

NCRI Complementary Clinical Studies Development Group

Introduction

The Complementary Therapies Clinical Studies Development Group (CTCSDG) is currently chaired by Mr. Andy Ritchie and supported by Ms. Julie Flynn (Research Development Coordinator).

The Group is approaching its fifth year of activity now and there is a sense within the Group that significant progress has been made in its activity and profile within the cancer research community. The Group continues to be busy, enthusiastic and productive; since the last reporting period it has made steady progress in a number of areas namely, group membership, group working and development practices, focus and activity, study development opportunities, portfolio development and collaborative working. The Group underwent its first Interim Progress Review in December 2008. A list of the key strengths and issues that the Group need to consider are listed in Appendix 1. It is worth noting that in the 6 months since the Interim Progress Review a significant proportion of the issues have been addressed. These are indicated by an asterisk.

The Group continues to work on several issues, particularly identifying research priorities for complementary therapy research and setting strategy to support its remit to develop a portfolio of high quality, clinically relevant national collaborative studies. The Group is mindful of a number of challenges that lie ahead this year, predominantly the availability of appropriate funding. The supportive and palliative care research community has been disadvantaged in the availability of funding opportunities with Cancer Research UK's strategic decision to cease funding studies which are focused on 'living with and beyond cancer'. However, other funding opportunities are emerging as appropriate and this has proved to be beneficial for a number of our members already.

Membership and structure

Membership of the CT CSDG has grown over the year and now consists of nineteen scientific members, three consumer representatives and five observers or funding body representatives.

The scientific members continue to represent the multidisciplinary nature of complementary therapy research with clinicians with an interest in oncology, complementary therapists, epidemiologists, research nurses and , various academic research expertise represented on the Group. However, diverse and appropriate membership of the Group was recognised as an area for improvement and as such a targeted recruitment process was initiated to increase expertise on the Group, particularly in oncology. The Group has subsequently welcomed four new scientific members this year: Dr Alasdair MacSween, Professor Kenneth Muir, Dr Deborah Fenlon, and Professor Richard Ashford. Ms Julie Flynn replaced Dr Lesley Storey as Research Development Coordinator in August 2008. Dr Jan Povey has rotated off the Group. The Group would like to thank the group members who stepped down for their valuable contributions over several years.

The Group consists of 4 subgroups which are the main route by which study ideas which come to the Group are effectively developed. All CT CSDG members are encouraged to become a member of a subgroup(s). The subgroups are:

- Symptom Management – Chaired by Dr Dawn Storey
- Self Management - Chaired Professor George Lewith
- Disease Management (formerly Tumour Progression) – Chaired by Dr Peter Fisher)
- Statistical Design - Chaired by Ms Sharon Love

Portfolio and accrual

The number of studies in the CT CSDG portfolio is steadily increasing. Over the reporting period, July 2008 – June 2009 two studies have been added to the portfolio and no studies have been closed during this period. A summary of studies can be found in Table 1. Two further studies, one which has received funding from the NIHR Research for Patient Benefit funding stream and one from the Macmillan Use Led Research Grant competition are in the process of being added to the portfolio.

Open studies

There are currently 5 studies open to recruitment in the CT CSDG portfolio. Three of these are focused on acupuncture, one on spiritual beliefs and one on the role of diet and lifestyle. Three studies are open to breast cancer patients and two to all cancers. Accrual to all open studies remains at a steady state. One study is experiencing problems with recruitment due to infrastructure issues at one particular site. However this is being addressed through recruitment at additional sites.

