Evidence Based Practice & Complementary Therapies

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Pre-Meeting Study Day

Nanna Friðriksdóttir, RN, MSc
Clinical Nurse Specialist in Oncology
Landspítalinn- National University Hospital of Iceland
Aims

• To identify issues which must be taken into account when developing a complementary therapy service

• To explore integration of complementary therapies into patient care

• To promote the adaption of evidence based practice when it comes to complementary therapies
Outline of presentation

1. Review of key definitions
2. Review of some key issues to consider when integrating complementary therapies (CT) into patient care
3. The experience of integrating CT into cancer care at Landspítalinn in Iceland
4. Conclusions
Key terms

From Alternative
to
CAM
to
Complementary
to
Integrative
Misleading terms

• Alternative therapies
  – Used instead of mainstream care
  – Usually biologically invasive, potentially harmful
  – Expensive

• CAM
  – A convenient term but...
  – Includes therapies that are proven and others that have little or no scientific basis
  – A group of diverse medical and health care systems, practices and products that are not generally considered to be part of conventional medicine.

Reference: http://nccam.nih.gov/
Leading terms

• Complementary Therapies
  – Therapy that is used together with conventional medicine or mainstream care (NCCAM, 2007). Intended to supplement, enhance or complement.
  – Non-invasive, inexpensive, safe and evidence-based
  – Measures that help control symptoms, enhance well-being and contribute to overall patient care
  – Most are not specific to a particular cancer diagnosis- but used to treat symptoms shared by most cancer patients
• Integrative Medicine

– Combines treatments from conventional medicine and complementary therapies for which high quality scientific evidence of safety and effectiveness is available (NCCAM, 2007)

– Integrative oncology/hematology is both a science and a philosophy focusing on the complex health of people with cancer and proposes the incorporation of complementary therapies with conventional treatments such as surgery, chemotherapy, molecular therapeutics, and radiotherapy to facilitate health

– Complementary therapies & Integrative medicine service = Evidence-based practice
CAM domains (NCCAM 2007; NCI OCCAM, 2009)

1. Alternative/Ancient medical systems
2. Energy therapies
3. Biologically-based methods
4. Manipulative and body-based methods
5. Mind-body interventions
6. Nutritional therapeutics
7. Pharmacologic and biologic treatments
   – Complex natural products
8. Spiritual therapies
Integrating CT into Patient Care
Overview of some key issues

1. Know your patient population
2. Know your staff /setting
3. Know the evidence -What is effective and safe to integrate?
4. Form a complementary therapy committee / integrative team with administrative approval up front
5. Develop a model and a service plan
6. Integrate with education and research
7. Define the nurses role in the context of CAM
1. Know your patient population
CAM use among cancer patients

- 30-40% average prevalence rate (range 10-90%)
- Majority use CAM therapies as complementary (not alternative)
- Users are more often younger, female, more educated, higher income and prior users
- Common reasons for use:
  - Improve physical and emotional well-being
  - Desire to do everything possible
  - To feel hope and gain control
  - Enhance the immune system and fight the disease
  - Manage symptoms and reduce side-effects
  - Improve QOL
• Family, friends and media more often the source of CAM information than health care professionals (Corner etal, 2009; Molassiotis etal, 2005; Scott etal, 2005)

• Low disclosure rates
  – 15-20% (Mao etal, 2011)
  – 23%-90% range (Robinson& McGrail, 2004)

• Some reasons for not using CAM
  – Lack of information and expert guidance about availability, safety & costs (Corner etal, 2009)

• Impact of a growing industry
  – Some patients/families pay large amounts
European Survey on the Use of Complementary and Alternative Medicine in Cancer Patients
(Molassiotis et al, 2005)

- 14 countries and 956 patients
- Mean prevalence rate: 36% ranging from 15% (Greece) – 73% (Italy)

