

## **NCRI Complementary Therapies Clinical Studies Development Group**

A proposal to establish a Complementary Therapies Clinical Studies Development Group (CTCSDG) was submitted to the NCRI in December 2002 on behalf of the Complementary Cancer Care Charities Partnership Group (4CP), a partnership of UK cancer charities to promote research into complementary and alternative medicines (CAM) in cancer care. The charities involved in that group are Marie Curie Cancer Care, Macmillan Cancer Relief, Foundation for Integrated Health, Bristol Cancer Help Centre and Breakthrough Breast Cancer. The proposal was accepted in July 2003 and the Chair was appointed in November 2003. The Group membership was established through an open recruitment process and has representatives from the following areas:

- Complementary therapy users
- Complementary therapists
- Cancer research networks
- Primary care research networks
- Oncologists
- Statisticians
- Health economists

Three members of the Group have either resigned or had their membership terminated due to poor attendance records in 2005/06. Two new members have been appointed this year, Dr George Lewith and Dr Janet Povey. Two further applications have been received and are currently being processed.

The remit of the Group is in line with the other Clinical Studies Development Groups. The primary aim is to develop a portfolio of high-quality national studies. The full group is concerned with developing a strategy for the Group and identifying priorities for research.

### **Priorities for research**

The priority areas for research identified by the Group are:

1. Contraindications of particular herbal remedies/interactions with conventional treatments
2. Use of complementary therapies to control physical effects of conventional treatments
3. Physical effects of specific therapies
4. Psychological effects of specific therapies
5. Use of complementary therapies to control the psychological effects of conventional treatment

### **Subgroups**

The Group has established three subgroups to work on protocol development. These subgroups are:

1. Specific Effects – chaired by Dr Tony Leathem.
2. Effectiveness – chaired by Professor Kate Thomas (until June 2006)
3. Delivery – chaired by Dr Jacqueline Filshie.

The protocols being developed are all at very different stages of their development with some being at a preliminary outline stage and others fully worked up. The

guiding principle of the work of the sub-groups is that they should support the study investigators and add value to the efforts of the research team.

### **Portfolio and accrual**

Designated members of the CTCSDG have provided comments to the Population and Behavioral Sciences Committee on submitted project and small grant applications in the area of Complementary Therapies.

Progress on developing studies from within the Group has been less rapid than hoped. Only one of the studies submitted for funding received funding and this was initially rejected.

The following studies have all been discussed and developed through the Group but have failed to find funding from PBSC or CTAAC.

1. Autogenic training
2. Flavanoids for brain tumours
3. Makuna honey for mucositis
4. Acupuncture & fatigue

The past year has been a challenging one for the Group.

In addition, attempts to include existing studies in the Group's portfolio have encountered problems. A study based at the Breast Cancer Haven could not be included in the portfolio because of problems with the peer review process. This study suffered from a lack of research infrastructure. The EPIC study on nutrition which has been funded in the UK by CRUK is not eligible for inclusion in the portfolio because it has not been reviewed by any of the relevant committees. In this case, the study has no need for NCRN resources which means it was not submitted for NCRN approval and is, therefore, ineligible for inclusion in the Group's portfolio. Both these studies illustrate a problem with way in which portfolio construction does not reflect the reality of the complementary therapy research context. If there is no CT infrastructure in the NHS then the research is done elsewhere, if the research is not in the NHS, then there is no need for NCRN resources and without that the research doesn't go through the necessary processes and, therefore, get into the Group's portfolio. This is an indicator of the ways in which the system is working against supporting good quality CT research. These are issues, which need to be addressed by the NCRN and funding bodies.

### **National meetings**

No national meetings are planned by the Group this year. The Group held a parallel session at the October 2005 NCRI Conference and will host a parallel session again at the NCRI cancer conference in October 2006. The 2005 session was very well attended. More than 50 people had to be turned away because of the size of the room. Discussions are underway about the possibility of holding a strategy meeting for the Group prior to the Group's progress review in September 2007.

