr Lorenzo Cohen, Dr Karen Mustian, Dr Susanne Danhauer, Dr Ramaswamy, Dr Senthil Kumar, Dr Arul Amuthan, Dr Narendra Bhatt, Dr Vadiraja HS, Dr Sangeeth from CCRYN Additional invitees From CCRS: Dr Ramaswamy, DG CCRS, Dr BG Senthil Kumar, Asst. Prof, National Inst of Siddha From CCRH: Dr Manchanda, DGCCRH or their representative, Dr Juhi Gupta, Bhopal, Dr BT Rudresh, Bengaluru From CCRAS: Dr Dhiman, DGCCRAS or their representative, Dr Prasann Shankar, IAIM,TDU

Resolutions of the Meeting

The members of the committee resolved the following:

1. The program to be known as Integrated Cancer Program I-Cap. It was decided to name this committee "AYUSH and Integrative Oncology" instead of only "Yoga and Integrative Oncology"
2. Development of Integrated Palliative care training program:
   Need: Around 30 lakh patients require active palliative care in India. There are 540 medical teaching AYUSH hospitals, 3000 district hospitals under NAM, 50 hospitals under research councils (total of around 4000 hospitals) Six hundred among them are exclusively teaching hospitals. There are approximately 56000 beds in AYUSH hospitals in India. Suggestion was to allocate certain percentage of beds in ayush hospitals in each district for palliative care and train doctors in these hospitals in Integrated Palliative care.
   i. Dr HR Nagendra suggested that the course certificate and PG Diploma can be approved and recognised through IGNOU. Suggested 2 weeks to complete course curriculum on IGNOU format : Dr Naveen Salins and Dr Raghavendra
   ii. Dr Manoj Nesari suggested to have the course curriculum approved by health varsities rather than IGNOU as this will add value to the course.
   iii. Development of curriculum framework document for PG diploma in Integrated palliative care for doctors and nurses for IGNOU
   iv. Development of curriculum framework document for certification in integrated palliative care for IGNOU- 3 or 6 month certification to be decided
   v. The course curriculum to be prepared and circulated to members of subcommittee who will approve and send the same to the core committee for discussion. Dr Naveen salins to convene a meeting on the same
3. Randomized control Trials in Yoga: It was decoded to have 3 multiinstitutional randomized controlled studies in Yoga on breast cancer, cervix cancer, head and neck cancer. the following suggestions were given by members:
   i. To have an active comparator arm with yoga

ii. To have a long term followup to check feasibility and long term outcomes
iii. To look at cost benefit analysis
iv. To evolve mechanism of action studies with subset of the population
v. To do studies in patients with vulnerabilities eg. . Insomnia, depression
vi. To align studies with NCI NCORP priorities. Dr Susan Danhauer shared the strategy and priority document
vii. To do small pilot and develop Indo US collaboration for large scale studies. Ministry of AYUSH to fund Yoga therapists in US and studies to be carried out Pan US and Pan India to test cultural differences
viii. Dr Karen Mustian and Dr Susan to be international members in the committee.
ix. DST and NC collaboration to have high impact projects was also discussed and high impact projects to be developed on same lines.
x. Pilot studies to be done in 2-3 locations in india- feasibility, data from randomization to calclulate effect sizes, PLUS LIMITED SITE PILOT IN NCORP for applying for large scale studies. Studies done using PET FmRI, FINRS, Polysomnography, Gene expression etc.

4. To do similar RCT in Ayurveda, siddha, and homeopathy in cancer
   i. CCRAS said they have 3 ongoing research trials in Oncology and the same to be shared with the committee.
   ii. All councils to identify priority areas for testing their medications/formulations in certain conditions such as anaemia, fatigue, neuropathy, constipation, oral mucositis, skin changes following radiation etc. and develop RCT protocols for the same for funding.
   iii. Dr Raghavendra to share draft of Yoga protocols with all councils. Dr Raghavendra to help with design and protocol framework document for each of the studies
   iv. All subcommittee heads to present the protocols for discussion in next meeting
   v. The protocols can be both preclinical and clinical.
   vi. Subcommittees for research to be formed by all councils
5. Tobacco cessation studies
   i. Policy decisions on tobacco – to have ayush ministry and other ministries work on the policy decisions to make tobacco expensive: Dr Vishal Rao to suggest action framework
   ii. Train asha workers in yoga module
   iii. Home remedy kits for withdrawal symptoms –develop from siddha, ayurveda etc.
   iv. To prepare these kits – siddha and ayurveda
   v. Can ayurveda and siddha find replacement for beeda for tobacco and arecanut
   vi. Sample size for doing the tobacco cessation study
   vii. Councils should deliberate on tobacco cessation strategies and come with a framework document on tobacco cessation
   viii. Tobaccum and calendula in Tobacco cessation to be studied
   ix. Animal studies to evaluate counter medicine for nicotine mimicking behaviours but not having its ill effects also to be evaluated.

6. Screening for breast oral and cervical cancer:
   Dr Raghavendra presented on the breast cancer risk assessment tool developed by NCI. Dr Nita nair suggested that the same risk tool is not valid for Indian population and this needs to be developed and validated. The development and validation will take a long time as these subjects have to be followed up over 10 years. Suggested to remove screening from the scope of the proposal as it needs expertise, manpower, infrastructure and long term followup to get some conclusive outcomes. Mere risk reduction on these questionnaires don't suffice.
7. A detailed budget plan to be made and booklet prepared for submission to AYUSH and MOHFW, Govt of India.
8. It was decided to convene the next meeting at New Delhi on 1st and 2nd December 2017. The venue will be intimated shortly.
9. It was decided to co-opt other members for carrying out the agenda forward by heads of respective subcommittees. These members will be paid Travel and DA by their respective councils. Councils to nominate coordinators for this program to take care of the logistics, coordination of subcommittees and maintaining minutes of meeting.

Members to be added in the committee under Y&N

- Dr Amritanshuram- Scientist HCG – amritram@gmail.com
- Dr Divya Kanchibotla- Executive director, SSIAR
- Dr E. Hemanth Raj, Chairman, Surgical Oncology, Adyar cancer institute. – sog@cancerinstitutewia.org ph- 9840014505
- Dr Shashibhushan- Dabur : yogamok – under CCRAS

Dr Nagendra HR,

Chairman, Yoga and Oncology Committee

Name of the Meeting	Meeting of AYUSH in Oncology
Date of the Meeting	29th November 2017
Place of the Meeting	SVYASA, Jor Bagh, New Delhi
Presided by	Dr H R Nagendra
Secretary / Convenor	Dr Ishwar N Acharya
Persons Attending the Meeting	Dr Dhiman (DGCCRAS), Dr Manchanda (DG CCRH), Dr Anl Khurana (DG CCRUM), Dr Ishwar N Acharya (Director, CCRYN), Dr Gazala (research Officer CCRUM), Dr Vadiraja HS (Research Officer, CCRYN), Dr Deepika Saraf (for NICPR), Dr Mani (CCRS), (Representative from Brahmakumaris - Dr Lakshmi), MR Ravi Tumuluri,
Resolutions of the Meeting	

1. Dr HR Nagendra appraised the members about the developments on AYUSH and Oncology program,
2. Dr Raghavendra gave an update on the of AYUSH and Oncology program

3. Members were affirmative about the course in Integrative Palliative program for AYUSH doctors but expressed legal issues on the same. Whether these people would be allowed to treat cancer patients with their modality. The members opined that we need to get clearance from MOHFW and MCI on the same. Others suggested that since we are treating with our own modality this may not be necessary, but this is required if they are required to prescribe morphine and pain medications
4. It was decided to make gender specific cancer risk questionnaires (Breast and cervix) for female and head and neck for male. To discuss with dept of epidemiology in TMH and develop an app for risk calculator.
5. For screening it was decided to screen 2 crore people in 100 districts with 2 lakh people/ district. It was decided to rope in AYUSH colleges, Bramakumaris, AOL volunteers, Ramachandra mission volunteers, Ekal vidyalaya teachers and other NGOS to carry out this task.
6. It was decided to train volunteers in Mt Abu, SVYASA and other institutions.
7. It was decided to develop materials for awareness and education using street plays, media, involving school children.
8. To give six weeks timeline for developing manuals and protocols
9. Respective councils to help in formation of committees
    - Ayurveda - Dr Ramakrishna
    - Siddha - Dr Ramaswamy
    - Unani - Dr Khurana/ Dr Ghazala
    - Yoga - Dr Vadiraj
    - Naturopathy - Dr Prashanth Shetty/ Dr Babina
    - Homeopathy - Dr Manchanda/Dr Praveen
10. It was decided to compile the proposal for approval in national board meeting

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Executive Summary

Introduction and Background

Cancer is a major cause of morbidity and mortality in developing countries(1). In many low-income and middle-income countries, including India, access to a well-organised and well-regulated cancer care system remains a problem with more number of tertiary cancer centres located in the cities inaccessible to the majority rural population. Patients have to travel several thousand kilometres to access cancer that poses significant costs of travel, loss of wages and relocation expenses. A diagnosis of cancer often leads to catastrophic personal health expenditures(2). Such expenditures can push entire families below the poverty line and may, especially when combined with an absence of what are seen as acceptable services, threaten social stability(3,4). Some of the major highlights of cancer scenario in India is described below:

- Incidence of all cancers cases in India is 1 million new cases with mortality ranging from 6 lakh-7 lakh
- Real incidence is estimated to rise by 7-8% annually driven by changes in demographics and increasing deterioration of key risk factors
- The prevalence of cancer in India is expected to increase from an estimated 3.9 million in 2015 to an estimated 7.1 million people by 2020.
- Increasing Ageing population >50yr from 228 million in 2015 to 262 million by 2020 leading to an increase in cancer incidence of 100,000 to 350,000 cases a year.
- Prevalence of all forms of tobacco use in India in 2015 is ~17% compared to 21% and 19% in the UK and US respectively.
- Alcohol per capita consumption in adults aged over 15 years has increased by ~55% between 1992 and 2012 .i.e. the third highest increase amongst 40 countries (OECD and partner countries).
- India has the third highest number of obese individuals in the world, after the US and China.
- According to a 2014 WHO report, 13 of the 20 most polluted cities in the world are in India.
- The reported cancer incidence in India is expected to increase from an estimated 1.1 million in 2015 to 2.1 million by 2020 driven by a narrowing diagnosis gap.
- Mortality rate in cancer remains as high as 50%

Population ageing is often assumed to be the main factor driving increases in cancer incidence, death rates, and health-care costs(5). However, the actual picture is more complex. In high-income countries, age-standardised cancer mortality is now typically decreasing in all age groups, although more than half of all cancer deaths are people older than 70 years. In India, despite the weakness of data in terms of population coverage, no evidence exists for a decrease in age-standardised cancer mortality rates, and most deaths occur in individuals younger than 70 years(1). These, differences are only partly due to India having a relatively younger population compared with high-income countries. They are also a product of contrasting causal patterns, with infections and unique local patterns of tobacco use playing a much greater part

in causing cancer in India than in richer countries. Poor access to screening and early-stage case-finding services also helps to explain the paradox of India's seemingly low cancer incidence rates but relatively high age-specific death rates. Although improvements in living standards and Human Development Index rankings are typically linked to increases in the occurrence of, for example, sex hormone exposure-related cancers, and cancers epidemiologically associated with reduced average family sizes,(6) the positive gains that economic and social development bring, for example, improved food quality, and obesity—normally far outweigh any such costs. The International Agency for Research on Cancer GLOBOCAN project1 has predicted that India's cancer burden will nearly double in the next 20 years, from slightly over a million new cases in 2012 to more than 1·7 million by 2035. These projections indicate that the absolute number of cancer deaths will also rise from about 680 000 to 1·2 million in the same period(1). India with a 1.2 billion plus population with 70% in rural areas has a dismal healthcare scenario compared to their urban counterparts (7). The inequitable distribution of healthcare facilities in rural urban areas has grossly affected healthcare system in the country.

Cancer incidence and mortality GLOBOCAN estimates that about 14 million new cancer cases were diagnosed worldwide in 2012 and slightly more than 8 million cancer deaths occurred. 1 million of these new cases and nearly 700 000 of the deaths occurred in India, which is home to about 17% of the global population. Even in age-adjusted terms the recorded incidence for India is, at 94 per 100 000 people, only slightly more than half of the world average of 182 per 100 000, and about a third of that recorded in the more developed countries (268 per 100 000). All cancers in Indian men other than oral, lung, stomach, colorectal, pharyngeal, and oesophageal cancers have an incidence of five per 100 000 men or less. This, according to US and EU definitions, makes such cancers orphan diseases. Women have an age-adjusted incidence rate of 104.5 per 100000 women. With the exceptions of breast, cervical, and colorectal cancers, all other cancers in Indian women also have a recorded incidence of less than five per 100 000 women. In 2012, almost 145 000 Indian women were diagnosed with breast cancer. Nearly 400 000 of those who had reportedly been diagnosed with breast cancer in the previous 5 years were still alive. In 2009, breast cancer became the most frequently diagnosed form of neoplastic disease in women in India and is now the most common cause of cancer death in the country, accounting for more than a fifth of all female cancer mortality. In men, the more common cancers are tobacco-related. For Indian women, cervical cancer is the second most common incident cancer. Cervical cancer is also the second most common cause of cancer deaths when both sexes are combined.

India's demographic and epidemiological transitions have been slow compared with the progress achieved in the past half century in many other parts of Asia. The population is still fighting relatively high rates of parasitic, bacterial, and viral diseases (which are collectively the direct cause of about a third of all deaths), while encountering increasing levels of illness caused by conditions such as stroke, ischaemic heart disease, type 2 diabetes, and cancer(8). This double burden (together with that associated with traffic and work place accidents and hazards such as snakebites) sets a complex health-policy challenge. Effective policies must bridge the continuing public-health task of infection control and the modern goal of non-communicable disease prevention and management. In the case of nutrition, for example, India needs a transition strategy that will both combat malnutrition and guard against the rapidly

increasing obesity rates seen in emergent nations such as Mexico and Egypt. Partly because of continued rapid population growth linked to both enhanced survival and only gradually decreasing birth rates, the proportion of the population aged over 65 years is still little more than 5%. Observers warn that high and still-increasing populations in themselves represent a key challenge to communities trying to escape poverty—they note that, as life expectancies rise, age-specific rates of disabling disease tend to fall in line with mortality. From this perspective, the pursuit of healthy and active ageing should already be as much a priority for modern India, as is the continuing reduction of maternal and child deaths.

