

Oncology Dietitians' Experiences of Implementing a Behaviour Change
Intervention for Patients with Head and Neck Cancers Receiving Radiotherapy

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Declarations

Statement of Originality

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. I give consent to the final version of my thesis being made available worldwide when deposited in the University's Digital Repository* subject to the provisions of the Copyright Act 1968.

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14/11/18

Karen Stafford

Date

Acknowledgement of Collaboration and Authorship

I hereby certify that the work embodied in this thesis has been done in collaboration with other researchers. I hereby certify that the work embodied in this thesis contains a scholarly work of which I am a joint author. I have included as part of the thesis a written statement, endorsed by my supervisors, outlining the extent of collaboration and contribution, with whom and under what auspices.

This study was developed within the context of an established randomised controlled trial, of which Professor Amanda Baker is the Chief Investigator and Dr Benjamin Britton is a Principal Researcher. For this research, my primary supervisor was Dr Sean Halpin, while Professor Baker and Dr Britton were secondary supervisors. I collaborated with all supervisors on the study design, application for ethics variation,

analytic approach and the interpretation of results. I conducted semi-structured interviews with all participants, transcribed and cross-checked all recordings, and conducted thematic analysis. Dr Kristen McCarter contributed as a second coder during the thematic analysis and therefore informed my analysis and interpretation. I wrote the manuscript that forms the body of this thesis, and edited the manuscript based on feedback obtained from my supervisors. Dr Alison Beck and Miss Erin Forbes provided assistance in connecting this study with the broader work of the overarching clinical trial, such as by providing information about the status of related analyses and publications, and assisting with the ethics variation application.

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Structured Abstract

Scope

Malnutrition and weight loss are common in patients with head and neck cancers (HNC) and are associated with increased morbidity and mortality. Dietetic counselling is integral to treatment, but many patients are non-compliant with dietetic advice. The Eating as Treatment (EAT) intervention aimed to improve nutritional status among patients with HNC receiving radiotherapy, by combining dietetic advice with strategies drawn from cognitive behaviour therapy (CBT) and motivational interviewing (MI). The EAT intervention was previously evaluated using a cluster randomised controlled trial across four sites in Australia and was associated with improved patient nutritional status.

Purpose

The purpose of this study was to examine the experiences of dietitians who implemented the EAT intervention. The primary goal was to inform future efforts to improve nutritional status in patients with HNC, including the potential enhancement and broader dissemination of the EAT intervention. A secondary goal was to contribute to the broader professional dialogue regarding the use of CBT and MI strategies in dietetics.

Methodology

Semi-structured telephone interviews were conducted with dietitians. A stratified purposive sampling strategy was initially adopted, in an attempt to recruit dietitians from all sites. Seventeen individuals were approached. Three were ineligible, two were on leave, one declined and seven did not respond. Four dietitians from two sites participated. Interviews were audio-recorded, transcribed and subjected to thematic analysis.

Results

Dietitians valued the practical training they received regarding the EAT intervention. They were able to integrate the intervention into their practice with patients who had HNC, although some aspects of the intervention or the clinical trial were challenging. On the whole, dietitians reported behaviour change strategies were often useful with this patient group, and supported the value of behaviour change strategies in dietetics more broadly. Dietitians highlighted several opportunities for enhancing the EAT intervention or the accompanying training.

Conclusions and Implications

The limitations of this study include a small sample size, the fact that not all trial sites were represented, and the reliance on dietitians' recall up to two years post-intervention. While the results cannot be generalised more broadly because of these limitations, the findings do highlight several considerations that may be relevant to the use of CBT and MI in dietetic practice and to improving nutritional status in patients with HNC who are receiving radiotherapy.

Oncology Dietitians' Experiences of Implementing a Behaviour Change
Intervention for Patients with Head and Neck Cancers Receiving Radiotherapy

This study examined the experiences of dietitians who implemented a behaviour change intervention designed to improve the nutritional status of adults with head and neck cancers undergoing radiotherapy. Head and neck cancers (HNC) affect the upper respiratory and upper digestive tracts, such as the mouth, jaw, nose, sinuses, pharynx and larynx. In 2009, they accounted for 3.4% of all new cancer diagnoses in Australia, with an incidence of 16.8 per 100,000 people. Those diagnosed with HNC in Australia have a five year survival rate of approximately 68%, similar to the five year survival rate across all cancers (Australian Institute of Health and Welfare, 2014; Australian Institute of Health and Welfare, 2017). As a result of the cancer and its treatment, people with HNC may experience facial disfigurement, eating difficulties, communication problems and psychosocial distress (Lang, France, Williams, Humphris & Wells, 2013; Lockett, Britton, Clover & Rankin, 2011).

Malnutrition in Head and Neck Cancer

Malnutrition and weight loss are common in people with HNC, and are multifactorial (Gorenc, Kozjek & Strojjan, 2015). The risk of HNC is increased by high consumption of cigarettes or alcohol, which are frequently associated with poor nutrition, so many patients have sub-optimal nutrition before diagnosis (Findlay, Bauer, & Brown, 2015). Tumours can cause obstruction, pain and swallowing difficulties, making it difficult for patients to eat (Gorenc, Kozjek & Strojjan, 2015; van Cutsem & Arends, 2005). Many patients with cancer experience cachexia, a metabolic syndrome of hormonal changes, inflammation, shifts in resting energy expenditure and disturbances in nutrient metabolism, which contributes to malnutrition (Gorenc, Kozjek & Strojjan, 2015; van Cutsem & Arends,

2005). Eating and nutrient absorption is also adversely impacted by side effects of chemotherapy or radiotherapy, such as food aversion, changes in taste and smell, dry mouth, nausea and vomiting, diarrhea or constipation, malabsorption of nutrients and painful mucous membrane inflammation (van Cutsem & Arends, 2005). In addition, many patients with HNC experience depression (McCarter, Baker, Britton, Wolfenden et al., 2018), which is associated with a higher risk of malnutrition (Britton et al., 2012). Estimates of the prevalence of malnutrition among patients with cancer vary widely, ranging up to 65%, but those with HNC are particularly at risk (Kruizenga et al., 2003; Marshall, Loeliger, Nolte, Kelaart, & Kiss, 2018).

Malnutrition and weight loss are associated with increased morbidity and mortality among people with cancer (Marshall, Loeliger, Nolte, Kelaart, & Kiss, 2018; van Cutsem & Arends, 2005), including those with HNC (Datema, Ferrier, & Baatenburg de Jong, 2011; Findlay, Bauer, & Brown, 2015; Langius et al., 2013; van Bokhorst-de van der Schueren et al., 1999). Malnutrition has been linked with compromised immune function, lower energy, reduced resistance to illness, lower quality of life, poorer response to therapy, increased risk of treatment side-effects and reduced survival time (Langius et al., 2013; van Cutsem & Arends, 2005). In patients with HNC receiving radiotherapy, malnutrition often leads to cessation or interruption of the treatment protocol, which is associated with poorer response to therapy and increased risk of mortality (Fesinmeyer, Mehta, Blough, Tock, & Ramsey, 2010; Murphy, 2007; O'Connor, 2013).

Dietetic counselling for patients with HNC during treatment is associated with improved nutritional status (Findlay, Bauer, & Brown, 2015; Isenring et al., 2013; Langius et al., 2013). Among those receiving radiotherapy, nutritional counselling may also be associated with improved quality of life, fewer unplanned admissions, and fewer

interruptions to treatment (Findlay, Bauer, & Brown, 2015; Isenring et al., 2013).

Nutritional recommendations may include alteration of food intake, use of liquid oral supplements, and enteral feeding via a percutaneous endoscopic gastrostomy (PEG) or a nasogastric tube (Findlay, Bauer, & Brown, 2015; Gorenc, Kozjek & Strojan, 2015).

However, patients with HNC may not always see nutrition as central to their treatment and are frequently noncompliant with dietetic recommendations (Britton et al., 2015). In one study of 40 patients with HNC receiving chemoradiotherapy, 47% did not comply with nutritional recommendations (Capuano et al., 2008). A larger study of 352 patients receiving radiotherapy found that 38% were not compliant with dietetic advice, and noncompliance was associated with increased morbidity and mortality (Kabarriti et al., 2018).

