

Digital health in Head and Neck Cancer: a systematic review

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Abstract

Introduction

Digital health tools are increasingly being recognised as effective interventions in monitoring chronic health conditions. This systematic review addresses how digital health is currently utilised in patients with Head and Neck Cancer (HNC) as an adjunct to care.

Methods

Studies of the development or evaluation of an eHealth, telemedicine or telemonitoring tool were eligible. A narrative synthesis was performed as per PRISMA reporting guidelines.

Results

Twenty-nine studies of digital health tools in HNC were identified. Nine were randomised-controlled trials but most had concern of bias. Fourteen (48%) of the interventions used multiple modes of delivery. The primary digital tool functions are symptom tracking and self-care, prehabilitation and rehabilitation, psychological support and education including decision-aids. Most tools aim to support patients during active cancer treatment.

Conclusion

There are a small number of digital health tools for HNC patients however there is a lack of well-designed randomised-controlled trials to demonstrate effectiveness.

MeSH Key Words: head and neck neoplasms; telemedicine; rehabilitation; survivorship; quality of life

1. Introduction

Digital health is an umbrella term encompassing eHealth, telemedicine and telemonitoring. The World Health Organisation highlights its role in the future of healthcare “in strengthening health systems and public health, increasing equity in access to health services, and working towards universal health coverage.” The adoption of digital communication within healthcare has accelerated since the start of the coronavirus pandemic¹ helping to facilitate remote consultations and maintain clinical services throughout lockdowns. There is growing recognition of the role digital health can play in monitoring of chronic conditions and providing equitable access to patients in remote and rural communities.² Digital health solutions can allow the expansion of clinical care in a resource efficient manner. This is reflected in a key ambition of the UK government’s NHS Long Term Plan, to make better use of data and digital technologies³.

The use of mobile devices has become ubiquitous in every-day life. Recent statistics show that approximately 83% of the global population own a smart phone⁴ with younger age, higher levels of education and higher income associated with greater digital connectivity.⁵ Ownership is higher in developed economies such as the UK where 92% own a smart phone including 83% of those over 55⁶ and 97% of households have internet access.⁷

Head and Neck Cancer (HNC) accounts for approximately 5.3% of malignancies world-wide with incidence of HPV-related oropharyngeal cancer increasing, especially in developed countries.⁸ HNC and its treatment have significant negative physical and psychological effects which persist beyond treatment and often continue life-long. HNC patients undergoing curative management have surgical resection, including total laryngectomy and neck dissection, radiotherapy, chemotherapy or combined modality treatment, all of which are

physically and psychologically demanding. Once patients complete treatment, they suffer from wide-ranging morbidity which may include dysphagia, dependence on tube-feeding, loss of voice, trismus, neck pain and stiffness and severe xerostomia. They can also experience significant levels of anxiety about cancer recurrence⁹, body image disturbance¹⁰, isolation and depression¹¹. Digital health tools could be used to address symptoms alongside standard treatment and may lead to quality-of-life benefit.

This systematic review aims to address how digital health is currently being used in patients with a diagnosis of HNC as an adjunct to usual care to improve outcomes relating to the disease or its treatment.

2. Materials and Methods

The remit and search strategy of the review were established and registered with PROSPERO a priori (CRD42021264791).¹² Findings are reported in concordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses reporting guideline (PRISMA).¹³ We also conducted an exploratory search of the Apple *App Store* for “head and neck” and “laryngectomy” to identify mobile applications available to the general public.

2.1 Eligibility Criteria

Studies were deemed eligible for inclusion if they described development, evaluation or trial of an eHealth, telemedicine or telemonitoring tool as defined by Aapro et al.¹⁴ They all involve provision of healthcare “supported by telecommunications or digital technology” to support or optimise services. Studies using both quantitative and qualitative methods were included if they presented original data. Full inclusion and exclusion criteria are listed below:

Inclusion criteria:

- Any publication type if it includes original research regarding the development, evaluation or clinical trial of an eHealth, telemedicine or telemonitoring tool.
- Tool is intended for use by patients with a diagnosis of Head and Neck cancer (HNC) or their carers, not for diagnosis or screening.
- Adult patients with HNC (including sinonasal, oral, oropharyngeal, laryngeal, salivary gland and thyroid) must be either the intended user or a defined group within the usership of the digital health tool.
- Full-text available in English language.

Exclusion criteria:

- Telemedicine or telephone consultation to provide *routine care* as an alternative to face-to-face. The use of telemedicine platforms for clinical consultation throughout the pandemic has been extensively reported in the literature and is not the intended subject of this review.
- Patient questionnaire performed on digital or web-based platform without an intervention.
- Malignancy of the head and neck other than those listed such as upper oesophageal or cutaneous.

2.2 Search and information sources

Searches were conducted on Embase (1974 to Apr 15 2022), Ovid MEDLINE (1996 to Apr 15 2022) and CINAHL (1999 to Apr 15 2022) for relevant studies performed in the last 10 years. Given the rapidly evolving nature of digital platforms and mHealth, this time limit was applied to ensure an accurate description of the current digital environment. The full search terms are listed in **Appendix 1**. Where a tool was the subject of multiple published papers, such as during piloting, sub-group analysis or cost-analysis, only the main publication describing the tool was included in the review. Bibliographies of the included records were screened to

identify further relevant records. EndNote20 was used to collate records and remove duplicates.

2.3 Selection process

Title and abstract screening were performed by the first author (KH), and two authors (KH and LL) independently screened the full text of the records. A third reviewer (CD) resolved any disagreements regarding inclusion.

2.4 Data items and charting

For each record, the country of origin, year of publication, study type, sample size, population of interest, intervention, outcome/s being assessed, and key results were obtained. Where HNC patients made up a subset of the study population but were not presented separately in the results, an attempt was made to contact the corresponding author to obtain this data. If the author could not be contacted or the subset data was not available, the record was included as a narrative description of the tool without assessment of HNC-specific outcomes.

