Dysphagia
https://doi.org/10.1007/s00455-022-10506-5

ORIGINAL ARTICLE

Head and Neck Virtual Coach: A Randomized Control Trial of Mobile Health as an Adjunct to Swallowing Therapy During Head and Neck Radiation

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Received: 9 May 2022 / Accepted: 25 July 2022

Abstract

Dysphagia is a common consequence of head and neck radiation and may be mitigated by performance of swallowing exercises during radiation treatment. Given historically poor adherence to such exercise protocols, we created a mobile health application, HNC Virtual Coach as an adjunct to standard clinical care. This randomized control trial investigated the impact of HNC Virtual Coach on adherence as well as swallowing outcomes by comparing those using the mobile app to those receiving only standard clinical care and paper logs. Both treatment groups were provided with the same exercise protocol as well as the same baseline educational information. Outcome measures included adherence rates, physiologic measures obtained during a Modified Barium Swallow Study (PAS, MBS-ImP, DIGEST), patient-reported outcomes (MDADI), diet levels (FOIS, PSS-HN), and quality of information received (INFO-25). Patients using the HNC Virtual Coach tended to have better adherence to treatment recommendations during radiation therapy. Increased adherence was associated with better patient-reported quality of life, but not physiologic function 2–3 months following completion of radiation. Results suggest that a mobile health application may provide benefit for some patients undergoing head and neck radiation.

Keywords Dysphagia · Head and neck cancer · Mobile health application · Adherence · Radiation · Swallowing

Introduction

Approximately 75% of patients diagnosed with head and neck cancer (HNC) receive radiation therapy (RT) at some point in their treatment, either in the definitive or in the adjuvant setting. Dysphagia, a common consequence of treatment for HNC, is experienced by approximately 50% of patients treated with RT and has been attributed to the effects of inflammation, fibrosis, and neuromuscular injury [1–3]. Post-treatment dysphagia has been associated with an increased risk of morbidity/mortality along with well-recognized deterioration in quality of life [4–6]. Performance of swallowing exercises during the RT treatment phase significantly reduces dysphagia risk; [7–9] however, patient adherence to swallowing exercises during RT is limited [10, 11]. A number of factors have been identified as potential contributors to poor adherence including treatment-related toxicities such as pain, lack of understanding of the rationale behind swallowing exercises, and difficulty recalling and performing exercises [12, 13]. Thus, poor adherence stands as a major obstacle to achieving the best swallowing outcomes.

We developed a mobile health application to directly address barriers cited by patients as common reasons for non-adherence. The application was designed to integrate behavioral strategies known to enhance adherence including behavioral practice, self-monitoring, and provision of information from a reputable source [14]. Initial testing revealed that a mobile application was feasible for patients to use as an adjunct to clinical visits while undergoing head and neck radiation [15]. 80% of the patients used the application and more than 50% logged completion of swallowing exercises

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Published online: 12 August 2022

at least once per day. Based on exit interviews, we optimized the design to make it more functional for patient use.

The objective of this study was to conduct a randomized control trial to test the impact of this mobile application on adherence to prophylactic swallowing exercises during RT for HNC compared with a standard paper and pencil method of recording exercises. Further, we planned to assess the comparative functional swallowing outcomes according to patient adherence with the prescribed exercise protocol. Our hypothesis was that the integration of a mobile health app into clinical care would improve patient adherence. Secondarily, we hypothesized that increased adherence to prescribed exercises would lead to improved swallowing outcomes.

Methods

Participants

Patients with elevated risk for developing dysphagia post-radiation were the target of this intervention. This included individuals with primary head and neck tumors in the oral cavity, oropharynx, nasopharynx, larynx, and hypopharynx requiring bilateral neck radiation. Patients undergoing surgical resection or induction chemotherapy were not eligible to participate. Patients with recurrent or metastatic disease were excluded from participation. All subjects were required to be > 18 years of age and fluent in English given the nature of the target intervention. Additionally, patients had to have access to a smartphone that was compatible with the "HNC Virtual Coach" mobile application as well as sufficient data and/or Wi-Fi access.

