Purpose:

Some pharyngeal and laryngeal cancer patients are compelled to undertake total laryngectomy due to the difficulty of eating and speaking. It is reported that some patients have problem eating (dysphagia and dysgeusia), excreting, sleeping and speaking after removing the larynx, making them feel anxiety and depression after discharge from hospital (Bussian et al., 2010; Campbell et al., 2000; Kazi et al., 2007, Maclean et al., 2009; and Kotake et al., 2012). Laryngectomees are likely to decrease their quality of life by facing a variety of problems unexpected before surgery (Weymuller et al., 2000; Vilaseca et al., 2006, Woodard et al., 2007, and Oridate et al., 2008). It is reported that informational and psychological support for laryngectomees are effective in improving their quality of life (Kotake et al., 2012), but there is no longitudinal study that investigates its intervention effect systematically. The purpose of this study is to examine the effect of nursing intervention by a randomized controlled trial on
laryngectomees’ quality of life from before surgery to twelve months after hospital discharge (the primary outcome) and its longitudinal changes (the secondary outcome).

Methods:
Subjects were 30 hospitalized pharyngeal and laryngeal cancer patients who planned to undergo laryngectomy and agreed to participate in this research. They were randomized into two groups: we offered relevant information and conducted interviews on subjects in the intervention group, whereas subjects in the control group were offered only relevant information. Interviewers were researchers who were not involved in the analysis of this study. Investigation on the intervention group and the control group was conducted five times (before surgery, before hospital discharge, and three months, six months, and twelve months after hospital discharge). Relevant information was offered on the control group only before surgery. The Japanese-language version of the SF-36v2 was used for measuring health-related quality of life by using a 3-point or 5-point Likert scale (Fukuhara et al, 1998a, 1998b, and, 2004). It was composed of eight concepts: (1) physical functioning (PF), (2) role physical (RP), (3) bodily pain (BP), (4) general health (GH), (5) vitality (VT), (6) social functioning (SF), (7) role emotional (RE), and (8) mental health (MH). The reliability and validity of this scale has been confirmed by other studies. Subjects were asked about the following basic attributes: age, sex, family structure, and occupational situations. Their diagnoses were checked from doctors’ notes. We treated only influential factors as adjustment factors and checked the variance of changes of subjects’ quality of life from before surgery to one year after hospital discharge. Missing values were replaced by the interpolation method of the singular value decomposition in the multiple imputation.

Results:
The age, sex and family structure of the intervention group were 69.7±10.9 years (before hospital discharge), 11 males (84.6%) and 2 females (15.4%), and 2 one family members (15.4%), 6 two family members (15.4%), and 4 three or more family members (30.8%). The age and sex of the control group were 69.5±11.1 years, 14 males (82.4%), and 3 females (17.6%). There was no significant difference between these two groups. Those who had jobs and did not have them were 5 (38.5%) and 8 (61.5%) in the intervention group and 9 (52.9%) and 8 (47.1%) in the control group, respectively, showing no significant difference between them (see Table 1). As Table 2 shows, on the intervention effect of the primary outcome the PF score of the intervention group (45.3) was higher than the control group (29.6) three months after hospital discharge. There was a longitudinal change from before surgery to twelve months after hospital discharge on the secondary outcome at a statistically significant level. The scores of RP (23.6) and GH (40.2) three months after hospital discharge were significantly lower than RP (39.8) and GH (49.8) before surgery. The scores of BP (44.2) and MH (44.8) six months after hospital discharge were significantly higher than BP (39.4) and MH (34.4) before surgery. The scores were the lowest on RP six months after hospital discharge (27.8 and 29.9) and SF twelve months after hospital discharge (26.8 and 27.4) without significant difference between two groups. The scores of PF on the control group and the intervention group declined and went up three months after hospital discharge, respectively.

Conclusion:
On the primary outcome the score of PF on the intervention group was higher than that on the control group, suggesting that there was an intervention effect. As the longitudinal study conducted by Kotake and others (2012) revealed, it tends to decline three months after hospital discharge. The control group in this research confirmed it. On the other hand, the scores of the intervention group tended to go up, suggesting the effectiveness of intervention. On the second outcome the scores of RP (23.6), RE (25.5), and GH (40.2) three months after hospital discharge were much lower than those before surgery, suggesting that they faced some difficulties in daily life. The RP score (27.8) declined six months after hospital discharge even in the intervention group, showing the necessity to help them to play a daily role. The SF scores twelve months after hospital discharge (26.8 and 27.4) also revealed that they had some difficulties in conducting daily activities.

Limitation and tasks:

Our analysis that took adjustment factors into consideration had some limits due to the small number of subjects in the analysis. This problem was partly due to the failure to check diagnoses of more than half subjects. We need to increase the number of subjects in future research. This analysis suggested that laryngectomized patients had difficulty in conducting daily activities after three months after hospital discharge, therefore, we also need to devise an effective way for them to engage in daily and social activities smoothly.

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**Title:**
The Effect of Continuous Nursing Intervention by a Randomized Controlled Trial on Laryngectomized Patients' QOL

**Keywords:**
Laryngectomized patients, QOL and Randomized Controlled Trial

**References:**

Abstract Summary:
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Content Outline:
Event theme is "The Effect of Continuous Nursing Intervention by a Randomized Controlled Trial on Laryngectomized Patients' QOL." The purpose of this study is to examine the effect of nursing intervention by a randomized controlled trial on laryngectomees' quality of life from before surgery to twelve months after hospital discharge (the primary outcome) and its longitudinal changes (the secondary outcome).

