

## **NCRI Psychosocial Oncology Clinical Studies Development Group**

### **Introduction**

Psychosocial oncology is a relatively new field which has been developing for around 30 years. Psychosocial oncology aims to identify and manage the more subtle subjective symptoms of cancer such as anxiety and depression and addresses the psychological, social, spiritual and behavioural dimensions of the cancer continuum (from prevention through diagnosis, treatment to survivorship, bereavement) from both patient and their social network perspectives. It is a broad multidisciplinary field with a variety of specialists involved from psychiatrists, psychologists, social workers, palliative care, nurses, oncologists to surgeons.

Psychosocial oncology research encompasses a wide range of research methodologies from qualitative research to understand patient perspectives, psychometric research to develop questionnaires, case/control and observational studies to capture e.g. survivorship experience or clinical trials to evaluate either psychosocial interventions or the impact on the psychosocial domain from different treatment regimes.

The remit of the Psychosocial CSDG is to:

- encourage the development of research protocols in psychosocial oncology, either freestanding or linked to trials of treatment within the NCRN.
- work closely with all the NCRI Clinical Studies Groups in order to develop site-specific psychosocial oncology protocols.
- work in collaboration with the other relevant Clinical Studies Development Groups.
- consider research protocols submitted to CTAAC or PBSC where the main outcome measures are within the field of psychosocial oncology.

The Group was established as a Clinical Studies Developmental Group in 2004. During 2007 the Group set a 3 year strategy as a result of which a revised subgroup structure was developed and is now in operation.

The Group had an interim review in November 2008. The strengths of the Group and issues it needs to consider are summarized in Appendix 1.

### **Membership and structure**

Members come from a wide range of specialisms. There has been some turnover this year with Dr Edward Estlin, Dr Adam Glaser, Dr Gill Hubbard and Dr Anne Thomas joining the Group and Dr Penelope Hopwood, Professor Amanda Ramirez and Dr Bill Noble stepping down. There are 3 consumer representatives all of whom are active members. The Group has a portfolio coordinator and has three subgroups, Psychosocial Effects and Participation in Clinical Trials, chaired by Professor Karen Cox, Impacts of Sides Effects, chaired by Professor Galina Velikova and Transition From Active Therapy chaired by Dr Ziv Amir and Dr Penny Wright. Membership is strong and there is good attendance at main and subgroup meetings.

### Portfolio and accrual

There are currently 24 studies in the Group's portfolio. Of these 8 are closed. A summary of studies in the portfolio can be found in Table 1 below. 1567 patients were recruited to Psychosocial Oncology studies in 2008/09 346 to RCTs and 1221 to non RCTs. The portfolio roughly reflects the Groups 3 priority areas for development. The Group has submitted 9 grant applications which have been developed within the subgroups, 3 have been successful, 3 are still under review and 3 were rejected. Cohort studies and case control studies have been developed in addition to clinical trials.

**Table 1: NCRI Psychosocial CSDG portfolio**

Acronym	Title	PI(s)	Status
A pilot psycho-educational intervention for cancer carers	Development and piloting of a brief, short-term psycho-educational intervention for informal carers of patients at the end of life	Dr Richard Harding	Open
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
ATT (Attention Control Study)	Quality of life (QOL) assessment in the care of individual cancer patients.	Professor Galina Velikova	Closed
Benefit finding in head and neck cancer patients	Assessing the psychological mechanisms related to benefit finding in head and neck cancer patients. Implications for a coping based intervention	Dr Carrie Llewellyn	Open
BresDex	A decision explorer for women deciding about breast cancer treatments: BresDex	Professor Glyn Elwyn	Open
BUMPS	Behavioural urinary management for prostate symptoms: A phase II trial for testing feasibility of a self-management intervention for urinary problems following prostate radiotherapy	Dr Sara Faithfull	Closed
Cancer-related Fertility Impairment	The experience of cancer-related fertility impairment among people of South Asian and White origin	Dr Karl Atkin	Open
CARIAD	The CARIAD Trial: Waiting for genetic risk information: a randomised controlled trial of a brief self-help coping intervention	Dr Ceri Phelps	Closed
Clinical meaning & utility of the SPI: longitudinal study	Clinical meaning and utility of the social problems inventory (SPI) in oncology practice: longitudinal study	Dr Penny Wright	Closed

