CareSearch Project Research Studies Register: Registration Proforma	0160

Study Title: CARE-IS Study – Care-IS Trial: A randomised controlled trial of a supportive educational intervention for caregivers of patients with high grade glioma

Brief description of the study: This study aims to evaluate the efficacy of a tailored nurse-led education and support intervention for carers of people with HGG in an RCT. Objectives: 1) Determine intervention's impact on carer preparedness and distress (primary endpoints). 2) Determine intervention's impact on carer anxiety and depression, carer quality of life, carer competence, and carer unmet supportive care needs (secondary endpoints) and grief. 3) Assess changes in costs related to HGG patient healthcare resource utilisation as a consequence of improved carer support, education and wellbeing, relative to the costs of implementing the intervention (secondary endpoint). Hypotheses: 1) This intervention will improve preparedness for caring and reduce carer distress, unmet needs, and subsequent complicated grief. 2) This intervention will reduce patient healthcare resource utilization and costs. Significance: This study will provide evidence whether using a preparedness for caring intervention reduces carer distress, improves carer outcomes and reduces patient healthcare resource utilisation and overall costs. If successful, the research will be highly significant as an intervention model that could also be adapted for carers of people with other aggressive cancers (e.g. pancreatic cancer) and progressive neurological disorders (e.g. motor-neurone disease)

Study Methodology: (Please mark with an x which type of study methodology)

	Epidemiology
	Health Services / Health Economics / Quality Improvement
	Qualitative, Observational or Descriptive
	Mixed Method
	Systematic Review
X	Intervention: RCT
	Intervention: Comparative or cohort study
	Intervention: Case series

Project details:

Funding source (Optional): Cancer Council WA						
Has the study received ethics approval?	**X**	Yes		No		Not applicable
Project starting date: 2014						
Project completion date: 2017						
Multi site:		Yes	**X**	No		Not applicable

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Researchers
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Associated publications / reports:
Topics (Admin only) Carers, Education and training