



# The effect of home-based program and outpatient physical therapy in patients with head and neck cancer: A randomized, controlled trial

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## ABSTRACT

**Objectives:** Physical therapy improves outcomes for patients with head and neck cancer (HNC) but home-based program (HBP) has not yet been investigated thoroughly. This study compared a HBP with outpatient physical therapy (OPT).

**Methods:** This trial categorized patients with primary HNC into OPT and HBP groups. The patients in the HBP group received home-based therapy once a day for 5 days per week. By contrast, the OPT group received various physical therapies, including aerobic, anaerobic, and stretching therapies, twice per week, plus a thrice-weekly home-based therapy that similarly consisted of aerobic, anaerobic, and stretching exercises. The major outcome was the Functional Assessment of Cancer Therapy—Head and Neck (FACT H & N), and secondary outcomes were the visual analog scale (VAS) of shoulder pain, 6-min walking test (6MWT), and shoulder range of motion (ROM), all of which were evaluated before, during, and after interventions.

**Results:** Significant improvements were found after 12 weeks of the HBP or OPT. The HBP was not inferior to OPT regarding FACT H & N ( $p = .074$ ), VAS of shoulder pain ( $p = .677$ ), 6MWT ( $p = .677$ ), and shoulder ROM ( $p = .145$  for flexion;  $p = .383$  for abduction).

**Conclusions:** Both the HBP and OPT can improve shoulder abduction, shoulder flexion and functional capacity.

## Introduction

More than 500,000 cases are diagnosed as head and neck cancer (HNC) annually worldwide [1,2]. In Taiwan, HNC is one of the top five increasing cancers over the past decade and the fifth most common cancer [3]. More than half of the patients with HNC survive more than 5 years [4], but this is accompanied by treatment-related complications and subsequent profound disability [5]. HNC treatments, including surgical dissection, chemotherapy, and radiation therapy, contribute to complications involving shoulder dysfunction, pain in the upper extremities, and physical inactivity [6–9]. A systemic review in 2015 indicated that many patients with HNC still had declined quality of life (QOL) at 1 year [10] and QOL in patients with oral cavity and oropharyngeal cancer is also known to decline 3–8 months post-treatment [11]. Because of the complexity of these complications, physical therapy interventions after standard tumor management have drawn

considerable attention in the past few years [12–16]. A systemic review by Capozzi et al. [17] supported the reported benefit of physical activity interventions for patients with HNC in separate studies, but the data were not pooled because of the heterogeneity of the studies.

Physical therapy and therapeutic exercise after surgical intervention and chemoradiotherapy have been reported to improve QOL [13–15], alleviate upper extremity pain [13], enhance upper extremity strength and endurance [13], improve shoulder abduction [18], augment fitness [19], and enhance functional capacity [13,14]. Considering the disability, fatigue, and declined QOL of patients with HNC, a home-based program (HBP) may not only be an alternative therapeutic choice, but also superior to outpatient rehabilitation programs in terms of availability and cost. However, to the best of our knowledge, only a few studies have been conducted regarding HBP for patient with HNC [12,19], and randomized controlled studies are still lacking in Asia.

This study compared the effects of a HBP and outpatient physical

**Abbreviations:** HNC, head and neck cancer; HBP, home-based program; OPT, outpatient physical therapy; FACT H & N, Functional Assessment of Cancer Therapy—Head and Neck; VAS, visual analog scale; 6MWT, 6-min walking test; ROM, range of motion

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therapy (OPT) among patients with HNC in terms of QOL, shoulder range of motion (ROM), functional capacity, and shoulder pain.

## Materials and methods

### Ethics and study oversight

The study protocol followed the seventh version of the Declaration of Helsinki and was approved by the Institutional Review Board and Regulatory Authority in Taiwan and the Chang-Gung Memorial Hospital Research Ethics Committee (Institutional Review Board number: 101-3913A3). Informed consent was acquired from all patients prior to participation in the study.

### Study design and patients

We designed this study as a randomized, controlled, parallel-group trial. Patients were recruited from a tertiary referral hospital in Southern Taiwan. A physical therapist accessed the patients for eligibility at first visit to ensure intervention was tolerable and safe. Inclusion criteria were as follows: (1) primary head and neck malignancy diagnosed within 6 months, (2) an age between 20 and 80 years, (3) receiving surgical intervention including tumor excision plus selective neck lymph node dissection, with accessory nerve preservation, and (4) a presurgical malignancy stage of II–IV, based on the Union for International Cancer Control TNM classification system [20]. Individuals were excluded from the study if they were unable to cooperate with the exercise program because of medical comorbidities or treatment-related fatigue, had impaired cognitive function, did not agree to sign the informed consent form, or did not agree to further evaluation. The assessor and participants are not blinded to group assignment in this trial.