India is a country traditionally more accustomed to accepting disparities in wealth and health between different community groups than with confrontation of social and gender inequities. Nevertheless, India's low rate of public expenditure on health care is, in some ways, a surprising as well as a serious problem. India invests less than 1·5% of its GDP on central government funded and state-funded health care, out of a total public plus private spend of little more than 4% of GDP. No other comparable nation spends as small a proportion of its national resources on public health care. The situation is further complicated by factors such as poor fiscal governance; sub-optimum (health sector-related) relationships between the federal and state governments; poor public health expertise (compounded by inadequate medical and other health professional education); substantial regional variations; and gross education, caste, and class-related inequalities in income and access to services. Provision of more acceptable standards of cancer care and enhanced preventive services will be very difficult without increased public expenditures on health at both the state and central government levels.

Promotion of cancer patients' interests from a health-gain standpoint, India's immediate priorities should include improving preventive and primary-care services to reduce the burden of disease linked to factors such as inadequately managed hypertension and, in the case of cancers, tobacco product use, indoor and outdoor pollution, and infections such as human papillomavirus, hepatitis B, and Helicobacter pylori(8). Diagnosis of diseases like oral, cervical, and breast cancers at earlier stages is also needed to save lives and reduce distress, especially when this can be linked to better and more accessible palliative care. Given that the poorest two-thirds of the population is in much greater need of better health-care provision than is the wealthiest third, increased public investment in health services needs to be a public policy priority for India. However, well-directed health spending should also benefit all sections of society. Innovations such as the establishment of the National Rural Health Mission (now being rolled out across the country as the National Health Mission), the introduction of insurance schemes such as the Rashtriya Swasthya BimaYojna (RSBY) and similar state-level initiatives, (9,10) and the recent publication plan for the provision of universal health coverage(11,12) by the Planning Commission of India are examples of positive progress. The development of comprehensive cancer centres in settings such as Ahmedabad, Chennai, Guwahati, Mumbai, and Thiruvananthapuram, with their community-outreach programmes, represent another important step forward in the specific sphere of cancer care. Nevertheless, improvements in healthcare access and delivery have been small so far, and public health improvement in India has been less of a political priority (notwithstanding relevant constitutional commitments) than in other countries at a similar developmental stage. The volume of calls for infrastructural improvements in India in non-health service areas, ranging from energy and clean water supply to improved transport and waste disposal facilities, might partly explain this difference.

Nevertheless, India is a highly stratified, ethnically diverse society, with a strong emphasis on family and other kinship linked responsibilities for provision of personal care. Equally, there has seemed to be a corresponding absence of a commonly perceived need to contribute to universal service funding. With respect to cancer services and all other forms of health-service delivery, this partly explains why costs are largely paid as out-of-pocket expenditures(3,8).

One core reason why the infrastructure for management of India's cancer burden is insufficient is the severe shortage of appropriately educated medical and other health personnel, and of the training facilities needed to produce them. (Table 4) Linked to this, factors such as the preferences of doctors and other health professionals for working in more affluent areas (Cities and metros), and the effects of a largely unregulated private sector, have resulted in a skewed geographical distribution of cancer treatment facilities. The available evidence suggests that about 60% of specialist facilities are located in regions to the south and the west of India.(3) However, more than 50% of the population live in the central and eastern regions, distorting service provision. For example, at least half of patients with cancer will be judged to need radiotherapy at some point. Yet data published by the Atomic Energy Regulatory Board indicate that the 26% of the population living in the eastern region of India have immediate access to only 11% of radiotherapy facilities .Cancer surgery and radiotherapy provision are available only on a highly inequitable geographical basis, and radiotherapy is significantly under-resourced 27 Addressing the social determinants of cancer and cancer-related needs must go hand-in-hand with improvement in cancer care capacity and delivery capability across India The burden of cancer in India is intimately linked to the country's major socioeconomic inequalities in access to health care and other areas. Rebalancing of the distribution of power, social goods, and resources33 will be a crucial determinant of how India will address its cancer burden in the long term. Failure to address social inequalities reduces survival and can needlessly increase the costs of cancer to individuals and Indian society as a whole.

One of the major causes for cancer in India is Tobacco. Tobacco alone is related to around 900000deaths/Year, 400000 cases of Cancer and 1300000 cases CVD. Economic costs of tobacco on Indian Healthcare is high. Tobacco economic burden is equivalent to 1.16% of GDP. Tobacco accounts for 112% of combined expenditures on healthcare by state and Centre. Taxes on tobacco get only 17% of economic costs due to tobacco. Tobacco accounts for 18% of direct medical costs due to hospitalization in India. Tobacco poses a significant economic burden on healthcare resources in the country. While there is a decrease in tobacco use from 36% to 28% from the year 2009-10 to 2016-17, according to the GATS 2 survey, more needs to be done to impart awareness and reduce tobacco consumption across the country. More taxes are needed to increase price of tobacco products to consumption. Farmers need to be educated on alternative crops to tobacco. Tobacco control, involves not just awareness and education but also changes at national level through policies that prevent cultivation, access and use of tobacco products. Even greater losses of welfare are associated with longstanding weaknesses in the country's public health system and its capacity to deliver preventive services(13).

These weaknesses have limited India's ability to protect its citizens from the key causes of cancer and treat the disease in a timely and successful way when it occurs. To achieve better outcomes will demand new ways of thinking among individuals and groups at all levels, including political leaders, the medical profession, patient organisations, and the public as a

whole. At the root of the solutions to India's cancer burden is the need for political commitment and action. Measures such as a fully committed effort to reduce, and, in the long term, eliminate, use of tobacco products through the vigorous implementation of the Framework Convention on Tobacco Control, would in time substantially decrease the incidence of, and consequently the mortality caused by, many common forms of cancer in India(14). So, too, could investments in cost-effective vaccination and screening programmes aimed at infection-related cancers, such as cervical cancer (human papillomavirus) and liver cancer (hepatitis B). Public health initiatives directed at improving nutrition, better urban planning to provide exercise space, awareness on tobacco and prevention of obesity in India's population would also slow increases in lifestyle-associated cancers. India's political challenge is to develop convergent health policies that address both communicable and non-communicable diseases(14). The continuing improvement of cancer outcomes will require changed priorities and strong national, regional, and district leadership(14). It will also demand increased public spending on both primary health care and specialist facilities in every Indian state4 and more emphasis on improvement of cancer research in India(8). Addressing of the cancer burden in India will require continued focus on other major social determinants of good outcomes— particularly education(15). In view of the acute suffering of people with advanced disease, oncologists and others with patient interests at heart will wish to see the requirements of seriously ill patients met as rapidly and fully as possible, especially when new palliative or curative opportunities become available. Prevention of cancer wherever possible will generate greater long-term benefit. In order to truly serve public interests, Indian policy makers should be aware of this last reality, along with the importance of focusing rigorously on overcoming the fundamental barriers to provision of affordable, equitable, and universal cancer care for the entire population.

The context of cancer care in India is characterized by high incidence, late detection, and lack of access to quality affordable care to majority of the populace and hence high mortality. It is agonising to observe high percentage of late detections, owing to issues of access, affordability and awareness, given that both the cost and success of treatment is favourably skewed towards earlier detection in a significant manner. Added to this is the anguish of the family that has to negotiate with the reality of losing their loved one, while knowing that it is a travesty, not tragedy, of destiny. Further, it is of great concern to observe increasing deterioration of the key risk factors that contribute to the sickness, viz. use of alcohol/tobacco, obesity, environmental pollution etc. It is imperative for the stakeholders of Indian healthcare to address this growing menace before it becomes a national catastrophe. We elucidate below an Integrated Cancer Control program that focusses on increasing awareness, making quality cancer care accessible and affordable to the masses through integration of AYUSH in Cancer Care. We propose a three-pronged strategy to improve Awareness, Affordability and Access to Care in Indian Cancer Patients by the following:

1. Primary prevention: Increasing awareness and education of major cancers in India (Breast, Cervix and Head and Neck) among the population and reduce the risk factors that cause them.
2. Tobacco cessation program: To evaluate AYUSH approaches like yoga , Ayurveda, siddha and homeopathy for tobacco deaddiction
3. Tobacco control policy: To work with farmers in using alternate crops instead of tobacco. To develop a whitepaper with inputs from experts on the same and facilitate

its implementation. In addition, to evaluate alternatives to Nicotine that causes addiction.

4. RCT on Yoga in Cancer directed treatment: To evaluate the cos effectiveness and efficacy of yoga in patients with breast, cervix and head and neck cancer undergoing conventional cancer directed treatment.
5. Five Pilot studies on each of the AYUSH systems on symptom management in cancer patients
6. Integrated Palliative Care Training of AYUSH doctors: To improve palliative care workforce in the country as less than 0.4% of cancer patients have access to palliative care. To impart palliative care training to AYUSH doctors and enable integrated palliative care across the country. To develop manuals of palliative care in each of the AYUSH systems of medicine.
7. To set up a centre for excellence on Yoga in Oncology : To further evaluate and understand the mechanism of action interventions of yoga in cancer patients

3) Chapter 1: Awareness, Education and Tobacco De-Addiction

Aims of Initiative

I. Primary Prevention through Awareness and Education
II. Promotion of Wellness and Healthy Lifestyle
III. Tobacco Deaddiction using AYUSH Approaches

3a) Primary Prevention through Awareness and Education

3a.i) Background and Objective

Data collected between 2009 and 2011 show that only 43% of breast cancer cases were diagnosed at an early stage (i.e. stage I or stage II) of the disease in India whereas 62%, 81% and 72% of breast cancers were diagnosed at an early stage in the US, UK and China respectively. Although this varies with the type of cancer, the stage of diagnosis in India is generally more delayed compared to other countries with only 20-30% of cancers being diagnosed in Stages I and II, which is less than half of that in the US, UK and China. Lack of awareness of cancer and screening for disease are significant contributory factors for the relatively late stage of the disease presentation and consequently low reported cancer incidences in India. Less than 1% of women in India aged between 40 and 69 years participated in recommended breast screening mammograms once in 24 months, as compared to 30% in China and 65% in the US in 2014. As a result, mortality rates are four to six times higher in India than the US. We propose to start primary prevention programs in around 20 districts in the country the population for their lifestyle, diet, risk behaviours, cancer etc. using a combination of Screening questionnaires specific for Breast, Cervix, Lung and Head and Neck cancer.

3a.ii) Plan of action

As part of this program, around two-lakh population in about 100 district would be screened for cancer using questionnaires developed for this purpose, covering a population of over two crore people. Those who score as high risk will be referred to district hospitals/ cancer referral centres for further investigations. A Consultant Oncologist will be employed at the District Level to follow up with suspected cancer cases in coordination with District Hospitals. (Such as sono-mammogram for breast with FNAC biopsy, biopsy for oral cavity, cervix, and CT scan of chest with CT guided biopsy) We will use POI Mapper software, apps and IT enabled databases to capture data on a large scale. We hope to screen and cover a population of two crore across 100 districts. We will involve local district hospitals, private cancer hospitals and Regional Centres in this initiative along with a 40,000 strong volunteer workforce that will be trained in screening methodologies. This volunteer workforce will primarily comprise yoga therapists and instructors from various yoga schools such as Brahmakumaris, SVYASA, Art of living, Ramakrishna Mission, Patanjali Yogpeeth and interns and doctors from AYUSH medical colleges. The risk based evaluation questionnaire will be developed in consultation with oncology experts, epidemiologists, cancer researchers etc. The positive and negative results of these histopathology reports will help develop the RISK BASED SCREENING

QUESTIONNAIRE FOR INDIAN POPULATION by weighing the factors that predict cancer with each of these questionnaires. The NICPR will be used as a stakeholder in developing IC materials for the cancer screening and awareness program, designing questionnaires in consultation with experts etc.

3a.iii) Deliverables

1. Develop a risk based questionnaire for Screening in Indian population for specific cancers
2. Use IT based app for screening of cancers and develop a demographic database for population studies in future
3. Identify the prevalence of risk factors for cancer in Indian population.
4. Screening of 2 crore population in over 100 districts

3b) Promotion of Wellness and Healthy Lifestyle

3b.i) Background and Objective

Real incidence of CANCER is estimated to rise by 7-8% annually driven by changes in demographics and increasing deterioration of key risk factors. The reported cancer incidence in India is expected to increase from an estimated 1.1 million in 2015 to 2.1 million by 2020 driven by a narrowing diagnosis gap. The prevalence of cancer in India is expected to increase from an estimated 3.9 million in 2015 to an estimated 7.1 million people by 2020. Increasing Ageing population >50yr from 228 million in 2015 to 262 million by 2020 leading to an increase in cancer incidence of 100,000 to 350,000 cases a year. Prevalence of all forms of tobacco use in India in 2015 is ~17% compared to 21% and 19% in the UK and US respectively. Alcohol per capita consumption in adults aged over 15 years has increased by ~55% between 1992 and 2012. I.e. the third highest increase amongst 40 countries (OECD and partner countries). India has the third highest number of obese individuals in the world, after the US and China.

3b.ii) Plan of Action

We will develop community based wellness programs that aim at imparting awareness and education among the public about cancer and its ill effects on Health. This will be done on a large scale in these 20 districts through exhibitions, poster displays, Awareness through media and social media platforms. We will assess changes in lifestyle and risk behaviour reduction before and after the program over a duration of 6 months. We will specifically develop Yoga based tobacco deaddiction programs and Evaluate efficacy of such programs in this population. We will also encourage the high-risk group to attend regular yoga classes in these districts to help mitigate the risk.

3b.iii) Deliverables

1. Develop Lifestyle Counselling centres with trained counsellors for community Health
2. Develop and introduce Yoga based deaddiction programs for Tobacco and alcohol
3. Conduct awareness and education camps with posters, media and social media platforms

4. Conduct a RCT on using Yoga or AYUSH approaches to Tobacco deaddiction

4) Chapter 2: Research Studies on AYUSH in Oncology

Aims of Initiative

Conduct studies under the following categories

I. Reduction of treatment side effects and improving cancer care affordability
II. Randomized Controlled Trials

4a) Reduction of treatment side effects and improving cancer care affordability

4a.i) Background and Objectives

With baseline cost of treatment (estimated INR 3-4 lacs) being higher than the annual household income for over 80-85% of households in India – cancer poses a significant threat to the Indian population. More over tertiary cancer care centers are concentrated in cities and people have to travel several hundreds of kilometres to avail treatment. This displacement and Being away from work poses loss of revenue and indirect hardships on the patients families. Many are driven into debt and poverty to take care of their illness. Coupled with this the treatment related toxicity discourages many to forego and default on their treatment that leads to significant morbidity and mortality. Patients have to often cope with stressors brought about by treatment related toxicity and symptoms, financial constraints due to loss of earnings, relocation, treatment costs etc. This is compounded by the fact that the treatment is purely directed towards cancer and not the individual. Understanding the factors that lead to treatment dropouts, and appropriate intervention strategies will help reduce default of treatment and reduce mortality and morbidity. Treatment related symptoms have been known to be a primary factor in treatment defaults. This is because these side effects impose hospitalization costs causing financial burden. Therefore, reducing treatment related distress would help improve patients to cope with treatment, reduce unnecessary hospitalization, and reduce costs. Secondly, treatment default is also because patients often take recourse to folklore and AYUSH treatments for cancer care (around 24% during primary treatment). Integrating AYUSH therapies through evidence based consultative approach may be a better strategy to reduce distress and default.

