

Draft PhD RESEARCH PROPOSAL

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“Measuring RNA expression changes and/or impacts from a psychological intervention on cancer patients”

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Research hypotheses

That there is a different and measurable genome RNA expression change and/or impact following a psychological intervention on selected cancer patients compared to a non-cancer control group.

I approached Dr Richard Eek, MBCHB MMED FCP FRACP, Medical Oncologist / Conjoint Lecturer Border Medical Oncology / University of New South Wales about this PhD request. He noted:

I think your proposal is both exciting and relevant and needs consideration. Will you be able to meet me for a brief discussion on this 3 June 09 at 15h00? I think the issues we need to discuss in more detail are, statistical power, financial backing etc.

Dr Eek further commented that when I was ready to undertake the clinical trial, I should come back to him and the hospital for support to run the trial.

Following a meeting on 11 May 2009 with the CEO of Australian Genome Research Facility and Head of Applied Genetics Research Unit ORYGEN Research Centre, the research direction will determine different and measurable genome RNA expression changes and/or impacts following psychological intervention across cancer, survival and non-cancer populations.

Following this decision, I propose this PhD based on the completion of a clinical trial to undertake and complete this research.

The clinical trial ostensibly will consist of using a previously trialed psychological/ psychosocial cancer intervention, extending that to include RNA genomic analysis and measuring any RNA changes/impacts against a control group. The elements will include:

- Psychological/psychosocial questionnaires
- General physical health & wellbeing questionnaires
 - Physiological
 - Environmental
 - Cancer questionnaire
- Blood and/or saliva samples
- RNE expression genomic analysis
- enquiries across these data sets.

Participants:

Participants will be cancer patients and a non-cancer control group. The number of participants required will be a statistically validated sample.

Procedure:

1. Selection of a psychological intervention used in previous clinical research that produced a statistically valid research outcome;
2. Participants will participate in the selected psychological intervention over a reliable period;
3. There may be a requirement to select a predefined participants sample that would align with the selected psychological intervention
4. Blood sample at the beginning and a second sample at the end of the intervention period;
5. Participants will complete personal and general health questionnaires at the beginning and end of the intervention period;
6. Participants will complete a psychological questionnaire, possibly a compilation from those used in the earlier intervention selected, at the beginning and end of the intervention period.

Variables to be studied include:

- Psychological variants
- Physiological co-founders
- RNA genomic expressions
- Gender variants

Rationale

Various experiments and clinical research have identified links between stressors and psychological, psychosocial, environmental factors and genes/genome which may provide a basis for treatment and prevention of cancers.

The findings of my analysis are in a paper I wrote. The paper considers existing research into cancer predisposing genes and the psychological, psychosocial, environmental and genome factors which may be involved.

The paper “Stressors, psycho-genomic pathways and cancers – *identifying psychological, psychosocial, physiological, environmental and genomic pathways to prevent and treat cancers*” is available on our website at www.psycho-genomics.org under Storyboard Talking Point.

The evidence presented demonstrates some relationships across psychological, psychosocial, environmental and gene pathways and cancer. While not determinative, the evidence provides opportunities for further high quality research in what is a psycho-genomic structure.

Research streams that form part of our psycho-genomics scientific enquiry include non-cancer, cancer, psychology, psychosocial, environmental, physiology, genes and the genome.

Four earlier research outcomes, discussed in the paper, provide a clue that by undertaking a cross sectional examination from psychological factors through our immune system to our DNA, we may impact on cancer treatment and

progression strategies: The four different and unrelated research findings dealing with the immune system and cancer note:

- That it may be possible to find ways to use the immune system to contain cancer when cancer cannot be eradicated, noted in a 2007 research finding that involved a researcher from the MacCallum Cancer Immunology Program in Melbourne;
- That psychological factors, such as stress, depression and social support are able to modulate many of the immunologic activities relevant to patients with malignant disease;
- That psychological interventions, eg emotional expression, can enhance psychological adjustment and improve immune function emotional expression may improve immune function and perhaps promote longer survival; and
- That psychosocial factors, such as social support and distress, are associated with changes in the cellular immune response, not only in peripheral blood, but also at the tumour level. These relationships were more robust in TIL (tumour-infiltrating lymphocytes). These findings support the presence of stress influences in the tumour microenvironment.

As almost all cancers are gene based, the evidence from earlier research indicates that there is potentially a very positive adjustment and/or survival outcome through psychological/ psychosocial interventions.