2.5 Critical appraisal of evidence

Randomised controlled trials (RCTs) were analysed for risk of bias based on the Cochrane RoB2 tool by KH and allocated a score of low risk, some concerns or high risk.¹⁵ All records are included in the review regardless of bias status. Non-RCTs were not subject to a formal risk of bias assessment.

2.6 Synthesis of results

The data items described above were obtained from each record and summarised in tabular form. A narrative synthesis of the key functions and outputs of the digital health tools was performed. Given the heterogenous nature of the randomised controlled trials, it was not possible to perform statistical comparison of outcomes or a meta-analysis.

3. Results

3.1 Selection and synthesis of evidence

The results of the search and selection process is illustrated in a PRISMA flow diagram [Figure I]. After duplicates were removed, 85 studies met the inclusion criteria and were sought for full-text review. After independent review by two authors, a total of 26 records were included in the analysis which are summarised in **Table I**. A further 3 studies were identified from cited papers of the included studies.

3.2 Characteristics of sources of evidence

Eighteen (62%) studies of digital health interventions in HNC were by research groups based in the USA and Canada. Nineteen (66%) studies were published in the second half of our review period. Seventeen (59%) records were 'development studies' which aimed to assess the usability, feasibility and/or acceptability of the digital health intervention as the primary outcome. There were 10 randomised controlled trials. A statistical synthesis of the RCTs was not possible due to the heterogeneity in population, interventions and outcome measures. The remaining 2 studies were quasi-experimental: one single-arm and one non-randomised controlled trial. 5 studies, including 2 RCTs, describe an intervention aimed at a mixed cancer population of which a proportion had HNC (5-30%).

3.3 Results of Synthesis

This systematic review aims to address how digital health is currently being used in patients with a diagnosis of HNC as an adjunct to usual care to improve outcomes relating to the disease or its treatment. We found 29 studies of digital health tools in HNC. The purpose of these tools can be considered in 4 categories: symptom tracking and self-care, prehabilitation or rehabilitation, psychological support and educational including decision-aids.

Symptom Tracking and Self-Care

Eleven of the digital health tools identified in the review facilitate symptom-tracking, mostly in patients actively undergoing (chemo)radiotherapy. The eHealth tools from Hauth¹⁶, and SK Peterson¹⁷ collect data during radiotherapy which is made available to clinical teams in real-time, facilitating early detection of treatment toxicity. Pelota¹⁸ and Pfeifer's¹⁹ studies both use telehealth to provide patient symptom questionnaires during active treatment and provide tailored self-management advice. Shah et al demonstrates the use of eHealth as an adjunct to follow-up in the immediate post-operative period after major surgery and the potential to reduce use of unscheduled care.²⁰

There has been increasing emphasis on the concept of long-term survivorship in HNC, especially with growing numbers of patients with human papilloma virus (HPV)-related oropharyngeal cancer surviving curative treatment. The HNC survivorship tool created by Salz et al helps clinicians address cancer-related symptoms at clinic appointments.²¹ The RCT by Van der Hout et al compares a web-based self-management programme for cancer survivors to usual care with specific HNC elements. They demonstrate an improvement in mouth pain, social eating, swallowing and trismus with the intervention compared to standard care.²² As well as modules to improve empowerment and self-management in oral cancer survivors, Manne's online intervention taught patients how to conduct surveillance for lesions with self-

examination.²³ This is the only tool that describes the use of eHealth to help patients monitor for recurrence.

Prehabilitation and Rehabilitation

The efficacy of prophylactic swallowing exercises on swallowing outcome in HNC patients is the subject of on-going international randomised-controlled trials.^{24,25} If they demonstrate a benefit to swallowing outcome, there will be expectation for Speech and Language services to provide exercises to patients. The digital tools created by Clossen, Shinn and Wall provided a swallowing exercise programme which can be performed independently at home and may be adapted for this purpose.^{26,27,28} The smartphone-enabled swallowing trainer developed by Constantinescu et al²⁹ gives feedback on the physiological mechanism of swallow to aid rehabilitation. Adherence to swallowing exercises in HNC is a problem, with identified barriers being the time investment and patients not understanding the benefit.³⁰ In the RCT by Jansen et al 17/41 (41%) of participants for whom adherence data was available reported low adherence to the rehabilitation programme despite several measures to optimise this.³¹

Psychological Support

Berry et al³² presents a generic cancer tool which encourages self-management of psychological symptoms with an alert to contact clinicians in circumstances such as suicidal ideation. Gabroyes et al created an intervention to specifically address psychological distress around body image³³ whereas Fang addresses more general cancer-related psychosocial challenges.³⁴ Importantly, they found that HNC patients who were more recently diagnosed and had higher baseline levels of cancer-specific distress were less likely to engage with the tool. Furthermore, both Ma³⁵ and Kilbourne³⁶ found that engagement declined during the second half of treatment, which the authors attributed to increasing treatment toxicity and fatigue.

Education and Decision Aids

Decisional conflict is experienced by patients where there is uncertainty about the best course of action when there is potential for significant risk or poor outcome. Decision aids help patients to process evidence-based information alongside personal values and have been shown to reduce decisional conflict in cancer patients.³⁷ Bigelow and Peterson both describe the challenge of developing a decision aid which contains all the relevant clinical information without being too complex or over-whelming.^{38,39} A multi-modal approach to provide tailored information to patients was used in the non-randomised trial by D'Souza and demonstrates a significant reduction in anxiety in users.⁴⁰ Furthermore, Sawka shows a significant reduction in decisional conflict related to adjuvant radio-active iodine treatment in patients with early papillary thyroid carcinoma when using a decision aid.⁴¹ A key function of the mobile app described by Wang was to sign-post patients to external resources with relevant information.⁴² Two interventions were designed for use by patients and a caregiver. For example, Badr et al provided intensive telephone-based support to patients and their spouses in separate but complimentary sessions.⁴³ Similarly, the Survivorship Needs Assessment Planning (SNAP) tablet-based tool by Sterba includes assessment of caregiver distress to inform a personalised care plan.⁴⁴ In summary, a range of digital tool related to information giving, education and decision-making is demonstrated with signs of possible utility in reducing anxiety and decisional conflict.