The Eating as Treatment (EAT) Intervention

Eating as Treatment (EAT) is a behaviour change intervention delivered by dietitians, which aims to improve nutritional status in patients with HNC who are receiving radiotherapy with curative (rather than palliative) intent (Britton et al., 2015). EAT has been evaluated using a stepped-wedge, cluster randomised controlled trial across four Australian sites. Sites commenced the trial in the control condition, providing treatment as usual, then shifted to the intervention condition in a randomised order (Britton et al., 2015). Upon joining the intervention condition, dietitians received training consisting of a two-day workshop, a one-day booster session, observation of dietetic consults and provision of feedback, and fortnightly telephone supervision (Beck et al., 2018).

The EAT intervention combined nutritional support according to best practice guidelines (Findlay, Bauer, & Brown, 2015; Isenring et al., 2013) with specific behaviour change counselling skills (Britton et. al., 2015; Britton et al., 2018). Behaviour change

strategies were drawn from Cognitive Behaviour Therapy (CBT) and Motivational Interviewing (MI), and were piloted by a clinical psychologist (Britton, et al., 2017), then incorporated into the EAT intervention for delivery by dietitians (Britton et. al., 2015). Given the association between depression and malnutrition in patients with HNC (Britton et al., 2012), the EAT protocol incorporated the two-question version of the Patient Health Questionnaire (PHQ-2; Kroenke, Spitzer, & Williams, 2003) as a screening tool for depression (Britton et al., 2015). Other recommendations from dietetic guidelines that were incorporated into the EAT intervention pertain to the frequency of consultation during and after radiotherapy and the use of a validated nutritional assessment tool (McCarter, Baker, Britton, Beck et al., 2018). The research team consulted with sites about practice change strategies to ensure that the intervention could be integrated into current systems of care (Britton et al., 2015; McCarter, Baker, Britton, Beck et al., 2018).

CBT and MI principles suggest people are more likely to change health behaviours when clinicians use an empathic, affirming and collaborative style, and elicit motivation and strategies from the patients themselves, rather than attempting to persuade or argue for change (Beck, 2011; Britton et al., 2015; Miller & Rollnick, 2013). The EAT intervention incorporated strategies that foster a collaborative therapeutic relationship and convey empathy, such as open questions, active listening and reflection of patients' perspectives. At week five of radiotherapy, when a therapeutic relationship had been established and when treatment side effects are typically problematic, clinicians conducted a motivational 'Eat to Live' discussion with patients. This involved eliciting the person's reasons for having radiotherapy, offering to provide information about malnutrition during radiotherapy among people with HNC (focusing on the group rather than the individual to minimise defensiveness), sensitively highlighting any variance between the patient's goals

and their nutritional behaviours, and collaborating with the patient to elicit a plan for action (Britton et al., 2015).

Change is supported when patients are actively involved in developing explicit behaviour plans, when they understand the rationale for the behaviour, and when adherence to the plan is monitored (Beck, 2011). During the EAT intervention, dietitians utilised a nutrition planner, collaborating with patients to develop an individualised program of oral intake and enteral feeding (if applicable) to meet nutritional needs. The nutrition planner featured check-boxes for each item and a copy was retained by clinician and patient. Patients were asked to tick the check-box when they completed a recommended behaviour and bring the plan in next session for discussion (Britton et al., 2015).

Behaviour Change Counselling Skills in Dietetics

In the past, the context of dietetic work and training tended to position dietitians primarily as information providers, rather than agents of behaviour change (Endevelt & Gesser-Edelsburg, 2014; Rapoport & Perry, 2000). There is now a growing emphasis on the use of behaviour change counselling skills in dietetic practice (Cant & Aroni, 2008; Chur-Hansen, 2012; Endevelt & Gesser-Edelsburg, 2014; Hollis, Williams, Collins, & Morgan, 2014; Whitehead, 2015). Behaviour change counselling strategies have proven beneficial in dietetic interventions for obesity, cardiovascular disease and type two diabetes (Spahn et al., 2010; Whitehead, Langley-Evans, Tischler, & Swift, 2009) and may enhance dietitian self-efficacy and role satisfaction (Marley, Carbonneau, Lockner, Kibbe, & Trowbridge, 2011; Whitehead, Langley-Evans, Tischler, & Swift, 2009). The EAT trial is believed to be the first to evaluate the use of behaviour change counselling skills by dietitians with patients who have HNC (Britton et al., 2015).

Some studies suggest that many dietitians would have valued additional training at university in behaviour change strategies (Endevelt & Gesser-Edelsburg, 2014; Rapoport and Perry, 2000; Whitehead, Langley-Evans, Tischler, & Swift, 2009). There is now an increased focus on these skills in some training programs (McIntosh, 2015; Simper, Breckon, & Kilner, 2017; Smart, Clifford, & Neyman Morris, 2014). Dietitians also access professional development in behaviour change skills post-graduation (Whitehead, Langley-Evans, Tischler, & Swift, 2009) and there is evidence to suggest that training can lead to changes in counselling style (Brug et al., 2007). To facilitate further research in this area, some authors have developed rating scales for behaviour change counselling skills within dietetic consultations (Bonner, Madden, Baker, & Jones, 2008; Whitehead, Langley-Evans, Tischler, & Swift, 2014).

Evaluation of the EAT Intervention

EAT was evaluated using a stepped-wedge, cluster randomised controlled trial across four Australian sites. Between July 2013 and January 2016, 307 adult patients with HNC receiving radiotherapy (alone or in conjunction with chemotherapy) were randomly allocated to the control ($n=151$) or intervention ($n=156$) condition (Britton et al., 2018). Evaluation criteria included the effectiveness of the EAT training (Beck et al., 2017), adherence to the intervention (Beck et al., 2018; McCarter, Baker, Britton, Beck et al., 2018), and patients' nutritional status and quality of life (Britton et al., 2018).

A pilot study of the training showed it promoted increased use of behaviour change counselling skills by dietitians in patient consultations, without a significant increase in consultation time (Beck et al., 2017). Dietetic consultations during the trial were audio recorded and a 20% sample was reviewed for adherence to the intervention and use of behaviour change counselling skills. Dietitians' use of these skills was significantly higher

during the intervention phase than the control phase, with an acceptable level of adherence and competence and no significant increase in the duration of consultations (Beck et al., 2018). The EAT intervention and accompanying practice change strategies – such as training, auditing, feedback and executive support – resulted in improved adherence with recommended clinical practices for patients with HNC (McCarter, Baker, Britton, Beck et al., 2018).

The EAT intervention was associated with improved patient outcomes. At baseline, there was no significant difference in demographics or nutritional status between the control and intervention groups. Following completion of treatment and follow-up, nutritional status was independently assessed by a non-intervention dietitian. Compared with the control group, patients in the intervention group lost a smaller proportion of body weight, had better quality of life, had lower depression scores, and were less likely to have experienced interruptions to radiotherapy (Britton et al., 2018).

A qualitative study was conducted with a sample of patients who received the EAT intervention, to explore their experiences (McCarter, Baker, Britton, Halpin et al., 2018). Semi-structured interviews were conducted with nine patients. Key themes were the challenges of HNC treatment, the provision of information, becoming aware of the importance of eating for survival, and the value of compassion and empathy in the dietitian's approach. Results suggested that the EAT intervention helped patients appreciate the importance of nutrition in their treatment and motivated them to persevere with recommended nutritional advice. Dietetic sessions were generally perceived as being delivered empathically and in a supportive manner, consistent with CBT and MI principles (McCarter, Baker, Britton, Halpin et al., 2018).

Rationale for the Present Study

The present study was designed to examine the experiences of dietitians who took part in the EAT trial, exploring their views about the intervention, the training, and the use of behaviour change counselling strategies. A qualitative approach is best suited to this enquiry. Qualitative methods are becoming more widely-used in health research and can be useful to explore complex phenomena (such as individual perceptions and organisational change) or to complement quantitative studies of health outcomes (Curry, Nembhard & Bradley, 2009).

