TBM

ORIGINAL RESEARCH

Effectiveness of clinical practice change strategies in improving dietitian care for head and neck cancer patients according to evidence-based clinical guidelines: a stepped-wedge, randomized controlled trial

Kristen McCarter,[1] Amanda L. Baker,[2] Ben Britton,[2] Alison Kate Beck,[2] Gregory Carter,[2] Judith Bauer,[3] Chris Wratten,[4] Sean A. Halpin,[1] Elizabeth Holliday,[5] Christopher Oldmeadow,[5] Luke Wolfenden[2]

[1]School of Psychology, University of Newcastle, Newcastle, New South Wales 2308, Australia

[2]School of Medicine and Public Health, Faculty of Health and Medicine, University of Newcastle, Newcastle, New South Wales 2308, Australia

[3]Centre for Dietetics Research, University of Queensland, St Lucia, Queensland 4072, Australia

[4]Department of Radiation Oncology, Calvary Mater Newcastle Hospital, Newcastle, New South Wales 2308, Australia

[5]Clinical Research Design, IT and Statistical Support Unit, Hunter Medical Research Institute, Level 3 Pod, HMRI Building Lot 1, Kookaburra Circuit, New Lambton Heights, New South Wales 2305, Australia

Correspondence to: K McCarter
kristen.mccarter@newcastle.edu.au

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Abstract

Best practice guidelines make a number of recommendations regarding dietitian management of head and neck cancer (HNC) patients. Randomized trials assessing the effectiveness of clinical practice change strategies for improving the nutritional management of HNC patients have not previously been conducted. The purpose of this study was to evaluate the effect of practice change strategies on improving the implementation of best practice guideline recommendations for the nutritional management of HNC patients. Four Australian radiotherapy departments participated in a stepped-wedge, randomized controlled trial. Baseline data were collected across all sites simultaneously, and the intervention was then introduced to each site sequentially, in a randomly determined order. During the intervention phase, sites received a range of supportive clinical practice change strategies to facilitate dietitian adherence to clinical practice guidelines. To assess the associated practice change by dietetic staff, we evaluated the change in implementation of six guideline recommendations for dietitians from preintervention to postintervention periods. Adherence to the clinical practice guidelines during the preintervention period was generally very low. The clinical practice change strategies significantly improved the odds of provision of four of the six guideline recommendations. The study found the intervention significantly enhanced dietitian provision of recommended care for HNC patients during the postintervention period. This finding holds clinical importance for clinician and health service effective implementation of guideline recommendations as well as HNC patient treatment outcomes. Trial registration number ACTRN12613000320752, https://www.anzctr.org.au.

Keywords

Head and neck cancer, Implementation, Nutrition

Implications

Practice: Oncology dietitians can deliver evidence-based care for cancer patients according to the best practice guidelines if well supported by a range of implementation support strategies.

Policy: Effective implementation of best practice guidelines for oncology clinicians requires multicomponent practice change support strategies including training, audit and feedback, executive support and endorsement, systems and prompts, and tools and resources.

Research: Future research should be aimed at implementing this successful intervention in other settings.

INTRODUCTION

Malnutrition is common in head and neck cancer (HNC), being present in approximately 30%–50% of HNC patients [1, 2]. The malignancy and its treatments can contribute to malnutrition through problems with eating, fatigue, decreased appetite, and weight loss [3]. Malnutrition is of particular concern for cancer patients given its association with increased risk of morbidity [3] and overall mortality [1]. Similarly, psychological distress can affect patient functioning, capacity to cope, treatment compliance, quality of life, and survival [4, 5], and depression increases the risk of malnutrition [6].

Given the importance of nutrition management, both the National Institute for Health and Clinical Excellence and the National Comprehensive Cancer Network (NCCN) guidelines recommend the inclusion of an oncology dietitian as a core member of a multidisciplinary team responsible for the care and management of HNC patients [7, 8]. To improve treatment outcomes, best practice guidelines make a number of recommendations regarding dietitian management of HNC patients including weekly consultation with a dietitian during radiotherapy; fortnightly consultations for at least 6 weeks after treatment; use of a validated nutrition assessment tool to assess nutritional status; and monitoring weight, intake, and nutritional status during and after (chemo) radiotherapy [9]. Clinical practice guidelines also recommend patients be screened for distress and indicated that

patients are provided with psychosocial support [9–11]. Despite such guidelines, research suggests that many patients do not receive care consistent with best practice guidelines [12, 13]. For example, a recent cross-sectional survey of 20 NCCN institutions reported that only 60% of services conducted outpatient distress screening, and even fewer services reported screening all patients (30%) as outlined in the NCCN standards [14].