Methods of Delivery

Table III. shows the methods used to deliver the interventions. 16 (62%) of the interventions used more than one method with off or online software being the most common whilst only 5 (19%) studies utilised a smartphone application. Only Constantinescu et al address the

potential for commercial wearable devices (FitBit™ activity tracker) in HNC patient monitoring.

Twelve studies reported interventions which involved additional interaction with the clinical team, either via telephone, video conference or face-to-face. For example, the intervention described by Badr involves 6 hours of telephone sessions for the patient and their spouse provided by a mental health counsellor.³⁹ The telemedicine programme from Gabroyes is delivered on a one-to-one basis with a clinical psychologist and therefore it must be considered whether the intervention is scalable in most health services.³⁰ The studies by Di⁴⁵ and Oldenmenger⁴⁶ include a human-to-human interaction element in a more limited capacity with clinical contact being available via e-mail or web chat if required. Selective use of remote telephone support was shown to be useful to improve adherence to interventions by TJ Wang et al.⁴⁷

An exploratory search of the Apple *App Store* for “head and neck” and “laryngectomy” found only two results. One application for HNC patients, called ‘Head & Neck Cancer Manager’ can help patients track symptoms, set appointment reminders, and connect to care providers. The tool is compliant with US laws for protection of health information. There was one application for laryngectomy patients created by Atos medical, a developer and manufacturer of laryngectomy devices, which provides product information and education related to their use. There is no evaluation of the app contents in the medical literature.

3.4 Bias of Evidence

A summary of the risk-of-bias assessment for the 10 RCTs is demonstrated in **Table II**. Overall, 1 study demonstrated a low risk-of-bias, 8 studies had methodological flaws which raised some concerns about bias and 1 study had a high risk-of-bias. A common feature is the

inability to blind the participants to treatment allocation as this is not possible when the intervention involves engagement with an eHealth tool.

4. Discussion

4.1 Summary of the evidence

The aim of this systematic review was address how digital health is currently being used an adjunct to usual care to improve outcomes relating to HNC or its treatment. Three key themes emerged from this review: the apparent value of symptom-tracking and self-management, issues with engagement and how digital tools can provide psychological support.

Firstly, the most common function of the digital tools is symptom-tracking and self-care advice designed for patients undergoing active treatment. This reflects the recognised morbidity associated with HNC treatment and the need for greater support at this time. Four of the RCTs focusing on active treatment support were able to demonstrate improvement of physical symptoms in the intervention group. Remote symptom monitoring has also been shown to be effective in reducing symptoms burden in several other cancer types. For example, the multi-centre 'eSMART' trial of Advanced Symptom Management System (ASyMS) during chemotherapy treatment for breast cancer, colorectal cancer, Hodgkin's disease and non-Hodgkin's lymphoma demonstrated significant improvements in anxiety, health related quality of life, self-efficacy, and supportive care needs.⁴⁸ Recent evidence shows that new symptoms after cancer treatment, such as pain, are a strong indicator that the cancer has returned ⁴⁹ therefore digital tools which track symptoms in the longer term may also lead to earlier detection of recurrence.

Self-assessment tools depend on patient engagement and studies employed various ways to promote this amongst trial participants. For example, Peltola¹⁷ used a weekly reminder email whereas Pfeifer et al¹⁸ had a device connected to the landline which flashed when assessments were due. Despite these efforts, engagement with the digital health tools were often poor. Ma and Kilbourn suggested that engagement could decline as symptom-burden increases^{35,36} and this issue therefore requires consideration in the development of future interventions.

Patients with HNC have amongst the highest incidence of suicide rates even compared to other cancer patients⁵⁰ and body image disturbance (BID) is a significantly under-recognised issue, with prevalence as high as 89% in the immediate post-treatment period.⁵¹ Psychological interventions are therefore an important component of post-operative care. The three studies identified in this review were development studies and were not powered or designed to prove clinical effectiveness. Nevertheless, Graboyes' cognitive behavioural therapy intervention resulted in improvement in BID at 1 month post-treatment compared to historical controls who showed no change in the first 12 months^{9,32} thus indicating potential for this approach.

4.2 Strengths and Limitations

Due to the heterogeneity of the tools, we could not perform a statistical synthesis of outcomes and the interventions described in the included studies were sometimes complex and involved multiple elements. This review is therefore unable to extricate what benefits were due to the digital tool as opposed to the other elements such as enhanced clinical interaction.

A strength of this review is the broad definition of digital health used and the inclusive search criteria. It is possible that studies have been missed if they did not use any of the expected terminology, but the authors consider this to be unlikely. Two authors screened the records to ensure papers were eligible to be included in the review.

Conclusion

In conclusion, there are a small number of digital health interventions for HNC. Most of the digital tools aim to promote self-management of symptoms and focus on supporting HNC patients during active treatment. There is a noticeable gap in tools designed for long-term follow-up and for delivery via smart-phone app. Several studies have found improved outcomes associated with the use of digital health interventions but currently there is a lack of well-designed randomised controlled trials to demonstrate their effectiveness. Cancer-related morbidity as a barrier to eHealth engagement should be carefully considered in the design and implementation of such tools.

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Conflicts of Interest: The authors declare no conflict of interest.

Key Learning Points:

- 29 digital health tools for Head and Neck cancer (HNC) patients were identified.
- The function of most of the tools was patient symptom-tracking and self-management.
- Only a 5 (19%) of the digital health tools in HNC utilise mobile applications.
- There is a lack of well-designed randomised-controlled trials of digital health tools in HNC.