4a.ii) Plan of Action

In this study, we will do a phase III large Randomized controlled trial in Breast, Cervix and Head and neck cancer patients undergoing adjuvant radiotherapy in at least 100 Oncology centres in the country with 100 patients in each centre. In this study, we will evaluate the role of yoga interventions in reducing treatment related symptoms, acute toxicity, and preventing delays and default in radiotherapy treatment. This reduction in treatment related distress and toxicity would help assess reduction in hospitalization, morbidity, additional costs and help evaluate cost effectiveness of these interventions.

4a.iii) Deliverables

1. Assessing Efficacy of Yoga Intervention in reducing treatment related distress, toxicity, hospitalizations, treatment delays and defaults
2. Developing Level I evidence for Integrating Yoga in Cancer care.
3. Evaluating Cost effectiveness of Yoga Interventions.

4b) Randomized Controlled Trials

4b.i) Yoga in Head and Neck Cancer patients

Introduction

Head and neck cancer is a wide term that comprises of epithelial malignancies which develops in paranasal sinuses, nasal cavity, oral cavity, pharynx and larynx. Prevalence rate of squamous cell carcinomas head and neck is almost 90%(16). The most frequent of uncommon head and neck carcinomas are in paranasal sinuses and salivary gland tumors. The symptoms mostly include hoarseness, sore throat, tongue pain, mouth ulcer otalgia, dysphagia and odynophagia, cough, mouth bleeding and stridor. The sixth edition of the American Joint Committee on Cancer (AJCC) staging is used mainly in staging classification, which is the most significant factor that helps to determine precise treatment decisions.

Epidemiology and risk factors worldwide

Head and neck cancer is found to be the sixth most common type of cancer. Worldwide every year approximately 560,000 new cancer cases and 300,000 cancer deaths were reported. Around world, South Asia and parts of central, and Southern Europe, the highest incidences of HNC were reported. Tobacco is the leading PREVENTABLE cause for development of HNSCC globally. The WHO Tobacco Free Initiatives has laid emphasis on Banning cultivation, manufacturing and marketing of tobacco related products across the globe.

Among all, Oral SCC (OSCC) is the most common HNC and representing more than 300,000 new cancer cases annually. Oral cavity cancer is mostly seen in the geographical region of Melanesia (sub-region of Oceania) and south-central Asia, western and southern Europe, and southern Africa(17). This primarily due to chewing of tobacco quid (18)

Prevalence and Incidence in India

The existing literature show, head and neck cancer prevalence in India is more when compared to the past decades. In 2020, it is assumed that nearly 75% of death in South-east Asia will be due to cancer. Same percentage of cancer deaths are estimated in India. Head and neck cancer (including thyroid lesions) is the third most common malignancy seen in both the sexes across the globe but is the commonest malignancy confronted by Indian males. A portentous project on 'Development of an Atlas of cancer in India' by World Health Organization was commenced in 2001. Gender and site was calculated by analysing around, 217,174 cases. As per this atlas districts rising as new sites for highest incidence of different cancers worldwide are Aizawl - tongue (10.2) and hypopharynx (16.1); Kolar - mouth (10.7). Five districts (Wardha, Kanyakumari, Pondicherry, Tiruvanthapuram and Kollam) have mouth cancer incidence ranging from 9.1 to 14.1 - much higher than recorded worldwide (19) .

Aetiology

The environmental factors which contribute primarily to head and neck squamous cell carcinoma at the highest degree include: smoking and chewing tobacco and alcohol and inhaling chemicals such as hydrocarbons, nickel, and wood dust, eating habits ; poor oral and dental hygiene; ultraviolet radiation and viruses, especially the papilloma virus (20)

All these factors, independently or in combination, increase the risk of developing HNCC, as they can modulate toxin and carcinogenic metabolism and have genotoxic effects(21).

Treatment

One of the standard treatments for HNCC is surgery. However late stage of presentation and more posterior tumours results in use of concurrent chemo radiotherapy. Though advancements of techniques in radiation have considerably improved with respect to toxicity, some of them are inevitable such as oral mucositis and cause significant distress and pain.

Moreover, serious aftermaths are noticed in chemotherapy and radiation therapy e.g., for local tumour control, concurrent chemo radiotherapy (CCRT) is highly recommended and at the same time studies show increase in toxicity after undergoing CCRT. Toxicity is classified as acute or late, relative to treatment. Acute toxicity subsequently fades away with time. In contrast, adverse effects are more in late toxicity and are considered irreversible and progressive. However, acute toxicity delays treatment and causes poor treatment response and earlier recurrence or relapse. Furthermore, treatment delays are often seen in patients with severe toxicity(22)(23), which causes poorer clinical outcomes. Validating evidence show that 55% of the patients during radiotherapy lose almost 10% or more of body weight (24)(25), leading to more CRT linked toxicity, which is related with poor treatment outcome(26)(27).

A meta- analyses showed, approximately 8% increase in 5 year survival rate, who had taken CCRT(28,29) when compared to radiation therapy, but acute toxicity which has led to symptoms like mucositis, taste perversion, dysphagia, odynophagia, weight loss, and xerostomia have also been reported (30). The severity of toxicity is high with dose increment in regions like floor of mouth, oral cavity, submandibular glands(31), parotid glands, and area postrema of the brain stem(32,33). One of the severe symptoms which are often encountered due to treatment toxicity is oral mucositis which is associated with poor pain-management and low cost effectiveness (34,35) of treatment. Predominantly 29-66% patients, receiving chemotherapy was reported to have severe oral mucositis, (36).

Quality of life (QOL) in HNC patients

The cancer directed treatment adversely affects Qol in cancer HNC patients. QOL is affected in HNC cancer survivor as the result of heightened psychological distress, which is due to the high risk treatment, pain, mucositis, mutilation, swallowing difficulties, breathing and communication difficulties(37). This is known to lead to depressed mood and anxiety that further exacerbates the symptoms and impacts Qol. (22,23)

Management of symptoms and distress

High incidence of survival rates are made possible through chemo radiotherapy, than surgery. Alongside, supportive care needs are also found to be increasing in such patients due to treatment related toxicity symptoms. It has become necessary to control these symptoms to avoid treatment delays, chemotherapy dose deviations and hospitalizations (39). Management

of symptoms, improved nutrition and Yoga have been found to reduce distress and symptoms during radiotherapy. Yoga has been found to be useful in speech articulation during radiotherapy, reducing mucositis pain, improving swallowing in HNC patients undergoing radiotherapy post-surgery. This has been integrated in cancer patients with much effectiveness in a comprehensive cancer care centre in Bengaluru where majority of patients are referred to the integrative oncology department with a multidisciplinary team.

Aims and Objectives

Aim

To evaluate the effectiveness and efficacy of yoga intervention in HNSCC patients undergoing radiotherapy

Objectives

1. To evaluate the effects of yoga in reducing treatment related toxicity and symptoms in HNSCC patients undergoing radiotherapy/ chemo radiation.
2. To evaluate the efficacy of yoga intervention in terms of reducing treatment delays, reducing hospitalization and medication costs for managing treatment related symptoms and improving treatment response in HNSCC patients undergoing radiotherapy.
3. To evaluate the effects of yoga intervention in managing quality of life in HNSCC patients undergoing radiotherapy.

Study Method

Subjects:

In this large prospective two arm randomized controlled study, HNSCC patients prescribed to undergoing adjuvant radiotherapy will be recruited from about one hundred comprehensive cancer care centres across the country.

Screening and Recruitment:

HNSCC Subjects to undergo radiotherapy will be enrolled into the Yoga study for improving health and physical activity by their treating oncologists. The study will be subject to IRB approval in each centre. The subjects will be recruited only on providing a written consent to participate in the study and on satisfying the selection criteria.

Selection Criteria:

Inclusion Criteria:

1. (Patients) Diagnosed with a primary HNC and going to receive at least 4 weeks of RT with at least 20 fractions
2. (Patients) ECOG performance status of 2 or lower
3. Patients must be (1) at least 18 years old
4. Patients able to read and speak English
5. Patients able to provide informed consent

Exclusion Criteria:

1. (Patients) regularly (self-defined) participated in a yoga practice in the year prior to diagnosis
2. (Patients) cognitive deficits that would impede the completion of self-report instruments as deemed by the clinical team

Randomization & Allocation concealment:
The patients will be randomized to receive yoga intervention or serve as controls in a ratio of 1:1 using block randomization from each centre. The randomization will be done by a third party with no relation to the trial using computer generated random numbers. Allocation concealment will be done using opaque envelopes with group assignments.

Blinding: it is not possible to blind the yoga intervention .however the assessors will be blind to the intervention arms.

Sample Size:
Prevalence of toxicity in head and cancer patients is around 34% (Grade 2-3). Considering Yoga to decrease toxicity by 20% for a large phase III multi-centric trial, the sample size required will be 89 subjects per arm/ centre. Considering 15% dropouts, we will recruit 100 subjects in each arm/ centre. For twenty centres, we will recruit 4000 head and neck cancer subjects.

Study Design:
A prospective two-arm Randomized Controlled trial.

Arms	Assigned Interventions
Experimental: Integrated Yoga Program Participants take part in a six- week Yoga program during the course of their adjuvant radiotherapy.	Behavioural: Yoga plus education and counselling Participants receive yoga sessions up to 5 days per week, based on the patient's schedule, over the course of patients' Radiation Therapy (up to 15 sessions, 45-60 min. each). Yoga sessions audio and video recorded.
Control Group (WLC) Participants receive standard of care adjuvant radiotherapy and counselling and reinforcing social support, managing symptoms etc.	Behavioural: Education and Counselling Patients receive education and counselling about radiotherapy and cancer directed treatment, managing symptoms at home and about lifestyle.

Study Outcomes:
1. Functional assessment of Chronic Illness therapy: Head and Neck:
2. FACT domains include physical well-being, social/family well-being, relationship with doctor, emotional well-being, and functional well-being. The FACT-HN module is a series of additional concerns related to the head and neck region that are written in the same style as the FACT scale questions. FACT-HN scale concerns include oral comfort, breathing, voice, eating, appearance, tobacco, alcohol, and communication. This has good validity and reliability with other scales(40).

3. Head and neck 35: The QLQ-H&N35 is a symptom scale that is responsive to differences between disease status, site and patients with different Karnofsky performance status, and to changes over time(41).
4. FACT Spiritual wellbeing: Two studies were conducted to demonstrate the internal consistency reliability and the convergent validity of the FACIT-SP with other measures of religion and spirituality. Results demonstrate that the FACIT-Sp is a psychometrically sound measure of spiritual well-being for people with cancer and other chronic illnesses. The Cronbach's alpha was 0.88.(42)
5. Adapted from Peterman AH, Fitchett G, Brady MJ, Hernandez L & Cella D. (2002). Measuring spiritual well-being in people with cancer: the Functional Assessment of Chronic Illness Therapy--Spiritual Well-Being Scale (FACIT-SP). Ann Behav Med 24(1),49-58.
6. FACT Patient satisfaction: FACIT TS-patient satisfaction (PS), a measure of patient satisfaction. CFA results were not optimal for a five-factor solution for PS. Internal consistency reliability met psychometric standards (C0.70) for all PS subscales. Construct validity was established for the PS subscales: Physician Communication, Treatment Staff Communication, Technical Competence, Confidence and Trust, and Nurse Communication.(43)
7. Toxicity evaluation by Common Terminology Criteria for reporting Adverse Events (CTCAE) Version 4.
8. The NCI Common Terminology Criteria for Adverse Events is a descriptive terminology, which can be utilized for Adverse Event (AE) reporting. A grading (severity) scale is provided for each AE term.(44)
9. Treatment delays/time to completion of treatment
10. Daily log of Yoga practices
11. Participants feeling about Yoga practices
12. Cost of symptom management during Radiotherapy
13. Response to treatment using RECIST Criteria (1- 3 Month) Assessment of the change in tumour burden is an important feature of the clinical evaluation of cancer therapeutics: both tumour shrinkage (objective response) and disease progression are useful endpoints in clinical trials. We will use a revised version of RECIST criteria (Ver1.1) for evaluation of treatment response following radiotherapy .(45)

<u>Study Intervention:</u>

In this study, we will evaluate the effects of yoga program tailored to reduce the symptoms in HNSCC patients undergoing radiotherapy. The intervention will be tailored to manage radiation-induced symptoms such as fatigue, oral mucositis, Trismus, facial pain, impaired speech articulation, neck stiffness, xerostomia etc. The intervention consists of a series of loosening exercises, breathing exercises, asanas, pranayama, yogic relaxation, and Meditation done over a period of 60 minutes. This will be followed up with advanced practices done once a week such as Cyclic Meditation (postures Interspersed with relaxation while supine) or chanting Om & Maha Mrutyunjaya mantra.

Video CD will be prepared of the yoga module for use by patients to practice at home. The intervention will be imparted by trained yoga therapists and the entire program coordinated by BNYS doctors in each centre.

Statistical Analysis:

Data will be analysed using statistical soft wares. Normality and distribution of the data will be extrapolated. The differences in outcome measures between groups will be assessed using ANCOVA with baseline measure as a covariate. This assessment will be done using intention to treat principle. Regression analysis will be done to evaluate the effects of predictor variables on the outcome measures. Cost effectiveness will be assessed using the direct and indirect costs.

4b.ii) Yoga in Breast Cancer patients

Introduction

Breast Cancer Global Scenario, Demographics and region

Cancer of the breast in women is a major health burden worldwide. It is the most common cause of cancer among women in both high-resource and low-resource settings, and is responsible for over one million of the estimated 10 million neoplasm diagnosed worldwide each year in both sexes(46) It is also the primary cause of cancer death among women globally, responsible for about 375,000 deaths in the year 2000(46).

Breast Cancer Scenario in India

Breast Cancer is rapidly catching up with Cervical Cancer as the most common type of Cancer among urban Indian women. In females, breast cancer was the leading site of cancer in all registries except Barshi with the relative proportion ranging from 19.3% to 27.5%. According to NCRP data, every year 80,000 new cases of Breast Cancer are detected in Indian cities. The disease claims 35,000 lives every year, up by 8 per cent since 1990 today. In 1970, for instance, the incidence of Breast Cancer in India was barely 20 per 1,00,000 urban women. Today, that number has shot up to 29.3 nearly a 50 per cent jump. Among the Parsis in Mumbai, a relatively westernized community in which few women have children and fewer breast-feed them, the incidence rate is higher at 43.8 per 1,00,000 women. Comparatively, in rural areas the incidence is only 8.5. This is still far less than the West, where one out of nine women gets the disease. But urban India is not far behind; the incidence of Breast Cancer is likely to double in the next 10 years(47)

Incidence rates and mortality rates increase dramatically with age(48). Among the less developed nations India stands first in line, factors may be mainly attributed to life style change, western influence and urbanization.