Unless clinical practice guidelines are implemented, their potential benefits in improving patient outcomes will not be realized. Systematic reviews suggest that guideline complexity, a lack of awareness of guideline recommendations, limited time, a lack of organizational support, and resources impede the alignment of clinical care with guideline recommendations [15–22]. To our knowledge, randomized trials assessing the effectiveness of clinical practice change strategies in overcoming such barriers and improving the nutritional management of HNC patients have not previously been conducted. Systematic reviews of clinical research more broadly, however, suggest multistrategic clinical practice change intervention can improve guideline adherence [23, 24]. The aim of this trial was to assess the impact of such practice change strategies (e.g., staff training, systems and prompts, audit and feedback) in improving dietitian implementation of best-practice guideline recommendations for the nutritional management of HNC patients.

METHODS

Context

This study was conducted as part of a multicenter trial of a dietitian-delivered health behavioral counseling intervention 'Eating As Treatment' (EAT). Full details of the EAT trial have been described elsewhere [25]. Briefly, EAT tested an intervention incorporating motivational interviewing and cognitive behavioral therapy strategies in reducing malnutrition in patients with HNC undergoing radiotherapy.

The EAT intervention was also developed to align with six clinical practice guideline recommendations [8]. These recommendations and the criteria for adherence are described in Table 1. The EAT intervention was aligned with these guideline recommendations to ensure sufficient exposure of patients to the dietitian-delivered intervention, the inclusion of behavioral monitoring strategies, and the provision of appropriate support due to the link between depression and malnutrition as well as other negative patient outcomes in this population [6, 26]. Clinical practice change strategies were implemented during the intervention phase at participating sites to improve adherence to the guideline recommendations relevant to the intervention. This provided an opportunity to conduct a nested study of the implementation of clinical guideline recommendations in radiotherapy departments around Australia.

The study protocol and methods were prospectively registered (ACTRN12613000320752). Coordinating ethics was granted by Hunter New England Health (HREC/12/HNE/108; HNEHREC: 12/04/18/4.06). Approval was also received from the following committees: Central Adelaide Local Health Network (HREC/13/RAH/75; SSA/13/RAH/102); Sir Charles Gairdner Group HREC (2012-136); Peter MacCallum Cancer Centre Ethics (SSA/13/PMCC/19); Western Sydney Local Health District Research Governance (SSA/13/WMEAD/110); and Metro South Hospital and Health Service (SSA/13/QPAH/240 and SSA/13/QPAH/241).

Study design

The study used a multisite, stepped-wedge, randomized controlled trial (RCT) design [25]. In a stepped-wedge trial, all clusters begin in the control condition and then progress in a randomized order to the intervention condition. The stepped-wedge, RCT design reduced the potential for contamination. The stepped-wedge, RCT design reduced the potential for contamination between sites. Trial

Table 1 | Guideline recommendations and adherence criteria

Guideline recommendation	Adherence criteria
Patient should be seen weekly by a dietitian during radiotherapy	A dietetic consultation was required for at least each 8-day interval throughout radiotherapy
Patient should receive minimum fortnightly follow-up by a dietitian for at least 6 weeks after treatment	At least 3 dietetic consultations at 8-day intervals within 42 days of the end of radiotherapy
Use of a validated nutrition assessment tool (e.g., PG-SGA) by the dietitian to assess nutritional status	Use of PG-SGA during Week 1 of radiotherapy
Monitor weight, intake, and nutritional status during and after radiotherapy	Use of PG-SGA at least once during or after radiotherapy in addition to Week 1 of radiotherapy
Patients should be screened for depression using the PHQ-2 in Week 1 of radiotherapy	Screening using the PHQ-2 in Week 1 of radiotherapy
Patients who screen positive (score of ≥3 on the PHQ-2) during Week 1 of radiotherapy should be offered referral for further assessment and/or psychosocial support	Referral for further assessment/and or psychosocial support for patients who screen positive (score of ≥3 on the PHQ-2) during Week 1 of radiotherapy

PG-SGA Patient-Generated Subjective Global Assessment; *PHQ-2* Patient Health Questionnaire-2.