Table I. Summary of included papers

Author, country, year pub.	Study type	Population	Intervention	Outcome/s	Result/s
SYMPTOM TRACKING and SELF-CARE					
Badr USA, 2018	RCT; N=30 1:1	HNC patients undergoing radiotherapy (RT) and their spouses.	Manual containing self-care, coping strategies, care-giving skills etc; plus educational DVD; plus 6x 60min telephone sessions corresponding to manual sections for patient and spouse.	Feasibility and acceptability. Secondary outcomes: physical symptoms (via MDASI-HN), psychological functioning (via PROMIS) and marital adjustment via Dyadic Adjustment Scale (DAS-7)	Retention 93%. Intervention arm had less severe HNC-specific symptoms ($p=0.03$) and depressive symptoms and cancer-specific distress. ($p<0.05$) No difference in marital adjustment.
Berry USA, 2014	RCT; N=752 1:1 of which 50 (6.6%) HNC	Cancer patients starting a new therapeutic regimen.	Self-reported cancer symptoms and quality-of-life (SxQOL) tool. Based on result patients given self-care advice, coached to explore symptoms, make journal entries and view trends. Controls completed SxQOLs without response.	Data collected at baseline, 3-6 weeks into treatment and 2 weeks after. Change in Symptom Distress Scale (SDS)-15 score.	SDS-15 score reduced by 1.2 in the intervention arm ($p=0.02$). No sub-group analysis for HNC patients.
Di China, 2018	RTC; N=132 (65 intervention and 67 control)	Patients completing (chemo)radiotherapy for nasopharyngeal carcinoma.	App functions include appointment reminder, rehabilitation exercises (nature not specified), patient-to-patient interaction and 'online expert' twice a week where a doctor answers patients' questions.	Complications after radiotherapy and chemotherapy, rehabilitation exercise compliance, and quality of life at discharge and at 3 months and 6 months after discharge.	At 6 months, incidence and severity of oral mucositis, trismus, xerostomia, and nasal obstruction in the intervention group was significantly lower than the control group ($p<0.05$) and overall quality of life via EORTC QLQ-C30 was higher.
Hauth Germany, 2019	Development study: N=21 of which 4 (19%) participants had HNC	Cancer patients receiving treatment involving radiotherapy.	Web-based application, 'PROMetheus', allows patients to submit ePROMs (PRO-CTCAE) to the treating team. Scores indicating toxicity were highlighted to the clinical team.	Usability by adherence to weekly web-based questionnaire. Acceptability is defined as meeting this requirement.	17/21 (81%) patients submitted at least weekly data. Fatigue was the single most reported symptom.
Ma USA, 2021	Development study (N=84)	Patients with HNC undergoing radiotherapy treatment.	Chat-bot (web-based interactive communication system) with artificial intelligence features use to help symptom reporting - weekly scheduled and on-demand chats. Results available to clinical teams and produces individualised educational material and self-care advice.	Presence and severity of patient-reported symptoms and adverse events and concordance with physician-reported outcomes. Engagement - defined as use of ChatBot at least once. Usability via participant survey.	Patients agreeing to participate significantly younger ($p<0.001$). 60/84 (71%) engagement with greatest use in the first 4 weeks of treatment. 58% (35/60) reported at least 1 severe adverse event and agreement with clinical reporting ranged from 31-65%.

Oldenmenger Netherlands, 2018	Development study: N=84 of which 4 (5%) had HNC.	Patients with cancer-related pain.	Web application consisting of 1) pain diary to monitor patients' pain and analgesic intake, 2) pain education and 3) eConsult email-like function to communicate with nurse specialist.	Trail period 6 weeks. Diaries completed (%) as indicator of feasibility, number of pain assessments, frequency with which analgesics were changed and the number of eConsults participated in.	40 (47.6%) patients stopped using the web application, 26 due to physical deterioration or death. Patients completed a median of 72% of the diaries (range 18-100%) and analgesic change a median of twice.
Peltola Finland 2016	Development study (N=5)	New HNC patients undergoing treatment with (chemo)radiotherap y	Self-assessment symptom questionnaires prompted weekly. Medical staff receive notification of reported side-effects to prompt action where indicated.	Compliance with self-assessments.	3/5 patients reported severe side-effects. 4/5 patients had a trigger medical intervention eg opioid analgesia and 1 admission for IV antibiotics.
Peterson SK USA, 2013	Development study (N=50)	Patients receiving radiotherapy to bilateral necks for curative HNC treatment.	Home-based sensors for collecting and communicating sitting/standing blood pressure, pulse, weight, and a symptom questionnaire. Data sent to the radiation therapy clinicians and reviewed daily to determine dehydration risk.	Study completion - defined by completing the second, and final, day 6 assessment. Secondary outcomes were acceptability, perceived usefulness of the intervention, and adherence to the monitoring protocol.	50/85 (59%) eligible participants began the study and 48/50 (96%) of those completed the study. High levels of perceived usefulness, ease of use and acceptability and low concerns about data privacy. The tool identified dehydration events in 29 (60%) of patients.
Pfeifer USA, 2015	RCT; N=86 48:38 randomisation grid stratified by treatment modality.	HNC patients undergoing any modality treatment.	Telehealth symptom questionnaire completed daily. Algorithm presents self- management depending on symptoms, including recommendation when to contact clinicians.	Functional Assessment of Cancer Therapy- Head & Neck Scale (FACT-HN) and the Memorial Symptom Assessment Scale (MSAS) were used to assess primary outcomes of QoL and symptom burden.	Physical symptoms demonstrated the greatest improvement with the intervention. No change observed in patients' social and emotional well-being. QoL and symptom burden were improved in the weeks after treatment but not during treatment.
Salz USA, 2018	Development study (N=10)	HNC survivors plus human-computer interaction experts, nurse practitioners	Head and Neck Survivorship Tool: Assessment and Recommendations (HN- STAR) combines the patient treatment summary and symptom self-assessment to generate a clinical decision support tool which informs clinic appointments and ensures symptoms are addressed.	Usability assessment via think-aloud study and usability checklist. Qualitative feedback on ease of use and usefulness.	Changes made as a result of feedback inc reducing text, addition of function to omit unrelated symptoms from care plan and free- text space in self-assessment tool for additional symptoms. NB. RCT protocol published 2021
Shah USA, 2021	Single-arm study (N=91)	HNC patients discharged following major surgery	Telephone call within 72 hours of discharge with option to send photographs and video conference with physicians or nurse practitioner.	Unscheduled hospital visits and re- admissions. Comparison to historical patient cohort from the preceding year.	83/91 (91%) successfully contacted. 18 (21.7%) patients with wound concerns would have attended the emergency department without the intervention. Significant reduction in emergency room attendances compared to historical cohort.
Van der Hout	RCT; N=625 1:1 block random	Cancer survivors 3 months – 5 years	Web-based application <i>Oncokompas</i> monitors cancer-generic and site-specific	Data collected at 1 week, 3 and 6 months. Primary outcome = patient activation	No difference in patient activation measure. HNC patients in intervention group had

