CHAPTER V

DISCUSSION

5.1 Part I Research methods

5.1.1 Research Design

The study design is a RCT, Randomized Clinical Trial. The identification and recruitment of respondents were carried out in conjunction with Ministry of Public Health, Department of Dental Institute and King Project (Project Dental Implant Honor).

5.1.2 Sample groups

Sample size was calculated by comparison of two means formula, at $\alpha=0.05$, power $=90\%$, using difference between means and standard deviation of primary outcome patients' satisfaction VAS scale from related study (Morais J.A et al., 2003). Therefore, the sample size obtained was appropriate for this research. Calculation of sample size that could explain and conclude the results, the appropriate size was at least 27 in each group. In this study, there were 33 participants in each group and adhesion was only one in "CDNEED" group i.e 32 participants after post 3 months assessment.

All participants were satisfied with the inclusion and exclusion criteria. Four seniors were excluded from the study since beginning due to, 2 had advance maxillofacial carcinoma with radiotherapy, 1 had retroviral infection with active pulmonary tuberculosis, and 1 had uncontrolled type 2 Diabetes Mellitus with end staged renal failure (Hb a 1c glycosylated hemoglobin > 13.0% or creatinine > 1.7 ml/dl).

The success rate of implant surgery in this study was 96.29% (127 out of 132) and all were success after reload the implants and till 6 months after intervention.

Furthermore, nutritional programs were provided separately between IOD and CD groups in different days. So, it can be concluded that there did not have contamination of information among the groups.

5.1.3 Research Instrument

5.1.3.1 Implementation instrument

The NEED nutritional program was based on the participatory learning process, which is composed of experimental learning and group process, and was used in arranging participatory learning activities, emphasizing developing old experiences and reflecting ideas from discussions until new knowledge is formed and used in various situations.(David A Kolb et al, 1991) This program was provided by conjunction with Bangkok Metropolitan Administration (BMA), Bureau of nutrition Bangkok. The entire implementation instruments such as NEED nutritional empowerment book, power points for teaching and nutritional assessment questionnaires were prepared and validated by experts from BMA.

All of the nutritional empowerment sessions were conducted by experts from BMA and assisted by dental team including 1 nutritionist and 1 public health nurse from the hospital.

5.1.3.2 Instruments for data collection

The questionnaire used for data collection were (1) for oral health related quality of health by OHIP 20 Thai version already adopted (John et al., 2006), translated and used in King Project for dental implant, Royal Thai Government (2) quality of mastication function adopted from original English language was translate to Thai by

researcher (3) Mini Nutritional Assessment (Guigoz Y et al., 1996) was adopted and translated to Thai by researcher (4) VAS (McDowell I et al., 1996), visual analogue satisfaction score was adopted and translated by researcher. All data collection instruments were appropriated for the study.

5.1.5 Statistics used in data analysis

The researcher used descriptive statistic, i.e frequency, percentage, mean and Standard deviation, to explain general information and relevant factors such as, age, sex, age at edentulous, education, occupation, and income etc. Also chi-square and one-way ANOVA were used to compare general characteristics among the four groups. Inferential statistics, ie one-way ANOVA was used to compare pretest OHIP, quality of mastication function, VAS score, anthropometric data, and blood parameters among the four groups. Pair-t test was used to compare before and after mean scores within groups. One –way ANOVA was also used to compare mean scores at post 6 months intervention among the four groups. At last, to compare mean scores among the timing and groups (4^x4) were test by repeated measure ANOVA. For the variables if equal variance was not assumed, Kruskal Wallis test was also used to compare mean among the four groups. For the cost-effectiveness, correlation and regression were also used. Assumption of variable normal distribution was accepted. The statistic used was appropriate, p-value at 0.05, with responses according with the objectives and hypothesis of the research.

5.2.1 General characteristics of the sample

The sample characteristics are presented in Table (4). All the participants matched with inclusion and exclusion criteria were assigned in experimental group I, (IODNEED), experimental group II (IOD), experimental group III (CDNEED) and control (CD) by random allocation.

As for comparing group difference of general characteristic among the four groups, there were no statistical significant difference in gender (p=0.014), age (p=0.261, age at edentulous (p=0.270), current living status (p=0.699), religious (p=0.388), monthly income (p=0.092), associated systemic disease (p=0.350), history of smoking (p=0.927). The research result found that all general characteristics were not statistically significant difference among the four groups; (IODNEED), (IOD), (CDNEED), and (CD). It was the same results of other study in Canada. (Morais J.A et al., 2003)

5.2.2 Research result according to the objectives and hypothesis of the research

5.2.2.1 To explore the usefulness of IOD plus NEED programme by making comprehensive comparison of the efficacies of NEED plus mandibular implant-supported overdentures (IOD), IOD only, conventional dentures (CD) plus NEED and conventional dentures (CD)

To compare before program patient satisfaction score, quality of masticatory function, daily diet intake, OHRQoL (OHIP) and nutrition status among intervention group I (IOD

NEED), intervention group II (IOD), intervention group III (CDNEED) and control group (CD).