Clinical meaning & utility of the SPI:X-sectional study	Clinical meaning and utility of the social problems inventory (SPI) in oncology practice: cross sectional study	Professor Peter Selby	Closed
CNS 2005 01 (In-depth QOL for Brain Tumour)	An in depth study over time on the effect of child and parent factors on the perceived quality of life of children treated for a brain tumour	Dr Colin Kennedy	Closed
Cognitive Behavioural Intervention	A randomised controlled trial of a cognitive behavioural intervention for women who have menopausal symptoms following breast cancer	Myra Hunter	In set up
COIN QoL Sub-Study	COIN Quality of life sub study	Professor Tim Maughan	Closed
Communication & Comprehension about Phase I trials	Communication and comprehension about phase I oncology trials	Professor Lesley Fallowfield	Closed
Computerised Adaptive Testing for EORTC QLQ-C30	Making the EORTC QLQ-C30 interactive: Development of computerized adaptive testing (CAT) for EORTC QLQ-C30 dimensions	Dr Mogens Groenvold	Closed
Continuity of Care Study-Phase IIb	Continuity of care in patients with cancer: Phase IIb-feasibility trial	Dr Louise Jones	Closed
COSTAR	COchlear Sparing therapy and conventional radiation: A multicentre randomised study of cochlear sparing intensity modulated radiotherapy versus conventional radiotherapy In patients with parotid tumours	Dr Christopher Nutting	Open
Determination of Quality of Life Instrument	Determination of quality of life instrument most preferred by head and neck cancer patients	Mr Hisham Mehanna	Open
Development of an EORTC Quality of life module for cholangiocarcinoma	Development of an EORTC quality of life module for cholangiocarcinoma		Open
Feedback of trial results	Feedback of trial results to participants: A literature review and stakeholder survey	Professor Karen Cox	Closed
FH01 - HTA Mammography Trial	Evaluation of mammographic surveillance services in women under 50 with a family history of breast cancer	Dr James Mackay	Closed
Health Behaviours in Cancer Survivors	Health behaviours in cancer survivors	Professor Jane Wardle	Closed
Health outcome	Protocol for developing a user-	Mr Colin	Closed

measurement for older patients with cancer	generated approach to health outcome measurement for older patients with cancer: pilot testing and validation of a questionnaire	Johnson	
Home but not Alone	Home but not alone: a research study to determine whether user mentor support can improve health related quality of life in the period immediately after discharge	Mrs Sheila Fisher	Open
Living with Secondary Breast Cancer -	A study of the experience of living with secondary breast cancer	Professor Jessica Corner	Closed
Mechanisms of fatigue in breast cancer survivors	An investigation in to the biological mechanisms and clinical correlates in disease free breast cancer patients following primary treatment	Dr Ollie Minton	Open
OES/STO Merge	A study to combine the EORTC quality of life questionnaire modules, the QLQ-OES18 and QLQ-STO22 to measure quality of life in patients with oesophageal or gastric cancer, or cancer of the oesophago-gastric junction	Professor Jane Blazeby	Closed
P4NET	Clinical and psychometric validation of a disease specific module in assessing the quality of life of patients with G.I.related neuroendocrine tumours.	Dr John K Ramage	Open
PSQ;H&N	Quality of life assessment in individual head & neck cancer patients	Mrs Sheila Fisher	Closed
Quality of Life in secondary liver tumours	a) Development of an EORTC QoL questionnaire for patients with malignant carcinoid tumours.(now closed) (b)A study of the clinical and psychometric validation study of a disease-specific questionnaire module(QLQ-LMC21) in assessing the quality of life of patients(open)	Professor Jane Blazeby	Closed
QUEST -	A multi-centre randomised trial to assess the impact of the type and timing of breast reconstruction on quality of life following mastectomy	Dr Zoe Ellen Winters	In set up
QuEST-Q1	The development of cancer site-specific questionnaires to	Professor Galina	Open

	measure symptoms, functioning and health related quality of life in oncology practice	Velikova	
Reducing Fatigue Through Telephone Support	Reducing fatigue in individuals with cancer undergoing chemotherapy through telephone support and education	Dr Emma Ream	Closed
SCNSUK05	Unidentified or unmet - what are the supportive care needs of people following cancer treatment?	Maggie Crowe	Closed
South Asian SDI Study	The social impact of cancer on people of south Asian origin: staff and patient interview studies	Dr Chris Bradley	Closed
Spiritual beliefs study	Study to explore the associations between beliefs and psychological status in patients receiving palliative care	Dr Louise Jones	Open
Survivors of Adult Cancer	Survivors of adult cancer: Their use of primary care services and unmet needs.	Dr Peter Rose	Open
TACT Trial Long Term QL (sub-study)	TACT Trial long term quality of life sub-study	Dr Paul Ellis	Open
Teams Talking Trials	Development and evaluation of a training intervention for cancer teams talking about randomised trials	Professor Lesley Fallowfield	Open
The Sheffield DEBRA trial -	The effects of a combined diet and exercise intervention on biomarkers associated with disease recurrence after breast cancer treatment: The Sheffield DEBRA trial.	Dr John Saxton	Closed
Using the internet for information exchange	Using the internet for information exchange: design and evaluation of a website for use in follow up of cancer patients at low risk of recurrence	Dr Penny Wright	Open

### **Trials in development**

There are a number of studies under development within the subgroups including:

- The use of charity oncology help lines
- Interventions for sexual dysfunction
- Issues surrounding return to work after cancer diagnosis
- Cancer as a chronic disease and specific focus on availability of expensive new drugs and what impact this may have on patients
- Use of Breast Cancer Care's discussion forum, analysis of conversation threads re clinical trials
- Peer support and clinical trial participation

- Developing and testing a model of feedback of trial results
- People's expectations prior to treatment finishing (what will life be like when treatment finishes) and the reality in the post treatment period (a few months around this transition point; what is life like now) and how this affects their self management of cancer/treatment related problems.