Netherlands, 2020	allocation of which 187 (29.9%) had HNC.	following completion of curative treatment.	symptoms and HRQOL, providing feedback and information based on the scores.	(knowledge, skills and confidence for self-management). Secondary outcomes included health-related quality of life, mental adjustment to cancer, supportive care needs and self-efficacy measures.	significantly less pain, social eating concerns, swallowing difficulty and trismus compared to controls which was sustained over the trial period.
PREHABILITATION and REHABILITATION					
Cnossen Netherlands, 2014	Development study N=33	HNC patients undergoing RT as single or multi-modality.	Self-help swallowing and exercise programme ('Head Matters') 15-minute per day with four categories of prophylactic exercises. Patients given instruction leaflet, booklet with DVD, or website log-in plus weekly coaching session via telephone or email.	Uptake among eligible patients, adherence (defined as at least one exercise a day) and exercise performance level via patient diaries. Barriers to exercise.	Uptake 83% of eligible participants. 58% of patients performing exercises in all categories at least once a day. Performance level was not significantly different between intervention formats.
Constantinescu Canada, 2019	Development study N=5	Patients with a history of HNC.	3 surface electromyography sensors (sEMG) measure the activity of submental muscles during swallow and swallow-like exercises. Data transmitted via Bluetooth to a smartphone app and presented as visual biofeedback to the user.	Usability (inc number of times patients needed help), system efficiency (inc time-on-task) and user satisfaction were assessed over 5 tasks.	Patients struggled to pair their device to their phone and patient struggled with some tasks indicating a lack of clarity in design.
Jansen Netherlands, 2020	RCT; N=92 1:1	Patients treated with total laryngectomy in the last 5 years.	Exercise program targeting speech, swallowing and shoulder problems; intervention arms asked to perform exercises 3 times daily for 12 weeks. Available as booklet and DVD or online application plus weekly coaching via email or telephone. Self-care educational resource to both arms.	Primary outcome: swallow problems measured by swallowing quality of life questionnaire (SWAL-QOL). Secondary outcomes: speech handicap index (SHI), shoulder disability questionnaire (SDQ), quality of life (via EORTC QLQ-C30) and patient activation.	Significant improvement in eating duration (p = 0.022), fear of eating (p = 0.008), mental health (p = 0.030) and social function (p=0.049) with intervention at 6 months. No significant difference in speech and shoulder problems or patient activation.
MacDonald Canada, 2020	Development study: N=35 of which 2 (6%) participants had HNC.	Patients during and after acute cancer treatment at a tertiary cancer centre.	<i>Care@Home</i> - 8-week programme comprised of: 1) individualised exercise prescription supported with a mobile application (Physitrack®) and wearable (Fitbit™) to track activity; 2) weekly e-modules to promote self-management skills; and 3) weekly telephone coaching from health professionals trained in motivational interviewing.	Recruitment and retention determined by health coaching call attendance, Fitbit™ and Physitrack® usage and e-module completion. Physical measures inc disability (WHO-DAS 2.0), physical activity (GSLTPAQ) and aerobic capacity and endurance (6-min walk test) collected at end of intervention and at 3 months.	30/35 (86%) wore the FitBit™ device for mean 87% of intervention days. 31/35 (89%) logged into Physitrack® app at least once. Mean of 4 e-modules completed but 7 (20%) didn't log on. Significant reduction in disability and increase in moderate-strenuous activity at 3 months.
Shinn USA, 2019	Development study; N=160	HNC patients about to start radiotherapy	Web-based intervention to increase patient adherence to prophylactic swallowing exercises during radiotherapy. Platform includes swallowing exercise videos and	Adherence to swallowing exercises at 3 weeks, end of treatment and 4 weeks after treatment. Secondary outcomes - MD	84/160 (52%) did not complete adherence data and were excluded from adherence analysis. Average 5.5 visits to website over 10 weeks. Of the included patients 51% and 53%