Insights from the dietitians may be useful to further develop the intervention and enhance its broader application. As such, this study was conceptualised within what Patton (2015) terms the paradigm of pragmatism. Qualitative pragmatic studies are widely used in health evaluation. They are concerned with practical consequences and applications, often aimed at solving real-world problems. Patton (2015) argues that such studies do not need to be aligned with formal declarations regarding ontology and epistemology, provided the pragmatic framing is explicit. Unlike other qualitative approaches, pragmatism is not concerned with generating theoretical models, nor with exploring the nature of reality, the essence of a phenomenon, or social constructions. The value of pragmatic studies is in the practical implications of their findings (Patton, 2015). In addition to informing future nutritional interventions for patients with HNC, the current study extends the professional dialogue relating to the use of behaviour change counselling skills in dietetics.

Method

This study is reported with reference to the Consolidated Criteria for Reporting Qualitative Research Checklist (COREQ; Tong, Sainsbury, & Craig, 2007) for interviews and focus groups. Ethical approval was granted by the Human Research Ethics Committee

of Hunter New England Health, which included approval agreements with other sites involved in the EAT trial (HREC/12/HNE/108; HNEHREC: 12/04/18/4.06; Appendix A). Approval was also endorsed by the Human Research Ethics Committee of the University of Newcastle (Reference Number H-2012-0150; Appendix B).

Methodological and Theoretical Orientation

Pragmatism was the methodological and theoretical orientation underpinning this study. This research is utilisation-focused (Patton, 2015), with an emphasis on the usefulness of the findings for informing future interventions. Utility and feasibility shape the design of pragmatic studies, with methods typically influenced by opportunity, context and available resources, rather than reflecting a purely theoretical paradigm (Patton, 2015). For example, given the small number of dietitians involved in the EAT trial, and their geographic dispersion across Australia, telephone interviews were selected as a practical option for data collection.

Interviewer Characteristics

The interviewer was a female postgraduate student in the Master of Clinical Psychology Program at the University of Newcastle. She held undergraduate qualifications in biology and psychology, with postgraduate qualifications in dietetics and health services management. The interviewer had several years' experience working in health settings, as a dietitian, health promotion officer and project manager. Her experience had included conducting and analysing key informant interviews during consultations and project evaluations.

Participants had no prior relationship with the interviewer, who was not involved in the EAT clinical trial. Participant knowledge of the interviewer was that she was conducting this research as part of her postgraduate studies in psychology, under the

supervision of researchers who had been involved in the EAT trial. The interviewer was the primary coder of the data. While interested in the intersection of dietetic and psychological practices, the interviewer was not personally invested in the implementation or evaluation of the EAT intervention, facilitating objectivity during data collection and analysis.

Sampling

A stratified purposive sampling strategy was adopted. Purposive sampling involves selecting participants who have insight into the topic of interest, and a stratified approach allows one to draw participants from subgroups of the sample to capture potentially important variation (Palinkas et al., 2015; Patton, 2015). Participants were recruited from the pool of dietitians who took part in the EAT trial. The goal was to include at least one dietitian from each site, to reflect possible context-specific factors affecting dietitians' experiences. While dietitians from all sites were approached, only two sites were represented among those who participated.

Method of Approach

A researcher who had been involved in development of the EAT intervention, and in training and supervision of dietitians, had maintained an email contact list. During the trial, some dietitians had discontinued their involvement owing to role changes, and additional dietitians had been trained (Beck et al, 2018). The contact list had been updated accordingly. The EAT trial researcher sent an introductory email to all members on the final contact list to inform dietitians of this follow-up study, and advise that they may be contacted by the interviewer.

The contact list contained 18 email addresses. The interviewer contacted individuals by email, initially selecting two addresses at random from each site.

Participants were sent a copy of the information statement and consent form (Appendix C) and were advised participation was voluntary and confidential. They were invited to ask questions if they required further information. If no response was obtained within two weeks, a follow-up email was sent. If there was still no response, contact ceased. As the study progressed, additional dietitians were approached, with a view to undertaking five to ten interviews and aiming for thematic saturation.

Participants

All 18 addresses on the contact list were used over a period of several months in 2017-2018. The message to one address was undeliverable. Three people on the contact list indicated they did not deliver the intervention, one being a nurse who assisted with recruitment, and two being dietitians who were only involved while their site was in the control phase. These individuals were not eligible for this study. Two people were on extended leave. One declined, citing a heavy workload. Seven individuals did not respond. Four dietitians consented and were interviewed. All participants were female.

Informed Consent

Participants signed and returned the consent form, before an interview was scheduled and conducted. Consent to participate, and to have the interview audio-recorded, was also confirmed at commencement of the interview. Participants were advised they could ask for the recording to be stopped during the interview. None chose to do so. Consent was again confirmed at the end of the interview. Participants were offered an opportunity to view a transcript of their interview before providing final consent. None chose to do so.

Data Collection

Interviews were conducted by telephone and audio-recorded, with only the interviewer and participant present. Interviews were open-ended, lasting on average 34.5 minutes (range 24-45 minutes). Three interviews took place in December 2017, and one in June 2018, approximately 1.5 to two years after dietitians had finished working on the EAT trial. Interviews were guided by a semi-structured interview protocol (Appendix D). The interview protocol was developed through an iterative process of discussion between the interviewer and three supervisors, all of whom were psychologists and researchers with prior involvement in the EAT trial. The approach incorporated reflection of content and feeling to encourage elaboration and allowed for prompts and follow-up questions where required to explore topics further.

The interview started with an open-ended question seeking general feedback about being involved in the EAT trial. The interviewer asked about dietitians' impressions of the training, their experiences delivering the intervention, the use of behaviour change counselling skills in dietetics, and opportunities to improve the EAT intervention and associated training. Prompts were provided where necessary regarding specific elements of interest, such as dietitians' experiences of the 'Eat to Live' discussion. Prior to finishing, the interviewer asked an open-ended question inviting any additional comments.

Data Analysis

Recordings were transcribed by the interviewer. Transcripts were checked against recordings for accuracy several times before being finalised. Data management and analysis was supported by QSR NVivo version 12. Thematic analysis was applied with reference to Braun and Clarke (2006), with the first step being developing familiarity with the full data set. The interviewer performed initial coding, which was inductive rather than

theory-driven. Coding was guided by the principles described by Braun and Clarke (2006), who recommend coding for as many potential themes or items as possible in the initial phase, linking a data extract to multiple codes if relevant, and keeping some surrounding data for context.

Once initial coding had been conducted by the interviewer, a second coder applied the draft coding framework to the data, with the understanding that different codes could be identified. The second coder was another researcher and psychologist involved in selected studies within the EAT trial, including the qualitative analysis of patients' experiences. Coders compared their findings and their conceptualisations of the codes, resolved any differences and discussed potential themes. Themes are higher-order groupings of codes, with their associated data extracts. Typically, some codes become major themes, while others may become sub-themes or may be discarded at this point (Braun & Clarke, 2006).

In keeping with the pragmatic orientation of this study, codes and themes were identified on the basis of their utility in informing future interventions, or contributing to the dialogue about behaviour change counselling in dietetics. Reported views were diverse and thematic saturation did not occur. The analysis focused on acknowledging and retaining multiple perspectives, rather than reducing findings to prevalent themes.

Data Management and Confidentiality

To protect participants' confidentiality, interviews and transcripts were assigned an identification code and were not associated with the contact list. Any potential identifying information – such as the dietitian's name, workplace, or state – was omitted from the transcript and not identified in the reporting of project results. Audio files and transcripts were stored on a password-protected computer. One of the chief investigators from the overarching EAT trial will keep a copy of audio files and transcripts on a password-

protected computer for a minimum of five years after project completion, to answer any queries about the data that may arise after publication. Given these steps to ensure confidentiality, and the fact that the interviewer had not been involved in the EAT trial or the training, participants could choose to speak candidly about positive or negative experiences.

Results

Coding and thematic analysis yielded five themes, each with several sub-themes. While results are presented in distinct sections for clarity, many points raised by participants were interrelated or relevant to more than one theme. Quotes are included, with the participant number in parentheses. The five themes identified were: the EAT training, implementation, impacts, improvements, and behaviour change counselling in dietetics.