- CAM use increased by 30% after dx
- Highest use among patients with pancreatic, liver, bone and brain cancer
- Users were more often female, younger, higher education, higher income

- 58 types of therapies were used
  - Herbs/remedies most common

- Most common reason for use: to increase the body’s ability to fight the disease (51%)

- Physicians (18%) and nurses (3%) were seldom the source of CAM information

- Average spending on CAM €123/month (max 4140/month)
Complementary and alternative medicine use in patients with haematological malignancies in Europe
(Molassiotis et al, 2005)

- 12 countries and 68 patients
- Female 51.5%, mean age 54
- 60% lymphoma, 28% leukemia and 12% myeloma

- 26.5% used some form of CAM after dx
  - Homeopathy 39%,
  - Herbal medicine 22%,
  - Various psychic therapies (healers, mediums, rebirthing or past life regression therapy) 22%

- Reasons:
  - increase body’s ability to fight cancer (55%)
  - improve physical wellbeing (50%)
  - improve emotional well being and hope (50%)

- Main source of information: friends (61%) and family (50%)
- Average spending on CAM: €127/month (range 10-474)
The use of CAM
Challenge and/or frustration?

- Many CAM therapies lack good data on safety, efficacy and mechanism of action
- Many health-care professionals lack knowledge of CAM
- Theoretical and personal opinion often replace evidence
Challenge and/or frustration?

- Evidence-based CAM practice is created in the same way as in conventional health care.
- Most cancer care programs require proof of general efficacy through RCTs.
- The gold standard for conventional medicine is the RCT but even there this standard is not always met.
- Complementary therapies are usually individualized.
- Health care providers should be able to provide evidence-based, patient-centered advice on complementary therapies to guide patients to receive benefit while avoiding harm.
2. Know your staff/setting

• How do health care providers perceive their role?
  – Comfortable about discussing CAM?
  – Recognize the benefits of communication about CAM?
  – Adequate knowledge and skills?

• Is the staff interested?
  – Positive view: Female > male; nurses > physicians (Risberg et al. 2004)
  – >50% of oncology health professionals had used CAM to treat their own illness (Kolstad et al., 2004)

• Which services are being provided and which are not?
  – Access to complementary therapies/integrative medicine programs within health care settings varies both between countries and between settings
3. Know the evidence
Evidence-based Clinical Practice guidelines

- Evidence-based practice in CAM is a young concept but growing
- Levels of evidence and evidence-based practice in CAM are created in the same way as those in conventional medicine
- If a therapy is established to be safe and effective it can be integrated into clinical practice
- Evidence-based Clinical Practice guidelines are widely accepted as a potential tool to improve quality of care
Evidence-Based Clinical Practice Guidelines for Integrative Oncology: Complementary Therapies and Botanicals

Authors
Gary E. Deng, MD, PhD, Memorial Sloan-Kettering Cancer Center, New York, NY
Moshe Frenkel, MD, The University of Texas M. D. Anderson Cancer Center, Houston, TX
Lorenzo Cohen, PhD, The University of Texas M. D. Anderson Cancer Center, Houston, TX
Barrie R. Cassileth, PhD, Memorial Sloan-Kettering Cancer Center, New York, NY
Donald I. Abrams, MD, University of California-San Francisco, San Francisco, CA
Jillian L. Capodice, LAC, MS, Columbia University Medical Center, New York, NY
Kerry S. Cournyey, PhD, University of Alberta, Edmonton, AB
Trish Dryden, ME, RMT, Centennial College, Toronto, ON
Suzanne Hanser, BMus, MMus, EdD, Berklee College of Music, Boston, MA
Nagi Kumar, PhD, RD, FADA, H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL
Dan Labriola, ND, Northwest Natural Health Specialty Care Clinic, Seattle, WA
Diane W. Wardell, PhD, RN, WHNP-BC, The University of Texas Health Science Center at Houston, Houston, TX
Stephen Sagar, MD, McMaster University, Hamilton, ON