Positive survival/adjustment outcome, therefore, may be reflective of changes in gene expression and/or gene mutation impacts that reflect on cancer prognosis and outcomes.

In comparison to current cancer screening, identification of abnormalities and treatments, there is potential for research with a focus on identifying psychological/psychosocial to genomics pathways across cancer, cancer survival and non-cancer populations.

Proposed psychological questionnaires

I have identified a series of psychological/psychosocial interventions used in early clinical trials from which I will select one for the clinical trial. They covered:

- Anxiety Management Training
- Relaxation Therapy
- Mindfulness Based Stress Reduction
- Relaxation, Supportive and Guided Imagery Therapy
- Cognitive Behavior Therapies
 - Distraction and Cognitive Restructuring
 - Adjustment Disorder Therapy
 - Adjunctive Psychological Therapy
 - Problem Solving Therapy
- Transtheoretical Model of Change & Motivational Interviewing

The PHD research will determine the most suitable related earlier clinical trial outcomes that used a psychological/psychosocial intervention with cancer patients with the highest positive indicator/result and the statistical power analysis. The intervention will use the most appropriate & related psychological questionnaires that provided the best indicator/result.

The selection of the psychological/psychosocial questionnaires may be from the following:

<ul style="list-style-type: none"> • Rosenberg Self-Esteem scale • Mastery Scale • Norbeck Social Support Questionnaire • Beck Depression Inventory • Spiritual Perspective Scale • Nottingham Health Scale • Hospital Anxiety & Depression Scale • Illness Intrusiveness Ratings Scale • Mental Health Inventory • Multidimensional Health Locus of Control Scales • Rank-36 Item Health Survey • Herth Hope Index 	<ul style="list-style-type: none"> • General Health Questionnaire • Life Orientation Test • COPE • Religious Coping Scale • Eysenck Personality Scale • Psychological Adjustment to Illness Scale • Quality of Life Index • Perceived Stress Scale • Psychological General Well-Being Index • Profile of Mood States • Modified Somatic Perception Questionnaire • Coping Strategies Inventory • Mini-mental State Exam
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Consultations:

Much consultation has occurred since the commencement of this research. These have included:

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10. Community workgroups with over 500 participants

About Psycho Genomics Research Institute Inc

The Psycho-Genomics Research Institute has been established to encourage and develop psycho-genomic research in order to explore these links and identify better, broader and innovative new methods of preventing and treating cancer.

We are establishing the new cancer research front of psycho-genomics. Various experiments and clinical research have identified links between psychological, psychosocial, environmental factors and genes which may provide some bases for treatment and prevention of cancers.

In psycho-genomics research we take an integrated approach to prevent and treat cancers, taking into account different cancers and our psychology, emotional expression & processing, psychosocial, environmental, physiology, DNA, genes and genomic pathways.

Personal profile of Theo Richter

Theo has worked in the ATO since 1991 and is a Director in S&ME. Prior to the ATO he worked in management and leadership positions in his own franchisee operation, in other retail and food operations. Theo brings over six years of mind body cancer research and is founder and President of Psycho-Genomics Research Institute Inc a charity & non-profit research organisation.

Theo has an ICF ACSTH Certificate of Coaching Skills, is an Executive Coach with Results Coaching Systems, has a Graduate Certificate in Management and a Graduate Certificate in Leadership in Education and Training with Victoria University. He is a member of International Coaching Federation (ICF) Australasia, is a Fellow Professional National Accountant with National Institute of Accountants. He has a Masters in Taxation from University of NSW.

The mind body cancer research organisation Psycho-Genomics Research Institute Inc is a community based non-profit organisation, previously registered as Power Thinking International Inc. It is a registered NSW charity. It is registered with the ATO as a Tax Exempt Charity and a DGR (Deductible Gift Recipient).

Theo started this organisation six years ago as a local community organisation to explore mind body links to identify psychological/psychosocial intervention affects on blood markers over time in order to treat cancers, to increase survivorship and prevent initiation of cancers.

The organization's research aims cover:

- identify gene expression and gene mutation marker differentials between cancer and non-cancer population;
- undertake a study over several years looking for blood markers of cellular dysfunctions which predispose to cancer, i.e. a step before the current screening phase, and
- identify psychological/psychosocial intervention affects on those blood markers over time in order to treat cancers, to increase survivorship and prevent initiation of cancers.

Theo Richter

(25 August 2009)