	Initiation	Step 1	Step 2	Step 3	Step 4	Step 5
Site 1	Control	Intervention	Intervention	Intervention	Intervention	Intervention
Site 2	Control	Control	Intervention	Intervention	Intervention	Intervention
Site 3	Control	Control	Control	Intervention	Intervention	Intervention
Site 4	Control	Control	Control	Control	Intervention	Intervention
Site 5*	Control	Control	Control	Control	Control	Intervention

Fig. 1 | Stepped-wedge, cluster randomized trial design. Asterisk denotes two hospitals.

sites were radiotherapy departments located within major metropolitan Australian hospitals. Consistent with the conventional complete stepped-wedge design, control period data were collected across all sites simultaneously [27]. The intervention was then introduced to each site sequentially. The order in which the intervention was introduced to sites was randomly determined. The study design is described in Fig. 1.

Participants and recruitment

The study was presented to the Trans-Tasman Radiation Oncology Group (TROG) at the 2012 Meeting, and sites interested in participating were encouraged to contact the research team. Written information about the study was also disseminated by TROG to members from large radiotherapy departments within Australian hospitals with an invitation to contact the research team regarding participation. Six dietetic departments were recruited.

Patient consent was sought to enable collection of data regarding patient receipt of care consistent with guideline recommendations during control and intervention periods. HNC patients who were scheduled for radiotherapy at each site were screened for eligibility. Sites generated a list of patients who met the eligibility criteria using treatment planning software, multidisciplinary team meetings, and/or clinician referrals. Eligible patients were those who were scheduled to undergo definitive or postoperative radiotherapy, were 18 years or older, had one or more of the following cancer diagnoses: nasopharynx, oropharynx, oral cavity, larynx, hypopharynx, and were receiving care from an oncology dietitian at a participating radiotherapy department. Eligible patients were approached with information about the study (by a radiation oncologist and/or an independent data manager) and were invited to participate.

Randomization and blinding

The order in which the intervention was introduced to radiotherapy departments was randomly allocated by an independent statistician using a uniform random number generator in Stata (StataCorp, College Station, TX). All clinical dietitians providing oncology services to HNC patients (participating in the EAT study) during the intervention phase were exposed to the clinical practice change intervention.

Due to the nature of the study design, it was not possible to blind radiotherapy departments, dietitians, or outcome assessors to preintervention and postintervention period allocation. However, patients were blind to condition.

Strategies to implement clinical practice guideline recommendations

A full description of the implementation strategies is described in the protocol paper [25]. During the intervention phase, sites received a range of supportive clinical practice change strategies to facilitate the delivery of the EAT intervention in addition to the provision and/or maintenance of clinical practice guidelines recommendations. This included recommendations regarding the frequency of dietitian contact during and after radiotherapy, the use of a validated nutritional assessment tool to assess and monitor the nutritional adequacy of patients, and the screening and referral of patients at risk for psychosocial support. The implementation support strategies were often integrated into strategies or processes to gain support for the trial and improve the fidelity of delivery of the behavioral counseling intervention by dietitians more broadly. Specifically, the research team provided sites with the following evidence-based, clinical practice change support strategies [24, 28–36].

Executive support and endorsement

Senior trial investigators solicited the support and endorsement of executive staff from each site for implementation of the intervention and recommendations based on clinical guidelines [28–30].

Provision of staff training

Radiotherapy department oncology dietitians received training over the course of a two-day workshop conducted by the research team. Dietitians were trained in the administration of a brief screening tool for symptoms of depression; the Patient Health Questionnaire-2 (PHQ-2) [31] and the Patient-Generated Subjective Global Assessment (PG-SGA) [37, 38] to assess the nutritional adequacy of patients, and consistent with guideline recommendations were asked to screen all patients using such tools. Approximately 2 months after the initial workshop, a booster training session was conducted

to troubleshoot any issues that may have arisen with implementation of the behavior change intervention or practice guideline recommendations.

Academic detailing

Clinical psychologists from the research team attended the radiotherapy department dietetic clinics to 'shadow' dietitians for 1 day following both the 2-day training workshop and the booster training session (2 months after initial training). The psychologists provided advice, feedback, and support to resolve implementation barriers including systems changes to facilitate regular patient appointments [32–34].