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Acknowledgment
SIO Guidelines
Recommendations in 8 categories

1. The clinical encounter
2. Mind-body modalities
3. Touch therapies
4. Fitness/exercise
5. Energy therapies
6. Acupuncture
7. Diet
8. Nutritional supplements
# SIO grading
*(based on American College of Chest Physicians)*

<table>
<thead>
<tr>
<th>Grade</th>
<th>Recommendations</th>
<th>Strenght of evidence</th>
<th>Implications</th>
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<tbody>
<tr>
<td>1A</td>
<td>Strong, high quality evidence</td>
<td>RCTs without important limitations</td>
<td>Strong recommendation, can apply to most patients</td>
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<tr>
<td>1B</td>
<td>Strong, moderate-quality evidence</td>
<td>RCTs with important limitations, or exceptionally strong evidence from observational studies</td>
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<tr>
<td>1C</td>
<td>Strong, low-or very low quality evidence</td>
<td>Observational studies or case series</td>
<td>Strong recommendation may change when higher-quality evidence is available</td>
</tr>
<tr>
<td>2A</td>
<td>Weak recommendation, high-quality evidence</td>
<td>RCTs without important limitations</td>
<td>Weak recommendation, best action may differ depending on circumstances</td>
</tr>
<tr>
<td>2B</td>
<td>Weak recommendation, moderate-quality evidence</td>
<td>RCTs with important limitations or strong evidence from observational studies</td>
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</tr>
<tr>
<td>2C</td>
<td>Weak recommendation, low- or very low-quality evidence</td>
<td>Observational studies or case series</td>
<td>Very weak recommendation, other alternatives may be equally reasonable</td>
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1. The clinical encounter

Two recommendations

• Inquire about the use of complementary and alternative therapies as a routine part of initial evaluation of cancer patients (1C)

• All patients with cancer should receive guidance about the advantages and limitations of complementary therapies in an open, evidence-based, and patient-centered manner by a qualified professional. Patients should be fully informed of the treatment approach, the nature of the specific therapies, potential risk/benefits, and realistic expectations (1C)
Recommended Web sites for Evidence-based CAM information

• NCI Office of CAM
  www.cancer.gov/cam/health_pdq.html
• Memoral Sloan-Kettering Cancer Center
• University of Texas M.D. Anderson Cancer Center
  Complementary/Integrative Medicine Education Resources
  www.mdanderson.org/CIMER
• Natural Medicines Comprehensive Database
  www.naturaldatabase.com/
• The Cochrane Review Organization
  www.cochrane.org/index2.htm
2. Mind-body medicine

Two recommendations

• Mind-body modalities are recommended as a part of a multidisciplinary approach to reduce anxiety, mood disturbance, chronic pain, and improve QoL (1B)
  – Rationale and evidence provided for meditation, Yoga, Tai Chi, hypnosis, relaxation techniques, and music therapy

• Support groups, supportive and expressive therapy, cognitive-behavioral therapy, and cognitive behavioral stress management are recommended as part of multidisciplinary approach to reduce anxiety, mood disturbance, chronic pain, and improve quality of life (1A)
3. Touch Therapies
Manipulative and body-based practices
Two recommendations

- For cancer patients experiencing **anxiety or pain**, massage therapy delivered by an oncology-trained massage therapist is recommended as part of multimodality treatment (1C)

- The application of deep or intense pressure is not recommended near cancer lesions or enlarged lymph nodes, radiation field sites, medical devices (such as indwelling iv catheters), or anatomic distortions such as postoperative changes or in patients with a bleeding tendency (2B)
4. Exercise and physical activity
One recommendation

- Regular physical activities can play many positive roles in cancer care. Patients should be referred to a qualified exercise specialist for guidelines on physical activity to promote basic health.