		treatment for stage II-IV disease.	self-management advice with 10 weeks of content aimed at treatment stage.	Anderson Dysphagia Inventory, pain and fatigue scores.	adhered to trismus and swallowing exercises respectively.
Wall Australia, 2020	RCT three-arm; N=79 1:1:1 random allocation	Patient with oropharyngeal SCC receiving (chemo)radiotherapy.	Swallowing therapy interventions: 1. clinician-directed face-to-face (FTF) therapy, 2. telepractice-assisted therapy using interactive application "SwallowIT," 3. patient self-directed therapy.	Data at baseline, 6 weeks and 3 months post treatment. Primary outcome = functional oral intake. Secondary endpoints inc. nutrition, swallow physiology assessed by videofluoroscopic swallow study (VFSS), patient-reported functional measures and patient perceptions of the 3 interventions.	No significant effects of service model observed with respect to any outcome. Swallow therapy adherence was low regardless of group with no significant difference between the groups.
Wang TJ Taiwan, 2019	RCT; N=68 1:1 random allocation	Post-operative oral cancer patients following discharge.	Intervention and active control instructed on a package of warm compress, masticatory muscle massage, jaw exercises and active and passive stretching plus the intervention group received remote support provided via telephone call.	Adherence to the intervention protocol, (maximal interincisal opening) MIO, and mandibular function via the Mandibular Function Impairment Questionnaire (MFIQ).	Significantly greater adherence to package, change in MIO and MFI in intervention group compared to active control (p<0.001).
PSYCHOLOGICAL					
Fang USA, 2020	Development study (N=55)	HNC patients treated with radiotherapy.	Web-based program 'My Journey Ahead' provides information and strategies for managing symptoms including speech, swallow, oral care and psychological coping strategies.	Coping with cancer-related stressors was assessed using the Cancer Behaviour Inventory (CBI-B), psychological distress via the Brief Symptom Inventory-18 (BSI-18). Programme evaluation via a questionnaire.	11/55 (20%) did not log into the website, non-users had more recent diagnosis and cancer-related distress. No significant changes from baseline to post-programme in CBI-B or BSI-18 but users found the website easy to use (4.7/5) and the information presented of value (4.2/5).
Graboyes USA, 2020	Development study (N=68)	HNC survivors with body image disturbance (BID).	One-to-one tele cognitive behavioural therapy delivered by clinical psychologist via tablet. 'BRIGHT (Building a Renewed Image after Head & neck cancer Treatment)' consists of 5 60-min sessions plus extra tasks to be performed.	Feasibility inc study dropout, session completion and technical issues. Acceptability inc content, number of sessions, and likelihood of recommending intervention. The primary outcome was change in Body Image Scale (BIS) score at 1 month.	7/10 participants were female and 8/10 had free flap reconstruction. 1 drop-out. Remaining 8/9 patients would recommend the intervention. 9/9 had reduction in BID at 3 months (mean decrease in BIS score = 3.56 [CI 1.15-5.96])
Kilbourn USA, 2013	Development study (N=16)	Recent diagnosis of HNC and receiving treatment involving radiotherapy.	<i>Easing and Alleviating Symptoms during Treatment (EASE)</i> programme delivered via 8 telephone counselling sessions: 1) ongoing assessment of physical, psychosocial, and functional needs; 2) a psychoeducational component around management of treatment side effects, and 3) coping skills training.	Acceptability measured via project records and post-intervention interviews and feasibility evidenced by retention rate – completing intervention defined as participating in at least 2 sessions. Quantitative measures collected: cancer-specific distress, quality of life, pain and social support.	14/16 (87.5%) satisfied with phone counselling. Patients more engaged with counselling at beginning of treatment. 63% were satisfied with the EASE programme and 16/21 (76.2%) completed at least 2 sessions. No significant improvement of quantitative measures from baseline.

EDUCATION and DECISION AID					
Bigelow USA, 2021	Development study (N=26)	16 physicians (HNC surgeons and oncologists), 4 patient education experts, and 6 OPSCC survivors.	Decision-aid for patients with oropharyngeal SCC undergoing curative treatment. Prototype inc. videos of HNC survivors, treatment timeline, treatment comparison and questionnaires to inform further clinic discussion.	Alpha testing to determine comprehensibility, usability, acceptability, and design by questionnaire and written feedback from users.	Changes to the tool based on feed-back and second cycle of tool assessment. Cycle 2 100% felt the design was acceptable and 77% indicated that they would be likely to use or share the DA.
D'Souza Canada, 2013	Non-randomised controlled trial; N=103 patients recruited from 2 sites, treatment allocation by site.	Newly diagnosed patients with stage III or IV primary or recurrent HNC.	Multimode Comprehensive Tailored Information Package (MCTIP), a multimedia tool comprised of 5 parts: 1) booklet, 2) interactive computer booth with tailored information about site/stage/treatment, 3) animation, 4) take-home DVD and 5) database of clinical and social information.	Hospital Anxiety and Depression Scale (HADS), difference of 2 points considered clinically significant. Face-to-face interviews at baseline, 3 and 6 months.	Depression was significantly associated with younger age ($p = 0.04$) and unemployment ($p = 0.02$) Fewer patients in the test group had clinical levels of anxiety at 6 months ($p=0.005$).
Manne USA, 2020	Development study (N=66)	Survivors of oropharyngeal cancer diagnosed 1-3 years previously.	Web-based, interactive information and support needs tool ' <i>Empowered Survivor</i> ' (ES). 6 modules including managing swallowing difficult and oral self-exam.	3 surveys at baseline, 2 months and 6 months. Feasibility measured as study enrolment and retention. Acceptability assessed by use and evaluation of ES on post-intervention questionnaire. Primary outcomes: oral self-care, cancer survivorship preparedness and health-related quality of life (HR QoL)	Acceptance rate 66/317 (20.8%) of eligible participants. 81.8% of participants viewed a least 3 modules. Mean Likert score from 1-5 (5 being positive): ease-of-use 4.21, use of information 3.82, satisfaction with tool 3.86. Significant improvement in all domains from baseline ($p<0.05$).
Peterson J Netherlands, 2019	Development study (phase 1 N=9, phase 2 N=14, phase 3 N=9) plus physicians.	HNC patients treated with total laryngectomy or (chemo) radiotherapy	Interactive web-based decision aid for patients with primary T3 to T4 larynx cancer receiving curative treatment.	Phase 1: needs assessment and barriers to counselling process via semi-structured interview. Phase 2: comprehensibility and usability via think-out-loud task and questionnaire. Phase 3: feasibility via same method as phase 2.	As a result of alpha-testing text changed to pictures and animations, changes to layout. In beta-testing, median score for usability and comprehensibility 5 out of 5. All patients would advise new patients to use the tool
Sawka Canada, 2012	RCT; N=74 (37 intervention and control arms)	Patients with pT1/2N0M0 papillary thyroid cancer (PTC)	Decision aid (DA) for patients with early-stage PTC where accepting or declining adjuvant radioactive iodine (RAI) would be clinically appropriate.	Self-administered medical knowledge questionnaire administered before and after exposure to DA versus control (usual care and counselling). Secondary outcome of decisional conflict via Decisional Conflict Scale.	Mean difference in medical knowledge between groups was 1.9/10 ($p<0.001$) and decisional conflict significantly lower in DA group ($p<0.001$). Rates of adjuvant RAI treatment not significantly different between groups.
Sterba USA, 2019	Development study N=26	HNC survivors who received at least two treatment modalities	Survivorship Needs Assessment Planning (SNAP) tablet-based assessment questionnaire including patient unmet needs, fear of recurrence, care-giver	Feasibility and acceptability. Change in outcome variables from baseline to 6-week follow-up. Primary outcomes were depression, unmet needs,	SNAP session protocol steps were completed for all patients. Care plans included an average of 19 messages and 13 educational materials and 4.5 referrals. SNAP session

