METHODS

Study design: Prospective cohort study

Prior to the selection of the industry for carrying out the study, sample size calculation (Mahajan 1997) was done to determine required sample size using the following formula:

$$n = \frac{4\,p\,q}{L^2}$$

where, n = sample size

p = incidence rate reported by similar studies (51.1%)

q = (1-p)

L = allowable error – 5% at 95% confidence interval.

Using this formula, n (the desired sample size for present study) was calculated to be 384. Accordingly, an industry located in urban Vadodara with employee strength of 650 was chosen as the study setting, assuming that at least 60% of the employees would consent to be part of the study. The study was initialized after obtaining permission from the Head of Human Resources and Administrative & Personnel head of the industry. Ethical clearance was obtained from the Department of Foods and Nutrition ethical committee prior to commencement of the research study (Ethical committee no. F.C.Sc./FND/ME/81). Before enrolling, each employee was explained the objectives of the study and his/her involvement in the same. A written, informed consent was obtained from each employee before collection of baseline data (Appendix 1).

The study was carried out in 5 phases as depicted in the experimental design flowchart (Figure 3.1).

Figure 3.1- Experimental Design

Phase 1

Selection of workplace

(Based on employee strength and

willingness of industry authorities to participate in the study)

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Situational analysis of:

- Nutrition health policies of the industry
- Health promotion activities of industry
- Screening programme for employees
- Recreational activities at workplace
  (Using the Worksite Wellness Index)
- Situational Analysis of ongoing canteen,
  tiffin food service in the industry

Phase 2

Enrollment of consenting employees from all categories of employment

Total (n=504); Males (n=450) and Females (n=54)

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Surveillance of NCD risk factors in the employees using

WHO STEPS METHODOLOGY (n=504)

STEP 1

Behavioral risk factors

- Socioeconomic status (SES)
- Diet pattern
- Alcohol/Tobacco consumption
- History of Diabetes/Hypertension
- Physical activity

STEP 2

Physical Measurements

- Height
- Weight
- Waist & Hip circumference
- Blood Pressure

Phase 3

Identification of "at risk" subjects - those having ≥3 risk factors (n=391)

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STEP 3 - Biochemical estimation of consenting 'at risk' employees (n=158)

- Fasting Blood Sugar
- Lipid Profile – Total Cholesterol, HDL-C, LDL-C, VLDL-C, Triglycerides, TC/HDL ratio, LDL/HDL ratio

Phase 4

Designing and pretesting of Information Education Communication (IEC) material for the health promotion programme

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Designing and pretesting of

Knowledge Attitude Practice (KAP) questionnaires

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KAP assessment of employees who attended the power point sessions (n=126)

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Implementation of health promotion programme at Worksite (industry)

Intervention period = 6 months

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First month: Active intervention – 2 Power point sessions

Next 5 months: Passive intervention –

Reinforcement of active intervention using IEC material;

Posters, Tablemats and Point-of-Decision prompts

Phase 5

Collection of Post intervention data at the end of intervention period of six months in terms of change from baseline, in:

- Knowledge, Attitude and change in Practices (n=83)
- STEP 1 & 2 of the STEPS METHODOLOGY (n=83)
- STEP 3 - Post intervention biochemical estimation for the 'at risk' employees (n=51)

Phase 1

In the first phase of the study, an industry located in urban Vadodara was selected as the study setting after obtaining permission from the Head of Human Resources (HR) as well as Admin. & Personnel Head of the industry. The Worksite Wellness Index Questionnaire (WWI) developed by Cardiovascular Health and Wellness Programme – Texas Department of State Health Services in 2004 was pretested, standardized and adapted before using on the local industry (Appendix 2). Being knowledgeable about all company policies and programmes, the Admin. & Personnel Head was identified as the appropriate resource person for filling the WWI questionnaire. The questionnaire was administered to the Admin. & Personnel Head and thereby, information regarding the industry's existing nutrition and health policies as well as canteen and recreational facilities were obtained. The answers so obtained were analyzed and the industry was evaluated regarding its strengths and weaknesses with respect to nutrition and health policies as per the WWI questionnaire format.

Phase 2

The second phase involved assessment of the risk factor profile of the consenting employees (n=504) using pretested, standardized and adapted WHO STEPS Questionnaire which was modified according to local conditions (Appendix 3). Before enrolling, each employee was explained the objectives of the study and his/her involvement in the same. A written, informed consent was obtained from each employee before collection of baseline data.