Table 1 Complementary Therapies CSDG portfolio

Acronym	Title	UK PI(s)	Status
ACU.FATIGUE	The effectiveness of acupuncture and self-acupuncture in managing cancer-related fatigue in breast cancer patients: a pragmatic randomised trial	Professor Alexander Molassiotis	Open
Acupressure CINV	- The effectiveness and cost effectiveness of acupressure for the control and management of chemotherapy-related acute and delayed nausea	Professor Alex Molassiotis	Open (NEW)
AMWELL-SL	An exploratory study to evaluate the use of acupuncture and moxibustion to promote wellbeing and improve quality of life in patients with secondary lymphoedema	Dr Beverley de Valois	Open (NEW)
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 complementary and alternative therapies among people undergoing cancer treatment	Professor Jessica Corner	Closed
DietCompLyf	The role of diet, complementary	Dr Tony	Open

	treatment and lifestyle in breast cancer survival	Leathem	
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	Closed
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
Spiritual beliefs study	Study to explore the associations between spiritual beliefs and psychological status in patients with life threatening illnesses	Dr Louise Jones	Open

558 patients were recruited to complementary therapies studies in 2008-09.

Trials in development

The CT CSDG subgroups are primarily responsible for developing new studies within the Group. Studies in development (study/trial ideas only) are listed in Tables 2a-c below under each subgroup heading. Historically there has not been an official process by which trials are developed within the Group. This was recognized as an area for improvement.

As of March 1st 2009 the CT CSDG implemented a process (adopted from the Lung CSG) to log and develop new study ideas coming to the Group, ensure that these are developed effectively utilising all relevant expertise (relevant Group members, other relevant CS(D)G's and external expertise) and to prevent unnecessary overlap of studies in the UK NIHR NCRN portfolio. Most importantly the intention of this processes are:

- that the proposer(s) of new study ideas retains ownership,
- to avoid unwanted 'overlap' in trials being developed
- to ensure a comprehensive portfolio of complementary therapy studies can be established and maintained,
- to ensure that the study has the best possible chance of being developed effectively and funded
- to track study ideas and map the current complementary therapy research capacity

Current there are five study ideas (in addition to the several other studies under development prior to March 2009) that are going through this process. They are identified by a protocol number, e.g. CT 09001 etc, in the tables below. Each study idea is reviewed and developed by the most relevant CT CSDG subgroup(s) and other relevant site specific Clinical Studies Groups where appropriate.

Table 2a Self Management studies under development

Protocol number	Title	Investigators	Current Status
	Qualitative study of mindfulness in terminal breast cancer	Professor George Lewith, Mr Gerry Laydon	Submitted to NIHR RfPB 23 September 2008 Funding subject to satisfactory resolution of a couple of points.
	Mindfulness based stress reduction in prostate cancer	Dr Sam Watts, Mr Gerry Laydon	Submitted to Prostate Cancer Charity for a PhD Studentship but not funded. Reviews were good. Funding for PhD to be sought elsewhere.
	Chinese Herbal Medicine oral preparations to inc Quality of Life in non-small-cell lung cancer.	Professor George Lewith	Is with NCRI Lung CSG to illicit collaborative involvement. Response is awaited.
CT09004	Aromastix [®] for self management of nausea, anxiety and sleep problems	Dr Jacqui Stringer	With Self Management subgroup for comments. Potential overlap with Symptom Management subgroup identified.
CT09005	A randomised controlled trial to assess the effectiveness and cost effectiveness of different psychological interventions designed to improve wellbeing in patients with cancer in an NHS setting.	Dr Sara Booth	With Self Management group for comments. Was submitted unsuccessfully to PBSC in 2008. Input from the CT CSDG in re writing grant application and redesigning study has been requested from PI.