			distress etc. Generates individualised care plan which is discussed with nurse in clinic.	survivorship knowledge, dyadic coping, caregiver burden.	made survivors and their care givers feel prepared for the post-treatment period (84% survivors, 80% caregivers), had right amount of information(100%, 84%), provided practical information (92%, 88%) and was helpful emotionally (80%, 80%).
Wang TF Taiwan, 2020	RCT; N=100 1:1 random allocation	Patients with oral cancer undergoing surgery.	Mobile application with information about oral cancer and treatment, instructions for self-recording symptoms and sign-posting to available support groups.	Cancer Needs Questionnaire (CNQ-SF), EORTC QTQ-C30 and the Science and Technology Acceptance Model (TAM) scale.	Multiple regression analysis demonstrated that the experimental group had significantly greater improvement in physiological needs compared to control group (p=0.022). TAM score improved with app use.

MDASI-HN = MD Anderson Symptom Inventory – Head and Neck

PROMIS = Patient-Reported Outcomes Measurement Information System

EORTC QTQ-C30 = European Organisation for Research and Treatment of Cancer quality of life questionnaire for cancer patients

FCCHL = Functional Communicative and Critical Health Literacy scale

PRO-CTCAE = Patient Reported Outcomes-Common Terminology Criteria for Adverse Event

WHO-DAS 2.0 = World Health Organization’s Disability Assessment Schedule 2.0

GSLTPAQ = Godin-Shephard Leisure-Time Physical Activity Questionnaire

EORTC QLQ-HN35 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, Head and Neck Module

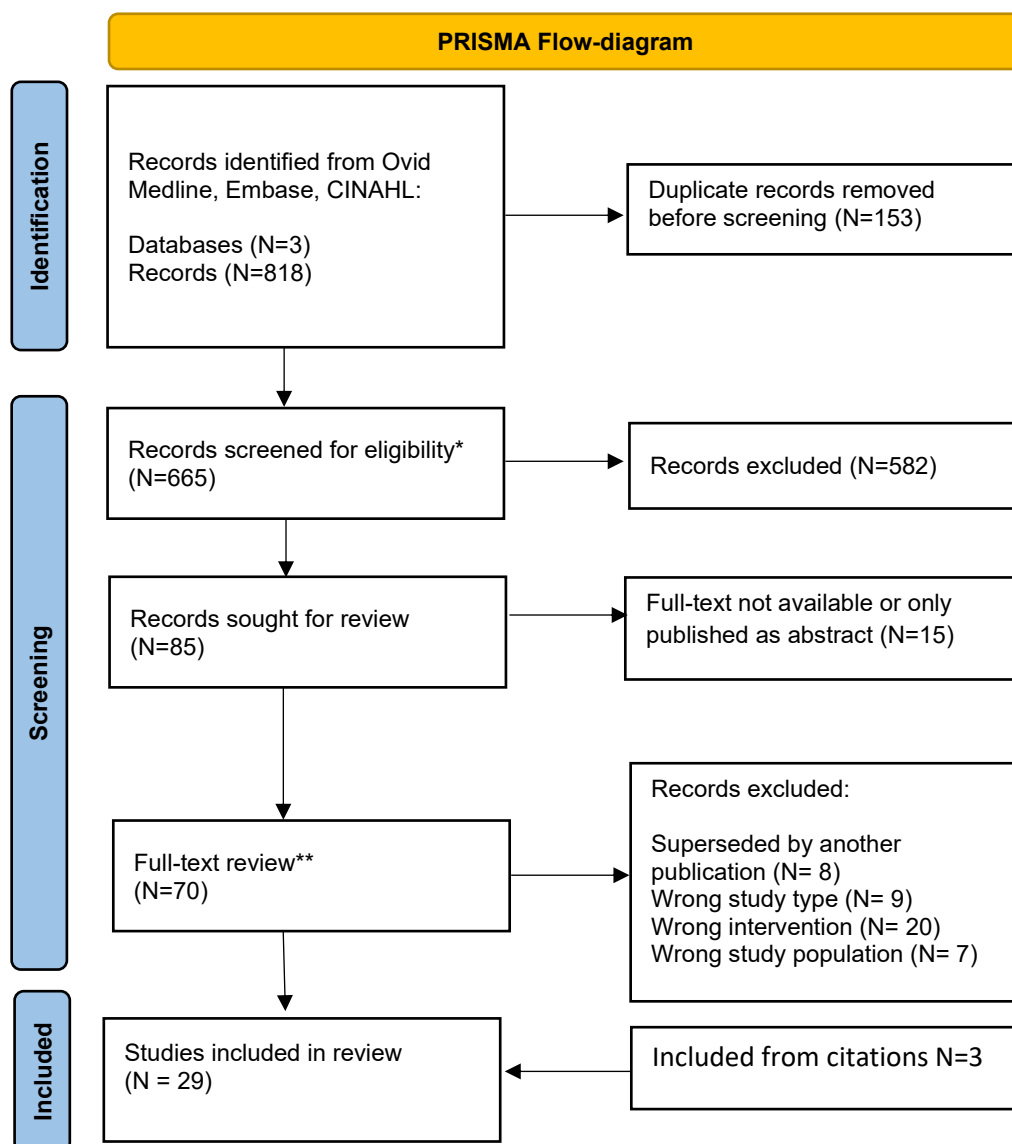
Table 2. Risk of bias (using RoB2 tool) – randomised controlled trials