As a consequence of changing exposures to reproductive and nutrition-related determinants over time, women are at increasingly high risk of breast cancer, with incidence rates increasing in most countries and regions of the world in the past few decades. Majority of the breast cancers present at an advanced stage (50-60%). This is primarily because of lack of awareness and screening (around 16.5%). The advancements in the treatment of breast cancer has considerably increased the life span, and patients who eventually die are living longer between diagnosis and death enduring cancer symptoms and treatment side effects for a longer time(49) Patients with breast cancer normally receive multimodal treatment over a long period of time(50,51) therefore, it is also necessary to take care of the related morbidity that accumulates over time. Most women with breast cancer usually undergo surgery and 4-6 months of

chemotherapy followed by 6 weeks of radiotherapy. They then receive palliative radiation and chemotherapy if the cancer relapses or reoccurs. A cancer diagnosis and treatment is a particularly potent stressor that is associated with physiological changes, the fear of death, social isolation and low self-esteem due to mastectomy, progression or recurrence of disease, treatment related distress, changes in QOL and social relationships, and an overall loss in sense of control(52,53).Breast cancer is a profoundly stressful disease posing both physical and psychological threats to the patient. Breast cancer patients confront a cascade of stressors, including the diagnosis itself, ongoing intrusive medical procedures and severe side effects of treatment, and a variety of personal, psychological, and physical losses(54,55). Such psychological distress and morbidity following diagnosis and treatment in early breast cancer patients affects about 80% of the patients during initial stages of their treatment(56–59).

However, the psychological impact of the diagnosis and women's emotional responses vary considerably depending on the patient's psychological make-up and coping abilities, and the availability of emotional support. Treatment regimens for breast cancer can pose serious side effects for these patients such as loss of breast, infertility, altered sexual functioning, hair loss, fatigue, nausea and vomiting, pain, infections and low blood counts, which grossly affect the patients overall quality of life (QOL)(60).

Fear and anxiety associated with invasive treatment procedures, sexual dysfunction secondary to surgery and radiation and problems associated with extended hospital care and aggressive medical treatment are among the most common treatment related side effects observed in cancer patients. These stress perceptions coupled with cancer-related intrusive thoughts, age, sociodemographic characteristics and financial concerns along with the tendency towards negativity (neuroticism) may conspire to heighten a women's risk for psychologic distress which in turn can worsen the treatment related symptoms such as nausea and vomiting, pain and psychologic distress. This treatment related distress can manifest as anxiety or depressive disorders in some of these cancer patients leading to a state of heightened helplessness/hopelessness, lack of will to survive, loss of control over ones lives, change in attitude towards cancer and survival and decrease in threshold for pain and discomfort, and low self esteem leading to lowered quality of life. Studies have also shown that such a state of mind can lead to sleep disturbances, poor antitumor immune response, decrease in overall and disease free survival with early relapse /recurrence and heightened distress.

Both, treatment related side effects and associated distress can act as potent short term and long term stressors constantly influencing patients to make lifestyle changes to cope and adjust with these problems and seek supportive care. However, the choice to accept the cancer diagnosis and live with it making necessary changes in their lives is left to the decision of cancer patients.

Evidence from research studies have shown complementary approaches such as Yoga is beneficial in reduce affective states such as anxiety, depression and perceived stress, reducing treatment related distress and toxicity such as fatigue, sleep disturbances, chemotherapy induced nausea and vomiting, constipation, speech problems and pain. Research studies from CCRYN funded studies have also shown Yoga to modulate antitumor and anti-inflammatory immune responses (TNF alpha, NK cell counts) following surgery(61,62), reduce genotoxic stress (DNA damage following adjuvant radiotherapy)(63) and normalize stress hormones such

as salivary cortisol thus modulating the psychoneuroendocrinoimmune axes(64). These studies have helped establish the stress reduction benefits of yoga through its influence on the hypothalamopituitary adrenal axes. Yoga has been widely used by cancer patients world over in oncology practice to allay distress and reduce symptom burden in cancer patients. Recent studies have evaluated the putative mechanisms of yoga intervention. These are with respect to immune modulation such as decrease in inflammatory cytokines(65), down regulation of inflammatory genes, improved antitumor immune response and reduction in stress hormones such as cortisol(66). Large randomized phase III trials have shown yoga to be a cost effective intervention in reducing treatment related distress, symptom burden and improving quality of life in western countries(67,68).

Aims and Objectives

Aim

To evaluate the effectiveness and efficacy of yoga intervention in Breast Cancer patients undergoing radiotherapy

Objectives

1. To evaluate the effects of yoga in reducing treatment related toxicity and symptoms in Breast Cancer patients undergoing radiotherapy/ chemoradiation.
2. To evaluate the efficacy of yoga intervention in terms of reducing treatment delays, reducing hospitalization and medication costs for managing treatment related symptoms and improving treatment response in Breast Cancer patients undergoing radiotherapy.
3. To evaluate the effects of yoga intervention in managing quality of life in Breast Cancer patients undergoing radiotherapy.

Study Method

Subjects:

In this large prospective two arm randomized controlled study, Breast Cancer patients prescribed to undergoing adjuvant radiotherapy will be recruited from about one hundred comprehensive cancer care centers across the country.

Screening and Recruitment:

Breast Cancer Subjects to undergo radiotherapy will be enrolled into the Yoga study for improving health and physical activity by their treating oncologists. The study will be subject to IRB approval in each center. The subjects will be recruited only on providing a written consent to participate in the study and on satisfying the selection criteria.

Selection Criteria

Inclusion Criteria:

1. (Patients) Diagnosed with a primary Breast Cancer and going to receive at least 6 weeks of RT with at least 30 fractions
2. (Patients) ECOG performance status of 2 or lower
3. Patients must be (1) at least 18 years old
4. Patients able to read and speak English

5. Patients able to provide informed consent

Exclusion Criteria:

1. (Patients) regularly (self-defined) participated in a yoga practice in the year prior to diagnosis
2. (Patients) cognitive deficits that would impede the completion of self-report instruments as deemed by the clinical team

Randomization & Allocation concealment

The patients will be randomized to receive yoga intervention or serve as controls in a ratio of 1:1 using block randomization from each center. The randomization will be done by a third party with no relation to the trial using computer generated random numbers. Allocation concealment will be done using opaque envelopes with group assignments.

Blinding: it is not possible to blind the yoga intervention. However, the assessors will be blind to the intervention arms.

Sample Size

Based on our earlier study that has shown yoga to reduce symptoms in breast cancer patients undergoing radiotherapy on EORTC Qol C30. The mean effect size for reduction in symptoms (Pain, fatigue, insomnia, dyspnoea) was 0.61. Considering an alpha of 0.05 and 80% power for a two group assignment we will need a sample size of 44 patients in each arm. Considering 15% dropouts we will recruit 50 patients in each arm/ center. For 20 centers we will recruit 2000 patients for the study.

Study Design

A prospective two-arm Randomized Controlled trial.

Arms	**Assigned Interventions**
Experimental: Integrated Yoga Program Participants take part in a six- week Yoga program during the course of their adjuvant radiotherapy.	Behavioural: Yoga plus education and counselling Participants receive yoga sessions up to 5 days per week, based on the patient's schedule, over the course of patients' Radiation Therapy (up to 15 sessions, 45-60 min. each). Yoga sessions audio and video recorded.
Control Group (WLC) Participants receive standard of care adjuvant radiotherapy and counselling and reinforcing social support, managing symptoms etc.	Behavioural: Education and Counselling Patients receive education and counselling about radiotherapy and cancer directed treatment, managing symptoms at home and about lifestyle.

Study Outcomes:

1. Functional assessment of Chronic Illness therapy: Breast Cancer
2. Therapy-Breast (FACT-B) version 3, a well validated multi-dimensional self-report questionnaire with subscales measuring physical, social, emotional, and functional well-

being, relationship with doctor, and breast cancer concerns. The FACT-B has a 5 point Likert-type response scale. It has good psychometric properties, discriminates well between clinically distinct groups, and is responsive to change.(69)

3. EORTC QLCBreast: Questionnaire measuring the quality of life in breast cancer patients and the conceptual and methodological issues underlying the construction of the questionnaire are described by its pioneering authors in detail elsewhere [7]. It incorporates two functional scales (body image, and sexual functioning) and three symptom scales (arm symptoms, breast symptoms, and systematic therapy side effects). The remaining items assess sexual enjoyment and shock due to hair loss. (70)
4. FACT Spiritual wellbeing: Two studies were conducted to demonstrate the internal consistency reliability and the convergen validity of the FACIT-Sp with other measures of religion and spirituality. Results demonstrate that the FACIT-Sp is a psychometrically sound measure of spiritual well-being for people with cancer and other chronic illnesses. The cronbachs alpha was 0.88.(42)
5. FACT Patient satisfaction: FACIT TS-patient satisfaction (PS), a measure of patient satisfaction. CFA results were not optimal for a five-factor solution for PS. Internal consistency reliability met psychometric standards (C0.70) for all PS subscales. Construct validity was established for the PS subscales: Physician Communication, Treatment Staff Communication, Technical Competence, Confidence and Trust, and Nurse Communication.(43)
6. Toxicity evaluation by Common Terminology Criteria for reporting Adverse Events (CTCAE) Version 4.
7. The NCI Common Terminology Criteria for Adverse Events is a descriptive terminology which can be utilized for Adverse Event (AE) reporting. A grading (severity) scale is provided for each AE term.(44)
8. Treatment delays/time to completion of treatment: We will assess
9. Daily log of Yoga practices:
10. Participants feeling about Yoga practices:
11. Cost of symptom management during Radiotherapy:
12. Response to treatment using RECIST Criteria (1- 3 Month) Assessment of the change in tumour burden is an important feature of the clinical evaluation of cancer therapeutics: both tumour shrinkage (objective response) and disease progression are useful endpoints in clinical trials. We will use a revised version of RECIST criteria (Ver1.1) for evaluation of treatment response following radiotherapy .(45)

Study Intervention

In this study we will evaluate the effects of yoga program tailored to reduce the symptoms in Breast Cancer patients undergoing radiotherapy. The intervention will be tailored to manage radiation induced symptoms such as fatigue, lymphedema, arm pain etc. The intervention consists of a series of loosening exercises, breathing exercises, asanas, pranayama, yogic relaxation, and Meditation done over a period of 60 minutes. This will be followed up with advanced practices done once a week such as Cyclic meditation (postures Intersped with relaxation while supine) or chanting Om &MahaMrutyunjaya mantra.

Video Cds will be prepared of the yoga module for use by patients to practice at home. The intervention will be imparted by trained yoga therapists and the entire program coordinated by BNYS doctors in each center.

Statistical Analysis:
Data will be analysed using statistical soft wares. Normality and distribution of the data will be extrapolated. The differences in outcome measures between groups will be assessed using ANCOVA with baseline measure as a covariate. This assessment will be done using intention to treat principle. Regression analysis will be done to evaluate the effects of predictor variables on the outcome measures.

4b.iii) Yoga in Cervical Cancer patients

Introduction

Ca Cervix- Global Scenario
Cervical Cancer, a largely preventable disease is one of the most common cancers in women especially in underdeveloped and developing countries.(71) Worldwide, cervical cancer was the fourth most common cancer among females in 2012. There were an estimated 528 000 new cases of cervical cancer, of which around 85% occurred in less developed regions. Around 266 000 females died of cervical cancer, accounting for 7.5% of all female cancer deaths. About 87% of cervical cancer deaths occurred in the less developed regions.(72)

Ca cervix- Indian Scenario
Every year in India, 122,844 women are diagnosed with cervical cancer and 67,477 die from the disease. India has a population of 432.2 million women aged 15 years and older who are at risk of developing cancer. It is the most common cancer in women aged 15–44 years. India also has the highest age standardized incidence of cervical cancer in South Asia at 22, compared to 19.2 in Bangladesh, 13 in Sri Lanka, and 2.8 in Iran. .(73)

Cervical cancer- Risk factors, Symptoms and Treatment
Cervical cancer is an important cause of early loss of life as it affects relatively young women and it presents clinically as bleeding per vagina, Leucorrhoea with or without foul smell, Dyspareunia and backache(74). Risk factors include exposure to human papilloma virus and other sexually transmitted infections, smoking, younger age at first intercourse and at first pregnancy, high parity, long term use of oral-contraceptives, malnutrition and immune-system dysfunction(75,76)

The most common treatment option includes Surgery and Concurrent Chemo-Radiotherapy. Adjuvant Radiotherapy is given to patients at intermediate risk of recurrence.(74) Patients in advanced stage of disease and at high risk of recurrence are also given brachytherapy along with the radiotherapy and concurrent chemotherapy.(77)

The treatment toxicity and its implications on quality of life
The treatment of cervical cancer with chemo-radiotherapy brings along with it certain toxicity in patients undergoing treatment. Physical, physiological and psychological changes are seen in women with cervical cancer due to disease per se and also due to the implications of treatment

administered. The most common adverse effects are diarrhoea, malaise, fatigue, nausea, hair loss etc. Haematological toxicity includes anaemia, thrombocytopenia and neutropenia and related symptoms. Few dermatologic changes like dermatitis, ulceration and desquamation are also seen.(78,79) Apart from these side effects, there are other major complications involved like urological complications (hypocontractility of the bladder, detrusor over activity, incontinence, low-compliance bladder, fistula and hydronephrosis), cervical necrosis, damage to the pelvic girdle post radiation.(80–83)Women who have been treated for cervical cancer have persistent vaginal changes that compromise sexual activity and result in considerable distress.(84) The chemo-radiotherapy have left women burdened by infertility, negative body image, and feeling flawed as a woman and sexually undesirable. Unfortunately, these concerns are rarely voiced and addressed, as patients often feel uncomfortable and embarrassed. (85) The disease per se and the treatment toxicity has affected the quality of life of ca cervix patients and resulted in immense psychological distress. Similarly, cervical cancer survivors also reported that they had greater difficulty with social and emotional well-being, sexual discomfort, and gynaecologic symptoms compared with the other women.(85,86)

Psychological stress, physical symptoms, general fitness and social support influence the treatment time and may cause treatment delay.(85) Treatment delay is detrimental to pelvic control(87) and this along with persistent distress results in poor prognosis. Clinical and epidemiological studies over the last 30 years have identified psychosocial factors including stress, chronic depression and lack of social support as risk factors for cancer progression. The use of complementary and alternative medicines (CAM) like herbal supplements, Acupuncture/ Acupressure and yoga among women with gynaecologic cancer is becoming increasingly popular. (88) Yoga is a 'mind-body' exercise, a combination of physical poses with breathing and meditation. It is proven to be very effective in combating side effects of cancer treatments like fatigue(89) nausea and vomiting(90). It has proven itself in improving reproductive health.(91) More than anything yoga is very effective in calming down the mind, improving sleep quality, reducing the psychological distress, depression and anxiety states and improving the quality of life.(88,92–94)

Aims and Objectives

Aim

To evaluate the effectiveness and efficacy of yoga intervention in Cervical Cancer patients undergoing radiotherapy

Objectives

1. To evaluate the effects of yoga in reducing treatment related toxicity and symptoms in Cervical Cancer patients undergoing radiotherapy/ chemo radiation.
2. To evaluate the efficacy of yoga intervention in terms of reducing treatment delays, reducing hospitalization and medication costs for managing treatment related symptoms and improving treatment response in Cervical Cancer patients undergoing radiotherapy.
3. To evaluate the effects of yoga intervention in managing quality of life in Cervical Cancer patients undergoing radiotherapy.