Grade 1B (1A for breast cancer survivors post-therapy for QOL)
5. Energy Therapies
One recommendation

- Therapies based on a philosophy of bioenergy fields are safe and may provide some benefit for reducing stress and enhancing QoL. There is limited evidence as to their efficacy for symptom management, including reducing pain and fatigue.

  Grade 1B for reducing anxiety;
  Grade 1C for pain, fatigue, and other symptom management
6. Acupuncture

Five recommendations

• Acupuncture is recommended as a CT when pain is poorly controlled, when nausea and vomiting associated with chemotherapy or surgical anesthesia are poorly controlled, or when the side effects from other modalities are clinically significant. Grade 1A

• Acupuncture is recommended as a CT for radiation-induced xerostomia. Grade 1B

• Acupuncture does not appear to be more effective than sham acupuncture for treatment of vasomotor symptoms (hot flashes) in postmenopausal women in general. In patients experiencing severe symptoms not amenable to pharmacologic treatment, however, a trial of acupuncture treatment can be considered. Grade 1B
• For patients who do not stop smoking despite use of other options or those suffering from symptoms such as cancer-related dyspnea, fatigue, chemotherapy-related neuropathy, or post-thoracotomy pain, a trial of acupuncture may be helpful, but more clinical studies of acupuncture are warranted. Grade 2C

• Acupuncture should be performed only by qualified practitioners and used cautiously in patients with bleeding tendencies. Grade 1C
7. Diet

Two recommendations

- Research in diet and cancer prevention is based mainly on studies of populations consuming dietary components in whole-food form, with secure food supplies and access to a variety of food and drinks. Therefore, nutritional adequacy should be met by selecting a wide variety of foods; dietary supplements are usually unnecessary. Grade 1B

- It is recommended that patients be advised regarding proper nutrition to promote basic health. Grade 1B
Nutritional supplements

Five recommendations

• Based on a current review of the literature, specific dietary supplements are not recommend for cancer prevention (1A)

• Evaluation of patients’ use of dietary supplements prior to the start of cancer treatment is recommended. Also recommended are referral of cancer patients to trained professionals for guidelines on diets, nutritional supplementation, promotion of optimum nutritional status, management of tumor- and treatment-related symptoms, satisfaction of increased nutritional needs, and correction of any nutritional deficits while on active treatment (1B)

• It is recommended that dietary supplements, including botanicals and megadoses of vitamins and minerals, be evaluated for possible side effects and potential interaction with other drugs. Those that are likely to interact adversely with other drugs, including chemotherapeutic agents, should not be used concurrently with immunotherapy, chemotherapy or radiation or prior to surgery (1B)
• For cancer patients who wish to use nutritional supplements, including botanicals for purported antitumor effects, it is recommended that they consult a trained professional. During consultation, the professional should provide support, discuss realistic expectations, and explore potential benefits and risks. It is recommended that use of those agents occur only in the context of clinical trials, recognized nutritional guidelines, clinical evaluation of the risk/benefit ratio based on available evidence, and close monitoring of adverse effects (1C).

• As with nutritional supplementation during treatment, survivors should be evaluated for supplement use and referred to a trained professional for evaluation to meet specific nutritional needs and to correct nutritional deficits as indicated. For older cancer survivors, nutritional supplementation may reduce nutrient inadequacies, although survivors who use supplements are usually the least likely to need them (2B).
Challenge!
Adjust Evidence-base guidelines to culture and needs

- Guidelines are for guidance (of wise people)
- Do these guidelines fit with our patient population and our setting?
- What change appropriate for adoption in practice?
- Translated into Spanish by ASOI (Asociacion de oncologia integrativa para iberoamerica)
- SIO guidelines are not specific for a particular cancer diagnosis
- SIO model for lung cancer:
  - Complementary therapies and integrative oncology in lung cancer: ACCP Evidence-based Clinical Practice Guidelines (Cassileth, Deng et al., CHEST, 2007)

- CT provide symptom relief during active leukemia treatment and improve QOL
- Mind-body interventions (meditation, hypnosis, guided imagery), acupuncture and massage are very beneficial for decreasing side effects
- Regular exercise important in maintaining physical strength and decreasing side effects
- Adequate nutritional intake through foods and not through the use of supplements is important
- Herbs and vitamin supplements may interfere with treatment and should be discussed before use and used only with supervision of the oncologist.