The EAT Training

Initial workshop. Impressions of the workshop were positive and participants valued the practical features. “The initial workshop was fantastic” (P2). “I liked the practical aspect to it” (P1). Role plays were considered beneficial, though recording and watching them could be uncomfortable. The training allowed dietitians to experiment with new skills: “finding your own way of putting things, in a totally non-threatening environment” (P4). Some valued the training beyond its immediate application to the EAT trial. “The training is really beneficial, not just for the purpose of EAT and head and neck patients ... I still remember a lot of the principles, which I will use from time to time” (P3).

Booster session. The booster session was valued as an opportunity for consolidation of learning. “The booster session was really helpful ... being able to just have a bit of a refresher” (P2). “It was wise to do an initial session and then a booster. I

think if we'd just had one face-to-face and then never seen the trainers again, that wouldn't have worked as well" (P4).

Trainers. Trainers were described as experienced, knowledgeable and approachable. Views varied as to whether training was best delivered by a psychologist, dietitian or both. One participant recommended a psychologist; one suggested either could deliver it, if well-trained; and two preferred a combination. "I think having the two together is really important because there's aspects of the training that the dietitians obviously will cover in terms of the nutrition side of things, but ... I think having a psychologist come out and do the training is really helpful" (P2).

Observation. Participants appreciated the value of having one of the trainers observe patient consultations and provide feedback afterward. "They sat in with us on the sessions, that was great" (P4). "They were able to give me some really practical advice" (P2).

Telephone supervision. Dietitians had mixed views regarding fortnightly telephone supervision. "The one-on-one phone sessions that continued fortnightly ... were essential. We wouldn't have been able to maintain incorporating the skills without that continual guidance" (P4). Some valued the supervision but were concerned about the time required. "It was probably a little time-consuming ... but it was good to speak with someone just to make sure that I was on the right track" (P2). One reported the supervision was beneficial initially, but later became onerous: "I think for that first month is really useful, but further on from that ... it's probably less beneficial and it felt like a bit more of a burden and time-consuming" (P3). Those who found it useful reported it promoted reflective practice and skill acquisition and helped them cope with the challenges of taking

part in the trial. "I picked up some additional techniques and skills throughout the phone coaching" (P1).

Implementation

Communication. The EAT intervention encouraged the use of communication strategies consistent with MI and CBT. "Reflective listening was quite useful in terms of helping to check in with the patient what they're thinking or saying, you know... if you're all on the same page" (P4). Some adopted a more client-led communication style: "letting the patient lead a little bit more on the topic of conversation. So, often, I would have started each consult in the same way, and started asking a heap of questions, whereas I changed my practice to be a little bit more just like, asking them about their week and getting them to talk about what was the most important thing for them" (P1).

Some dietitians reported that they explicitly set a session agenda and fostered a shared understanding of therapeutic goals. "That had been something that I had incorporated into my practice anyway, you know, describing how often they would see the dietitian, why they would see the dietitian, what would be the point of maintaining their weight during treatment ...but ... the formal intervention from EAT gave quite a formal structure to that" (P4). "Using one or two sentences to outline what you're going to do in a session really helped to set it up for people. I think people don't like it when they're just asked a whole pile of questions" (P4).

Motivating patients. In MI, people are encouraged to explore advantages and disadvantages of change and identify their own barriers and potential solutions (Miller & Rollnick, 2013). Some dietitians found such strategies helpful and continued to use them after the trial. "If I get patients that kind of are really struggling with symptoms and not following advice ... even sort of getting them to tell me what their barriers are, and sort of

putting the onus on the patient to sort of drive their own care" (P3). Motivating patients became a stronger focus of consultations. "If you build a patient's *capacity* to *want* to continue eating, no matter what, they will usually find their own way. ... I think the trial really highlighted the importance of building that capacity, with *some* information about *how* to do that ... a more even distribution between ... building capacity and ... information-giving" (P4).

The 'Eat to Live' conversation. One dietitian found this element challenging. "I found it a hard conversation to have, and I found it tricky to do it well ... I just didn't have the, the skills necessary to do that well, if they didn't understand what I was getting at" (P1). Two indicated it became easier with practice. "To start with it was a bit challenging to ... get the conversation right" (P2). "It got better the more I did it ... It was hard to get your head around the concept initially, but once you did it a few times - and I did see it work with some patients - then you have, kind of have a respect for the approach, and then you're happy to do it" (P3).

One dietitian reported this conversation was difficult in some cases, where patients had limited capacity to increase their oral intake and did not have access to enteral feeding. Dietitians could recommend enteral feeding but the final decision rested with medical staff. "Our site ... doesn't do any prophylactic enteral feeding, and is quite slow on the reactive enteral feeding ... Sometimes, I guess, we might have felt that what we were asking the patients to do – in terms of continued eating and drinking in the face of extreme oral pain – was possibly unrealistic" (P4).

Nutrition planner. The nutrition planner was considered useful. "They were really effective" (P2). Dietitians might previously have written guidelines on a piece of paper, but the planner formalised their practice and the check-boxes increased patient

accountability. "It was very simple, very easy to tick off, it made patients accountable to what they were doing, so it was great" (P4). Most believed the planner was acceptable to patients. "It was fantastic, very simple, patients really responded very well to it" (P4). "I quite enjoyed the process ... and I found people were pretty compliant with doing that" (P1). One dietitian suggested that some patients might prefer a set of flexible recommendations for intake over the day. "It just puts a bit less pressure on them to have to follow a specific plan, when they've got treatment daily and so much other stuff going on. ... Occasionally it can cause stress amongst patients" (P3).

The plan served as a structured prompt for reviewing nutrition-related behaviours and consistently reinforcing their importance. "It was nice to have a nice calm way, like [the trainer] really emphasised to us just to keep writing it out again, like, even if they came back each week and said they'd lost it, or forgotten it, or didn't complete it. That you'd just calmly kind of pull out another piece of paper and write it again" (P4). While dietitians saw the benefits of the planner, and said patients often want a meal plan, their capacity to integrate plans into routine practice was constrained by time. "It's not something that I have a lot of time to sit down and do, complete meal plans with patients ... we just don't have those resources. ... It's a bit disappointing, it's ... not so satisfying from a clinician point of view, because I think those tools could be really helpful" (P2).

Depression screening. Dietitians reported no difficulty administering the PHQ-2. "I just handed it to the patients and got them to fill it in ...if the score was above a certain number, I organised a referral" (P3). One suggested it might be administered by other clinicians: "maybe in ... an overall nursing assessment where they look at everything each week ... they do an oral health check and look at the skin" (P1).

Impacts

Time and workload. Participation in the EAT trial increased perceived time pressure and workload. “It did add a little extra time to the consultation” (P2). “In standard consultations that you didn’t have to do the ‘Eat to Live’ conversation, it probably only took an extra couple of minutes to do the planner ... The ‘Eat to Live’ conversation probably did feel like it added an extra five to ten minutes” (P3). Some believed consultations took longer, while others were not sure. “Whether the actual sessions themselves took longer, I don’t know, probably not” (P1). “I don’t think it was *significantly* more” (P4).

However, even a small increase in consultation time could have considerable impact if a dietitian had several EAT trial patients in a busy clinic. “Sometimes you’ve got 13 patients to see in the space of three hours ... we have to do our notes as well ... Usually, our consults don’t go for more than ten minutes” (P3). “In a setting where a clinic possibly was overbooked or quite busy, if a patient wasn’t in the EAT trial I would have capacity to perhaps do a quicker review with them and omit something like a nutrition plan ... there just wasn’t as much opportunity to save time” (P4). “If ... I had too much on ... there were just too many people, sometimes I would decide that I couldn’t do [the intervention]” (P1).

One dietitian reported that EAT trial patients were seen more frequently than those receiving usual care, particularly in the follow-up period after radiotherapy, creating additional workload. Staffing changes, unpaid leave and changes in caseload allocation increased pressure on EAT-trained dietitians. There was also increased cognitive load: “just remembering all the steps that I needed to do, to follow the trial protocol, whilst being flat out in clinic ... you go to the clinic, you’re seeing patients, you’re trying to tick them

off as quickly as you can, and then you go: 'Oh, but then I've got to do this'. It's just, like, more things to think about" (P3).