Experimental Design

This study used a randomized control trial design with two arms: the experimental "HNC Virtual Coach" app group (Group A) and a paper logging control group (Group B). Participants were randomized between treatment groups at a 1:1 ratio using pre-determined randomization blocks of 3. Participants were recruited from three NCI designated Comprehensive Cancer Centers between April 2019 and December 2021. All participants consulted with a speech-language pathologist (SLP) prior to the initiation of RT. At that time, baseline evaluations of swallowing function were performed, and participants in both groups were educated regarding potential radiation-related side effects and trained in the same series of swallowing exercises by the SLP. Participants in Group A received a comprehensive swallowing rehabilitation mobile application ("HNC Virtual Coach"). Participants in Group B were given paper exercise logs to fill out. Group B participants recorded the number of sets of exercises performed in each of two sessions per day. They rated their pain on a scale of 1–10 and noted the amount of food consumed orally as all, some, or none. Logs were collected weekly. The education, recommendations, and content provided to the patient by the SLP was the same for both groups.

Patients were screened for eligibility, consented, enrolled, and randomized prior to the initiation of RT. Subjects met with a member of the research team for a baseline visit to review details on how to download and use the "HNC Virtual Coach" mobile application (Group A) or how to complete paper exercise logs (Group B). Written instructions regarding the mobile "HNC Virtual Coach" were provided for patient reference at home. Each participant in Group A was given a competency test, which encompassed logging sample data through the "HNC Virtual Coach." Participants were instructed to use the "HNC Virtual Coach" mobile application or paper logs to record daily exercises over the course of their treatment. The "HNC Virtual Coach" mobile application time stamped the date and time of data entry. Paper logs were collected by study personnel weekly and entered into a central Redcap database.

All study subjects proceeded with routine clinical care, consisting of standard fractionated radiotherapy with or without concurrent chemotherapy (based on standard clinical indications). The active study duration for each participant began on the first day of radiation and ended at the conclusion of radiation. All participants received standard care with the SLP, consisting of planned clinical visits scheduled at the beginning, mid-way, and at the conclusion of radiation. Irrespective of the method of recording exercises, each patient was instructed to complete 3 sets of ten repetitions of four different exercises, twice each day: Jaw stretches, the Effortful Swallow, the Mendelsohn Maneuver, and the Masako Maneuver.

Participants in the experimental arm (Group A) received a notification reminder to complete target exercises as well as a link to a video workout twice each day through the "HNC Virtual Coach" mobile application. Additional educational videos were also made available through the HNC Virtual Coach app to support Group A patients with treatment-related toxicities that may impact exercise adherence during radiation (such as pain, fatigue, and xerostomia). Participants in Group B did not have access to these educational videos but had written handouts provided prior to the start of RT. All the provided exercises and additional information were within the normal standard of care and were simply facilitated outside of the clinical setting by the "HNC Virtual Coach" mobile application. At the end of each workout, participants were asked to self-report what percentage of exercises were completed in 20% increments from 0 to 100%. When two sequential exercise sessions in a row were not completed, the application pushed a survey to the

participant to ascertain the reason why the sessions were not completed. The HNC Virtual Coach app also gave participants the option to skip viewing the instructional video and log a workout. Available reasons for missed or skipped workouts included the following: (1) Didn't have time, (2) Pain, (3) Not feeling well/no energy, (4) Don't know how to do them, (5) Don't think they are necessary, (6) Issues with technology, and (7) Other. In addition to these features, the app also collected data regarding level of pain, rated on a slider scale daily from no pain to most severe pain. This allowed investigators to monitor pain as a variable that may impact adherence. Participants in Group B were also instructed to enter their pain levels daily on their paper logs, but other reasons for skipped workouts were not logged by Group B. The primary outcome of adherence to therapy was the percentage of participants completing at least 50% of prescribed exercises over the 7-week course of treatment.