• http://www.mskcc.org/mskcc/html/11570.cfm
4. Form a team/complementary therapy committee- with administrative support

- The best method for integrating CT has not yet been established and in general integration is slow (Frenkel & Cohen, 2008)
- Research on integration of CT into conventional cancer care is limited
- Most information from integrative centers relate to their experiences rather than the integration process
- Many models have been proposed (Cassileth et al, 2002; Leckridge, 2004; Boon, Verhoef, O´Hara, et al, 2004; Frenkel, & Cohen, 2008)
- Mostly US literature
5. Develop a model and a service plan
Important practical issues

• Define the service
• What should be integrated and for whom
• Give it a name
• Who coordinates the service and who provides what
  Identify facilities, equipments needed
• Ensure that treatment records/patient database can be documented
• Decide on outcome measurements
• Decide on how to promote and make the service known
• Estimate the costs and secure funding
Outcome measures (Sagar, 2008)

- Symptom control
- Quality of life
- Adherence to treatment
- Individual outcomes
- Prevention
- Rehabilitation
- Advantages of a whole –systems health approach
- Economics (cost-effective) (Doran et al, 2010; Ford et al, 2010)
Outcome database by the Canadian Network for CAM
www.outcomesdatabase.org/

- Physical
- Psychological
- Social
- Spiritual
- QOL
- Holistic
- Individualized
- Process outcomes
- Context outcomes
6. Integrate with education and research

- Part of a academic institution?
- Research and training activities
- Faculty & students
- Staff
- Therapists
- Outcomes
7. Define the nurses role

Integrative oncology nursing role

Nightingale (1820-1910)

2007 NY Memorial Sloan: Icelandic nurses learning how to integrate CT
Holistic nursing!

- Majority of CT are based on a holistic philosophy
- Holistic nursing is not defined by specific therapy but rather by a way of thinking and practicing
- Selected CT are appropriate for competent nurses to use and are to be integrated into a holistic nursing practice
- CT are appropriate nursing interventions and are not meant to replace conventional nursing or medical therapies
Main message for nurses

1. **Approach CAM with non-judgmental attitude and open communication**
   - Evaluate and understand our own beliefs and values
   - Gain understanding of CAM and evidence-based practice with regard to safety and efficacy

2. **Do routine assessment of use and close monitoring of patients using CT (documentation)**
   - Assess unmet needs, symptoms and distress, understanding of therapies

3. **Inform the patient (patient education) and assist with decision-making – direct to credible information**

4. **Advocate that health systems provide patients with opportunities to choose CT**

5. **Conduct and participate in research**

6. **Seek proper education, training and credentials if practicing CT/integrative therapies**
Landspítalinn – The National University Hospital In Iceland

A short story on complementary therapies in cancer/hematology/palliative care
Cancer in Iceland

- Population of 300,000
- Now 1,360 diagnosed yearly
- Today more than 10,000 survivors
- Overall 5 year survival rates: women 66% and men 61% (Icelandic Cancer Registry, 2011)
- Adult stem cell transplants:
  - Autologous started in Iceland if 2004: 16 /year
  - Allogenic go to Sweden: 5/year (3-7)
Majority (> 90%) get treatment at Landspítalinn

**Onc/Hem Medical Outpatient**
- 2010 visits: 20,000

**Radiotherapy**
- 2010 visits: 11,000

**Med-Onc inpatient**
- 2010: 4600 inpatient days

**Hem inpatient**
- 2010: 3900 inpatient days

**Palliative care team**
- 2010: 857 patient visits

**Palliative home care**
- 2010: 4600 home visits

**Palliative care inpatient**
- 2010: 3700 inpatient days

**COMPLEMENTARY THERAPIES?**
A short version of a short story

- Four studies (from 2002-2006) on CAM use
  - Prevalence from 30-97%
    - Herbs/natural products 60-70%
    - Spiritual methods (40-70%)
    - Exercise (70%)

- **1994-2003 massage therapy** provided in- and outpatient by a certified nurse-aid and massage therapist. Therapy was documented, audited and well-received.