### **Other activities**

The Chair of the CTCSDG is also a member of the Palliative Care Clinical Studies Development Group and has been invited to be a member of the Psychosocial Clinical Studies Development Group Spirituality Subgroup. The CTCSDG's Research Development and Co-ordinator has been invited to attend meetings of the Psychosocial Clinical Studies Development Group in order to establish a formal link between the two groups. In addition to these formal links, the Group's Research Development and Co-ordinator has attended meetings of the majority of the clinical studies groups over the past year to raise the profile of the Group and to identify possible areas for collaboration.

### Strategy for 2006

The strategy for next year is as follows:

1. To establish a portfolio of studies.
2. To raise the awareness of the group's activities to the wider research community
3. To network with other national and international complementary therapies research groups
4. Support methodological capacity building for complementary therapy research

### Complementary Therapies Group Portfolio

Acronym	Title	PI(s)	Status
CAM and cancer	Male cancer patients' views on and use of complementary and alternative medicine (CAM): a qualitative study		Closed
	Complementary and alternative therapies and cancer: A study of the use of complimentary and alternative therapies among people undergoing cancer treatment	Professor Jessica Corner	Closed
DietCompLyf	The role of diet, complementary treatment and lifestyle in breast cancer survival	Dr Tony Leathem	Open
PERI	A randomised, controlled study of the psychoneuroimmunological effects of relaxation therapy and guided imagery, alone and in combination, in colorectal cancer	Professor Leslie Walker	Open
Reflexology Study	RCT of the effects of reflexology on QOL (including mood, adjustment, function coping & patient satisfaction) and host defences in early breast cancer	Professor Leslie Walker	Closed

Dr Susie Wilkinson, Chair

## **Appendix 1: Subgroup and Research Development Coordinator Reports**

### **Subgroup Specific Effects**

Sub-group 1 has had a relatively quiet year. This has been because the protocols for consideration and development, which have come to, the Group have been outside its remit. A submission to CTAAC on the use of flavanoids for brain tumours was unsuccessful but is being resubmitted elsewhere in a new form following developments in clinical practice

Other prospective projects for the coming year are a study of the use of lycopene in prostate cancer and a proposal around the effects of herbal medicines on transfusion requirements in patients with myelodysplasia in Wales, which is based on some very early data on a case- study basis.

### **Subgroup Effectiveness**

In the past year this sub-Group has had one study funded and one study rejected. The funded study was Touch or Talk, which had previously received considerable input from the sub-group. It was funded in a revised form as a feasibility study in 1 centre for 2 years and due to start in October 2007. It is hoped that this study can be adopted into the Group's portfolio as an NCRN local study; however, NCRN has recently suspended the adoption process.

The acupuncture and fatigue study has been less successful. This study had to be amended following substantial input from the sub-group because it duplicated (in part) an existing completed study, which had been carried out by another member of the Clinical Studies Group. The amended study was submitted to the CRUK Feasibility Committee and also to Breakthrough Breast Cancer but was unsuccessful in both attempts.

The MYCAW study was withdrawn from the February PBSC meeting in order to allow time to address referees comments. It will be resubmitted for the August deadline.

Future areas for development in this sub-group are a poetry therapy study and a crystal therapy study. A study being developed by Caroline Hoffman at Breast Cancer Haven is also likely to be considered over the next 6 months.

### **Subgroup Delivery**

As with the Specific Effects Subgroup, the protocols for consideration and development, which have come to, the Group have been outside its remit. So work has been confined to internally generated protocols.

This Group had its most recent meeting in June as the latest in a series of meetings over the past year. There has been constructive discussion about the development of a programme of work on safety in acupuncture.

In order to speed up progress, the sub-group has decided with submit a small qualitative study for funding to PBSC small grants as a stand-alone project. This will look at perceptions of safety amongst acupuncture users and practitioners.

### Research Development co-ordinator

The post is funded 50% by the 4CP charities and 50% by NCRI/NCRN. The present post-holder (Lesley Storey) was appointed in April 2005. A summary of her activities from April 2005 to date is listed below.