Secondary Outcomes

Secondary outcome measures of swallowing were completed in all participants at baseline and 2–3 months after the completion of RT. These measures included modified barium swallow studies (MBS) and patient-reported outcome measures (PROMS) including the MD Anderson Dysphagia Inventory (MDADI) and the Performance Status Scale – Head and Neck (PSS-HN). Additionally, diet levels (as measured by the Functional Oral Intake Scale) and weight were assessed and recorded by the SLP at each clinical visit.

Modified Barium Swallow Procedure

All MBS studies followed a standard protocol. Additional boluses or strategies may have been employed by the treating clinician only after the completion of the study trials. Examinations were recorded using a minimum of 30 frames per second. Studies were saved in AVI or MPEG format. Patients were evaluated while seated in lateral and frontal views with imaging to include the soft palate superiorly, the cricopharyngeus inferiorly, the lips anteriorly, and the cervical spine posteriorly. Lateral and frontal views were obtained. Varibar thin liquid (5 cc, 10 cc, 20 cc, and ungraded cup sip) and pudding (5 cc) contrast were used. Solid trials included a cracker or cookie coated in Varibar pudding.

To measure physiologic swallow function during MBS studies, three assessment tools were chosen. The Penetration Aspiration Scale is an 8-point interval scale used to describe degree of bolus entry into the laryngeal vestibule and patient response to this material. Lower scores reflect more normal function. It has been shown to have favorable intra- and inter-judge reliability [16].

The Modified Barium Swallow Impairment Profile is a tool designed to quantify degree of impairment on 17 individual physiologic components visualized during a MBS study where higher numbers reflect greater dysfunction. The oral composite score is ascertained by adding the first 6 components, the pharyngeal composite score consists of components 7–16, while component 17 stands alone in measuring esophageal dysphagia. This tool correlates significantly with other measures of swallowing including Penetration Aspiration Scale scores, diet scores, and quality of life [17].

The Dynamic Imaging Grade of Swallowing Toxicity (DIGEST) was established to rate the safety and efficiency of the pharyngeal swallow during MBS studies using the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE) framework. The scale has been shown to correlate with the MBS-ImP pharyngeal composite score, MDADI, and oral intake levels [18].

MBS studies were reviewed by a single MBS-ImP trained SLP with > 20 years-experience. All videos were deidentified withregard to timing of examination and treatment group.

Secondary Clinical Measures

The MDADI was selected to capture and quantify the patient perception of swallowing dysfunction. This 20-item patient-reported survey measures the impact of dysphagia on patients with HNC. Each item is rated on a scale of 1–5 with lower numbers indicating poorer function. Mean subscale scores are multiplied by 20 to provide a final score between 20 and 100. This scale has been validated as a reliable tool to measure the impact of dysphagia on HNC patients [19].

To describe patient diet levels, the Functional Oral Intake Scale (FOIS) was selected. The FOIS is a 7-point ordinal scale used to describe oral intake where lower scores reflect more limited oral intake, and higher scores reflect more normal and unrestricted diet levels. Originally validated in patients with dysphagia following stroke, the FOIS was found to have very good inter-rater reliability and validity [20]. It has been used extensively in studies of dysphagia in the head and neck cancer population.

The Performance Status Scale—Head and Neck (PSS-HN) was chosen to provide additional detail regarding diet and eating restrictions, as the PSS-HN provides more granular detail about the types of consistencies consumed whereas the FOIS provides more detail regarding the use of tube feedings. This measure has been validated and shown to have good correlation with other measures of function in this population [21].

The European Organization for Research and Treatment of Cancer (EORTC) INFO-25 was collected 2–3 months following radiation to determine the patient perspective

regarding information received over the course of their treatment. This scale is a reliable and validated tool used in interventional cancer studies [22]. Higher scores are associated with greater patient satisfaction with information received from their cancer care team.

Statistical Analysis

To ensure compatibility between Group A and Group B, we first compared their baseline sociodemographic and clinical characteristics. For continuous variables, we compared characteristics using t-test for normally distributed variables and the Kruskal–Wallis test for non-normally distributed variables. We used the chi-squared test or Fisher exact test for categorical variables, where appropriate. The same tests were used for comparison between the participants who demonstrated adherence and those who did not.