- **1998-2007 outside exercise/walking-group** 3x/week, 1.5-3.0 km. Led by a nurse and physiotherapist. Documented and audited.

- **1995- Relaxation treatment** provided by a oncology nurse with diploma in relaxation and hypnosis. Documented and audited.

- Some nurses/nurse-aids have diplomas/certification in massage treatment but few use it in daily practice
- In general staff are interested in and supportive of CT for the management of symptoms and side-effects
CT integrating committee: policy maker 2006

Oncologist Agnes

Nurse and relaxation therapist Lilja

Clinical nurse specialist Nanna

Nurse, massage therapist and assistant professor: Thora
Policy on integrating Complementary therapies into Cancer Care at LSH

From 2006-2007:
- Weekly meetings
- Literature search
- SIO clinical practice guidelines - model
- A visit to Memorial Sloan-Kettering Cancer Centre and St. Vincent Cancer Centre NY
- Dr. B. Cassileth lectured in Iceland
- Policy included a model, recommendations of treatments, workforce, housing, documentation, outcome measures, costs and funding...

• In 2008 the policy was accepted and ready for implementation.....
To integrate evidence-based CT with conventional treatment

To reduce symptoms and improve QOL

To inform and educate patients and staff about the use of complementary therapies

Provide massage, relaxation, exercise and acupuncture and document the outcomes

Herbal supplements during cancer treatment or if on prescription medication is not recommended

To improve assessment and documentation on what patients use

To integrate education and research
Complementary therapies integrated for cancer patients at LSH
Integrative Team

Clinical Service
Clinical consultation

Inpatient
Information
Relaxation
Massage
Acupuncture

Outpatient
Information
Relaxation
Massage
Acupuncture

Research Outcomes

Students
Clinical outcomes
-relaxation
-massage
Documentation

Education

Staff
Students

Information

CT
Herbs
Nutrition
Supplements
Iceland goes bankrupt !!!
And we needed to relax ourselves

And dream about what could have been.......
Taking smaller infant steps

- All nursing staff trained in providing simple hand- and foot massage and relaxation to apply in daily care
- **Palliative inpatients** are all offered foot massage in the evenings
- Reflexology and relaxation is offered weekly at **inpatient hematology** by a certified nurse-aid and massage therapist
- Some physiotherapists have certification in acupuncture
- **Relaxation therapy is still offered**
  - Well documented
  - In 2010: 460 treatments and 394 patients (mean 2.9)
  - ESAS symptom assessment pre and post: significant results both in symptom prevalence and symptom ratings
- 2011 Patient Survey (n=145) shows that **many patients want more information on**:
  - Use of vitamins, herbs and supplements (47%)
  - Nutrition (38%)
  - Exercise (31%)
  - Relaxation (35%)
In conclusion

- The reality is that a large number of patients use CAM
- Patients can access CAM outside the conventional health care setting and may not report the use which can be unsafe and costly
- There is evidence that selective CAM therapies can benefit the patients
- Clinical guidelines exist that can be adjusted to practice and models of integration have started to develop
- Integrated service is supervised and monitored by knowledgeable health care professionals
- Integrated service improves safety, communication, trust and symptom management
- Therefore it is important to promote the integration of complementary therapies into cancer patient care
A few references
Models of CIM integration


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CT in hem

The nurses role

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