### Visits, meetings and outcomes

<b>Date</b>	<b>Event</b>	<b>Purpose/category</b>	<b>Action/outcome</b>
12 April 2005	Meeting with Research Council for Complementary Medicine	General induction/establish contact	RCCM invited to present at NCRI conference. RCCM to supply info about research & library
12 April 2005	Meeting with Jane Cope (NCRI)	General induction	Given background reading. Introduced to ICR database.
13 April 2005	Attend Psychosocial Clinical Studies Development Group	General induction	Agreed to act as link between Psychosocial group and Complementary Therapies Group
14 April 2005	Meeting with Julie Hearn (TRICC)	General induction	Informed about work of TRICC committee.
15 April 2005	Meeting with Kate Law (CTAAC)	General induction	Informed about CTAAC processes. Advised to make contact with PBSC. Given report on medicinal use of mushrooms to read. Provided KL with list of CT referees.
21 April 2005	Meeting with Richard Sullivan (CRUK)	General induction	Discussed general challenges facing complementary therapies research. Suggested possible ways of overcoming challenges e.g. standard protocols for different types of therapy. Provided RS with list of CT referees.
22 April 2005	Attend meeting of Gynae Clinical Studies Group	General induction	Opportunity to see an established group in operation
22 April 2005	Phone meeting with Kate Thomas	Work of sub-group 2	Agreed way forward for work of sub-group and KT suggested changes to be made to ICR database information previously circulated to group members.
29 April 2005	Meeting with research	Research development	Informed researchers about CT group's priority areas

	group Sussex University		and discussed possible avenues for future research.
3 May 2005	Meeting with Professor Parmar (MRC/NCRI)	General induction	Informed about work of MRC cancer groups and advised to make contact with Chris Parker @ Royal Marsden to discuss collaboration on prostate studies.
5 May 2005	Attend meeting of Operational Steering Group	General induction	Background about work of clinical studies groups and issues of importance to NCRI
6 May 2005	Meeting with Mark Lodge of Cochrane Cancer Network	Establish contact.	Given background about work of Network and discussed possibilities for collaboration.
10 May 2005	Meeting with Rick Kaplan (NCRN/NCRI)	General induction	Given background to establishment of NCRN/NCRI and information about priorities for future.
11 May 2005	Meeting with Tony Stevens (NCRI consumer Liaison)	General induction	Given background to establishment of NCRI consumer liaison group. Discussed possibility of collaboration on consumer-led audit of cancer help lines.
12 May 2005	Meeting with Dr Kohn (Kohn Foundation)	Response to approach from Dr Kohn/Prof Markham (CRUK)	Discussion of possibility of research into use of garlic in cancer treatment. Suggested that issue should be discussed by Group. Drafted paper for agenda at next meeting
12 May 2005	Meeting with Charlotte Moore (PBSC)	General induction	Informed about PBSC application processes. Agreed to investigate whether 2 protocols being worked on by CT sub-groups would be eligible for resubmission to PBSC.
16-18 May 2005	Visit to Leeds CTU	General induction	Observation of day-to-day working of clinical trials unit. Identified training needs re EU directive
19 May 2005	Meeting with Sheila Casserly (NCRN)	General induction	Updated SC on progress with the CT group and given information about NCRN priorities for future. Discussed possibility of NCRN funding for CT Group training/workshop.
20 May 2005	Attend meeting of NCRI Chairs Group	General induction	Information about challenges facing rare tumours. (some parallels with CT research)
27 May 2005	Meeting with Sue Ziebland	Establish contact	Agreed that there would be merit in a DipEX model on

	(DipEX)		Complementary Therapies. Discussed possibility of DipEx presenting at November mtg of Group
31 May 2005	Sub-group 3 meeting with protocol authors	Work of sub-group 3	No sub-group members attended, but the co-opted members attended. Useful development and expansion of the protocol. To go back to sub-group members for agreement & discussion.
6 June 2005	Visit to Bristol CTU	General induction	This visit took a day which was slightly too short. It consisted of meeting the main researchers who are part of the collaboration as well as the head of the unit. The BRTC is different from other units in that it does research on a wide range of diseases and using a variety of methods. It is fundamentally multi-disciplinary. It is applying for infrastructure funds from the university to enable it to take on some of the more traditional trials unit functions such as telephone randomisation.
7 June 2005	Advanced GCP/EU directive training course	Induction and training	This was a useful course which covered all the main areas of GCP and the implications of the EU directive. I have used some of the information learned on the course in writing the guidance notes.
8 June 2004	Teleconference with portfolio coordinators	Introductory meeting	Useful exchange of experiences with other coordinators.
10 June 2005	Consumer Liaison Group meeting	General induction	This was an interesting meeting, which focused on the issue of which stakeholders were in control of research. I attended all the plenary sessions and 2 interactive workshops.
21 June 2005	Sub-group 2 - teleconference	Work of sub-group 2	Productive discussion of protocols
30 June 2005	Breast Clinical Studies Group	General induction	Interesting and useful
20 July	CRUK CTU Sutton	General induction	I have been working with the CTU on how to include questions about complementary therapies into mainstream trials – TACT & radiotherapy. Questionnaire