Table 2b Symptom Management studies under development

Protocol number	Title	Investigators	Current Status
	Pilot study of Auricular acupuncture vs Cyproterone Acetate for hot flushes in prostate cancer	Dr David Chadwick, Ms Andrea Harris, Dr Alasdair Macsween	Resubmitted to CTAAC May 09. Outcome due July 09.
	Autogenic training for insomnia	Professor Nicky Robinson Dr Teresa Young	Submitted to RfPB 30th January 2009. Outcome due mid to end July 2009. Lead investigator to be notified.
CT09001	Acupuncture for cancer induced bone pain	Ms Carole Paley	The Symptom Management Subgroup have submitted comments to the investigators. After significant discussion the group could not support the study in its current design.
	Acceptability of acupuncture or gabapentin for hot flushes in breast cancer	Dr Jacky Filshie	In development – stalled
	NEVASIC - The effectiveness and cost effectiveness of Nevasic audio cd for the control and management of chemotherapy-related anticipatory, acute and delayed nausea.	Professor Alex Molassiotis, Dr Lesley Storey, Mr Hirst,	Received CEC0 small/seed grant of £2,500 for a very small pilot study. Top up funding is being sought from the company.
CT09002	To explore the effectiveness of acupuncture to alleviate the effects of chemotherapy induced neutropenia, fatigue, nausea and well-being	Dr David Kelsey	Sent to the Symptom Management Subgroup for review. Likely to have input from Palliative Care, Psychosocial and Breast CSG when relevant.
CT09003	Management of fungating lesions using essential oils	Dr Jacqui Stringer	Sent to CT CSDG Symptom Management Subgroup and Head and Neck and Breast CSG's for comment.

Table 2c Disease Management studies under development

Protocol number	Title	Investigators	Current Status
	Sabal Serrulata in homeopathic dilution for prostate cancer: rodent model	Dr Peter Fisher (PF), Dr Alan Cooper	In development: An outline protocol has been developed and collaborators are being sought. PF has emailed Noel Clark (Chair Prostate CSG) to seek collaboration, but has had no response. A new Chair of the prostate CSG is to be appointed shortly. PF will pursue when the new Chair in post. The CRUK drug development office has also been contacted for advice on development procedure. The New Agents Committee does not fund stand alone preclinical studies.
	A survey of the use of CAM by brain tumour patients	Dr Peter Fisher (PF), Professor Susan Short, Professor Alex Molassiotis, Dr Sosie Kassab	In development: A questionnaire has been developed in collaboration with Dr Susan Short (chair NCRI Brain Tumour CSG, palliative care subgroup) with advice from Alex Molassiotis and the North London Cancer Research Network. The questionnaire is currently being piloted on approximately 50 patients
	A study of Boswellia in brain tumour patients undergoing radiotherapy	Dr Peter Fisher, Susan Short, Dr Saul Berkovitz	In development: A study looking at the use of the herb Boswellia in the reduction of dexamethasone requirements in primary brain tumour patients undergoing radiotherapy with cerebral oedema resistant to dexamethasone has been proposed. The number of patients in this category is small. The possibility of including patients with cerebral metastases and approaching the radiotherapy CSG is under consideration.
	Whole body hyperthermia as a potentiator of chemotherapy in pancreatic cancer	Dr Peter Fisher, Dr Helmut Roniger	Identified as an idea for development - The hyperthermic equipment will be purchased through a grant obtained from the RLHH. Funding is still to be sought for the study.
	Homeopathy in breast cancer	Dr Alex Tournier Dr Peter Fisher	Ideas presented at the February CT CSDG meeting. Feedback was given re study aim, methodology. PF agreed to guide Alex through the development process. Alex has not made contact with subgroup as yet.

Statistical Design Subgroup

The Statistical Subgroup provides a statistical review of proposals after they have received a favourable scientific report from one of the other subgroups and will take part (where required) in projects being developed by one of the other subgroups. Beyond statistical review, the Statistical Subgroup helps the Principal Investigator link with a registered CTU and may offer the statistical input required to get the proposal into the form of a grant application.

During the previous year, statistical input to grant application has been given to the Auricular Acupuncture trial being supported through the Symptom Management Group and to the Autogenic Training trial submitted to the RfPB for funding. Statistical input has also been given to the design of a trial of mistletoe which is expected to make a grant application later this calendar year.

Meetings

The Group has not held any national trials meetings but aim to investigate the feasibility of a joint trials meeting with the Psychosocial CSDG and other relevant CSG's in the near future.

However, the Group has been successful in securing a breakfast workshop session at the 2009 NCRI conference. The workshop will focus on 'Methodologies in Complementary Therapy Research' and will feature national and international speakers.

Collaborations

During her induction period the Research Development Coordinator carried out a level of pre-consultation with relevant Clinical Studies Groups¹ (where there exists immediate potential for collaboration between group members) with regards to interest and collaborative research development with the CT CSDG group. This has raised the profile of the Group with other CSG's/expertise where there had been little contact.