Other aspects of taking part in the trial also increased time pressure and workload. "I think the trial in general took up a lot of time ... I had to fill out various forms, I had to voice record all of the sessions ... there was a lot of other bits and pieces" (P1). "I think the paperwork related to the trial did mean that sometimes things took a bit longer" (P4). Fortnightly telephone supervision was experienced by some as time-consuming. One dietitian felt that managers did not respond to the additional pressure staff were experiencing. "I don't think ... the workload was recognised by my managers or dealt with very well ... We were under quite a lot of pressure" (P1).

Negative impacts. Some dietitians reported that participation in the trial was challenging or stressful, although they may have valued certain aspects. "Definitely it was a challenging time, for me" (P1). "It became stressful in that last phase of the trial" (P4). "I know that not all colleagues that I worked with necessarily had a positive experience, and they tended to be clinicians that maybe worked with head and neck cancer patients solely ... It could potentially be a little bit ... full-on" (P2). One participant reported a decline in confidence in working with patients with HNC and took a break from working with this group for a time, but later returned to that area of practice.

The 'Eat to Live' conversation created discomfort for some. "I found the 'Eat to Live' conversation extremely difficult, for me personally" (P1). "As dietitians we don't normally have the really tough conversations with patients regarding prognosis and survival. That's often left to the doctors, so doing the 'Eat to Live' statement really made us more involved in those conversations, which is a bit out of the comfort zone" (P3). Time pressures and workload may have contributed. "I really had to get in the right head

space to have that conversation, and then after that session I felt I needed time to, to collect my thoughts ... I was scheduled to see too many people, so found that hard ... I do think I would have been able to do it better had I ... not been so pressed for time and ... had space to deal with the emotions that I was feeling" (P1).

Patient responses to the 'Eat to Live' conversation could create uncertainty or discomfort. "When you got a patient who, you couldn't get them to make that statement: that they were eating to live ... and ... patients that turned around and, and said maybe I've had enough, maybe I don't want to ... they were depressed, and not wanting to continue" (P2). "I guess, for me, I felt a little bit, um ... helpless? Because I felt that I wasn't able to do anything further for him" (P2).

Positive impacts. Despite the challenges, some dietitians enjoyed aspects of taking part in the trial, or valued the learning and growth opportunities. "It was interesting. ... It was a great experience. ... I feel like I was very lucky to be involved in a, a large research project that was, you know, multi-site across Australia ... I enjoyed it" (P2). "It was a great learning experience" (P4).

Two reported an increase in confidence in working with patients with HNC in outpatient settings. "It wasn't a cohort that I had a lot of experience in an *outpatient* setting ... so after the training, I definitely felt more confident in seeing those patients" (P2). "I had a high level of confidence working with this patient group, because I had quite a degree of experience ... but I feel that that was higher after the training. ... Just in terms of having some different skills to use, and ways to phrase things, and what to think about when you were seeing them" (P4).

One participant reported the communication style associated with the EAT intervention could have positive impacts for dietitians. "It's very refreshing, being able to

just say less in a conversation, and use techniques to elicit more from the individual. I think sometimes dietitians are conditioned to try and say a lot and give a lot of information and talk a lot in a consult, whereas these techniques obviously, you're aiming to get a lot more out of the patient. ... And that in a way almost takes pressure off the clinician" (P4).

Impacts on patients. Most participants reported that the EAT intervention could be effective in helping patients make positive nutrition-related changes. Specific feedback centred particularly on their response to the 'Eat to Live' conversation, the element of the intervention that differed most markedly from dietitians' usual practice. "It works - I think getting the patients to understand and realise their motivation, reasons for wanting to live ... often helped move the conversation along and motivated patients to make changes and to, to keep pushing through their treatment" (P2). "I've seen it work in front of me. I've had that 'Eat to Live' conversation with a patient, and then the next week they've done considerably better than they did the weeks before" (P3).

Dietitians indicated that a small proportion of patients became distressed by the 'Eat to Live' conversation. "Some of them ... became upset ... I found that I didn't necessarily have the skills to be able to deal with that well, either, or to get back on track" (P1). "There were possibly maybe a small handful that didn't take the conversation well, but I would say that was a very small percentage of the number of patients that I saw, and generally I did find it was helpful in motivating the patients" (P2).

Therapeutic relationship. When patients became upset by the 'Eat to Live' conversation, this sometimes resulted in disruption or breakdown of the therapeutic relationship. "I repaired that relationship with the patient ... I continued to see her and we got back on track" (P4). "We had a few instances where patients complained about the intervention. ... or got quite upset ... with the 'Eat to Live' discussion, and requested not to

be seen by that same dietitian” (P4). Apart from these incidents, most dietitians reported that they already had positive, empathic relationships with patients in general, and felt that the EAT intervention had no impact on the therapeutic relationship. “I don’t think it necessarily changed my working relationship with patients” (P3).

Improvements

EAT intervention and training. Several participants recommended developing suggested phrases or scripts that could help dietitians find a more natural and concise way to deliver the ‘Eat to Live’ discussion. “Maybe working between the psychologists and dietitians to maybe tweak that a little bit ...to make it feel something a bit more natural” (P3). “Even a cheat sheet ... scripts or statements around specific issues ... rather than struggling with what to say on the spot” (P4).

One participant recommended exploring other potential motivating factors in addition to survival. “I wonder if there is a different way to motivate people to make changes, that doesn’t rely on them saying if they don’t eat they’re going to die ... or even tailoring that to the individual ... A lot of people seem to be motivated by their treatment having to be re-planned. So they get told by the radiation therapist that if they lose a lot of weight ... that the mask won’t fit and they have to have it re-fitted ... that’s something that they don’t want. Some people are motivated by trying to avoid a nasogastric tube” (P1).

Suggestions for improving the EAT training included delivering material at a slower pace, breaking it into distinct modules, and extending opportunities for role play and observation – including peer observation and feedback, as well as observation by trainers in the clinic. Dietitians were interested in seeing experienced practitioners use CBT and MI with real patients, rather than simulated discussions. Dietitians also recommended incorporating advice about how clinicians might respond to patients and manage their own

discomfort when the 'Eat to Live' conversation did not proceed as expected – for example, if patients were ambivalent about treatment, or became upset. “Simple things that the clinician can say ... I did speak throughout the time with the coach, because I had a couple of instances, where I thought: I don't know where else to go with these patients that maybe haven't had a successful 'Eat to Live' conversation. And they gave me some good strategies, but maybe knowing those early on would be helpful” (P2).

Sustainability. If EAT were disseminated further, participants recommended promoting the benefits to dietitians and integrating strategies into standard practice across an entire clinic. “If you show dietitians how effective an intervention can be, and that it could potentially save them time, and particularly follow-ups, down the track, and the patient does better nutritionally, they will follow something and want to do it” (P3). Many of the strategies, such as empathic communication and nutrition planners, were already used to some extent in dietetic care and were readily integrated. However motivational interviewing strategies and the 'Eat to Live' conversation required training. “If it's going to be usual care, I would say that pretty much all dietitians working in radiotherapy should be trained in motivational interviewing with patients. ... When we did the trial, only a handful of us that were doing radiotherapy clinic were trained ... you're then having to shuffle patients around, depending on who's available” (P3). Some said dietitians would benefit from flexibility in implementation, and the capacity to use their clinical judgement about how and when to use strategies, rather than following a specific protocol as required in a clinical trial.

Behaviour Change Counselling in Dietetics

Current use. Dietitians reported that behaviour change counselling strategies, such as those drawn from CBT or MI, are highly relevant to the work of dietitians. They are

most commonly associated with the management of chronic disease: “more in that obesity, diabetes, kind of lifestyle change setting” (P4). Some mentioned applying motivational principles from the EAT training to other populations, such as renal patients.

Training and professional development. Three participants reported they had received some training in behaviour change counselling at university, such as theories about stages of change. “That was probably one thing that I wish we had done more of” (P2). One reported not receiving any behaviour change counselling training at university. “We should have training in communication and in motivational interviewing, regardless. Because it’s not just cancer and radiotherapy for head and neck ... I firmly believe that it’s relevant for all patients that you see” (P3). Some dietitians had undertaken further reading and professional development in behaviour change counselling post-graduation, and mentioned that there are professional development opportunities available, though usually relating to other clinical populations.