Systems and prompts

To facilitate patient attendance for dietetic treatment, services were encouraged to amend patient booking systems to schedule outpatient appointments adjacent to radiotherapy appointments and according to the recommendations of the clinical guidelines. Medical records of participating patients included colored printed prompts (PG-SGA and PHQ-2), and for services without existing referral pathways for psychosocial support, a referral policy for those patients screened as at risk for depression was collaboratively developed.

Performance audit and feedback

Feedback on site performance relative to agreed benchmarks was provided in written reports and during telephone contacts every 3–4 months to the head of the dietetics departments [32–34].

Provision of tools and resources

Given the identified barriers to implementation of clinical guidelines including lack of information and clinical uncertainty [24, 36], services and staff had access to nutrition assessment and depression-screening tools that were provided during training, so as to facilitate discussion and practice [28, 29, 35].

Preintervention

During the preintervention phase, each hospital was instructed to deliver treatment as usual.

Outcomes and data collection

Patient characteristics

As part of the assessment battery of the trial, patients were asked to report their gender, age, country of birth, Aboriginal and Torres Strait Islander status, marital status, education, and employment status. The data manager at each site completed pen and paper clinical research forms with patients to collect this demographic information at baseline (during Week 1 of radiotherapy).

Outcomes: implementation of clinical practice guideline recommendations by oncology dietitians

The primary outcomes in this report were the proportion of patients receiving dietetic care consistent with each of the six clinical practice guideline recommendations. Chart reviews of patient medical records from the dietitian clinical consultations were conducted by data managers at each site during the first week of radiotherapy and at 12-week postradiotherapy. Implementation of clinical practice guidelines was assessed by the research team using the chart review data. The six implementation outcomes are presented in Table 1.

Delivery of intervention strategies

Project records were used to determine the delivery of the practice change strategies to sites.

Helpfulness of practice change strategies

During booster training (approximately 2 months after the initial workshop during the intervention period), all dietetic staff at the initial workshop were asked to complete a questionnaire regarding their attitudes toward the helpfulness of the practice change strategies that supported implementation of the EAT intervention and care according to the best practice guidelines. Dietitians were asked to rate the strategies on a Likert scale with five responses: very unhelpful, unhelpful, neither helpful/unhelpful, helpful, very helpful.

Sample size

The target sample size of 400 patients was based on the primary outcome (change in nutrition score) of the EAT intervention trial. For the practice change outcomes, this sample size was sufficient to detect an absolute increase in the implementation of clinical practice guideline recommendations of approximately 14% assuming a conservative implementation rate in the control phase of 50%, with 80% power and an alpha of .05. Such an effect size is consistent with improvements in clinical practice following clinical practice change interventions of similar intensity [39–41].

Statistical analysis

All analyses were conducted in SAS v9.4 (SAS Institute, Cary, NC) statistical software. Descriptive statistics were used to summarize the characteristics of the study sample. The impact of the strategies in improving implementation of each of the six clinical practice recommendations was assessed under an intention to treat framework, using six logistic regression models, including fixed effects for study stage (intervention or control phase) and study site (hospital). Penalized maximum likelihood estimation was used due to quasi-complete separation of data, and effect sizes