First author	Randomisation Process	Deviations from intended intervention/s	Missing outcome data	Measurement of the outcome	Selection of the reported results	Overall
Badr	No detail given on allocation process and group patient characteristics not described. Imbalance in spousal anxiety at baseline.	Unable to blind participants or those delivering intervention. Intention-to-treat analysis includes couples deviating from protocol.	1/15 couples lost to follow-up from both intervention and control groups.	Validated scoring tools for HNC-specific physical symptoms, depression and anxiety and marital adjustment. Numerical score objective to outcome assessors.	Protocol published on ClinicalTrials.gov in advance of enrolment and outcomes reported as planned.	Some concerns
Berry	Computer randomisation 1:1 in blocks of 4. Participants significantly younger ($p=0.04$) in intervention group.	Unable to blind participant. Intention-to-treat analysis from point of randomisation in all eligible participants with outcome data.	30.5% missing data; likely to be older ($p=0.0002$) and ethnic minorities ($p=0.06$). Older patients have greater effect size therefore likely impact is to diminish effect size.	SDS-15, although originally validated for lung cancer, is a widely used scoring system in multiple cancers including HNC. SDS-15 is self-reported therefore not subject to bias by assessors.	Single outcome domain specified prior to randomisation.	Some concerns
Di	Random number table method, no difference in several key variables.	Unable to blind allocation. As intervention was self-guided and self-reported it is unclear what intervention each patient experienced.	Outcome of exercise compliance incomplete, 2 examples given.	Patients' use of app was self-reported therefore compliance with intervention is subject to reporting bias.	Results presented on compliance appear to be selected from multiple outcome measures not detailed in the methodology.	High
Jansen	Randomised 1:1 and stratified for potentially influencing factors but method not stated. Significant baseline difference in HRQOL in favour of intervention.	Participants and researchers aware of assigned intervention, no changes from assigned intervention. Intention-to-treat analysis.	Greater number lost to follow-up in intervention arm, not likely to influence overall result.	Outcome measures self-reported by participants and may be influenced by knowledge of treatment allocation. Recruitment below required sample size for power.	Results reports in accordance with pre-specified plan.	Some concerns
Pfeifer	Randomisation grid 'considered treatment modalities', presumed stratification. No significant difference between groups.	No participants or research team blinded.	6/48 (12.5%) allocated to intervention did not receive the intervention. Further 3/48 did not complete. Not intention-to-treat analysis.	Validated outcome measures appropriate to clinical question.	Outcome measures FACT-HN and MSAS broken down into component parts during statistical analysis, not stated in methods and no	Some concerns

					adjustment for multiple comparisons.	
Sawka	Computer block (in 2 or 4) randomisation 1:1	Participant/study staff not blinded but statistician blinded at point of data analysis.	No missing outcome data.	Method of measuring knowledge acquisition and decisional conflict is appropriate – both performed in same visit therefore effects may be short-lived.	Data analysed according to pre-specified plan published on ClinicalTrials.gov.	Low
Van der Hout	Block (size 68) randomisation 1:1 stratified by tumour type, performed by independent person.	Unable to blind participants. 48% in intervention arm did not engage with the intervention but included in intention-to-treat analysis.	Total missing data - 17.7% control and 29.7% intervention but in HNC subgroup missing data more closely matched (74.4% versus 68.7%).	Patient-activation measure validated and widely used however self-reported score may be influenced by knowledge of group allocation.	Intention-to-treat. Multiple subgroup analysis with no correction for multiple testing or separate power calculation.	Some concerns
Wall	Computer randomisation 1:1:1, stratified by baseline measure of dysphagia. Significant difference in type of radiation at baseline but adjusted for.	Unable to blind participants. Speech and language pathologists (SLPs) not blinded when performing videofluoscopic swallow study (VFSS)	Despite relatively little missing data, the final sample size was below size required for power for some outcome measures.	Acceptable score of functional oral intake. Adherence and quality of life self-reported. Independent rating of VFSS by 2 SLPs to minimise bias.	Trial protocol not registered in advance. Intention-to-treat analysis and results as described in methodology.	Some concerns
Wang TJ	Computer randomisation 1:1 performed by independent researcher and groups balanced.	Subjects, care providers and outcome assessors blinded to group allocation.	4/34 patients excluded in both groups unlikely to have effected results. Outcome data otherwise complete.	MFIQ has not been subject to Construct Validity–Hypothesis Testing. Jaw-opening measured by blinded researcher.	Analysis performed as stated in the method. Protocol published on ClinicalTrial.gov appears to be after study completion date.	Some concerns
Wang TF	No detail given on process of random allocation. Cancer stage approaching significant difference (p 0.06).	Intervention was self-guided and no test of engagement therefore unclear what patients experienced.	18% intervention group and 15% of control group did not attend follow-up, unlikely to have impacted result.	Outcomes were self-reported and not subject to assessor bias. Valid and reliable outcome measures used.	Study registered prior to participant enrolment and analysis performed as stated.	Some concerns

The risk-of-bias judgement in each domain is colour-coded as follows: **Low risk of bias**; **some concerns**; **high risk of bias**. As per RoB2 guidelines, the overall RoB judgement is taken as the highest risk level in any domain or may represent the presence of several domains with concern of bias.

Figure 1.



* Manual screening of title and abstract against inclusion and exclusion criteria.

** Independent two-author review of full-text records with final decision by a third author if disagreement.

Adapted from Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71

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