We used Poisson regression models to examine both bivariable and multivariable associations between candidate covariates and overall adherence to prescribed exercises. A robust variance estimator was applied to adjust for potential overdispersion in the models. Demographic covariates were forced into the multivariable model and we utilized stepwise backwards selection (significance level $\alpha = 0.05$) to remove factors that were not significantly associated with adherence. Relative risks along with their 95% confidence intervals were calculated.

Linear modeling with repeated measures was used to examine both bivariable and multivariable associations of candidate covariates with MDADI scores, as the MDADI was measured across multiple timepoints. A group by week interaction term was initially included in the multivariable model to explore the potential different trajectories over time; however, it was dropped when found to be statistically insignificant. All models were fitted using unstructured correlation structure among visits within patients. The final model also used stepwise backward selection approach. All analyses were performed using SAS system, version 9.4 (SAS Institute Inc., Cary, NC).

This study was conducted in accordance with the Declaration of Helsinki, and individual institutional review board approvals were obtained. This study was registered on ClinicalTrials.gov (NCT 03,832,686) and funded through the National Institutes of Health Small Business Innovation Research grant mechanism (SBIR HHSN261201700003C).

Results

Over the course of the study, 98 participants were screened and consented to participate across three sites. A small number of participants ($n = 7$) either failed to enroll or withdrew from the study prior to any data collection yielding a final sample size of 91 patients. There were 44 participants randomized to Group A and 47 to Group B. There was no significant demographic or tumor-related difference between groups (Table 1). Additionally, there were no differences in marital status, insurance status, or highest educational degree attained between treatment groups.

Overall, 29.9% of participants demonstrated at least 50% adherence over the course of treatment. Individuals in Group A were more likely to have > 50% adherence though this did not reach statistical significance (34.9% versus 25.0%; $p = 0.31$). In both treatment groups, adherence declined over the course of RT, with the greatest decrements noted following the 4th week (Fig. 1). In both treatment groups, a significant degree of variability was seen in terms of the numbers of sets logged (Fig. 2). Participants with higher levels of adherence had lower pain scores, particularly at weeks 3 ($p = 0.03$) and 5 ($P = 0.01$) (Fig. 3). After adjusting for demographic factors (age, sex, and race), Poisson regression revealed that the patients in group A were 55% more likely to be adherent than those in group B (although not statistically significant), patients with oropharyngeal tumors were significantly less likely to complete exercises, and those with higher baseline MDADI scores were more likely to adhere to exercises (Table 2).

Overall, swallowing outcomes following RT were favorable in this cohort. Participants had low levels of dysphagia, whether considering overall DIGEST scores (mean = 0.89), PAS scores (mean 2.57), or MBS-ImP Pharyngeal composite score (mean = 8.73). Despite better overall adherence in Group A, there were no significant differences between treatment arms regarding swallowing outcomes measured 2–3 months post-RT (Table 3). While it did not reach statistical significance, nearly three times more patients in Group B had feeding tubes at the time of their post-treatment MBS in comparison with those in Group A (8.33% versus 2.9%; $p = 0.62$). Patients in Group A had significantly higher INFO-25 scores following treatment (68.70 versus 62.62; $p = 0.045$). CONSORT flow diagram of enrollment (Fig. 4) demonstrates final sample analyzed at the week 19 time point.

Given the significant variability in adherence among participants in both treatment groups, post hoc analysis of swallowing outcomes by adherence level was performed. Only patient-reported swallowing-related quality of life (as measured by MDADI) was significantly different between groups according to adherence (81.13 versus 73.10; $p = 0.04$) (Table 4).