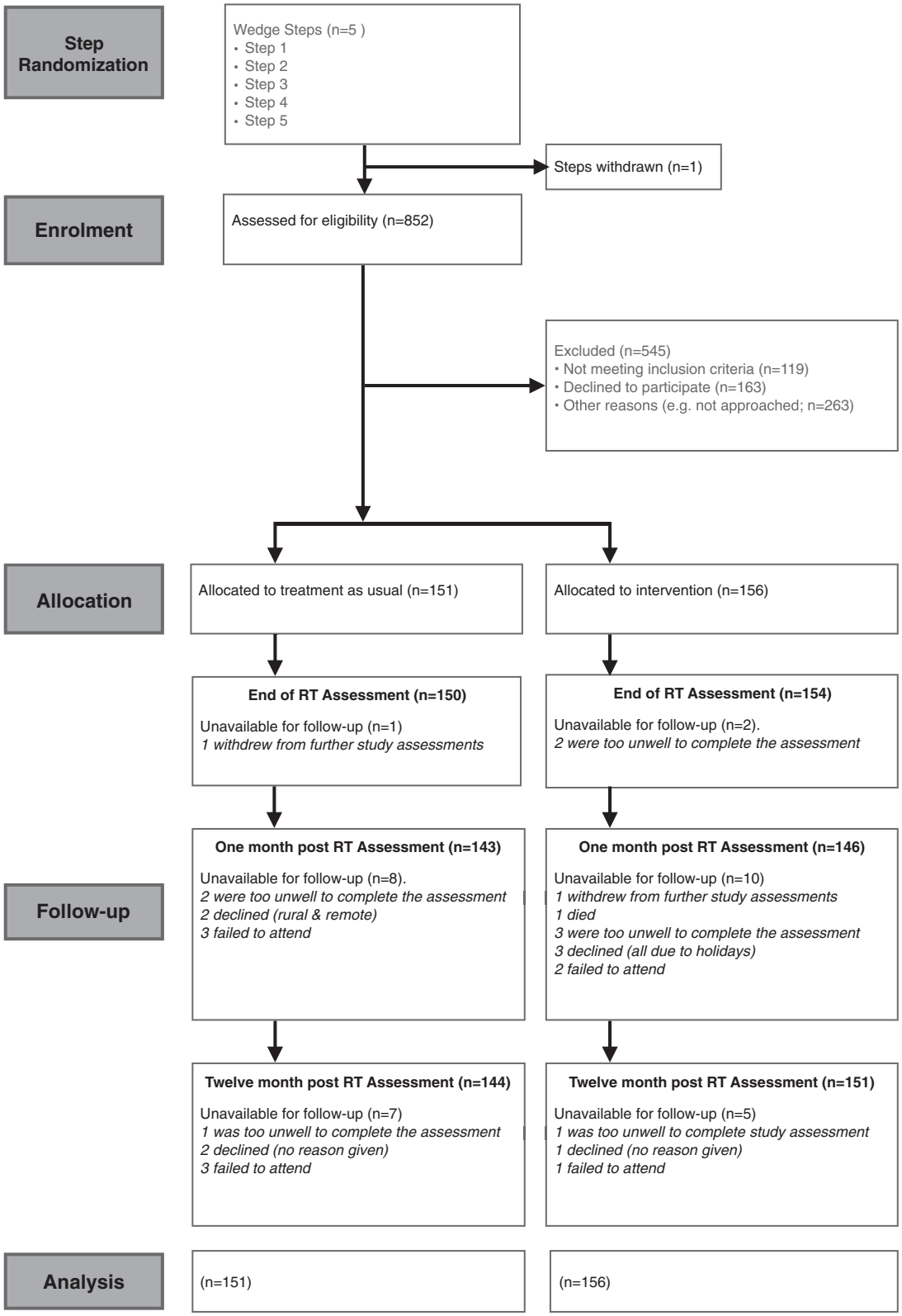

Fig. 2 | Flow of participants through the trial.

were reported as odds ratios (ORs) and 95% confidence intervals (CIs). Complete case analysis was performed due to very low missing data rates. Statistical analyses were two tailed with a significance level of .05.

The dietetics department in one site serviced two hospitals. Although patients were recruited from two different hospitals, they were treated as one progression step in the stepped-wedge study design and moved to the intervention period at the same time (Fig. 1).

RESULTS

Recruitment and participant characteristics

Recruitment began in June 2013 and ended in December 2015, with follow-up finishing in May 2016. Of the 852 patients identified as eligible, 516 patients were approached with information about the study and 313 (61%) of these patients were enrolled in the study (Fig. 2). Four patients were later withdrawn due to late recognition of ineligibility. Of the 152 patients allocated to the control condition, 151 (99%) patients completed follow-up measures. Of the 157 patients allocated to the intervention condition, 156 (97%) patients completed follow-up measures. Patient characteristics are described in Table 2. The mean age was 58 (*SD* 10), most were male and just over half were married. Sixty percent of the patients were employed full time or part time in the past year. Fifty-six percent had cancer of the oropharynx, 22% had cancer of the oral cavity, 9% had cancer of the larynx, 8% had cancer of the nasopharynx, 4% had cancer of the hypopharynx, and 2% had an unknown primary. Sixty-five percent of the patients had Stage IV cancer, and 19% and 13% had Stages III and II, respectively.

