



Fatigue Clinic Protocol: Evaluation of interventions for cancer related fatigue

Chief Investigators

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Rationale

Prolonged fatigue states (i.e lasting a month or more) are prevalent in both primary care and tertiary referral practice. A subset of these fatigue states persist for six months or more (i.e. chronic fatigue) and remain medically-unexplained. Despite the lack of knowledge as to the pathophysiology of chronic fatigue syndromes and by extension the lack of treatment options targeting the cause(s), a number of interventions have been investigated ¹. To date the most promising results have been achieved with cognitive behavioural therapy (CBT)²⁻⁶. or graded exercise (or graded exercise therapy – GET) ^{4,7,8}. By analogy with other medically-unexplained chronic fatigue states, notably chronic fatigue syndrome (CFS), it is likely that CBT ⁹ and GET ^{4,10}. will also improve functional outcomes and consequently the quality-of-life of patients across the spectrum of those treated for cancer who experience PCF. It is proposed that the combination of both GET and CBT will be more effective than either treatment alone.

Cancer related fatigue (CRF)

Fatigue and psychological distress (depression and anxiety) are perhaps the most prevalent symptoms experienced by patients being treated for cancer ¹¹⁻¹³. Cross-sectional studies also consistently record a high prevalence of chronic fatigue often persisting many years after successful treatment for cancer ¹⁴⁻¹⁸. Recent prospective studies in both testicular cancer and Hodgkin's disease survivors also identified high rates of unexplained fatigue lasting months to years after treatment ^{12,13,19,20}. The term *cancer-related fatigue* (CRF) and a diagnostic criteria set have been proposed to describe this syndrome in the oncology setting ²¹⁻²³. These criteria also

emphasize the complaint of fatigue, accompanied by disturbances in cognitive performance and sleep, as well as loss of motivation. These components are very similar to those of the diagnostic criteria for CFS. At present there is no clear understanding of the biological basis of medically unexplained fatigue persisting after cancer treatment (termed here *post-cancer fatigue* - PCF), and no effective prevention or treatment strategy has been defined.

Aim

This pilot program aims to establish the infrastructure, and to ensure feasibility of an integrated assessment and rehabilitative management program for patients who have received potentially curative treatment for cancer.

The project will initially be targeted at women treated for breast cancer and patients (male and female) treated for colorectal cancer, but will then be extended to other patients including those treated for testicular cancers and Hodgkin's disease. The program will subsequently be extended to patients who have been diagnosed with chronic fatigue syndrome (CFS)²⁴ including those with post-infective fatigue syndrome (PIFS)²⁵, and patients with major depression accompanied by prominent fatigue.

Methods

A prospective, non-randomised, single arm, intervention study.

A combined graded exercise/activity and cognitive behavioural program individualised for each patient will be provided. The general content of the program will be standardized, but will be individually-tailored based on data derived from: report of symptoms and functional status, the initial assessment of functional capacity, and psychological assessments.

The primary endpoints of the study will be improvements in self-reported symptom severity and functional status measures recorded at weekly throughout the 12 week intervention and 6 months post-intervention:

- Fatigue
- Pain severity
- Sleep disturbance
- Mood disturbance
- Functional status

In addition, improvement in functional capacity will be evidenced by changes in

- Diary-recorded activities

Fatigue Clinic program at the Lifestyle Clinic

Enquiries or further information regarding the research trial may be directed to Professor David Goldstein (medical oncologist and study co-investigator - 02 9382 2577); Dr. Barbara Bennett (psychologist with experience in post-cancer fatigue and study co-investigator – 02 9382 2353) or Chris Tzar (Lifestyle Clinic Director and Exercise Physiologist - 02 9385 3352).

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Additional Reading

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