Hypothesis: There are no different between before program patient satisfaction score, quality of masticatory function, daily diet intake, OHRQoL (OHIP) and nutrition status among intervention group I (IODNEED), intervention group II (IOD), intervention group III (CDNEED) and control group (CD).

Before the beginning of the intervention, mean of scores of pretest OHIP oral health related quality of health (OHIP), quality of mastication function (QMF), satisfaction for maxilla (VASMX), body mass index (kg/m^2) (BMI), body fat percentage (skin fold thickness) (BFAT%,SFT) , lean body mass (kg) (LBM), Plasma cobalamin (B12) (pmol/L), Serum and erythrocyte folate (nmol/L), and Hb (g/L) among the four groups were not significant different.

Before the beginning of the intervention, mean scores of pretest satisfaction for maxilla mandibular (VASMD) among the four groups; there were statistically significant lower mean in (IODNEED) group than (CDNEED) group and (IOD) group than (CD) group. It could assumed the pretest satisfaction scores for mandibular were lower in IODNEED group and IOD group than CD and CDNEED groups.

Regarding the Mini nutritional assessment (MNA), the mean score was lowest in "IODNEED" group than others; meanwhile the "IODNEED" group had a significant lower mean score than "CD" group.

Similarly, for serum albumin level, mean score in "IODNEED" group was significantly lower than the other groups.

The mean score of serum Fe was significantly higher in "IODNEED" group than (IOD) group. Furthermore, the mean score of total red blood cell count and total lymphocyte count in "IODNEED" was also significantly higher than (IOD) group and (CD) group.

From these finding it would be concluded that there were no different between "Before program scores" of the most of the variables among the four groups, that accept the hypothesis.

5.2.2.2 To compare before and after program patient quality of masticatory function, daily diet intake, OHRQoL (OHIP) and nutrition status within intervention group I "IODNEED" group.

Hypothesis: The after program patient quality of masticatory function, daily diet intake, OHRQoL (OHIP) and nutrition status are different from before program in intervention group I "IODNEED" group.

Comparison of mean scores between pretest and after 6 months intervention in "IODNEED" group (Paired T-test), found: mean scores for OHIP, QMF, VAS for Maxilla, VAS for mandibular, MNA, BMI, Hip Circumference (HC), serum albumin, plasma B^{12}, Serum and erythrocyte folate, serum Fe, RBC, Hb were statistically significance higher than pretest. Moreover, lean body mass (LBM) was increased than pretest but there was no significant difference. This revealed that combined effect of surgery and nutritional empowerment have good achievement in not only better mastication function but also simultaneous increase in body mass index and lean body

mass. It can be concluded that the senior persons can chew meat, fruits and vegetables in order to choice healthy diet.

Moreover, mean score for Hip Circumference (HC) and (BFAT%, SFT) were significant lower than pretest. And also there were no significant lower mean score of skin fold thickness (SFT) biceps, triceps and Waist Circumference (WC) than pretest. It revealed that, the participants have knowledge and attitude to modify their diet especially not to eat saturated fat and intention to do light exercise such as regular walking, yoga and light body exercise for elderly (isometric exercise).

5.2.2.3 To compare before and after program patient quality of masticatory function, daily diet intake, OHRQoL (OHIP) and nutrition status within intervention group II "IOD" group.

Hypothesis: The after program patient quality of masticatory function, daily diet intake, OHRQoL (OHIP) and nutrition status are different from before program in intervention group I "IOD" group.

Comparison of mean scores between pretest and after 6 months intervention in "IOD" group, found: mean scores for OHIP, QMF, VAS for Maxilla, VAS for mandibular, MNA, BMI, sub-scapular and abdominal skin fold thickness, HC, and Hb were statistically significance higher than pretest. On the other hand, there were no significant higher mean score of skin fold thickness (SFT) biceps, triceps, Waist Circumference (WC), BFAT%, LBM, serum albumin, plasma B^{12}, Serum and erythrocyte folate, serum Fe, and RBC.

It can be clearly seen that their skin fold thickness and body fat percentage were higher than pretest; increase in BMI would be due to body fat percentage. As comparison, there were significant lower mean score for Hip Circumference (HC) and (BFAT%. SFT), and also there were no significant lower mean score of skin fold thickness (SFT) biceps, triceps and Waist Circumference (WC) than pretest. It was different from the study that they concluded implant subjects had significant increases in the biceps, sub-scapular, and abdominal skin-fold thickness measurements (Morais J.A et al., 2003)

This revealed that effectiveness of surgery had a good achievement in only better mastication function but not increase in blood parameters and not effective on healthier distribution of adipose tissue. It can only be concluded that the senior persons can chew meat, fruits, nuts and vegetables. Our finding is similar to other studies; they reported that a significant number of those who received the implant overdentures reported that they had increased their intake of cheese, raw carrot, raw apple, nuts, and bacon (Allen and McMillan, 2002). Morais (Morais et al., 2003) confirmed that the provision of mandibular dentures supported by 2 implants increases food choice for individuals accustomed to wearing conventional dentures. They find it easier to consume hard, tough, and crisp foods, such as raw vegetables and fruits, as well as different types of meats.