Study Method

Subjects:
In this large prospective two arm randomized controlled study, Cervical Cancer patients prescribed to undergo primary/ adjuvant radiotherapy will be recruited from about one hundred comprehensive cancer care centres across the country.

Screening and Recruitment:
Cervical Cancer Subjects to undergo radiotherapy will be enrolled into the Yoga study for improving health and physical activity by their treating oncologists. The study will be subject to IRB approval in each centre. The subjects will be recruited only on providing a written consent to participate in the study and on satisfying the selection criteria.

Selection Criteria:
Inclusion Criteria:

1. (Patients) Diagnosed with a primary Cervical Cancer and going to receive at least 4 weeks of RT with at least 20 fractions
2. (Patients) ECOG performance status of 2 or lower
3. Patients must be (1) at least 18 years old
4. Patients able to read and speak English
5. Patients able to provide informed consent

Exclusion Criteria:

1. (Patients) regularly (self-defined) participated in a yoga practice in the year prior to diagnosis
2. (Patients) cognitive deficits that would impede the completion of self-report instruments as deemed by the clinical team

Randomization & Allocation concealment:
The patients will be randomized to receive yoga intervention or serve as controls in a ratio of 1:1 using block randomization from each centre. The randomization will be done by a third party with no relation to the trial using computer generated random numbers. Allocation concealment will be done using opaque envelopes with group assignments.

Blinding: it is not possible to blind the yoga intervention .however the assessors will be blind to the intervention arms.

Sample Size:
Prevalence of toxicity in Cervical cancer patients is around 51.3% (Grade 2-3). Considering Yoga to decrease toxicity by 20% for a large phase III multicentre trial, the sample size required will be 102 subjects per arm/ centre. Considering 10% dropouts, we will recruit 112 subjects in each arm/ centre. For ten centres, we will recruit 2240 cervical cancer subjects.

Study Design:
A prospective two arm Randomized Controlled trial.

Arms	Assigned Interventions

Experimental: Integrated Yoga Program Participants take part in a six- week Yoga program during the course of their adjuvant radiotherapy.	Behavioural: Yoga plus education and counselling Participants receive yoga sessions up to 5 days per week, based on the patient's schedule, over the course of patients' Radiation Therapy (up to 15 sessions, 45-60 min. each). Yoga sessions audio and video recorded.
Control Group (WLC) Participants receive standard of care adjuvant radiotherapy and counselling and reinforcing social support, managing symptoms etc.	Behavioural: Education and Counselling Patients receive education and counselling about radiotherapy and cancer directed treatment, managing symptoms at home and about lifestyle.

Study Outcomes:

1. FACT Cx: FACT-Cx is the FACT-G plus a cervix cancer-specific subscale. FACT-G is a 27-item self-report QoL measure developed and validated with cancer patients and designed for clinical trials. There are four subscales in the FACT-G: Physical Well Being (PWB) with seven items, Social Well-Being (SWB) with seven items, Emotional Well Being (EWB) with six items, and Functional Well-Being (FWB) with seven items. The cervix cancer subscale (CCS) contains 15 items. Each item is scaled as 0=not at all, 1=a little bit, 2=somewhat, 3=quite a bit, and 4=very much. A subscale scale score was calculated by summating each item score. Each subscale produces a separate score which can be summed into one total QoL score. A high score reflects better QoL(95,96).
2. FACT Spiritual wellbeing: Two studies were conducted to demonstrate the internal consistency reliability and the convergen validity of the FACIT-Sp with other measures of religion and spirituality. Results demonstrate that the FACIT-Sp is a psychometrically sound measure of spiritual well-being for people with cancer and other chronic illnesses. The Cronbach's alpha was 0.88.(42)
3. FACT Patient satisfaction: FACIT TS-patient satisfaction (PS), a measure of patient satisfaction. CFA results were not optimal for a five-factor solution for PS. Internal consistency reliability met psychometric standards (C0.70) for all PS subscales. Construct validity was established for the PS subscales: Physician Communication, Treatment Staff Communication, Technical Competence, Confidence and Trust, and Nurse Communication.(43)
4. Toxicity evaluation by Common Terminology Criteria for reporting Adverse Events (CTCAE) Version 4.
5. The NCI Common Terminology Criteria for Adverse Events is a descriptive terminology which can be utilized for Adverse Event (AE) reporting. A grading (severity) scale is provided for each AE term.(44)
6. Response to treatment using RECIST Criteria (1- 3 Month) Assessment of the change in tumour burden is an important feature of the clinical evaluation of cancer therapeutics: both tumour shrinkage (objective response) and disease progression are useful endpoints in clinical trials. We will use a revised version of RECIST criteria (Ver1.1) for evaluation of treatment response following radiotherapy .(45)
7. Treatment delays/time to completion of treatment:

8. Daily log of Yoga practices:
9. Participants feeling about Yoga practices:
10. Cost of symptom management during Radiotherapy:

Study Intervention:

In this study, we will evaluate the effects of yoga program tailored to reduce the symptoms in Cervical cancer patients undergoing radiotherapy. The intervention will be tailored to manage radiation induced symptoms such as fatigue, oral mucositis, Trismus, facial pain, impaired speech articulation, neck stiffness, xerostomia etc. The intervention consists of a series of loosening exercises, breathing exercises, asanas, pranayama, yogic relaxation, and Meditation done over a period of 60 minutes. This will be followed up with advanced practices done once a week such as Cyclic meditation (postures interspersed with relaxation while supine) or chanting Om & Maha Mrutyunjaya mantra.

Video CDs will be prepared of the yoga module for use by patients to practice at home. The intervention will be imparted by trained yoga therapists and the entire program coordinated by BNYS doctors in each centre.

Statistical Analysis:

Data will be analysed using statistical soft wares. Normality and distribution of the data will be extrapolated. The differences in outcome measures between groups will be assessed using ANCOVA with baseline measure as a covariate. This assessment will be done using intention to treat principle. Regression analysis will be done to evaluate the effects of predictor variables on the outcome measures. Cost effectiveness will be assessed using the direct and indirect costs.

5) Timelines of Project Implementation

AIMS	ACTIVITY	TIMELINES in Months					
		0-2	3	6	9	12	16
Aim 1	Awareness						
	To promote Awareness, Education and Primary Prevention						
	Screening camps in 100 districts						
Aim 2	Accessibility						
	To promote wellness and healthy Lifestyle						
	Conduct community health camps						
Aim 3	To reduce treatment related side effects and make cancer care more affordable.						
	3 RCT s, Head and Neck cancer, Breast Cancer and Cervical Cancer						
	Identification of Study Centers						
	Recruitment and training of project Personnel						
	Screening and Recruitment of Study Subjects						
	Data Collection Pre						
	Data Collection Post						
	Data Analysis						
	Report						

6) Consolidated Budget for AYUSH in oncology

1. Screening, Awareness and Education	-
1a. Budget for Screening (Education and Awareness)	₹ 960,884,000.00
1b. Budget for the Wellness Promotion	₹ 28,000,000.00
1c. Budget for Yoga and Tobacco De-Addiction Study	₹ 2,520,000.00
1d. Budget for AYUSH and Tobacco De-Addiction Study	₹ 2,720,000.00
2. Evidence Generation	-
2a. Budget for Side effect Reduction & improving cancer care affordability and Randomized controlled trials in Yoga for Oncology	₹ 150,416,000.00
2b. Budget for the Mechanism of action study (Centre of Excellence in AYUSH and Oncology)	₹ 71,890,000.00
3. Budget for Integrated Palliative care training:	-
3a. AYUSH workshop at IAPCON 2018/2019	₹ 2,415,000.00
3b. International Consultative Meet on Palliative Oncology	₹ 2,400,000.00
3c. IAPC Training of AYUSH Doctors	₹ 40,200,000.00
3d. IAPC Training of Yoga therapists	₹ 2,340,000.00
3e. Budget for Palliative Care Research Studies in AYUSH	₹ 65,500,000.00
3f. Budget for AYUSH Palliative care centres	₹ 156,000,000.00
Total	**₹ 1,485,285,000.00**
Contingency	₹ 119,152,500.00
Institutional Overheads	₹ 178,234,200.00
Total	**₹ 1,782,671,700.00**

Deliverables:

S.NO	ICAP PROGRAM	DELIVERABLES
1	**SCREENING**	
	1	Awareness, education and early detection of cancers
	2	Screening of 2 crore population across 100 districts
	3	Involvement of NGOs, Yoga institutions, Medical colleges, universities, Oncology centers etc in the initiative
	4	Philip to NHM s program on early detection of cancer
	5	Awareness on tobacco illeffects
	6	Education on Hypertension, CVD, Stroke, diabetes, obesity and cancer
	7	Use of medi, street plays and advt on awareness and education
2	**AWARENESS &YOGA LIFESTYLE**	
	1	Yoga based community programs to promote healthy lifestyle
	2	Yoga based community programs to promote tobacco and alcohol deaddiction
	3	
3	**RCT on YOGA in Breast, CX, Head and neck cancer**	
	1	Evaluating yoga module for breast cancer, cervix, and head and neck cancer patients
	2	Reduction in cancer treatment related toxicity
	3	Evaluating cost effectiveness of yoga intervention

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7) Appendix I: Minutes of Meetings of the Committee for Integrated Cancer Program

7a) Minutes of the First Meeting held on 24/08/2017

Agenda for the First Meeting on Yoga and Integrative Oncology

1. Welcome note by Dr HR Nagendra
2. Welcome note by Dr Ishwar Acharya
3. Presentation of the objectives of the proposal by Dr Raghavendra Rao
4. Discussion on Aims and Objectives
    - AIM 1: To promote Awareness, Education and Primary Prevention
    - AIM 2: To promote wellness and healthy Lifestyle
    - AIM 3: To reduce treatment related side effects and make cancer care more affordable.
    - AIM 4: To improve access to Palliative care Services and Integrate AYUSH into Oncology Mainstream
5. Holding IDY 2017 :Yoga and Oncology meeting of ministry of AYUSH in 2nd Indian Cancer Congress on Nov 8th-9th – Adopting resolution
6. Addition points for discussion if any
7. Closing Remarks: Dr Ishwar Acharya
8. Sign off on Minutes of meeting

Minutes of meeting on Yoga and Oncology

Date: 24/08/2017

Venue: Prashanthi kuteeram, SVYASA, JIGANI

Presided By: Dr HR Nagendra

Secretary/ Convenor: Dr Ishwar N Acharya

Members present: Dr Nagarathna, Dr Raghavendra, Dr Ravi Mehrotra, Dr RK Grover, Dr Ramesh Bilimagga, Dr Kumara swamy, Dr Vinoda Kochupillai, Dr Vishal Rao, Dr Navin Salins, Dr Nita Nair, Dr Ravi Nayar, Dr Narendra Bhatt, Dr Ramakrishna BR, Dr Vetrivendan,

In Absentia: Dr Bharath Agarwal, Dr LorenzoCohen, Dr Kashinath, Dr Sen Pathak, Dr Rajendra Badwe, Dr Ajaikumar, Dr Gopinath KS, Dr Manoj Nesari.

Screening and primary prevention

1. Screening and primary prevention to be done based on National cancer screening framework document . Dr Ravi from NICPR will provide the document
2. Training to be done based on ECHO program (NICPR) training modules prepared to be shared and facilitated by NICPR
3. Training of SDM personnel (1200 subjects) to be roped in training for screening imparted to them by NICPR
4. Screening for 1.8 lakh population screened in SDM program to be done again with a new checklist and mobile app. Patients who are suspicious to be sent to nearest cancer center for further diagnosis. Basic screening and POI mapper to be used.
5. National cancer grid to be involved for further diagnosis and treatment
6. To evaluate the risk based screening tool in population
7. Training of AYUSH doctors in screening. Fellowship in preventive oncology from NICPR- Duration and structure of course to be brought out
8. Training of local resources for screening by master trainers. Training of master trainers to be done.
9. Pilot studies on GDV, Naditarangini, Iris Diagnosis and other diagnostic methods such as urine examination in siddha to be correlated in validation studies using PETCT in cancer and non cancer patients. Proposals to be written for individual investigations

Randomized controlled Trial

1. It was decided to do 3 randomized controlled trials 1. Breast Cancer 2. Ca Cx and 3. Head and Neck cancer in patients undergoing adjuvant / primary radiotherapy. This would be conducted across 20 centers . Detailed protocols of these studies with study centers, investigators and budget to be prepared.
2. Dr Nita Nair expressed reservations as Breast / radiotherapy was already done . She proposed a long term study with followup. However HRN emphasised that the protocol needs to be implemented and done within one year and hence the design.
3. Dr Arun Gupta, Clinical Head DABUR suggested that Clinical trials should be done with global standards, with proper monitoring, using CRM, Database etc. The studies should be done in consonance with ICH GCP guidelines with ethics committee approval.
4. The studies will be submitted to the National and international advisory committee for suggestions and critique
5. HCG centers, AIIMS, DSCI, TMH will presently be involved as active participating centers in these RCTs.
6. A Translational component may be added for these studies based on suggestions by investigators
7. Dr Vinoda kochupillai suggested mechanism of action studies
8. Dr Raghavendra Suggested that CCRYN may set up one Center of Excellence in yoga and oncology (at HCG KR Rd, Bangalore) and 3 joint collaborating centers (DSCI,TMH, AIIMS)

Palliative care training

1. Dr Naveen Salins emphasised on palliative care training for AYUSH doctors.

2. A fellowship or certification in palliative care training to be given for AYUSH doctors.
3. These AYUSH doctors will undergo training via distance education with compulsory internship for 1 month in a tertiary cancer care hospital in department of palliative medicine
4. Modalities of course curriculum, fellowship certification etc to be worked out
5. AYUSH handbook module for palliative care to also be developed
6. Govt permission for AYUSH doctors to prescribe morphine and its derivatives
7. Ayurvedic preparations equivalent to morphine and cannabis to be researched
8. Effects of ayurvedic formulations in palliative care to be researched before implementation. Low cost intervention approaches to be given preference.