Outcomes

Guideline implementation

Table 3 reports descriptive and inferential statistics representing improvements in the provision of care consistent with each of the measures of clinical practice guideline recommendations. For each guideline, the percentage of patients that received care

Table 2 | Characteristics of sites and patients

Variable	Statistic/class	Preintervention (*n* = 151)	Postintervention (*n* = 156)
Clinical characteristics			
Number of dietitians		11	18
Patient demographics			
Age (in years)	Mean (*SD*)	58 (10)	58 (11)
Sex	Male	126 (83%)	118 (76%)
Country of birth	Australia	100 (66%)	98 (62%)
	UK and Ireland	13 (9%)	25 (16%)
	Other	38 (25%)	33 (21%)
Speak language other than English at home	Yes	11 (7%)	11 (7%)
Marital status	Married/de facto	102 (68%)	91 (59%)
	Widowed	4 (3%)	8 (5%)
	Separated/divorced	28 (19%)	29 (19%)
	Single/never married	17 (11%)	23 (15%)
Education	4 years of high school or less	54 (49%)	58 (40%)
	6 years of high school/TAFE	65 (50%)	63 (41%)
	University	31 (21%)	35 (22%)
	Other	1 (<1%)	
Employment	Full-time or part-time employment	87 (58%)	86 (55%)
	Home duties, studying, volunteer, casual, unemployed, other	23 (15%)	30 (19%)
	Retired	41 (27%)	40 (26%)
Tumor site	Nasopharynx	12 (8%)	11 (7%)
	Oropharynx	83 (55%)	88 (56%)
	Oral cavity	30 (20%)	36 (23%)
	Larynx	14 (9%)	15 (10%)
	Hypopharynx	9 (6%)	2 (1%)
	Unknown primary	3 (2%)	4 (3%)
Tumor stage	1	6 (4%)	6 (4%)
	2	22 (15%)	17 (11%)
	3	25 (17%)	32 (20%)
	4	98 (65%)	101 (65%)
Center	Site 1	7 (5%)	16 (10%)
	Site 2	30 (20%)	70 (45%)
	Site 3	46 (31%)	37 (24%)
	Site 4	68 (45%)	33 (21%)

Table 3 | Results of logistic regression models testing for intervention effects on guideline implementation

Guideline	Postintervention %	Preintervention %	OR	Lower 95% CL	Upper 95% CL	*p* value
Dietitian contact weekly during RT	71.5	63.5	1.84	1.05	3.23	.0339
Dietitian contact fortnightly for 6 weeks post-RT	47.7	48.6	1.08	0.65	1.77	.7686
Nutritional assessment at Week 1 of RT	89.7	69.1	4.30	2.01	9.19	.0002
Monitor weight, intake, and nutritional status during and after RT	88.8	56.7	11.00	4.74	25.54	<.0001
Depression screening at Week 1 of RT	81.3	0.7	348.82	69.31	1755.62	<.0001
Depression referral at Week 1 of RT	42.1	0.0	37.70	0.93	1530	.0537

Postintervention and preintervention % columns show the percentage of patients who received care according to each guideline during the postintervention and preintervention periods. *CL* confidence limit; *OR* odds ratio; *RT* radiotherapy.

according to the guideline recommendation is shown for both preintervention and postintervention periods. Also shown are ORs representing the within-site odds of guideline implementation during the postintervention period versus preintervention period. The clinical practice change strategy significantly improved the odds of implementation of four of the six guideline recommendations ($p < .05$). The greatest improvements were found for patient screening for depression (OR = 349; 95% CI: 69–1756; $p < .0001$). Other guidelines showing improved implementation had estimated odds ratios ranging from 1.84 (weekly contact with dietician) to 11 (monitor weight, intake, and nutritional status). Note that although statistical significance was not achieved for distress referral, there was an increase from 0% in the control period to 42.1% in the intervention period ($p = .0547$). The absence of events during the control period necessitated the use of the less powerful penalized maximum likelihood parameter estimation method.

Helpfulness of practice change strategies

The staff booster questionnaire was completed by eight (of 18) dietitians. The majority of responses indicated that the implementation strategies were seen as helpful/very helpful by the dietitians (Table 4).