Discussion

Many elements of the EAT intervention were readily integrated into dietitians’ practice, such as reflective listening, agenda-setting, shared exploration of goals, discussing barriers, and conveying empathy. This is consistent with reports from several EAT trial patients, who valued the supportive partnership developed with their dietitians, as well as the information provided (McCarter, Baker, Britton, Halpin et al., 2018). Patients appreciate empathy in dietetic consultations (Goodchild, Skinner, & Parkin, 2005; Hancock, Bonner, Hollingdale, & Madden, 2012; Sladdin, Chaboyer, & Ball, 2018) and it may promote greater shared understanding between patients and dietitians about decisions made (Parkin, de Looy, & Farrand, 2014).

Dietitians were able to implement the PHQ-2 and make referrals. This is consistent with recommendations that clinicians screen for and address distress in patients with HNC (Cancer Council Australia, 2016). While screening does not directly address nutrition-related behaviours, it gives dietitians an opportunity to discuss with patients the impact of mood on eating, a potential benefit of retaining this in the dietitian's role rather than delegating to other clinicians.

Dietitians used and valued the nutrition planner but found it slightly time-consuming. The format combined a nutrition plan with check-boxes for patient self-monitoring, strategies that have good evidence of effectiveness in dietetics (Spahn et al., 2010). The planner offered dietitians an opportunity to work collaboratively with patients and tailor their advice to individual needs and circumstances, an approach that is valued by patients in dietetic consultations (Hancock, Bonner, Hollingdale, & Madden, 2012; McCarter, Baker, Britton, Halpin et al., 2018; Sladdin, Chaboyer, & Ball, 2018).

The 'Eat to Live' Conversation

The 'Eat to Live' conversation was perceived by some as time-consuming and could be personally challenging. Some of the dietitians' discomfort may reflect a perceived need to elicit from patients an explicit declaration of a desire to live, creating a sense of failure if this did not occur. Trying to elicit this specific statement is understandable in the context, and perhaps implicit within the intervention, but the developers of MI recommend exploring patients' own motivations, rather than advocating for the clinician's perspective (Miller & Rollnick, 2013). If the 'Eat to Live' conversation is utilised in future, it may be helpful to incorporate into training a focus on responding to patients who do not readily identify survival as the underlying purpose of undergoing radiotherapy. For example, strategies might include continued use of reflective listening to explore patients' own

perspectives further, while looking for opportunities to connect patients' goals with nutritional intake (Miller & Rollnick, 2013).

It is reasonable to expect that it could be challenging for dietitians if patients became discouraged, distressed, or expressed ambivalence about treatment. The developers of MI suggest there is value in reflecting and exploring discomfort or ambivalence and acknowledging patients' autonomy, even when their perspectives differ from the clinician's agenda (Miller and Rollnick, 2013). It may be useful to explore in training how dietitians might respond to patient ambivalence, discomfort or distress and how they may manage their own discomfort.

Despite some challenges, dietitians in this study were able to persevere with the 'Eat to Live' strategy. It became easier with practice for some, and it was viewed as worthwhile once they had seen it work well with some patients. Reports from some EAT trial patients indicated that the link between eating and survival was a key message for them and a useful aspect of their dietetic consultations (McCarter, Baker, Britton, Halpin et al., 2018).

EAT Training

While there are opportunities to enhance the EAT training in regard to the 'Eat to Live' conversation, the initial workshop and booster session were viewed positively by most participants. This is consistent with feedback on evaluation forms completed after sessions (A.K. Beck, personal communication, 13 June, 2018). Future training should retain the practical focus and be delivered by psychologists and/or dietitians with relevant clinical experience.

Consideration could be given to providing sample statements for the 'Eat to Live' conversation. No script would suit all situations or personal preferences, so trainees would still need to find their own delivery style. Extending opportunities for practice, peer

supervision and facilitator feedback may be beneficial, but would likely lengthen training. This would need to be weighed up against available resources and the length of time participants are willing or able to invest in professional development.

Time and Workload

Increased workload and time pressures were attributed in part, by some dietitians, to longer consultations. Previous analysis based on a 20% random sample of consultations showed no significant difference in average consultation length between the intervention and control phases (Beck et al., 2018). It is possible that a larger sample may have revealed differences that were not detected. It is also possible that clinicians' perception of the time taken for consultations does not always coincide with actual duration. Time perception can be influenced by cognitive and affective factors, perceived stress, and physiological arousal (Matthews & Meck, 2016; van Hedger, Necka, Barakzai, & Norman, 2017). Some dietitians attributed perceived time pressure and workload to other factors associated with being part of a clinical trial, such as audio-recording and documentation, telephone supervision, or the fact that only some staff were trained in the intervention. If the EAT intervention or a similar approach was adopted throughout a clinic as standard practice, and all dietitians were trained, some of these challenges may not occur.

Some participant comments suggest that dietitians were already practicing under conditions of high workload and time pressure, independently of the EAT trial. Dietitians described short consultations and limited time for individualised nutrition plans, with the EAT trial exacerbating but not necessarily creating these difficulties. If resource limitations and booking practices necessitate frequent, short consultations, dietitians may be more likely to resort to brief information provision, rather than completing individualised plans and using the full range of behaviour change counselling strategies. Limiting

investment in outpatient dietetic clinics for patients with HNC might represent false economy if consultations are less effective, since malnutrition in this population is associated with increased morbidity, mortality, treatment interruptions, and healthcare costs (Langius et al., 2013; Murphy, 2007; van Cutsem & Arends, 2005).

Behaviour Change Counselling in Dietetics

Behaviour change counselling skills, particularly those drawn from CBT and MI, have demonstrated value in dietetic practice, especially in regard to cardiovascular disease, obesity and diabetes (Spahn et al., 2010). Improved patient outcomes in the EAT trial (Britton et al., 2018) suggest they are also effective in supporting patients with HNC. Findings from this study are consistent with other research in which dietitians have reported that they value behaviour change counselling strategies and would have welcomed a greater focus on these in university training (Endeveldt & Gesser-Edelsburg, 2014; Rapoport & Perry, 2000; Whitehead, Langle-Evans, Tischler & Swift, 2009; Whitehead, 2015). While professional development and self-education opportunities exist beyond graduation, and will remain important, it may be difficult for practicing dietitians to access relevant training and integrate learning into their work with patients (Whitehead, 2015).

Strengths and Limitations

It is not possible to generalise the findings of this research to all clinicians who took part in the EAT trial, nor to all services treating patients with HNC, as data was only obtained from four individuals and two sites. Experiences may or may not be representative of other clinicians. This research also relied on recall. Dietitians completed the EAT trial 1.5 to two years earlier and reports may differ had they been interviewed during the trial. Despite these limitations, the findings from this study represent a useful contribution to the evaluation of the EAT intervention, complementing the research on

intervention adherence (Beck et al., 2018), clinical outcomes (Britton et al., 2018) and patient experiences (McCarter, Baker, Britton, Halpin et al., 2018). A strength of this research is that the interviewer had no prior connection with the EAT trial, allowing dietitians to speak freely in interviews and facilitating objectivity.

Conclusions

Dietitians were readily able to integrate behaviour change counselling skills from the EAT intervention into their practice with patients who had HNC. On the whole, they found these strategies useful with this group and supported the value of behaviour change counselling skills in dietetics more broadly. Some felt an increased focus on behaviour change counselling skills may be valuable in training and professional development for dietitians.

The EAT training was viewed positively. Any future iterations of the training should retain the practical focus, the use of role plays, and facilitation by experienced clinicians. Perceived workload and time pressures, and difficulties in the 'Eat to Live' conversation, were the main challenges described by dietitians when reflecting on the EAT trial. Participants highlighted opportunities to improve the intervention and the training, particularly in regard to the 'Eat to Live' conversation. Strategies for consideration include providing suggested scripts and discussing responses to patients' ambivalence, distress, or lack of identification with survival as a motivating factor. The findings of this study may be useful in informing future iterations of the EAT intervention, or similar initiatives with patients who have HNC and are receiving radiotherapy.