As a result of this, and other mechanisms, the Group has had fruitful collaborations during the development of a number of studies with the Prostate, Brain and Palliative Care CS(D)G's.

The Chair of the CT CSDG is also co-leading the Survivorship Cross working group with Professor Brown, Chair of the Psychosocial Group which may lead to collaborative opportunities in the future.

Other activities

Of particular current strategic interest to the Group is the National Cancer Survivorship Initiative (NCSI) which aims to improve patients' experiences of living with and beyond cancer. The NCSI is currently working on several projects which are expected to result in the development of a research agenda in which complementary therapy and integrative care are highly likely to feature. During this reporting period the Research Development

¹ Brain, Breast, Head and Neck, Lung, Psychosocial, Palliative Care, Gynaecological, Teenage and Young Adult. Still to attend –, Prostate, Primary Care.

Coordinator was seconded for 2 days a week for 4 months to support a project within the research work stream of the NCSI. This has resulted in complementary therapy research being kept high on the work stream's agenda. Through her membership of the work stream the Research Development Coordinator will continue to provide a valuable link between the Group and the NCSI.

3 year-strategy

The primary strategy for the Group will involve developing and having had funded a number of robust research studies.

It has been recommended that the Group to focus more and identify clear research priorities that are deliverable and to pick 'low hanging fruit' and develop quick or easy wins. Therefore the Group has developed a strategy to address these recommendations and is currently working in collaboration with the other CSG's and relevant external organisations and initiatives to identify research priorities for complementary therapy research. Results are expected by the end of 2009.

Priorities for next year

The Group's priorities for next year are to:

- Identify research priorities in complementary therapy research and to develop a process for study prioritisation
- Establish and enhance its portfolio of studies particularly establishing a 'pipeline' approach to the generation of research submissions.
- Establish and maintain a momentum of submissions to funding bodies with the aim of each subgroup submitting at least one study per funding year.
- Monitor trials within the portfolio identifying those which require additional support to address any recruitment issues.
- Start to think about tracking and identifying other complementary therapy research which is taking place throughout the UK.
- Hold a meeting with the Palliative Care, Psychosocial Oncology and Primary Care CS(D)G's (to be organized by the Palliative Care Clinical Studies Group)
- Raise the profile of complementary therapy research through member attendance and participation at relevant high profile scientific meetings.

Mr Andy Ritchie, Chair

Appendix 1

Key strengths and issues from the Progress Review, December 2008

The key strengths of the Group identified at the December review are:

- A strong sense of energy and excitement
- Reasonable progress since the last review in terms of accrual, funding submissions and submissions approved
- A pipeline of studies in development
- A new subgroup structure which appears to be understood and working well
- Various steps have been taken to raise the Group's profile
- The development of a new strategy

The Panel identified the following issues which the Complementary Therapies CSDG needs to consider:

- Renaming the tumour Progression Subgroup so that there is no confusion in the Group or the wider research community that the remit of the Group does not extend to alternative medicines (*)
- Appointing a new chair for the Statistics and Design Subgroup (*)
- Appointing additional oncologists to the Group and subgroups (*)
- Broadening the membership of the subgroups to include researchers who are not on the main Group and also young researchers
- Face to face meetings of the Chair, Subgroup Chairs and Research Development Co-ordinator on a three monthly basis (*)
- Updating the Group's flyer
- Holding an open meeting or a joint meeting with other CSDGs
- Attendance at the annual trials meetings of other CSGs
- Finalising their strategy for the next 3-5 years
- Ensuring that submissions are made and funded (*)
- The Tumour Progression Subgroup linking with CRUK DDO (*)

The Panel agreed that the NCRN needed to:

- Raise the CRUK decision with senior colleagues in NCR

Appendix 2

2008/09 Publications and abstracts report

Barlow F, Lewith G, Walker J. The experience of proximate spiritual healing in women with breast cancer, who are receiving long term hormonal therapy. *JACM.* 2008; 14 (3): 227-231