Discussion

Prior publications have established that performance of prophylactic swallowing exercises during head and neck radiation is associated with more favorable swallowing outcomes

Table 1 Participant characteristics

	Group A Experimental arm ($n=44$)	B Control arm ($n=47$)	*P* value
Mean age (±SD), years	59.3 (±9.9)	61.0 (±9.6)	0.16
Sex (% male)	85.7%	87.2%	0.57
Marital status			0.66
Married	73.8%	66.0%	
Single	7.1%	17.0%	
Divorced/widowed	16.7%	14.9%	
No response	2.4%	2.1%	
Insurance status			0.61
Private	66.7%	66.0%	
Government	26.2%	31.9%	
Other/no response	7.2%	2.1%	
Highest educational degree			0.95
≤High school	16.6%	21.7%	
Some college/Associates	28.5%	28.3%	
Bachelors	26.2%	26.1%	
Post-Graduate	28.6%	21.7%	
Prefer not to answer	0.00%	2.2%	
Tumor site			0.66
Oropharynx	76.7%	78.7%	
Other	23.3%	21.3%	
T stage			0.56
Tx, T0-2	72.4%	74.4%	
T3-4	27.6%	25.6%	
N stage			0.81
Nx, N0-1	66.0%	67.1%	
N2-3	32.0%	32.5%	
AJCC stage			0.67
I-II	76.7%	80.8%	
III-IV	23.35%	19.2%	
HPV status			0.75
Positive	81.4%	83.0%	
Negative or unknown	18.6%	17.0%	
Treatment			0.60
Radiation	9.3%	12.8%	
Chemoradiation	90.7%	87.2%	
Chemotherapy			0.73
Cisplatin	69.0%	70.2%	
Other	31.0%	29.8%	

[7–9]; however, adherence to such protocols is challenging. To address commonly cited barriers to adherence, we developed the "HNC Virtual Coach" mobile application as a facilitator for patients undergoing head and neck radiation. The application was designed to provide rationale for prophylactic exercises, video along with written exercise instructions, exercise reminders, and other supportive resources. Our data suggest that patients offered such an application had an increased tendency to perform at least 50% of prescribed exercises over the course of RT. These findings are consistent with prior work done by Wall and colleagues [10] which also demonstrated better adherence in a patient group when provided with a mobile application.

Consistent with prior studies [10, 11], adherence in this cohort, regardless of treatment arm, decreased over the course of radiation with best adherence reported during the first two weeks of RT. This suggests that a mobile application with daily reminders may not be enough to keep some patients engaged in treatment toward the latter half of radiation. It is well established that treatment toxicities increase

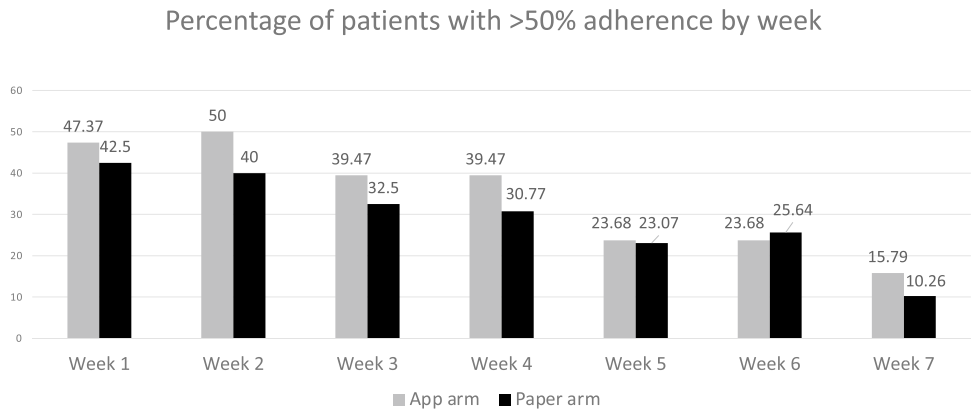

Fig. 1 Percentage of participants achieving at least 50% adherence to swallowing exercises by treatment group and radiation week