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Appendix A: Ethical Approval from Hunter New England Health



8 May 2017

Professor A Baker
Priority Research Centre for Translational Neuroscience & Mental Health
University of Newcastle

Dear Dr Baker

Re: Eating as treatment (EAT): a stepped wedge, randomised control trial of a health behaviour change intervention provided by dietitians to improve nutrition in head & neck cancer patient undergoing radiotherapy (12/04/18/4.06)

HNEHREC Reference No: 12/04/18/4.06
NSW HREC Reference No: HREC/12/HNE/108
SSA Reference No: SSA/12/HNE/248 – HNE Mental Health
SSA/12/HNE/249 - CMN

Thank you for submitting a request for an amendment to the above project. This amendment was reviewed by the Hunter New England Human Research Ethics Committee. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

I am pleased to advise that the Hunter New England Human Research Ethics Committee has determined the variation meets the requirements of the National Statement on Ethical Conduct in Human Research and has granted ethical approval for the following amendment requests:

| Document | Version | Date |
|--|---------|---------------|
| Information and Consent Form – Follow-up Dietitian Interview | 3 | 25 April 2017 |
| Semi-structured Interview Protocol – Follow-up Dietitian Interview | 3 | 25 April 2017 |

- For the addition of Ms Karen Stafford as student researcher; and
- For student researcher to contact dietitians who implemented the EAT study and provide an information sheet and consent form. Those who consent to take part will be interviewed via telephone and the conversation recorded with the participant's consent

Approval has been granted for this study to take place at the following sites:

- Calvary Mater Newcastle, NSW
- Hunter New England Mental Health, NSW
- Mater Centre, QLD

Hunter New England Research Ethics & Governance Office

Locked Bag No 1

New Lambton NSW 2305

Telephone: (02) 49214950

Email: HNELHD-HREC@hnehealth.nsw.gov.au

<http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx>

- Princess Alexandra Hospital, QLD
- Radiation Oncology Queensland, QLD
- Toowoomba Hospital, QLD
- Peter MacCallum Cancer Centre, VIC

The *National Statement on Ethical Conduct in Human Research (2007)*, which the Committee is obliged to adhere to, include the requirement that the committee monitors the research protocols it has approved. Ethics Approval will be ongoing subject to the following conditions:

- A report on the progress of the above protocol is to be submitted at 12 monthly intervals. A proforma for the annual report will be sent at the beginning of the month of the anniversary of approval. Your review date is May 2017.
- All variations or amendments to this protocol must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.
- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled.
- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
 - Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: *Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009*
https://www.nhmrc.gov.au/files/nhmrc/publications/attachments/e112_nhmrc_position_statement_monitoring_reporting_safety_clinical_trials.pdf
 - Unforeseen events that might affect continued ethical acceptability of the project.
- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand as soon as possible.

The Hunter New England Human Research Ethics Committee also has delegated authority to approve the commencement of this research on behalf of the Hunter New England Local Health District. This research may therefore commence.

Should you have any queries about your project please contact Dr Nicole Gerrand as per the contact details at the bottom of the page. The Hunter New England Human Research Ethics Committee Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Hunter New England Local Health District website.

Please quote 12/04/18/4.06 in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Ms M Hunter
Chair
Hunter New England Human Research Ethics Committee

Hunter New England Research Ethics & Governance Office

Locked Bag No 1

New Lambton NSW 2305

Telephone: (02) 49214950

Email: HNELHD-HREC@hnehealth.nsw.gov.au

<http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx>

Appendix B: Ethical Approval from the University of Newcastle

RESEARCH INTEGRITY UNIT



Registration of External HREC Approval

| | |
|--|--|
| To Chief Investigator or Project Supervisor: | Professor Amanda Baker |
| Cc Co-investigators / Research Students: | Ms Kristen McCarter Miss Erin Forbes Ms Katrina Bell Ms Sandra Dowley Associate Professor Judith Bauer Doctor Luke Wolfenden Doctor Chris Wratten Doctor Ben Britton Doctor Patrick McElduff Doctor Alison Beck Conjoint Professor Gregory Carter Miss LOUISE Thornton Ms Karen Stafford |
| Re Protocol: | Eating As Treatment (EAT): A stepped wedge, randomised control trial of a health behaviour change intervention provided by dietitians to improve nutrition in head and neck cancer patients undergoing radiotherapy |
| Date: | 18-Aug-2017 |
| Reference No: | H-2012-0150 |
| External HREC Reference No: | 12/04/18/4.06 |

Thank you for your **Variation** submission to the Research Integrity Unit (RIU) seeking to register an External HREC Approval in relation to the above protocol.

Variation to add Karen Stafford as a Student Researcher.

For student researcher to contact dietitians who implemented the EAT study and provide an information sheet and consent form. Those who consent to take part will be interviewed via telephone and the conversation recorded with the participant's consent

Your submission was considered under an **Administrative Review** by the Ethics Administrator.

I am pleased to advise that the decision on your submission is **External HREC Approval Noted** effective **18-Aug-2017**.

As the approval of an External HREC has been noted, this registration is valid for the approval period determined by that HREC.

Your reference number is **H-2012-0150**.

PLEASE NOTE:

As the RIU has "noted" the approval of an External HREC, progress reports and reports of adverse events are to be submitted to the External HREC only. In the case of Variations to the approved protocol, or a Renewal of approval, you will apply to the External HREC for approval in the first instance and then Register that approval with the University's RIU, via RIMS.

Linkage of ethics approval to a new Grant

Registered External HREC approvals cannot be assigned to a new grant or award (ie those that were not identified in the initial registration submission) without confirmation from the RIU.

Best wishes for a successful project.

Mr Alan Hales
Manager, Research Compliance, Integrity and Policy

For communications and enquiries:

Human Research Ethics Administration

Research & Innovation Services
 Research Integrity Unit
 The University of Newcastle
 Callaghan NSW 2308
 T +61 2 492 17894
Human-Ethics@newcastle.edu.au

RIMS website - <https://RIMS.newcastle.edu.au/login.asp>

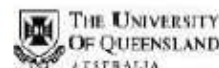
Linked University of Newcastle administered funding:

| Funding body | Funding project title | First named investigator | Grant Ref |
|--|---|--------------------------|-----------|
| Calvary Mater Newcastle/Project Grant(**) | Head and neck cancer patient experience of EAT: A new dietitian-delivered health behaviour intervention | McCarter, Kristen | G1700913 |
| NHMRC (National Health & Medical Research Council)/Project Grant(**) | Eating As Treatment (EAT): A stepped wedge, randomised control trial of a health behaviour change intervention provided by dietitians to improve nutrition in head and neck cancer patients undergoing radiotherapy | Baker, Amanda | G1100093 |

Appendix C: Information Statement and Consent Form



HUNTER NEW ENGLAND
NSW HEALTH



ATTACHMENT 1

EATING AS TREATMENT - FOLLOW-UP DIETITIAN INTERVIEW INFORMATION FOR PARTICIPANTS

Thank you for your participation in the EAT Project, which aimed to improve nutrition among head and neck cancer patients undergoing radiotherapy. Dietitians who delivered the EAT intervention are invited to participate in a follow-up telephone interview. Please read this information sheet carefully. Feel free to ask for clarification on any aspect of this project that you do not understand.

What is the research about?

The aims of this project are to better understand the experiences of Dietitians who implemented the EAT intervention and obtain any feedback on how the intervention might be improved.

Where is the research being done?

The study is being conducted within the University of Newcastle by Karen Stafford, a Masters student supervised by Dr Sean Halpin from the School of Psychology. The project is co-supervised by Professor Amanda Baker and Dr Benjamin Britton from the EAT research team.

Who can participate in the research?

We are seeking Dietitians who implemented the EAT intervention to participate in this research.

What choice do you have?

Participation in this study is entirely voluntary. You do not have to take part in it. Only those people who give their informed consent will be included in the project. If you do take part, you can withdraw at any time without having to give a reason. At the end of the interview you can choose to withdraw your audio recorded discussion if you wish. You will also be given an opportunity to review a transcript of your interview, if you wish, before providing consent.

What will you be asked to do if you agree to participate?

If you agree to participate in this study, you will be asked to sign the Participant Consent Form below and return it either electronically to Ms Stafford, or in hard copy to Dr Sean Halpin at the University of Newcastle School of Psychology. You will then be asked to participate in a telephone interview (expected to take up to 1 hour) with Ms Stafford, to discuss your experiences with the EAT project. This interview will be audio recorded to facilitate data analysis. Please note, consent to audio record this interview is a requirement of study participation (see item 8 on the accompanying consent form).