### **Meetings**

A cross cutting meeting to discuss survivorship issues was held in July 2009.

### **Collaborations**

Professor Brown regularly attends the Chairs Forum. The Group is collaborating with the Primary Care CSDG on a study of long term follow up of survivors. The CSDG collaborate with, Supportive and Palliative Care Collaboratives (SuPaCs), COMPASS and CeCo, EORTC Quality of life Group, British Psychological Outcomes Society (BPOS) and the International Society for Quality of Life Research (ISQUOL). The Transition From Active therapy Subgroup is collaborating with CECO on a funding submission to Dimbleby

The Group has links to several other CSGs (e.g. Bladder and Translational) the CCLG Psychosocial Group, and to CSDGs (Primary Care, Palliative Care, Teenage and Young Adults and Complementary Therapies). Members of our Group have been nominated as link person for each of these groups.

### **Other activities**

The Chair led a collaborative meeting of CSGs and funders to discuss the CRUK new research strategy in Feb 2009. She has also be organized and lead a cross CSG working group to discuss survivorship cross cutting themes.

### **3-year strategy**

The overall strategy of the Group was developed and agreed by the group membership at an away day in February 2007 and was taken forward from April 2007.

The strategy is to concentrate on building the research portfolio of the Group, to increase and widen participation in the Group's research portfolio and to acquire full clinical studies group status. In order to achieve this strategy we will be:

- Revising the subgroup structure to focus on key areas that the Group have identified as priorities in order to drive the development of new research
- Reviewing Group membership and identifying and filling gaps in expertise
- Co-opting individuals onto the new subgroups in order to include a wider range of expertise and also to start to develop and build new researcher capacity (i.e. inclusion of post docs, research fellows)
- Inputting into the NCRI's forthcoming strategic review of survivorship and highlighting funding scarcity and lack of research capacity in this area
- Inputting into the NCRI's strategic review of Health Services Research, once again, identifying the funding scarcity and lack of research capacity in this area

- Raising the profile of the Group through stronger links with CSGs, CSDGs and other national and international psychosocial groups.
- Developing a clearer system for identification of portfolio studies

The Group has already achieved aims 1-5 and 7. We are still working on raising our profile. The publication of the new CRUK research strategy will affect delivery of the CSDG strategy since a key funding source both for research projects and key infrastructure to support some of the main research groups within our CSDG will no longer be available. The CSDG will review and update our strategy at the end of 2009/early 2010 when future funding arrangements for psychosocial research are clearer.

**Priorities for next year**

The priority remains to develop high quality research grant submissions.

Professor Julia Brown, Chair

## Appendix 1

### Key strengths and issues from the Interim Progress Review, November 2008

The Psychosocial CSDG had its first 3 year review in February 2007 and an interim review on 17<sup>th</sup> November 2008.

The key strengths of the Group identified at the November review were:

- Making considerable progress since the last review and undergone a marked change
- Addressing the majority of issues since the last review and making concrete progress
- A strong and inclusive Chair
- Good working relationships between members who work collaboratively with each other and other CS(D)Gs
- A subgroup structure which is clearly understood and working well
- Active consumers who participate well in the Group's activities and who are welcomed and supported
- Attracting national and international interest
- Broadening membership

The Panel identified the following issues which the Psychosocial Oncology CSDG needs to consider:

- Holding a one off meeting with funders and interested CS(D)G chairs to see who may pick up the areas of research which will be no longer covered by CRUK
- Other areas of work which it might move into e.g. prevention and early diagnosis
- Which areas of work they wish to discard
- Continuing and extending links with the Palliative Care and Primary Care CS(D)Gs and other relevant CSGs
- Developing collaborative studies with these groups

The Panel agreed that the NCRN needed to:

- Raise the CRUK decision with senior colleagues in NCRI

The Panel agreed with the Group's wishes to remain a CSDG.

## Appendix 2

### NCRI Psychosocial CSG 2008/09 Publications and abstracts report

**Reed E, Simmonds P, Corner J** (2009) Surveying the experience of living with metastatic breast cancer: comparing face-to-face and online recruitment. *Journal of research in Nursing* 2009, Vol 14(1) p 43-55

**Wright P, Marshall L, Smith A, Velikova G, Selby P.** Measurement and interpretation of social distress using the social difficulties inventory (SDI). *Eur J Cancer*. 2008;44:1529-35

**Penny Wright, Laura Marshall, Adam B. Smith, Galina Velikova and Peter Selby,** Measurement and interpretation of social distress using the social difficulties inventory (SDI) Psychosocial and Clinical Practice Research Group, Cancer Research UK Clinical Centre, Section of Oncology and Clinical Research, University of Leeds, St James's University Hospital, Beckett Street, Leeds LS9 7TF, United Kingdom, *European Journal of Cancer* Volume 44, Issue 11, July 2008, Pages 1529-1535