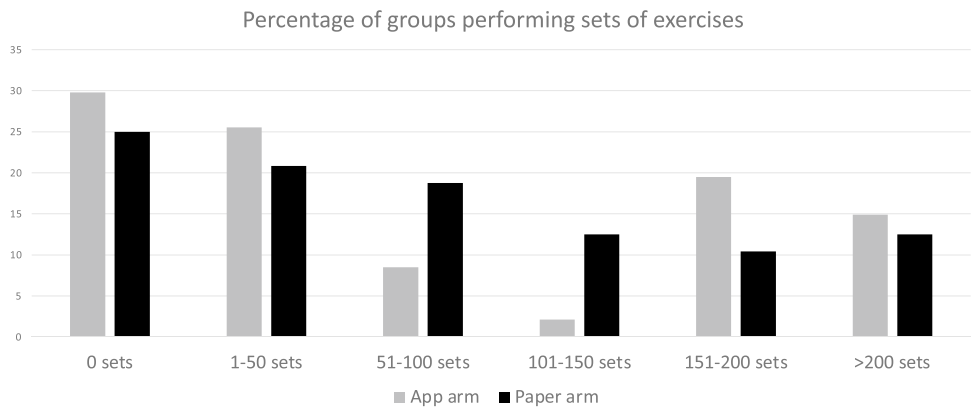

Fig. 2 Total number of sets performed according to treatment group

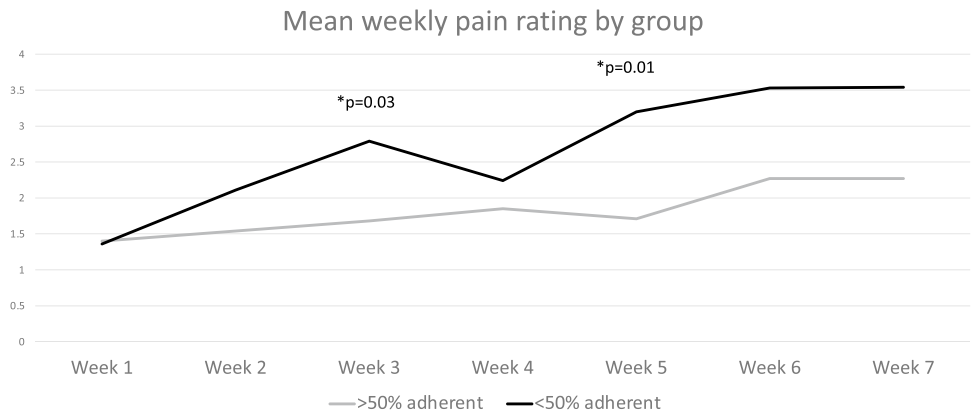

Fig. 3 Average pain levels by week reported according to adherence levels

Table 2 Multivariable Poisson regression for adherence

	Relative Risk	*P* value
App group vs. paper	1.55 (0.85, 2.81)	0.15
Caucasian vs. others	1.20 (0.40, 3.66)	0.75
Age (per 10 years)	0.99 (0.78, 1.25)	0.92
Male vs female	0.63 (0.34, 1.17)	0.14
Oropharynx vs others	0.49 (0.29, 0.84)	*0.01
Baseline MDADI	1.05 (1.02, 1.08)	*0.002

*$P \leq 0.05$

over the course of radiation and the proactive management of those toxicities may be a worthy target in future interventions. A recent study by Van den Bosch et al. [23] described the development of a Normal Tissue Complication Probability (NTCP) model to identify risks of acute and chronic radiation toxicities in patients undergoing head and neck radiation. This model can be used to calculate toxicity risk for an individual patient based upon patient factors, tumor characteristics, and treatment variables. Future studies may benefit from identifying toxicity risk and developing personalized strategies ranging from radiation planning alterations,

Table 3 Secondary outcomes 2–3 months following completion of treatment according to treatment arm

	Group A ($n=32$)	Group B ($n=34$)	P value
Mean MDADI	75.66	76.35	0.55
Mean PAS	2.73	2.42	0.82
Mean DIGEST	0.97	0.82	0.64
Mean MBS-ImP Oral	3.90	4.21	0.41
Mean MBS-ImP Pharyngeal	9.33	8.18	0.24
Mean FOIS	6.06	5.94	0.89
Mean PSS-HN Eating in Public	90.15	86.12	0.51
Mean PSS-HN Normalcy of Diet	79.12	76.94	0.75
Presence of feeding tube	2.9%	8.33%	0.62
Mean INFO-25	68.70	62.62	*0.045