### Randomization and group allocation

Randomization in a 1:1 ratio was performed by a computer-generated randomization list. All the included patients were categorized into one of two groups: OPT or HBP. Participants in both groups were instructed not to change their regular daily activities or habits. Details of the interventions in both programs are described in the following paragraphs.

### HBP group

The patients allocated to the HBP group received home-based therapy once a day and 5 days per week for 12 consecutive weeks. The estimated total training time was 60 h over the 12 weeks. The participants and their families received an individual education session that explained the HBP on the first visit. The session lasted 1 h, during which an experienced physical therapist demonstrated the therapies, which included aerobic exercise, anaerobic exercise, and static stretching. The aerobic exercises consisted of five 10-min ambulation sessions per week in the participant's community. Borg's Rating of Perceived Exertion (RPE) was used to self-monitor exercise intensity; specifically, the participants were asked to walk at a constant moderate intensity (RPE of 12–13 on the Borg's RPE 6–20 scale). Exercise duration was gradually increased up to 30 min as tolerated. The anaerobic exercises included strengthening exercises for the middle trapezius, lower trapezius, rhomboid major, biceps brachii, triceps brachii, deltoid, and pectoralis major muscles. These exercises were performed twice a week at home, in two sets with 10 repetitions. The intensity was set at RPE of 12–13 on the Borg's RPE 6–20 scale, and was maintained throughout the study period. Finally, the static stretching focused on exercising the participants' sternocleidomastoid, upper trapezius, anterior scalene, deltoid, and shoulder internal rotator muscles twice every day. Each stretch was performed for 10 s in sets of 5 repetitions, with a 15-s rest

**Table 1**

Baseline patient characteristics (n = 37).

	OPT group	HBP group	P value
Case number	19	18	
Gender			.79
Male	16	18	
Female	3	0	
Age <sup>a</sup>	48.89 (10.46)	48.44 (9.84)	.89
Cancer type			.83
Tongue	9	7	
Buccal	7	7	
Other	3 <sup>b</sup>	4 <sup>c</sup>	
Stage			.09
II	3	8	
III	2	3	
IV	14	7	
Operation side			.68
Right	8	7	
Left	5	7	
Bilateral	6	4	
Chemotherapy			.14
Yes	6	10	
No	13	8	
Radiation therapy			.24
Yes	4	7	
No	15	11	

Abbreviations: OPT, outpatient physical therapy; HBP, home-based program.

<sup>a</sup> Values are mean; standard deviation (SD).

<sup>b</sup> Retromolar trigone (n = 1), epiglottis (n = 1), larynx (n = 1).

<sup>c</sup> Gum (n = 3), tonsil (n = 1).

between each stretch.

A HBP educational pamphlet was provided to all patients, and a research assistant telephoned all patients weekly to confirm the execution of the home program.

### OPT group

The participants in the OPT group received two OPT sessions and three HBP sessions per week for 12 consecutive weeks. The home-based therapy in this group consisted of the same aerobic exercises and static stretching as that for the HBP group, but did not include the anaerobic exercises; these participants also received a similar individual education session regarding the HBP portion on the first visit by the same physical therapist. A HBP educational pamphlet was provided to each participant in the OPT group and a research assistant telephoned all of them weekly to confirm the execution of the program.

Each OPT session last for 60 min, and the estimated total training time was 60 h over the 12 weeks that followed initial enrollment. The OPT, ran by the same aforementioned physical therapist, comprised aerobic exercise, anaerobic exercise, and static stretching. The aerobic training was performed on a treadmill (Gaitkeeper 2000T, LiteGait, USA) at moderate intensity (RPE of 12–13 on the Borg 6–20 scale). Once the participants could run for 10 min continuously, the exercise duration was gradually increased up to 30 min. The anaerobic strength training targeted the middle trapezius, lower trapezius, rhomboid major, biceps brachii, triceps brachii, deltoid, and pectoralis major muscles. First, one repetition maximum (RM) was determined for each exercise, and then 30% of 1 RM was performed by each participant in two sets with 10 repetitions. Exercise weight was gradually increased by 5% of 1 RM every week, up to 60% of 1 RM as tolerated. Finally, for the static stretching component, each participant was instructed to stretch their sternocleidomastoid, upper trapezius, anterior scalene, deltoid, and shoulder internal rotator muscles. All of the stretches were performed for 10 s in sets of 5 repetitions, with a 15-s rest between each stretch.

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