General

1. International advisory board to be identified among the delegates to ICC
2. National advisory board to be formulated
3. Preliminary invites to be sent to new members after finalization of advisory board by the committee
4. To form sub committees and leaders for Primary prevention and Screening, palliative care &Training, Randomized controlled studies, Mechanism of action studies/ Translational research
5. To evaluate role of yoga in tobacco deaddiction. Dr Vishal Rao and Dr Raghavendra Rao to look at its feasibility
6. It was decided to Have Dr Manjunath NK, from SVYASA and Dr Vadiraja HS from CCRYN as members. Dr Vinoda suggested Dr Nisha of AOL for ayurveda

Manuals: Following manuals to be prepared and approved by Committee

1. Cancer Screening framework document: Dr Ravi Mehrotra
2. Palliative care Handbook: Dr Navin Salins
3. AYUSH Hand book for palliative care : Dr Nagarathna, Dr Ishwar, Dr Raghavendra, Dr Vadiraj, , Dr Narendra Bhat, Dr Ramakrishna BR, Dr Sashi Bhushan/ Shastry, Dr Naveen Salins (Training Manual)

FOLLOWING STUDIES TO BE CONDUCTED

1. Correlation of Iris diagnosis with PETCT
2. Correlation of GDV with PET CT
3. Any other diagnostic tests in AYUSH
4. CAM PREVALNECE IN CANCER: NATIONWIDE SURVERY

Following will be the CORE National committee who can be co-opted in all subcommittees

- Dr HR Nagendra,
- Dr Rajesh Kotecha
- Dr Manoj Nesari,
- Dr Ishwar N Acharya
- Dr Nagarathna

- Dr GK Rath
- Dr Ravi Mehrotra
- Dr Manjunath NK
- Dr Raghavendra Rao M
- Dr Gopinath KS
- Dr Navin Salins
- Dr Vadiraja HS

FOLLOWING SUBCOMMITTEES WILL BE FORMED

Position	Prevention and Screening	Randomized Controlled Trials	Palliative Care	Mechanism of action studies
Chairman	Dr Ravi Mehrotra	Dr GK Rath	Dr Navin Salins	Dr Nagarathna
Secretary	Dr Ishwar N Acharya	Dr Ishwar N Acharya	Dr Ishwar N Acharya	Dr Ishwar N Acharya
Members	Dr Vishal Rao	Dr Raghavendra	Dr RK Grover	Dr Vinoda Kochupillai
	Dr Ramesh Bilimagga	Dr Manjunath	Dr Raghavendra	Dr Raghavendra
	Dr Ravi Nayar	Dr Nita Nair	Dr Shashidhar	Dr Vadiraja
	Dr Narendra Bhatt	Dr Gopinath KS	Dr Prasann Shankar	Dr Kumaraswamy
	Dr Vetri Vendan	Dr AjaiKumar	Dr Manoj Nesari	Dr Vishal Rao
	Dr Raghavendra	Dr Arun Gupta	Dr Nagarathna	Dr Ravi Nayar
	Dr Vadiraja HS	Dr Shastry		Dr Rajendra Badwe
	Dr Sashibhushan	Dr Vadiraja HS		Dr RK Grover
	Dr RK Grover	Dr Kumaraswamy		Dr Lorenzo Cohen
	Dr Rajendra Badwe	Dr Nagarathna		Dr Manoj Nesari

	Dr OP Mathur	Dr Rajendra Badwe		Dr Manjunath NK
	Dr Bharath Agarwal	Dr SenPathak		
	Dr Kashinath	Dr Manoj Nesari		
	Dr Manoj Nesari			
	Dr Manjunath NK			
	Dr Nagarathna			

Proposals in Palliative Care, Mechanisms of Action of Yoga to be invited

JOINT COLLABORATING CENTERS

1. To set up joint collaborating centers in Yoga and Naturopathy: Committee will decide on the centers- 4 such centers to be setup with inputs from committee on research
2. Setup Center of Excellence on Yoga: Committee will decide on the institution.

IDY MEETING 2017

IDY YOGA AND ONCOLOGY MEETING TO BE SHIFTED TO 8^{TH}-9^{TH} NOVEMBER 2017 IN 2^{ND} ICC CONFERNECE: CLARKS CONVENTION CENTER. Dr HR Nagendra and Dr Ishwar Acharya will coordinate for the same.

Dr HR Nagendra

7b) Minutes of the Subcommittee meeting on primary prevention

Agenda for the First Subcommittee Meeting on Primary Prevention and Screening

1. Evaluation of national framework document on primary prevention and screening
2. Evaluation of sites for launching screening program
3. Evaluation of training modules for screening program
4. Feasibility of training master field trainers
5. Identification of trainers and field trainees
6. Budget evaluation for screening program
7. Estimation of sample size and geographical area of the program

Minutes of the Meeting

Date: 28/08/2017

Venue: SVYASA, JORBAGH, New Delhi

Presided By: DR H R Nagendra

Secretary/ Convenor: Dr Ishwar N Acharya

Chairperson of Committee: Dr HR Nagendra

Chairman of Subcommittee: Dr Ravi Mehrotra, NICPR

Attended by: Dr HR Nagendra, Dr Ishwar Acharya, Dr Raghavendra Rao, Dr Ravi Tumuluri, Dr Ravi Mehrotra, Dr Narendra Bhatt, Dr Rajesh Grover, Dr Ravi Mehrotra, Dr Roopa, Dr JLN Shastry, Dr Arun, Dr Vadiraja HS

7c)Minutes of the Third meeting of AYUSH and Oncology Program

Agenda for the Third meeting of AYUSH and Oncology program

1. Discussion on naming the integrated cancer program: suggestion from members
2. Discussion on screening and awareness program
3. Presentation of Tobacco cessation program and budget
4. Discussion and Finalization of Yoga modules for RCT in breast, cervix and Head and Neck cancer
5. Finalization of centers for the RCT and study budget
6. Subcommittee presentation and discussion on AYUSH manuals
7. Coopt members suggested by councils into the ayush and Oncology program
8. Discussion on program timelines
9. Presentation of palliative care training program for AYUSH doctors
10. Development of curriculum framework document for PG diploma in Integrated palliative care for doctors and nurses
11. Development of curriculum framework document for certification in integrated palliative care
12. Finalization of timelines and budget

Minutes of 3rd meeting of AYUSH & Oncology Program

Venue: Prashanthi Kuteeram, SVYASA on 7th

Clarks exotica convention Center, Indian Cancer Congress on 8th and 9th November 2017.

The following members were present: Dr HR Nagendra, Dr Manoj Nesari, Dr R Nagarathna, Dr Raghavendra, Dr Vinoda Kochupillai, Dr Naveen Salins, Dr Rajesh Grover, Dr Kumaraswamy, Dr Lorenzo Cohen, Dr Karen Mustian, Dr Susanne Danhauer, Dr Ramaswamy, Dr Senthil Kumar, Dr Arul Amuthan, Dr Narendra Bhatt, Dr Vadiraja HS from CCRYN, Dr Sangeeth from CCRYN

Additional invitees

From CCRS: Dr BG Senthil Kumar, Asst. Prof, National Inst of Siddha, Dr Ramaswamy, DG CCRS

From CCRH: Dr Juhi Gupta, Bhopal, Dr BT Rudresh, Bengaluru, Dr Manchanda, DGCCRH

From CCRAS: Dr Dhiman, DGCCRAS or their representative, Dr Prasann Shankar, IAIM,TDU

Minutes of the Meeting

The members of the committee resolved the following:

Name of the Program

The program to be known as Integrated Cancer Program I-Cap. It was decided to name this committee "AYUSH and Integrative Oncology" instead of only "Yoga and Integrative Oncology"

Development of Integrated Palliative care training program:

Need: Around 30 lakh patients require active palliative care in India.

There are 540 medical teaching AYUSH hospitals, 3000 district hospitals under NAM, 50 hospitals under research councils (total of around 4000 hospitals) Six hundred among them are exclusively teaching hospitals. There are approximately 56000 beds in AYUSH hospitals in India. Suggestion was to allocate certain percentage of beds in ayush hospitals in each district for palliative care and train doctors in these hospitals in Integrated Palliative care.

i. Dr HR Nagendra suggested that the course certificate and PG Diploma can be approved and recognised through IGNOU. Suggested 2 weeks to complete course curriculum on IGNOU format : Dr Naveen Salins and Dr Raghavendra
ii. Dr Manoj Nesari suggested to have the course curriculum approved by health varsities rather than IGNOU as this will add value to the course.
iii. Development of curriculum framework document for PG diploma in Integrated palliative care for doctors and nurses for IGNOU
iv. Development of curriculum framework document for certification in integrated palliative care for IGNOU- 3 or 6 month certification to be decided
v. The course curriculum to be prepared and circulated to members of subcommittee who will approve and send the same to the core committee for discussion. Dr Naveen salins to convene a meeting on the same

Randomized control Trials in Yoga

It was decided to have 3 multiinstitutional randomized controlled studies in Yoga on breast cancer, cervix cancer, head and neck cancer. the following suggestions were given by members:

1. To have an active comparator arm with yoga
2. To have a long term followup to check feasibility and long term outcomes
3. To look at cost benefit analysis

4. To evolve mechanism of action studies with subset of the population
5. To do studies in patients with vulnerabilities eg. . Insomnia, depression
6. To align studies with NCI NCORP priorities. Dr Susan Danhauer shared the strategy and priority document
7. To do small pilot and develop Indo US collaboration for large scale studies. Ministry of AYUSH to fund Yoga therapists in US and studies to be carried out Pan US and Pan India to test cultural differences
8. Dr Karen Mustian and Dr Susan to be international members in the committee.
9. DST and NC collaboration to have high impact projects was also discussed and high impact projects to be developed on same lines.
10. Pilot studies to be done in 2-3 locations in india- feasibility, data from randomization to calculate effect sizes, PLUS LIMITED SITE PILOT IN NCORP for applying for large scale studies. Studies done using PET FmRI, FINRS, Polysomnography, Gene expression etc.

<u>To do similar RCT in Ayurveda, siddha, and homeopathy in cancer</u>

i. CCRAS said they have 3 ongoing research trials in Oncology and the same to be shared with the committee.
ii. All councils to identify priority areas for testing their medications/formulations in certain conditions such as anaemia, fatigue, neuropathy, constipation, oral mucositis, skin changes following radiation etc. and develop RCT protocols for the same for funding.
iii. Dr Raghavendra to share draft of Yoga protocols with all councils. Dr Raghavendra to help with design and protocol framework document for each of the studies
iv. All subcommittee heads to present the protocols for discussion in next meeting
v. The protocols can be both preclinical and clinical.
vi. Subcommittees for research to be formed by all councils

<u>Tobacco cessation studies</u>

- Policy decisions on tobacco – to have ayush ministry and other ministries work on the policy decisions to make tobacco expensive: Dr Vishal Rao to suggest action framework
- Train ASHA workers in yoga module
- Home remedy kits for withdrawal symptoms –develop from siddha, ayurveda etc.
- To prepare these kits – siddha and ayurveda
- Can ayurveda and siddha find replacement for beeda for tobacco and arecanut
- Sample size for doing the tobacco cessation study
- Councils should deliberate on tobacco cessation strategies and come with a framework document on tobacco cessation
- Tobaccum and calendula in Tobacco cessation to be studied
- Animal studies to evaluate counter medicine for nicotine mimicking behaviours but not having its ill effects to also be evaluated.

<u>Screening for breast oral and cervical cancer:</u>

Dr Raghavendra presented on the breast cancer risk assessment tool developed by NCI. Dr Nita nair suggested that the same risk tool is not valid for Indian population and this needs to be

developed and validated. The development and validation will take a long time as these subjects have to be followed up over 10 years. Suggested to remove screening from the scope of the proposal as it needs expertise, manpower, infrastructure and long term followup to get some conclusive outcomes. Mere risk reduction on these questionnaires don't suffice.

A detailed budget plan to be made and booklet prepared for submission to AYUSH and MOHFW, Govt of India.

It was decided to convene the next meeting at New Delhi on 1st and 2nd December 2017. The venue will be intimated shortly.

It was decided to coopt other members for carrying out the agenda forward by heads of respective subcommittees. These members will be paid Travel and DA by their respective councils. Councils to nominate coordinators for this program to take care of the logistics, coordination of subcommittees and maintaining minutes of meeting.

Members to be added in the committee under Y&N

- Dr Amritanshu Ram, Scientist HCG, amritram@gmail.com
- Dr Divya Kanchibotla, Executive director, SSIAR
- Dr E. Hemanthraj, Chairman, Surgical Oncology, Adyar cancer institute. – sog@cancerinstitutewia.org, ph- 9840014505
- Dr Shashibhushan- Dabur, yogamok, under CCRAS

Dr Nagendra HR,

Chairperson, Yoga and Oncology Committee

7d) Minutes of fourth meeting of AYUSH and Oncology Program

Date: 29/11/2017

Venue: SVYASA, JORBAGH Center

Presided By: Dr HR Nagendra

Attendees: Dr Dhiman (DGCCRAS) Dr Manchanda (DG CCRH), Dr Anl Khurana (DG CCRUM) Dr Ishwar N Acharya (Director, CCRYN) Dr Gazala (research Officer CCRUM), Dr Vadiraja HS (Research Officer, CCRYN), Dr Deepika Saraf (FOR NICPR), Dr Mani (CCRS), (Representative from Bharmakumaris- Dr Lakshmi), Ravi Tumuluri,

Minutes of the meeting

1. Dr Raghavendra presented the minutes of the earlier meeting and appraised the new members on the program components.
2. The members expressed concern on ethical and legal issues in using AYUSH systems of medicine in Oncology care. Dr Raghavendra said that even now a major proportion of cancer patients take recourse to therapies. This should not however be used in adjuvant settings concomitant to Other therapies unless otherwise shown to have no drug interaction effects. All these therapies have to be used in cancer survivor ship

settings following treatment or used palliative care. Legality of prescribing morphines and integrated practice needs to be thought of. Members expressed that it may not be possible to do preclinical similar to allopathy medicine in all settings and AYUSH hospitals would not have infrastructure for same. So it was agreed that only those that have been used routinely and for which evidence exists will be used and preclinical studies may not be warranted in all cases.