What are the risks and benefits of participating?

We do not expect that you will receive any direct benefits from this research. We do not anticipate that you will experience any significant risk or inconvenience from participating. If you find that taking part in this study causes distress, you can speak with Ms Stafford about ways you may be able to access support. In addition, 24-hour telephone counselling is provided by Lifeline on 13 11 14.

Will the study cost you anything?

Participation in this study is not associated with any direct costs, nor will you be paid for taking part.

What will happen to the information you provide?

By signing the consent form, and confirming your consent after your interview, you agree to allow Ms Stafford and relevant research staff to collect, store and use the information you provide in the following manner. The interview will be recorded, then transcribed for analysis. Identifying information, such as your

EAT FOLLOW-UP DIETITIAN INTERVIEW
School of Medicine and Public Health, University of Newcastle
In collaboration with Hunter New England Health

name and workplace, will be omitted from the transcript and will not be identified in the reporting of project results. Information collected will remain confidential and will be disclosed only with your permission, or except as required by law. For example, we would legally be required to inform relevant authorities if you indicated that you planned to harm yourself or someone else, if you disclosed information about criminal activities, or if child abuse or neglect was suspected.

The identity of Dietitians who take part will be protected by assigning an identification (ID) code to each recording and its corresponding transcript. Transcripts will form the basis for data analysis. If you decide to withdraw your participation before analysis occurs, your transcript will not be included in the analysis. Participant details and ID codes, along with audio files and transcripts, will be stored on a password protected computer by Ms Stafford until her Masters thesis is finalised. A copy of audio files and transcripts will be retained on a password protected computer by Professor Amanda Baker for a minimum of five years after project completion, to answer any queries about the data that may arise after publication.

Who has reviewed the research project?

Research in Australia involving people must be reviewed by an independent Human Research Ethics Committee (HREC) and carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies. The ethical aspects of this research have been approved by the HREC of Hunter New England Health and by the HREC of the University of Newcastle.

What will happen with the results of the research?

Findings will be reported in Ms Stafford's Masters thesis and may be disseminated through additional means such as journal articles, conferences and digital media. However, information in these publications will be provided in such a way that you cannot be identified. If you would like a summary of the findings, please indicate 'yes' at item 10 on the accompanying consent form.

Who should I contact if I have concerns about the conduct of this research?

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, you can contact one of the following people:

Professor Amanda Baker
0412 267164
Amanda.Baker@newcastle.edu.au

Ms Karen Stafford
0413 771633
Karen.Stafford@uon.edu.au

The conduct of this study has been authorised by Hunter New England Local Health District. Any person with concerns or complaints about the conduct of this study may also contact Dr Nicole Gerrand, Manager Research Ethics & Governance Unit on (02) 4921 4950 and quote reference number 12/04/18/4.06.

Who do I contact for advice after hours?

If you have any distressing emotional symptoms and need to speak to someone urgently after hours please contact:

Lifeline: 13 11 14

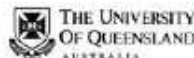
Thank you for taking the time to consider being part of this research project.

If you wish to take part in this research trial, please sign the attached consent form.

This information sheet is for you to keep.



HUNTER NEW ENGLAND
NSW HEALTH



**EAT FOLLOW-UP DIETITIAN INTERVIEW
PARTICIPANT CONSENT FORM**

By giving my consent I confirm that:

1. I have read, or have had read to me in a language I understand, the Participant Information Sheet (Version 3, 25 April 2017) for the above research project.
2. I have had the opportunity to consider the information and ask questions and have had any questions answered to my satisfaction.
3. I understand the purpose, procedures and risks of the research described in the project.
4. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my legal rights being affected.
5. I agree that research data collected from me during this study may be published, provided that I cannot be identified.
6. I agree to take part in the above research project.
7. I understand that I should retain a signed copy of this document for my records.
8. I give permission for my interview with Ms Stafford to be audiotaped. I understand that this is a requirement of participation and that it is for the purpose of transcription and analysis. I understand that I can ask for the tape to be stopped or decline to answer questions during the interview.
9. Upon completion of the interview, I give permission for the audio file and transcript to be kept by Professor Amanda Baker for a minimum of five years as outlined in the information sheet.
10. I would like a copy of this research project's results sent to me when available. I understand that my name and email address will be provided to the University of Newcastle for this purpose.

☐ No ☐ Yes. Please indicate preferred email address: _____

Participant Name

Signature

Date

EAT FOLLOW-UP DIETITIAN INTERVIEW
School of Medicine and Public Health, University of Newcastle
In collaboration with Hunter New England Health

Participant Information Sheet and Consent Form

[Version 3, 25/04/2017]

Page 3 of 3

Appendix D: Semi-Structured Interview Protocol

General Prompts – *for use throughout interview*

- Could you tell me more about that?
- What was that like?
- What did you mean when you said?
- Can you give me an example of that?

Introduction

- Hello, my name is Karen Stafford and I am calling about the EAT project. Is now still a suitable time for our phone interview? It may take up to an hour.
If not – reschedule telephone interview.

Confirming Consent

- You have signed and returned the consent form, but I would like to confirm that you agree to take part and you consent for me to record this interview.

Participant Rights

- I'm going to ask you a series of open-ended questions about your experiences of the EAT trial. If you wish, you can decline to answer any of the questions. You can also ask me to stop the recording at any time. I will check in with you again at the end to make sure you're happy for your responses to be used in the research.

Opening Question

When you think back to your experiences of the EAT trial, what are the first things that come to mind?

Training

- The training for EAT had three components: an initial workshop, a booster session, and then ongoing coaching. What were your impressions of the training?

Potential prompts:

What feedback can you offer on the other component(s)? – *prompt re the workshop & booster (both incl. video feedback) or ongoing coaching (audio feedback) if needed*

Which parts of the training were most effective? Which parts were least effective? Why?

How confident did you feel working with this patient group before and after the training? – *If there was a change: Why do you think that changed? What could be done to help build dietitians' confidence in using these strategies?*

In what ways could the training be improved?

Is the training best delivered by a psychologist, a dietitian or a combination of both?

The EAT Intervention

- Thinking now about the intervention and your work with patients ... what were the *most* beneficial parts and the *least* beneficial parts of the intervention?

Potential prompts:

What were the benefits for patients? Benefits for dietitians?

What were the least beneficial parts? Why? (*if not already mentioned*)

What was it like to have the 'Eat to Live' discussion with patients? This was where you highlighted any variance between patients' goals and their behaviour.

What was it like to use the two-question screening tool for patient depression? Were there any barriers to implementing this?

What was it like to use the nutrition planner? How was this similar to or different from plans you usually develop with patients?

Could you comment on any impact of the EAT intervention on the amount of time spent with patients?

Could you comment on any impact of the EAT intervention on your working relationship with patients?

Challenges

- What did you find most challenging about implementing EAT?

Potential prompts:

Why was that part challenging?

How did you respond to that challenge?

Were there any other significant challenges or barriers?

EAT in the Future

- What advice would you give to other health professionals who might implement EAT in the future?
- In what ways could the EAT intervention be improved?

Behaviour Change Counselling Strategies

The EAT intervention made use of specific behaviour change tools, like motivational interviewing and cognitive behavioural strategies.

- How useful were the behaviour change strategies in EAT, when working with head and neck cancer patients?

- How relevant are behaviour change strategies like those to the broader work of dietitians?
- To what extent are behaviour change strategies typically used by dietitians?
- To what extent are behaviour change strategies included in dietetic training or professional development?

Inviting Further Comments

Is there anything else you would like to tell me about your experience of working on the EAT trial?

Checking consent

- We are coming to the end of our discussion now. I would like to check your consent for this interview to be used in the research.
- Would you like to review a transcript of this interview, before deciding on whether to give your consent?

If yes – confirm email address.

If no – So, I can confirm that you are happy for this information to be used in the research.

- Just to remind you, you have the right to contact me and withdraw your consent at any time prior to the analysis being completed.

Thank you for taking part in the interview today.