*$P \leq 0.05$

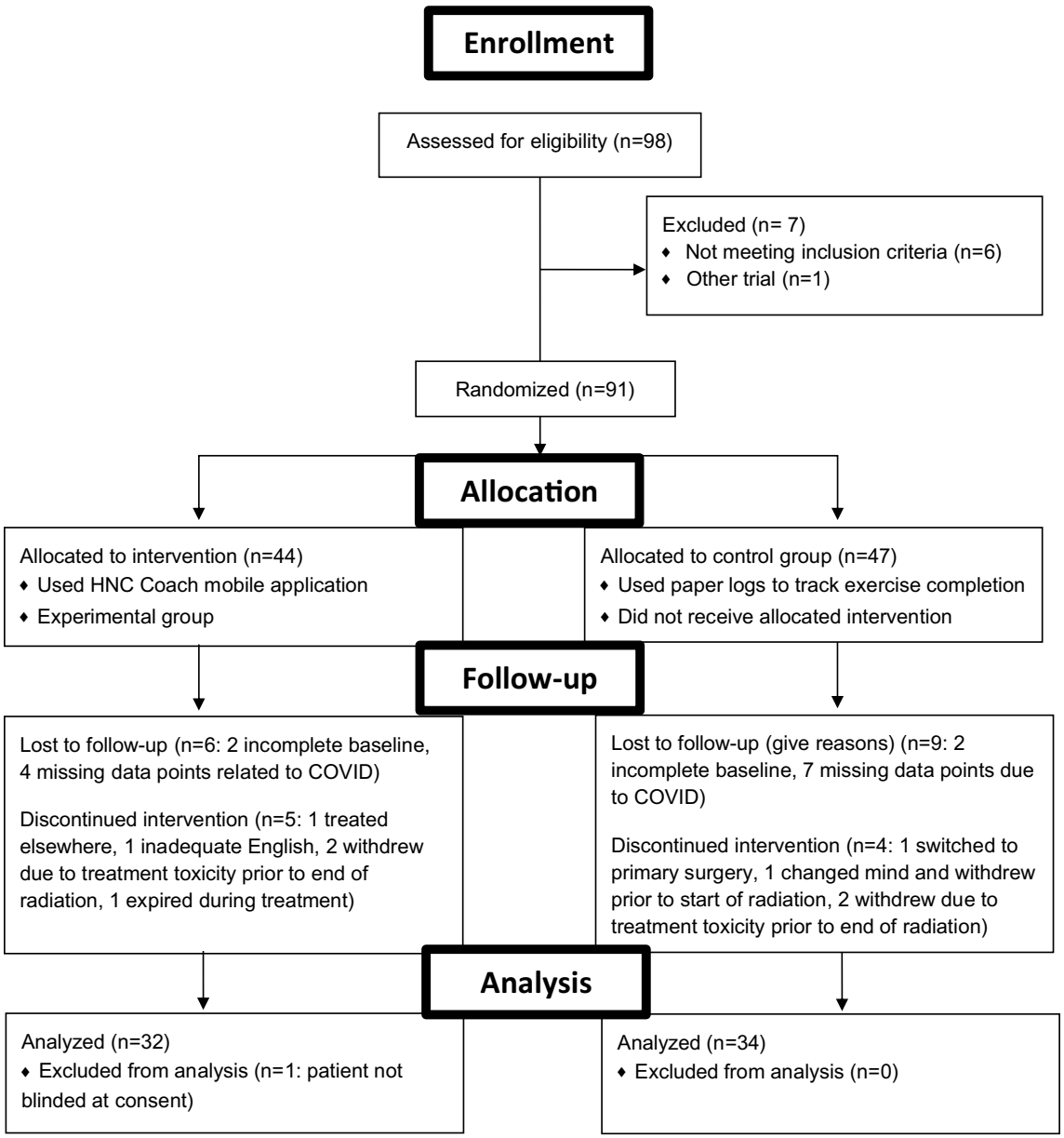

Fig. 4 CONSORT flow diagram for enrolled participants to week 19

Table 4 Swallowing outcomes according to adherence to exercises

	> 50% adherence ($n = 26$)	< 50% adherence ($n = 61$)	P value
Mean MDADI	81.13	73.10	*0.04
Mean PAS	2.17	2.8	0.21
Mean DIGEST	0.70	1.00	0.20
Mean MBS-ImP Oral	4.22	3.98	0.73
Mean MBS-ImP Pharyngeal	8.70	8.75	0.96
Mean FOIS	6.24	5.87	0.24
Mean PSS-HN Eating in Public	89.00	87.61	0.81
Mean PSS-HN Normalcy of Diet	82.8	75.33	0.26
Presence of feeding tube	4%	6.67%	1.00

*$P \leq 0.05$

enhanced rehabilitative care at critical time points, or other toxicity mitigation interventions. In our sample, it was somewhat surprising that those with oropharyngeal primary tumors demonstrated poorer adherence to swallowing therapy. We postulate that this may be related to higher functional status and quality of life in these individuals at baseline and more difficulty coping with the substantial burden of treatment-related toxicities. This may suggest that targeted interventions for such patients may need to be established, particularly in light of the fact that many such individuals are expected to live longer with the sequela of treatment.

Interestingly, adherence to swallowing exercises was not significantly associated with physiologic swallowing outcomes. While those with greater adherence had MDADI scores that were both statistically and clinically more favorable, this did not equate to better swallowing physiology on the MBS-ImP pharyngeal composite score, airway protection on the PAS, or overall impairment on DIGEST scores. This is consistent with recent work presented by Barbon [24] where participants performing exercise during RT had better diet outcomes and quality of life, but not physiologic function. One potential explanation for this finding may be related to the timing of these swallowing evaluations. Development of neuromuscular impacts from radiation including fibrosis may develop at a later timepoint [3, 25] and thus may not be optimally identified 2–3 months post-RT.