3. Members agreed to revisit the cancer-screening questionnaire in consultation with experts.
4. The members agreed to screen 2 crore population in 100 districts for a large impact and assessment of burden
5. The members opined that street plays, videos, awareness programs, tobacco deaddiction, social media, camps IC materials to be prepared for awareness and preventive aspect
6. Major emphasis to be on tobacco/obesity control
7. It was discussed to have all councils spearhead the subcommittees
8. Development of protocols in various systems to be done by following personnel in coordination with Dr Raghavendra. Dr Vadiraj to help facilitate meeting of all subcommittees. Manuals to be prepared in 6 weeks

- For Ayurveda- Dr Ramakrishna
- Siddha- Dr Ramaswamy
- Unani- Dr Khurana/ Dr Ghazala
- Yoga - Dr Vadiraj
- Naturopathy- Dr Prashanth Shetty/ Dr Babina Nandakumar
- Homeopathy- Dr Manchanda/Dr Praveen

9. The committee should evolve a standard protocol for RCT as well as for palliative care.

8) Appendix II: Cancer Screening Form

Integrated Cancer Program

Registration form & Screening Schedule

State		District			Village/Town				Area				Camp Code				Serial No				
									Urban	○	Rural	○									

DP	Demographic Profile	Code Label	Value
DP01	Name of the participant		
DP02	Email-ID		
DP03	Phone No		
DP04	Residential Phone no		
DP05	Age in completed years		
DP06	Sex	Male 1 Female 2	
DP07	Place of residence	Urban 1 Rural 2	
DP08	Marital status	1. Married 2. Unmarried	

		3. Divorcee / Separated 4. Widow / Widower 5. Others (specify if any)	

G	General Information	Code Label	Value
G01	Highest level of education attained	1. No formal schooling 2. Up to primary school 3. Up to high school 4. Up to intermediate 5. Up to university 6. University completed or higher 7. Others (specify if any)	
G02	Which of the following best describes your main work status in the last 12 months?	1. Professional/Executive/ Big business 2. Clerical/ medium business 3. Self-employed/ skilled 4. Unskilled/ landless laborer 5. Homemaker 6. Retired 7. Unemployed (able to work) 8. Unemployed (unable to work) 9. Others(specify if any)	
G03	Do you do any kind of work currently?	No 0 Yes 1	
G04	What was your personal income in the last month?	1. ≥ Rs. 36,017 2. 18,000 – 36,016 3. 14,395 –17,999 4. 8,989 – 13,494 5. 5,387 – 8,988 6. 1,803 – 5,386 7. <1,802	
G05	Is (Are) there any other earning member(s) in your family?	No 0 Yes 1	
G06	What was your household income in the last month?	1. ≥ Rs. 36,017 2. 18,000 – 36,016 3. 14,395 –17,999 4. 8,989 – 13,494 5. 5,387 – 8,988 6. 1,803 – 5,386 7. <1,802	
G07	Not counting yourself, How many other adults (older than 18) live in your household? (Number of members currently sharing the same kitchen)	None 0 1 1 2 2 3 3 4 4 5 5 More than 5 6	

HEA	Medical History Heart	Code Label	Value
	Have you ever had any of the following operations or procedures related to your heart? (circle one answer on each line)		

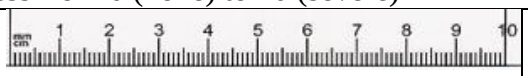
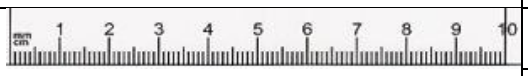
HEA1	Coronary artery bypass surgery (open heart surgery)	No Yes	0 1	
HEA2	Coronary angioplasty ("balloon" heart procedure)	No Yes	0 1	
HEA3	Heart catheterization (Angiogram)	No Yes	0 1	

BCH	**Medical History Breast Cancer**	**Code Label**		**Value**
BCH1	How many of your sisters, daughters or mother had breast cancer?	None 1 2 or more	0 1 2	
BCH2	How many benign breast biopsies have you had? Benign" means no cancer. Have you ever had a biopsy result showing "atypical hyperplasia"? (Not applicable or unknown, No atypical hyperplasia, atypical hyperplasia)	None 1 2 or more	0 1 2	
BCH3	At what age did your menstrual cycles begin?	14 years or later 12-13 years <12 years	0 1 2	
BCH4	Are you likely to undergo regular mammography screening?	No Yes	0 1	
BCH5	Are you taking Tamoxifen?	No Yes	0 1	
BCH6	Does your mammogram show a dense breast tissue? How dense? Risk increases when breasts contain mammographically dense fibro-glandular tissue	Unknown 0% fatty density 1-24% fatty density 25-49% fatty density 50-74% fatty density 75-100% fatty density	0 1 2 3 4 5	
BCH7	Do you drink Alcohol? Risk increases with amount of alcohol consumed. (One beer has 13 grams of alcohol, a glass of wine has 11 grams, and a shot of liquor has 15 grams, on average)	not specified <1.5gms/day <5gms/day <15gms/day <30gms/day <60gms/day 60gms and above)	0 1 2 3 4 5 6	
BCH8	Have you had a breast biopsy showing "lobular carcinoma in situ" (LCIS)? If so, how old were you?	Not Applicable <40 years 40-44 years 45-49 years 50-54 years >55 years	0 1 2 3 4 5	
BCH9	When did you start using birth control pills?	never used BCPs age <20 years age 20-24 years age 25-29 years age 30+ years	0 1 2 3 4	
BCH10	When did you stop using BCPs?	not applicable currently using BCPs stopped 1-4 years ago	0 1 2	

		5-9 years ago 3 10-14 years ago 4 >15 years ago 5	
BCH11	What was your age at first child birth	_____ Years	
BCH12	Did you Breastfeed? For how long?	Not Applicable 0 Yes 1 (_____Months) No 2	

CCH	Medical History Cervical Cancer	Code Label	Value
CCH1	Have you ever been diagnosed with cancer except for non-melanoma skin cancer?	No 0 Yes 1	
CCH2	Have you ever had a hysterectomy? (a medical procedure to take out your uterus, sometimes your ovaries and/or all or part of your cervix)	No 0 Yes 1	
CCH3	Do you smoke cigarettes?	No 0 No but I used to 1 Yes 2 <14 cigarettes/day 3 15 to 25 cigarettes/day 4 >25/day 5	
CCH4	How many sexual partners have you had in your life?	0 0 1-2 1 3 or more 2	
CCH5	How old were you when you had sex?	Not Applicable 0 Younger than 16 1 16 or older 2	
CCH6	Throughout your life, have you regularly used condoms or diaphragms?	No 0 Yes 1	
CCH8	How many times have you given birth?	Never 0 Once 1 Twice 2 3 or more times 3	
CCH9	Have you ever had a sexually transmitted infection (STI) also known as a sexually transmitted disease (STD)? Examples include human papillomavirus virus (HPV), genital herpes, gonorrhea, chlamydia and HIV/AIDS.	No 0 Yes 1 Don't know 2	
CCH10	Have you had a Pap test (also known as a Pap smear) within the last 3 years?	No 0 Yes 1	
CCH11	Have you been vaccinated against HPV (that is, been given Gardasil® or Cervarix®)?	No 0 Yes 1	

CO	Any other disease or complications	Code Label		Value
CO1	Have you ever been told by a health care provider that you have any other disease or complications at present?	No Yes	0 1	
	Details of disease or complications			
C02	Do you now take medication for your other disease or complications?	No Yes	0 1	
C03	What is the name of the other disease or complications for which medication prescribed by your family physician?			
CO4	How many tablets a day do you have to consume for any other disease or complications?	1. 1 tablet at each intake 2. 2 tablets at each intake 3. 3 tablet at each intake 4. >4 tablets at each intake 99 Don 't Know/Not Sure		
CO5	How many times a day do you have to take your medication for any other disease or complications?	1. Once a day 2. Twice a day 3. Three times a day 99 Don 't Know/Not Sure		

ST	Stress	Code Label	Value
	Indicate daily stressors and rate the level of stress you feel form the following sources during THE LAST MONTH. In each case, please indicate your response by placing an "X" on the small ruler and rate the level of stress from 0 (none) to 10 (severe)		
ST1	Work	 'none' 'Severe'	
ST2	Family	 'none' 'Severe'	
ST3	Health	 'none' 'Severe'	
ST4	Financial	 'none' 'Severe'	
ST5	Social	 'none' 'Severe'	
ST6	Other	 'none' 'Severe'	

Tob	Tobacco Use	Code Label		Value
Tob1	Have you smoked at least 100 cigarettes, cigars, pipefuls, bidi or any other tobacco containing products in your lifetime?	No Yes Uncertain	0 1 2	
Tob2	Have you ever smoked daily (= almost every day for at least one year)?	No Yes Uncertain	0 1 2	

Tob3	Do you currently smoke cigarette / bidi or any other tobacco containing products?	No 0 Yes 1	
Tob4	Do you use those products daily?	No 0 Yes 1	
Tob5	On average how many cigarettes, cigars, pipefuls, and bidi do you smoke each day?	1. ≤5 daily 2. 5 to 10 daily 3. 10 to 15 daily 4. 15 to 20 daily 5. >20 daily	
Tob6	How many years have you been smoking?	1. < 6 months 2. 6 mon to 1 yrs 3. 1 to 5 yrs 4. 5 to 10 yrs 5. More than 10 yrs	
	How many pack years have you smoked? Calculated by multiplying the number of packs of cigarettes smoked per day by the number of years the person has smoked.		

STO	**Smokeless Tobacco**	**Code Label**	**Value**
STO1	Have you ever used any smokeless tobacco products? (Pan with tobacco, Gutkha, Khaini, Snuff)	No 0 Yes 1	
STO2	Do you currently use any smokeless tobacco product?	No 0 Yes 1	
STO3	Do you currently use these products daily?	No 0 Yes 1	
STO4	Do you currently use smokeless tobacco on daily basis, less than daily, or not at all?	1. Daily 2. Less than Daily 3. Not at all 4. Don't Know	
STO5	You are consuming this for how many years	1. < 6 months 2. 6 mon to 1 yrs 3. 1 to 5 yrs 4. 5 to 10 yrs 5. More than 10 yrs	

AL	**Alcohol Usage**		
AL01	Have you ever consumed a drink that contains alcohol such as beer, whisky, rum, gin, brandy, or other local products?	No 0 Yes **1**	
AL02	You are drinking for how many years	1. < 6 months 2. 6 mon to 1 yrs 3. 1 to 5 yrs 4. 5 to 10 yrs 5. More than 10 yrs	
AL03	Have you consumed any products in the three months?	No 0 Yes **1**	

AL04	In the past 3 months, how frequently have you had at least one drink?	Once in 3 months 0 At least once a month 1 At least once a week 2 Everyday 3	
AL05	Have you consumed any products in the last month?	No 0 Yes 1	
AL06	In the past one month, how frequently you have been drinking?	On special occasions 1 Only on weekends 2 Once a week 3 3-5 times a week 4 Every day 5	
AL07	On average how many drinks do you have during one day in the last one months?	less than 1 drink 1 1 or 2 drinks 2 3 or 4 drinks 3 5 or 6 drinks 4	
AL08	Type of drink:	1. English/ Hard Drink 2. Desi/ Local 3. Beer 4. Wine	
AL09	How milliliters per day	1. 60 ml 2. 90 ml 3. 180 4. 250 ml 5. 500 or above ml	

DT	**Diet: On weekly basis, how often do you:**		
DT1	Skip breakfast?	Usually / Often 1 Sometimes 2 Rarely / Never 3	
DT2	Eat less than 2 servings of whole grain products or high fiber starches in a day?	Usually / Often 1 Sometimes 2 Rarely / Never 3	
DT3	Eat less than 2 servings of fruit a day? **Serving** = ½ cup or 1 med. fruit or ¾ cup 100% fruit juice.	Usually / Often 1 Sometimes 2 Rarely / Never 3	
DT4	Eat less than 2 servings of vegetables a day? **Serving** = ½ cup vegetables, or 1 cup leafy raw vegetables.	Usually / Often 1 Sometimes 2 Rarely / Never 3	
DT5	Eat or drink less than 2 servings of milk, yogurt, or cheese a day? **Serving** = 1 cup milk or yogurt; 60 grams cheese.	Usually / Often 1 Sometimes 2 Rarely / Never 3	
DT6	Eat more than 250 grams (see sizes below) of meat, chicken, turkey or fish per day? Note: 100 grams of meat or chicken is the size of a deck of cards or ONE of the following: 1 regular hamburger, 1 chicken breast or leg (thigh and drumstick), or 1 pork chop.	Usually / Often 1 Sometimes 2 Rarely / Never 3	
DT7	Eat fried foods such as fried	Usually / Often 1	

	chicken, fried fish, French fries, chips, Samosa, Kachori, Bonda or Bhajji?	Sometimes 2 Rarely / Never 3	
DT8	Eat regular potato chips, nacho chips, corn chips, baked food typically made from flour, regular popcorn, nuts, and air-popped popcorn?	Usually / Often 1 Sometimes 2 Rarely / Never 3	
DT9	Eat sweets like cake, cookies, pastries, donuts, muffins, chocolate and candies more than 2 times per day.	Usually / Often 1 Sometimes 2 Rarely / Never 3	
DT10	Drink ½ litre or more of non-diet soda, or fruit drink / punch a day?	Usually / Often 1 Sometimes 2 Rarely / Never 3	
DT11	Your staple food	1. Rice 2. Ragi 3. Wheat 4. Bajra 5. Jowar 6. Maize 7. Other	

PA	**Physical activity: These are some questions about your physical activity during last one month**.		
PMI1	How many days do you go for a mild activity that causes no increases in breathing or heart rate like walk at a slow or normal pace?	None 0 Once a month 1 2 to 3 times a month 2 Once a week 3 2 to 3 times a week 4 4 to 5 times a week 5 Every day 6	
PMI2	On average, how many minutes of mild activity each day?	None 0 At least 10 minutes 1 10 – 30 minutes 2 30mins - 1hr 3 1hr - 1.5hrs 4 >1.5hrs 5	
PMO1	How many days do you go for moderate-intensity activity that causes small increases in breathing or heart rate such as brisk walking [or carrying light loads, cycling, swimming, volleyball]?	None 0 Once a month 1 2 to 3 times a month 2 Once a week 3 2 to 3 times a week 4 4 to 5 times a week 5 Every day 6	
PMO 2	On average, how many minutes of moderate-intensity activity each day?	None 0 At least 10 mins 1 10 - 30mins 2 30mins - 1hr 3 1hr - 1.5hrs 4 >1.5hrs 5	