First Primary Presenting Author
Primary Presenting Author
Kumiko Kotake, PhD, RN
Nara Medical University
Faculty of Nursing, Graduate school of Nursing
Professor
Nara
Kashihara
Japan
Author Summary: I am a teacher and researcher of home care nursing for undergraduate and graduate students. My themes are to exploring how to care of psychological adjustment of laryngectomized patients, and nursing education.

Second Secondary Presenting Author
Corresponding Secondary Presenting Author
Kazuyo Iwanaga, MSN, RN
Fukuoka-University
Faculty of Medicine, School of Nursing
Associate Professor
Jonan-ku
Fukuoka
Japan

Author Summary: I am belonging to the division of fundamental department as a researcher. I teach fundamental nursing classes and practices for undergraduate students etc. I am also a member of the research ethics committees at our university.

Third Author
Ichiro Kai, PhD, MD, MPH
The University of Tokyo
Social Gerontology - School of Public Health
Honorary Professor
Tokyo
Japan

Author Summary: I teach Doctoral degree course in medical department. I search a social support for elderly and patients with disability. I cure patients and family in home.

Fourth Author
Yoshimi Suzukamo, PhD
Tohoku University, Graduate School of Medicine
Department of Physical Medicine and Rehabilitation
Associate Professor
Aoba-ku
Sendai
Japan

Author Summary: I teach Doctoral degree course in medical department. I am a associate professor. My theme is Quality of Life scale development of people with disability.

Fifth Author
Aya Takahashi, MSN, RN, PHN
Saitama Prefectural University
Faculty of Health Sciences Department of Nursing
Associate Professor
San-nomiya
Koshigaya
Japan

**Author Summary:** I am belonging to the division of fundamental department as a research associate. I teach fundamental nursing classes and practices for undergraduate students and graduate of school.

Sixth Author
Kaori Haba, MSN, RN, PHN
Nara Medical University
Faculty of Nursing
Assistant Professor
Nara
Kashiwara
Japan

**Author Summary:** I am belonging to the division of fundamental department as a research associate. I teach fundamental nursing classes and practices of Home care nursing for undergraduate students etc. I research how to care disabled people using cochlear implants and laryngecomized patients.

Seventh Author
Yoko Ishibashi, MSN, RN
Fukuoka University
School of Nursing
Assistant Professor
Nanakuma
Johnan-ku
Fukuoka
Japan

**Author Summary:** I am belonging to the division of fundamental department as a research associate. I teach fundamental nursing classes and practices for undergraduate students, and researcher of Nursing. I research of social support to laryngecomized patient's family for improving quality of life of patient and family.

Eighth Author
Mami Kurita, MSN
Nara Medical University
Faculty of Nursing
Assistant Professor
shijyo-cho
Author Summary: I am a teacher and researcher of home care nursing for undergraduate students. My themes are to exploring how to sharing experience-based knowledge (knowledge assets) of expert nurses, on home care nursing.

Ninth Author
Mami Miyazono, PhD
Fukuoka Nursing College
Department of Nursing
Professor
Fukuoka
Japan

Author Summary: Research theme are to clarify the care of cancer patients, sleeping, and promoting the health of Home Care Nursing and Public Health. In addition, I was exploring research on the construction of a nursing education model of EBN practice.

Tenth Author
Ichiro Ota, PhD
Nara Medical University
Faculty of Medicine
Lecturer
Nara
Kashiwara
Japan

Author Summary: I am a doctor and researcher of Otolaryngology and, Head and Neck Surgery in Nara Medical University, Japan. My themes are to exploring how to cure to patients of Otolaryngology and, Head and Neck Surgery.

Eleventh Author
Hirokazu Uemura, PhD
Nara Medical University
Faculty of Medicine
Associate Professor
Nara
Kashiwara
Japan

Author Summary: I am a doctor and researcher of Otolaryngology and, Head and Neck Surgery in Nara Medical University, Japan. My themes are to exploring how to cure to patients of Otolaryngology and, Head and Neck Surgery.

Twelfth Author
Author Summary: I am a doctor and researcher of Otolaryngology and, Head and Neck Surgery in Nara Medical University, Japan. My themes are to exploring how to cure to patients of Otolaryngology and, Head and Neck Surgery.

Thirteenth Author
Sakae Matuoka, RN
Nara Medical University
Hospital
Leader nurse
Nara
Kashihara
Japan

Author Summary: I am a leader nurse and researcher of Otolaryngology and, Head and Neck Surgery in Nara Medical University, Japan. My themes are to exploring how to care to patients of Otolaryngology and, Head and Neck Surgery.

Fourteenth Author
Hiromi Taniguchi, RN
Nara Medical University
Hospital
Head nurse
Nara
Kashihara
Japan

Author Summary: I am a head nurse and researcher of Otolaryngology and, Head and Neck Surgery in Nara Medical University, Japan. My themes are to exploring how to care to patients of Otolaryngology and, Head and Neck Surgery.

Fifteenth Author
Naomi Mine, RN
Nara Medical University
Hospital
Leader nurse
Nara
Kashihara
Japan
**Author Summary:** I am a leader nurse and researcher of Otolaryngology and, Head and Neck Surgery in Nara Medical University, Japan. My themes are to exploring how to care to patients of Otolaryngology and, Head and Neck Surgery.