5.2.2.4. To compare before and after program patient quality of masticatory function, daily diet intake, OHRQoL (OHIP) and nutrition status within intervention group III (CD NEED).

Hypothesis: The after program patient quality of masticatory function, daily diet intake, OHRQoL (OHIP) and nutrition status are different from before program in intervention group III (CDNEED).

Comparison of mean scores between pretest and after 6 months intervention in "CDNEED" group (Paired T-test), found: mean scores for OHIP, QMF, VAS for Maxilla, VAS for mandibular, MNA, BMI, LBM, Hip Circumference (HC), serum albumin. Serum and erythrocyte folate, and RBC were statistically significance higher than pretest.

Moreover, SFT biceps, triceps, and sub-scapular, WC, plasma B^{12}, serum Fe, Hb, and Lymphocyte count were increased than pretest but there was no significant difference.

Further more, mean score for WC and SFT abdominal were significant lower than pretest. And also there were no significant lower mean score of BFAT% (SFT) than pretest.

This revealed that combined effect of new CD and nutritional empowerment have good achievement in not only better mastication function than old CD but also increase in nutritional assessment, LBM, and lower body fat percentage (SFT).

It can be concluded that, the participants have better mastication function, better knowledge and attitude to modify their diet especially not to eat saturated fat and intention to do light exercise such as regular walking, yoga and isometric exercise.

5.2.2.5 To compare before and after program patient quality of masticatory function. daily diet intake, OHRQoL (OHIP) and nutrition status within control group (CD).

Hypothesis: The after program patient quality of masticatory function, daily diet intake, OHRQoL (OHIP) and nutrition status will be the same as before program in control group (CD).

Comparison of mean scores between pretest and after 6 months intervention in "CD" group (Paired T-test), found: mean scores for OHIP, QMF, and VAS for Maxilla, VAS for mandibular, and SFT sub-scapular were statistically significance higher than pretest. On the other hand, there were no significant higher mean score of MNA. BMI. skin fold thickness (SFT) biceps, triceps, SFT abdominal, WC, (BFAT%, SFT). plasma B^{12}, serum Fe, and RBC.

It can be clearly seen that their skin fold thicknesses and body fat percentage were higher than pretest even though BMI was not increased. As comparison, there were significant lower mean score for LBM and also there were no significant lower mean score of serum Fe, serum and erythrocyte folate, than pretest.

This revealed that effectiveness of new CD had a good achievement in only better mastication function and oral health related quality of health but not increase in nutritional status, blood parameters and anthropometric measurement. It is the same result mentioned "there is good evidence that people adapt to tooth loss by altering their dietary intake to compensate for the increased difficulty of eating certain foods, even if masticatory function is restored with conventional dentures". (Wayler and Chauncey. 1983; Chauncey et al., 1984; Fontijn-Tekamp et al., 1996).

5.2.2.6. To compare after program patient quality of masticatory function, daily diet intake, OHRQoL (OHIP) and nutrition status among intervention group I (IODNEED), intervention group II (IOD), intervention group III (CDNEED) and control group (CD).

Hypothesis: The after program patient quality of masticatory function, daily diet intake, OHRQoL (OHIP) and nutrition status in intervention group I (IODNEED) are different from intervention group II (IOD), intervention group III (CDNEED) and control group (CD).

As in the result after 6 months of intervention, it revealed that:

(i) Comparison between IODNEED and IOD, there had significant higher mean score in serum albumin, serum Fe, and RBC, and significant lower mean score in body fat percent (skin fold thickness).

(ii) Comparison between IODNEED and CDNEED, there had significant higher mean score in OHIP, QMF, VASMD, serum albumin, serum and erythrocyte folate, serum Fe, and RBC.

(iii) Comparison between IODNEED and CD, there had significant higher mean score in OHIP, QMF, VASMD, VASMX, serum albumin, plasma B^{12}, serum and erythrocyte folate, serum Fe, and RBC.

(iv) Mean scores in MNA, BMI, LBM, Hb and lymphocyte were not significant different among the groups at post 6 months intervention.

Analysis of the data presented in this report of an RCT suggests that replacing a mandibular two implant-retained overdentures plus nutritional empowerment allows

patients to modify their diet. This leads to improvements in selected important nutritional variables 6 months later. We accepted hypothesis, IODNEED has the best outcomes.