PVI1	How many days do you go for a vigorous-intensity activity that causes large increases in breathing or heart rate like [carrying or lifting heavy loads, digging or construction work, running or football or in a gym]?	None 0 Once a month 1 2 to 3 times a month 2 Once a week 3 2 to 3 times a week 4 4 to 5 times a week 5 Every day 6	
PVI2	On average, how many minutes of vigorous-intensity activity each day?	None 0 At least 10 mins 1 10 - 30mins 2 30mins - 1hr 3 1hr - 1.5hrs 4 >1.5hrs 5	
PCL1	How many days do you climb flight of stairs (10 steps)?	None 0 Once a month 1 2 to 3 times a month 2 Once a week 3 2 to 3 times a week 4 4 to 5 times a week 5 Every day 6	
PCL2	On average, number of times you climbed up a flight of stairs (10 steps)?	None 0 1 to 5 times 1 6 to 10 times 2 11 to 15 times 3 16 to 20 times 4 more than 20 times 5	
PSE1	On average during a typical work-day and excluding work time, how many hours do you watch TV or sit at a computer or play video games?	None 0 < 1hr 1 1hr - 2hrs 2 2hr - 3hrs 3 3hr - 4hrs 4 >4hrs 5	
PSE2	On average during a non-working day, how many hours do you watch TV or sit at a computer or play video games?	None 0 < 1hr 1 1hr - 2hrs 2 2hr - 3hrs 3 3hr - 4hrs 4 >4hrs 5	
PTR1	Which form of transport do you use most often apart from your journey to and from work?	Walk 1 By Cycle 2 By Two Wheelers 3 By Public transport 4 By Car 5	
PTR2	How did you normally travel to Job?	Walk 1 By Cycle 2 By Two Wheelers 3 By Public transport 4 By Car 5	
PTR3	On average, distance travel to Job?	Less than one km 1 01 - 05kms 2 06 - 10kms 3	

		11 - 15kms 4 more than 15kms 5	
PWA 1	On average, how many kms do you walk per day?	less than one km 1 01 - 05 kms 2 06 - 10 kms 3 11 - 15 kms 4 more than 15 kms 5	
POC 1	What type of physical activity do you perform in your occupation (or in your daily life)?	1. Basically, I'm seated and I walk very little (administrative, ...) 2. I am seated but I very often perform moderate intensity efforts (cashier...) 3. Basically, I am standing and I walk very little 4. I walk a lot but I do not perform vigorous effort (salesperson, shopkeeper...) 5. I walk a lot and I perform vigorous effort (mail carrier, delivery person...) 6. Basically, I perform vigorous effort (construction worker...)	

SL	**Sleep**	**CodeLabel**	**Value**
	The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month		
SL0l	What time do you normally get up on weekday?	Before 5:00 AM 1 5:00 – 6:30 AM 2 6:30 – 7:30 AM 3 7:30 – 8:30 AM 4 8:30 – 9:30 AM 5 After 9:30 AM 6	
SL02	What time do you normally get up on weekend?	Before 5:00 AM 1 5:00 – 6:30 AM 2 6:30 – 7:30 AM 3 7:30 – 8:30 AM 4 8:30 – 9:30 AM 5 After 9:30 AM 6	
SL03	What time do you normally go to bed on weekday?	Before 8:00 PM 1 8:00 – 9:00 PM 2 9:00 – 10:00 PM 3 10:00– 11:00 PM 4 11:00– 12:00 AM 5 After 12 AM 6	
SL04	What time do you normally go to bed on weekend?	Before 8:00 PM 1 8:00 – 9:00 PM 2 9:00 – 10:00 PM 3 10:00– 11:00 PM 4 11:00– 12:00 AM 5 After 12 AM 6	

SL05	How long has it taken you to fall asleep each night?	None 0 At least 10 mins 1 10 - 30mins 2 30mins - 1hr 3 1hr - 1.5hrs 4 >1.5hrs 5	
SL06	During the past month, how would you rate your sleep quality overall?	Very good 1 Fairly good 2 Fairly bad 3 Very bad 4	

SU	Surgery	Code Label	Value
SUP1	**Any surgery in last one year (PAST)**	**No 0** **Yes 1**	
SUP2	HEENT Surgery	No 0 Yes 1	
SUP3	Breast Surgery	No 0 Yes 1	
SUP4	Trunk Surgery	No 0 Yes 1	
SUP5	Abdominal Surgery	No 0 Yes 1	
SUP6	Pelvic Surgery	No 0 Yes 1	
SUP7	Extremity Surgery	No 0 Yes 1	
SUP8	Others	No 0 Yes 1	
SUR1	**Recent Surgery (last 3 months)**	**No 0** **Yes 1**	
SUR2	HEENT Surgery	No 0 Yes 1	
SUR3	Breast Surgery	No 0 Yes 1	
SUR4	Trunk Surgery	No 0 Yes 1	
SUR5	Abdominal Surgery	No 0 Yes 1	
SUR6	Pelvic Surgery	No 0 Yes 1	
SUR7	Extremity Surgery	No 0 Yes 1	
SUR8	Others	No 0 Yes 1	

PS00	**Perceived Stress Scale** *The questions in this scale ask you about your feelings and thoughts **during the last month**. In each case, indicate with a check how often you felt or thought a certain way.*		
PS01	In the last month, how often have you been upset because of something that happened unexpectedly?	Never 0 Almost never 1 Sometimes 2	

		Fairly often 3 Very often 4	
PS02	In the last month, how often have you felt that you were unable to control the important things in your life?	Never 0 Almost never 1 Sometimes 2 Fairly often 3 Very often 4	
PS03	In the last month, how often have you felt nervous and "stressed"?	Never 0 Almost never 1 Sometimes 2 Fairly often 3 Very often 4	
PS04	In the last month, how often have you felt confident about your ability to handle your personal problems?	Never 0 Almost never 1 Sometimes 2 Fairly often 3 Very often 4	
PS05	In the last month, how often have you felt that things were going your way?	Never 0 Almost never 1 Sometimes 2 Fairly often 3 Very often 4	
PS06	In the last month, how often have you found that you could not cope with all the things that you had to do?	Never 0 Almost never 1 Sometimes 2 Fairly often 3 Very often 4	
PS07	In the last month, how often have you been able to control irritations in your life?	Never 0 Almost never 1 Sometimes 2 Fairly often 3 Very often 4	
PS08	In the last month, how often have you felt that you were on top of things?	Never 0 Almost never 1 Sometimes 2 Fairly often 3 Very often 4	
PS09	In the last month, how often have you been angered because of things that were outside of your control?	Never 0 Almost never 1 Sometimes 2 Fairly often 3 Very often 4	
PS10	In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	Never 0 Almost never 1 Sometimes 2 Fairly often 3 Very often 4	

PH00	**PATIENT HEALTH QUESTIONNAIRE** *Over the last 2 weeks, how often have you been bothered by any of the following problems?*		
PH01	Little interest or pleasure in doing things	Not at all 0	

		Several days 1 More than half the days2 Nearly every day 3	
PH02	Feeling down, depressed, or hopeless	Not at all 0 Several days 1 More than half the days2 Nearly every day 3	
PH03	Trouble falling or staying asleep, or sleeping too much	Not at all 0 Several days 1 More than half the days2 Nearly every day 3	
PH04	Feeling tired or having little energy	Not at all 0 Several days 1 More than half the days2 Nearly every day 3	
PH05	Poor appetite or overeating	Not at all 0 Several days 1 More than half the days2 Nearly every day 3	
PH06	Feeling bad about yourself — or that you are a failure or have let yourself or your family down	Not at all 0 Several days 1 More than half the days2 Nearly every day 3	
PH07	Trouble concentrating on things, such as reading the newspaper or watching television	Not at all 0 Several days 1 More than half the days2 Nearly every day 3	
PH08	Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	Not at all 0 Several days 1 More than half the days2 Nearly every day 3	
PH09	Thoughts that you would be better off dead or of hurting yourself in some way	Not at all 0 Several days 1 More than half the days2 Nearly every day 3	

MDE	**Medical Expense**	
MDE1	Average Monthly expenditure in health events(Approx.)	
MDE2	Average Monthly household expenditure(Approx.)	

HSV	**Hospital Visit**	
HSV1	No of Emergency department visits during last one year?	
HSV2	No of Emergency department visits during the three months?	
HSV5	How many days were you hospitalized for due to other diseases in the last year?	
HSV6	How many days were you hospitalized for due to other diseases in the last three months?	

	Body Vitals		
	First Reading	Second Reading	Third Reading
Date			

Height (cms)												
Weight (kgs)												
Hip circumference (cms)												
Blood Pressure	Sys				Sys				Sys			
	Dia				Dia				Dia			
Respiratory Rate (bpm)												
Bhramari Time (seconds)												

9) Appendix III: Questionnaires to be used in the RCT and Mechanism of Action Studies

Cohen Perceived Stress

The following questions ask about your feelings and thoughts during THE PAST MONTH. In each question, you will be asked HOW OFTEN you felt or thought a certain way. Although some of the questions are similar, there are small differences between them and you should treat each one as a separate question. The best approach is to answer fairly quickly. That is, don t try to count up the exact number of times you felt a particular way, but tell me the answer that in general seems the best.

For each statement, please tell me if you have had these thoughts or feelings: never, almost never, sometimes, fairly often, or very often. (Read all answer choices each time)

	Never	**Almost Never**	**Sometimes**	**Fairly Often**	**Very Often**
B.1. In the past month, how often have you been upset because of something that happened unexpectedly?	0	1	2	3	4
B.2. In the past month, how often have you felt unable to control the important things in your life?	0	1	2	3	4
B.3. In the past month, how often have you felt nervous or stressed?	0	1	2	3	4
B.4. In the past month, how often have you felt confident about your ability to handle personal problems?	0	1	2	3	4

B.5. In the past month, how often have you felt that things were going your way?	0	1	2	3	4
B.6. In the past month, how often have you found that you could not cope with all the things you had to do?	0	1	2	3	4
B.7. In the past month, how often have you been able to control irritations in your life?	0	1	2	3	4
B.8. In the past month, how often have you felt that you were on top of things?	0	1	2	3	4
B.9. In the past month, how often have you been angry because of things that happened that were outside of your control?	0	1	2	3	4
B.10. In the past month, how often have you felt that difficulties were piling up so high that you could not overcome them?	0	1	2	3	4

Perceived Stress Scale Scoring

Each item is rated on a 5-point scale ranging from never (0) to almost always (4). Positively worded items are reverse scored, and the ratings are summed, with higher scores indicating more perceived stress.

PSS-10 scores are obtained by reversing the scores on the four positive items: For example, 0=4, 1=3, 2=2, etc. and then summing across all 10 items.

Items 4, 5, 7, and 8 are the positively stated items.

Your Perceived Stress Level was _____

Scores around 13 are considered average. In our own research, we have found that high stress groups usually have a stress score of around 20 points. Scores of 20 or higher are considered high stress, and if you are in this range, you might consider learning new stress reduction techniques as well as increasing your exercise to at least three times a week. High psychological stress is associated with high blood pressure, higher BMI, larger waist to hip ratio, shorter telomere length, higher cortisol levels, suppressed immune function, decreased sleep, and increased alcohol consumption. These are all important risk factors for cardiovascular disease.

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:				
Your birthdate (Day, Month, Year):				
Today's date (Day, Month, Year):				
	Not at All	**A Little**	**Quite a Bit**	**Very Much**
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a long walk?	1	2	3	4
3. Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4
During the past week:	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4

28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

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FACT-Cognitive Function (Version 3)

Below is a list of statements that other people with your condition have said are important. **Please circle or mark one number per line to indicate your response as it applies to the past 7 days.**

	PERCEIVED COGNITIVE IMPAIRMENT	Never	About once a week	Two to three times a week	Nearly every-day	Several times a day
CogA1	I have had trouble forming thoughts	1	2	3	4	5
CogA3	My thinking has been slow	1	2	3	4	5
CogC7	I have had trouble concentrating	1	2	3	4	5
CogM9	I have had trouble finding my way to a familiar place	1	2	3	4	5
CogM10	I have had trouble remembering where I put things, like my keys or my wallet	1	2	3	4	5
CogM12	I have had trouble remembering new information, like phone numbers or simple instructions	1	2	3	4	5
CogV13	I have had trouble recalling the name of an object while talking to someone	1	2	3	4	5
CogV15	I have had trouble finding the right word(s) to express myself	1	2	3	4	5
CogV16	I have used the wrong word when I referred to an object	1	2	3	4	5
CogV17b	I have had trouble saying what I mean in conversations with others	1	2	3	4	5

CogF19	I have walked into a room and forgotten what I meant to get or do there	1	2	3	4	5
CogF23	I have had to work really hard to pay attention or I would make a mistake	1	2	3	4	5
CogF24	I have forgotten names of people soon after being introduced	1	2	3	4	5
CogF25	My reactions in everyday situations have been slow	1	2	3	4	5
CogC31	I have had to work harder than usual to keep track of what I was doing	1	2	3	4	5
CogC32	My thinking has been slower than usual	1	2	3	4	5
CogC33a	I have had to work harder than usual to express myself clearly	1	2	3	4	5
CogC33c	I have had to use written lists more often than usual so I would not forget things	1	2	3	4	5
CogMT1	I have trouble keeping track of what I am doing if I am interrupted	1	2	3	4	5
CogMT2	I have trouble shifting back and forth between different activities that require thinking	1	2	3	4	5
	COMMENTS FROM OTHERS	**Never**	**About once a week**	**Two to three times a week**	**Nearly everyd ay**	**Several times a day**
CogO1	Other people have told me I seemed to have trouble remembering information	1	2	3	4	5
CogO2	Other people have told me I seemed to have trouble speaking clearly	1	2	3	4	5
CogO3	Other people have told me I seemed to have trouble thinking clearly	1	2	3	4	5
CogO4	Other people have told me I seemed confused	1	2	3	4	5
	PERCEIVED COGNITIVE ABILITIES	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very Much**
CogPC1	I have been able to concentrate	1	2	3	4	5
CogPV1	I have been able to bring to mind words that I wanted	1	2	3	4	5

	to use while talking to someone					
CogPM1	I have been able to remember things, like where I left my keys or wallet	1	2	3	4	5
CogPM2	I have been able to remember to do things, like take medicine or buy something I needed	1	2	3	4	5
CogPF1	I am able to pay attention and keep track of what I am doing without extra effort	1	2	3	4	5
CogPCH1	My mind is as sharp as it has always been	1	2	3	4	5
CogPCH2	My memory is as good as it has always been	1	2	3	4	5
CogPMT1	I am able to shift back and forth between two activities that require thinking	1	2	3	4	5
CogPMT2	I am able to keep track of what I am doing, even if I am interrupted	1	2	3	4	5
	IMPACT ON QUALITY OF LIFE	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very Much**
CogQ35	I have been upset about these problems	1	2	3	4	5
CogQ37	These problems have interfered with my ability to work	1	2	3	4	5
CogQ38	These problems have interfered with my ability to do things I enjoy	1	2	3	4	5
CogQ41	These problems have interfered with the quality of my life	1	2	3	4	5