

Challenges in Recruiting into a Current Randomized Controlled Trial in Refractory Cancer Cachexia



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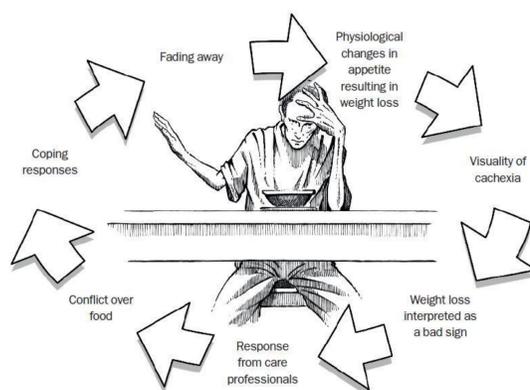
Introduction

Cancer cachexia is defined as a multifactorial syndrome characterised "by an ongoing loss of skeletal muscle mass (with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support" (1).

Refractory cachexia refers to the 'stage where reversal of weight loss seems no longer possible' (1) and the majority of patients at this stage will be receiving palliative care.

Background

Previous research in this area has demonstrated the holistic impact of the syndrome (2-5).



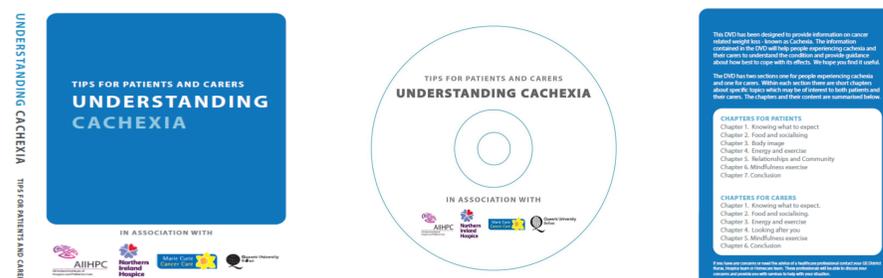
In the absence of a recognized treatment solution, an evidence-based psycho-educational DVD health care intervention has been developed for this patient cohort and their family members by a team of researchers and healthcare staff in Northern Ireland.

Recruitment

Similar to previous studies with this population recruitment has been challenging – this is because cachexia is rarely acknowledged or diagnosed by health care professionals who lack protocols to manage the syndrome.

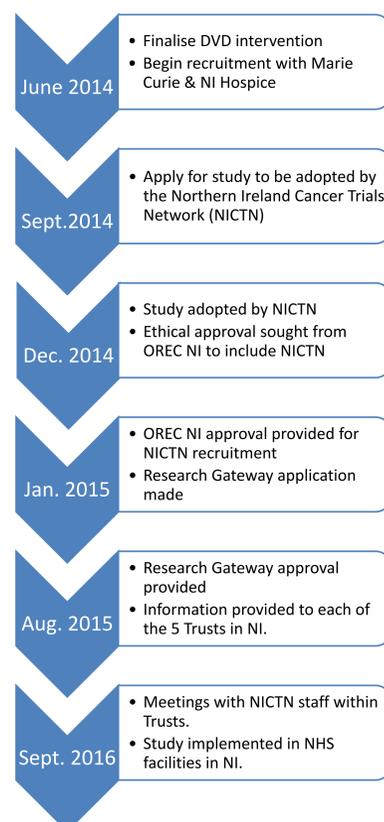
DVD Intervention

This DVD intervention will be evaluated in a randomized controlled trial with a palliative cancer population who have refractory cachexia(6). The team's experience thus far highlights the inherent difficulties in conducting research with this client group.



Refractory cancer cachexia is rarely acknowledged or diagnosed due to a lack of clear clinical diagnostic guidelines and local protocols for clinical management and this has hindered identification of potential participants. Indeed previous research has demonstrated the lack of clinical awareness of this syndrome among health care professionals (7).

Progress to date



- Extensive engagement with partner organisations (30 face-to-face meetings with NI Hospice, Marie Curie and NICTN staff).
- Study adopted by the Northern Ireland Cancer Trials Network to allow participants to be recruited in the NI Regional Cancer Centre and four additional satellite units.
- Study amended to facilitate more flexible recruitment and to reduce the burden for participants.
- Amendments through the NHS Research Gateway and research governance permissions provided by each of the Health and Social Care Trusts in Northern Ireland.
- Recruitment through the NHS Cancer Centres has begun.

Current Recruitment Sites

- Northern Ireland Hospice
- Marie Curie Belfast
- Northern Ireland Cancer Trial Network, which includes all 5 Health Trusts in Northern Ireland

Conclusion

To positively influence clinical practice in relation to cachexia health care professionals need access to 'best available evidence' There is a clear need for the urgent development of evidence based guidelines to aid in the education, diagnosis and management of refractory cancer cachexia.

Such guidelines will undoubtedly provide the clinical diagnostic criteria necessary to assist healthcare professionals in identifying refractory cachexia and allow them to respond appropriately. This in turn will make it easier to identify and recruit appropriate patients for future studies in palliative care.

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