			for TACT 2 currently being piloted in Southend.
25 July	Visit North London Cancer network	General induction	General information about work and running of cancer network
11 August	Visit to Sutton Coldfield Cancer Centre	Research Development	Discussed possible avenues for future research and provided information about Group's priority areas.
15 August	Visit to Breakthrough Breast Cancer Research Centre	General Information	Useful information about Breakthrough's current research activity
30 August	Visit to Freshwinds Centre, Birmingham	Research Development specific to Touch or Talk study	Discussed issues about how the centre might manage its involvement in TOT project
15 September	Macmillan research Centre, Southampton	General Information	Information about Macmillan's research priorities and current activity
19-21 September	12 <sup>th</sup> Annual Symposium on Complementary Healthcare, Exeter	General Information	Attended many useful presentations looking at CT research worldwide in a variety of disease areas
22 September	Consumer Liaison Group meeting	General information	Useful information about the work of the consumer research panels
26 September	3 Counties user research panel meeting	Spoke about the work of the group	Discussed possibilities for a consumer-led research project.
3-5 October	NCRI annual conference	CT Group held parallel session	Session very well received and over-subscribed.
11 October	Conference in Walsall	Spoke about the work of the Group	Received good feedback on the session and had useful discussions with other participants
19 October	Visit to Bristol Cancer Help Centre	General information	Due to have a follow-up meeting to discuss possible research.
24 October	UCL/MRC research seminar	Spoke about research issues in Complementary therapies	Talk generated a useful discussion about methodological challenges in research in this area.
28 October	CTAAC meeting	Induction programme – postponed from 7 July	Observed how CTAAC evaluated applications in order to be able to advise those planning a CTAAC application.

24 November	Britain against cancer conference	General information	I am currently following up leads from discussions with 2 drug companies who exhibited at the conference
16 December	Radiotherapy Trials meeting	General Information	Contributed to discussion about how CT could be useful in trials looking at radiotherapy toxicity
19 December	Breast trials meeting	General Information	TACT 2 CT questions being piloted in Southend
30 January	NCRI methodology mtg		Following up links with collaboratives & MRC
3 February	Sub-group 2 teleconference	Work of sub-group 2	Productive discussion of protocols
23-24 February	EORTC conference	General Information	Following up information strategy with Stephane Lejeune
27-28 February	Sarcoma strategy meeting	Spoke about research issues in Complementary therapies	Working on research options for phantom limb pain and palliative care
2 March	Mtg on charity help lines	Promoted inclusion of CT question in survey	Work ongoing
13 March	Sub-group 3 mtg	Work of sub-group 3	Productive discussion of protocol
24 March	Mtg with independent researcher (Leicester)	Research development (crystal therapy)	Working on protocol
27 March	Prostate CSG	General Information	Interesting and useful
5 April	Psychosocial CSG	Link between groups	Chair asked me to circulate paper to 4CP
20 April	Lymphoma CSG	General Information	Consumer expressed interest in CT for post-treatment rehabilitation. Currently following-up
27 April	Brain CSG	General Information	Interesting and useful
5 May	Trials unit meeting	General information	Interesting and useful
9 May	Nutrition in cancer lecture	General information	Interesting and useful
23 May	Sarcoma CSG meeting	Research development	Presentation of review on CT and phantom limb pain
25 May	Mtg with researcher (University of Brighton)	Research development (osteopathy)	Working on protocol
31 May	Mtg with independent researcher	Research development (poetry therapy)	Working on protocol
2 June	ACHRN meeting	Networking	Interesting and useful

29 June	Mindfulness conference	General information	Interesting and useful
3 July	Mtg with Sarcoma surgeon	Research development	Working on protocol
10 July	Mtg re links with Bristol RTC	Capacity building	Taken on co-ordination role