Additionally, for detail inferential analysis, repeated measure ANOVA. (4 factors * 4 groups) was used to analyzed for pairwise comparisons of mean scores among timing (within groups) and among groups (between groups). The research result about the variables OHIP. QMF, VASMX, VASMD, MNA, and BMI would be revealed as follow:

1. As for comparisons among the timing of assessments (within groups), mean scores of OHIP. QMF and MNA were significantly lower in pretest than post 1 month, post 1 month than post 3 months, and post 3 months than post 6 months. This revealed that there was a steady increase in mean score of oral health related quality of health, mastication function and mini nutritional assessment from time to time.

Regarding the mean scores of body mass index, it remain stable between pretest and post 1 month, then significant increase in post 3 months than pretest, and post 6 months than post 3 months. This revealed that the longer the post treatment duration the higher the BMI.

Regarding the mean scores of satisfaction for both maxilla and mandibular, there was significantly lower in pretest than post 1 month, post 3 months, and post 6 months than post 6 months. The satisfaction was gradually increased from time to time and become saturated.

2. As for comparisons among the studied four groups, mean scores of BMI and MNA were not significantly different among the group even though the scores were higher in

"IODNEED" group than "IOD" group and "CDNEED" group than "CD" group. It revealed that nutrition program had some positive effect.

On the other hand, the mean scores in "IODNEED" group were not significantly different from "IOD" group. This shown that effective of mandibular two implanted over dentures was equally effective in terms of oral health related quality of life, mastication function and satisfaction in the two groups. Moreover, the mean scores of oral health related quality of life, mastication function and satisfaction were also significantly higher in "IODNEED" group than "CD" group and "IOD" group than "CD" group. This could be concluded than effective of mandibular two implant-retained over dentures was more effective in terms of oral health related quality of life, mastication function and satisfaction than new conventional dentures. It was the same result with the study mentioned better post-treatment scores for the IOD than the CD group for general satisfaction (P<0.001) (Boerrigter et al., 1995), significant post-treatment between group difference in general satisfaction (P<0.005) (Thomason et al.,2003)

Regarding comparison of satisfaction score between "CDNEED" group and "CD" group, there was a significant higher score in "CDNEED" group and this could revealed that regular participatory learning opportunities for nutritional empowerment had positive effect on patients' satisfaction.

5.2.2.7 To determine the cost-effectiveness among the four groups.

Hypothesis: The cost-effectiveness in intervention group I (IODNEED) are different from intervention group II (IOD).

The cost-effectiveness in intervention group I (CDNEED) are different from intervention group II (CD).

The cost in this study seems to be cheap because the cost is only in public sector not in market price. In the market price and private sectors it will be higher than the cost in this study, not only capital cost of prosthesis but also the cost of NEED programme.

From the results, R^2 becoming increased from time to time; more or less .500, it can be revealed that how the two variables (cost and effectiveness in scores) correlate to each other in this study was only can tell round about 50% in posttest 6 months. Remaining might be due to other factors such as age, history of medical diseases, and public sector price of prosthesis.

From the results of correlation and regression analysis of cost-effectiveness, it could be concluded that there were OHIP (oral health related quality of life) (0.5 score) and satisfaction score for mandibular (5.5 scores) increased in "IODNEED" group than "IOD" group at one month post intervention, and then OHIP (oral health related quality of life) (1 score) and satisfaction score for mandibular (6.5 scores) increased in "IODNEED" group than "IOD" group at three months post intervention. Moreover, there was no change in OHIP score at post 6 months intervention than from post 3 months, even though there had the stronger the linear relation between the two variables but satisfaction score for mandibular (8 scores) increased.

Regarding comparison between two CD groups, it could be also concluded that there were OHIP there were OHIP (0.2 score) and satisfaction score for mandibular (2.2 scores) increased in "IODNEED" group than "IOD" group at one month post intervention, and then OHIP (oral health related quality of life) (0.4 score) and satisfaction score for mandibular (2.6 scores) increased in "IODNEED" group than "IOD" group at three months post intervention. Moreover, there was no change in OHIP score and satisfaction score for mandibular (8 scores) increased at post 6 months intervention.

It could be clearly seen that "NEED" program had a gradual improvement in terms of oral health related quality of health and clients' satisfaction.

Additionally, It could be found from the cost-effectiveness analysis that quality of mastication function (18 scores) increased in "IOD" group and (3 scores) increased in "CD" group at one month post intervention, then quality of mastication function (36 scores) increased in "IOD" group and (6 scores) increased in "CD" group at three months post intervention. But there was no change in score increased at post 6 months intervention than post 3 months. It could be concluded in our study and in our studied population, mandibular two implant-retained overdentures was 6 times more effective than conventional dentures in term of quality of mastication function.