Table 4 | Distribution of dietitian attitudes toward helpfulness of the practice change strategies ($n = 8$)

Questionnaire item	Very unhelpful (*n*)	Unhelpful (*n*)	Neither helpful nor unhelpful (*n*)	Helpful (*n*)	Very helpful (*n*)
Staff visits					
The information provided by program staff during their visit to the clinic				3	5
Feedback reports					
The information provided in the feedback reports from the program staff				4	4
Resources					
The prompts for key workshop principles and strategies (e.g., stickers, mugs)				4	4
The PHQ-2 sticker			1	5	2
The medical record prompts relating to best practice clinical guidelines[a]			1	2	4
The depression referral policy developed in collaboration with your team[a]				7	
Supervision					
Meeting with the program clinical psychologist				1	7
Receiving feedback on audio recordings				2	6
Scheduling					
Changing the scheduling of dietetic consultations (i.e., to occur on the same day as radiotherapy appointments)[b]				1	3

PHQ-2 Patient Health Questionnaire-2.
[a] $n = 1$ missing.
[b] $n = 3$ already occurring at site.

Discussion

This was the first randomized trial to evaluate the impact of a multistrategic practice change intervention in improving the implementation of best-practice guideline recommendations for the nutritional management of HNC patients by dietitians. The study found the intervention significantly enhanced implementation of guideline-recommended care during the postintervention period. The findings of our study demonstrate that practice change in this setting is possible if clinicians and health services are adequately supported to achieve guideline implementation and have important implications for health services interested in optimizing the care provided to HNC patients to improve their treatment outcomes and prognosis.

The effects of the intervention in improving the provision of best practice care to patients were larger than the effects of trials in other clinical settings. For example, a Cochrane review of tailored interventions to overcome barriers to change including 26 trials reported an increase in the odds of recommended care provision by clinicians of about 50% (OR = 1.54, 95% CI: 1.16–2.01) [42]. Five of the six measures of care provision reported in this setting reported greater effect sizes. Similarly, a review by Grimshaw on guideline dissemination and implementation strategies found a median absolute increase in the improvement in measures of recommended clinical practice by clinicians was 10% [43]. The median absolute improvement reported in this trial was 26% (−1% to 81%). Such findings suggest that the intervention overcame many of the barriers to the provision of care consistent with guidelines. The practice change intervention described in this trial, therefore, provides one model to support clinicians to improve the nutritional management of HNC patients.

The intervention, however, was not effective in increasing the provision of fortnightly appointments with the dietitian for 6 weeks after treatment. Anecdotally, funding constraints in many sites limited the availability of staff to support such frequent dietetic contact. Similarly, patients often report time and logistical difficulty in attending regular clinical consultations [44]. Identifying more cost-efficient models to provide frequent dietetic patient contact post-treatment may be required. For example, reducing the time of clinical consultation may increase the number of staff who are able to provide care to patients. Similarly, providing telephone support to patients who are unable to attend clinical consultations in person may improve the likelihood that such patients receive frequent dietetic care after treatment. Such models of care should be the subjects of future scientific inquiry.

The trial has a number of strengths including a sample sufficient to detect small but meaningful improvements in clinical practices, the use of random assignment, and high participation and retention rates. Nonetheless, a number of limitations of the study should be considered when interpreting trial findings. Site staff (dietitians, data managers) were not blind to participant allocation, which may have introduced bias into dietitian documentation of the provision of guideline recommendations and data manager chart reviews of patient medical records. Furthermore, although audio-recoding may represent the gold standard in assessing delivery of care during clinical consultations, this was not feasible due to the scale of the intervention and outcomes measured. Nonetheless, record audits have been found to be a valid measure of care provision, and in this study, for two guideline recommendations (distress screening at Week 1 of radiotherapy and distress referral at Week 1 of radiotherapy), record audits corresponded closely with audio recordings in a sample of patient consultations.

The findings of this research have important implications for the provision of care according to the best practice guidelines for HNC patients. Given the efficacy of the practice change strategies to improve oncology dietitian provision of care according to the evidence-based guidelines for HNC patients, their implementation in other sites providing care to cancer patients is warranted.

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Compliance with ethical standards

Conflict of interest: The authors have no conflicts of interest to disclose.

Authors' Contributions: BB, ALB, GC, and CW developed the intervention; BB and GC developed the stepped wedge study design; KM, SAH, and LW developed the practice change strategies; KM, BB, ALB, JB, AKB, and LW conducted the research; EH conducted the statistical analysis; CO provided advice on the statistical model and analysis and interpretation of results; KM and LW drafted the paper; and all authors read, edited, and approved the final manuscript.

Primary data: The data and findings reported have not been previously published, and the manuscript is not being simultaneously submitted elsewhere. The authors have full control of all primary data, and they agree to allow the journal to review their data if requested.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all individual participants included in the study.

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