Another possible explanation for the lack of difference between the two arms is low overall rates of severe dysphagia and feeding tube use in this cohort. Overall, participants in both arms had extremely low levels of dysphagia, which may have limited our ability to identify statistically significant differences between our groups. Furthermore, the overall feeding tube rate of 5% is substantially lower than other recent reports, for instance, a 27% feeding tube use during RT in a recent oropharyngeal cancer experience [26].

As with any study, limitations must be acknowledged. As has been demonstrated in prior studies, accurately measuring adherence to behavioral intervention is challenging. While actively discouraged from doing so, it is possible that participants on both arms could have indicated exercise performance when none occurred. Such misrepresentation could not only impact our ability to detect differences in adherence but also secondary swallowing outcomes by treatment arm. Alternatively, as patients completed the same exercises daily, it is possible that they completed the exercises from memory, without the support of the mobile application or paper logs. Newly developed portable EMG units may provide improved ability to monitor adherence in future trials [27, 28]. Additionally, while we had a reasonable sample size, we may not have been adequately powered to detect a difference in swallowing outcomes, particularly in light of the generally favorable swallowing outcomes in this sample.

Conclusions

This study demonstrates that a mobile health application can be used to enhance adherence with prophylactic swallowing exercises in patients undergoing head and neck RT. While differences in swallowing outcomes were not demonstrated between those using a mobile application versus paper logs, it is important to consider that overall rates of dysphagia were exceptionally low in the subacute period. It will be important to revisit these outcomes at a later timepoint given the evolution of tissue changes post-radiation. Analysis of swallowing outcomes between these two treatment groups one-year post-radiation is ongoing.

Acknowledgements Special thanks to Meghan Bauman, Kathleen Donocoff, Barbara Ebersole, Jeffrey Edwards, Jocelen Hamilton, Rachael Kammer, Jennifer Kizner, John Kolman, Allecia Lewis, Jason Smith, and our patients for your contributions to this research.

Funding This work was funded through the National Institutes of Health Small Business Innovation Research grant mechanism (SBIR HHSN261201700003C).

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