Baseline data was collected regarding:

- Background information
- Education level
- Designation
- Housing status – whether living alone/with family
- Marital status
- Behavioural risk factors
- Addiction pattern

- Low Fruit and vegetable intake (< 400 gm/day)
  WHO Geneva 2003 & National Institute of Nutrition, India 2007
- Frequency of eating out
- Dependence on food service available at workplace for meals
- Physical activity (as per CDC 2008 guidelines & Consensus for Asians criteria 2009)
- Medical history

- Anthropometric measurements

- Height
- Weight
- Waist circumference (as per WC Classification for Asian adults, 2000)
- Hip circumference

- Blood pressure measurement (as per JNC VII Classification for Blood Pressure 2004)

Phase 3

The data collected in Phase 2 was analyzed and subjects who showed presence of 3 or more risk factors out of all the following were identified as being 'at risk' (n=391):

- Current Tobacco consumption
- High Alcohol consumption (CDC 2010)
- Low fruit and vegetable intake (< 400 gm/day)
  (WHO/FAO 2002, NIN 2007)
- Physical activity (CDC 2008, Misra et al 2009)
- Medical history of hypertension and/or diabetes
- High blood pressure (JNC VII 2004)
- High Body Mass Index (Misra et al 2009)
- High Waist Circumference (Misra et al 2009)

After analyzing the results of STEP 1 and STEP 2, the results were communicated to the Admin. & Personnel Head as well as to the employees themselves. The 'at risk' subjects were asked to undergo biochemical estimation (blood test for fasting blood sugar and lipid

profile). For the consenting subjects, fasting (12 hour) samples of venous whole blood were collected by a registered lab technician for the blood estimations. Fasting blood sugar estimation was done by enzymatic kit procured from Accurex Biochemicals Pvt. Ltd. using GOD/POD method. Lipid profile estimations were done using kits procured from Aggape. Total cholesterol was estimated by enzymatic end point method (Allain et al 1974) while serum triglycerides were measured using GPO/PAP method (McGowan 1983). Direct HDL-cholesterol estimation was done using enzymatic kit procured from Aggape. LDL-cholesterol, VLDL-cholesterol, TC/HDL and LDL/HDL ratios were then calculated using standard formulae (Freidwald et al 1972). The results of the blood tests were communicated to the employees and each employee was given a photo copy of their respective test report. Also, a brief interpretation of the test results along with health and dietary guidelines to prevent and manage blood sugar and cholesterol were provided to all of them via e-mail.

Phase 4

In the fourth phase of the study, all the employees of the industry, irrespective of their participation in the research study were invited to attend the health promotion programme activities. Active intervention was given during first month of the intervention period by conducting 2 power point sessions covering important health related topics. Each presentation was of 30 minute duration.

Presentation 1 included information regarding:

- What are NCDs?
- Risk factors of NCDs
  Modifiable and Non modifiable
- What is BMI?
  Formula for calculation, Normal values
- Overweight & Obesity
  Causes, Consequences, Prevention and management
- Importance of physical activity
  Recommendations for healthy lifestyle, weight management & maintenance

- Hypertension

  Normal values, Causes, Consequences, Prevention and Management
- Processed foods

  Hidden dangers, Importance of nutrition labeling

Presentation 2 included information regarding:

- Diabetes – Causes, Consequences, Prevention and management
- Heart diseases – Causes, Consequences, Prevention and management
- Healthy eating behaviours for healthy living
- Quick tips for sustainable healthy diet

One month's time was dedicated by the researcher for imparting the above information via 2 presentations to each employee of the industry (Appendix 4-A & 4-B). Prior to the initiation of the power point sessions, pretested and standardised KAP questionnaires (Appendix 8) were distributed among the subjects and the questionnaire was explained to them point-by-point. They were then asked to fill up the questionnaire in the presence of the researcher. Information regarding healthy diet and lifestyle behaviours, such as awareness of normal levels of BMI, B.P., cholesterol and fasting blood sugar, formula to calculate BMI, importance of following healthy lifestyle, perceptions about own health as well as awareness and knowledge about NCDs was thus collected.

Following this, active intervention sessions were held. After consulting with the industry management and obtaining the requisite permission from them, sessions of Presentation 1 were held for the first 2 weeks of active intervention every day from Monday to Friday between 12.00 p.m. and 4.00 p.m. in the industry premises. Similarly, during the following 2 weeks, Presentation 2 sessions were held. Details of the topic of presentation, date, time and duration were communicated to all employees via e-mail by the Admin. & Personnel Head. All those employees who had participated in Phase 2 of the study and had provided information regarding their general information, diet, lifestyle as well as biophysical parameters (as per WHO STEPS questionnaire) were personally contacted by the researcher via e-mail and invited for the power point sessions to ensure good participation in the sessions.

Over and above this, all the employees (those who attended the sessions as well as others) were provided with soft copy of the presentation via e-mail for ready reference. Along with this, all the industry employees were also provided with the researcher's e-mail address as a helpline which they were encouraged to use to contact the researcher in case of any queries regarding nutrition and health. The queries so received were promptly and efficiently replied to by the researcher. In the next 5 months of the intervention period, the intervention was reinforced using pretested and standardized IEC material:

- **A3 size coloured posters** were placed at strategic points (near the water cooler, in the common entrance corridor wall and canteen) in the industry campus. These posters included information regarding – weight management, adequate fruit and vegetable intake, regular physical activity, prevention and management of diabetes, hypertension and cardiovascular disease (Appendix 5).
- **A4 size black and white sheets** printed with key messages pertaining to healthy diet & lifestyle behaviours were made available to the subjects to be used as table mats at the workplace during meal times (Appendix 6).
- **Point-of-decision prompts** in the form of posters placed near lifts-encouraging use of stairs instead of lift were also placed (Appendix 7).

Phase 5

At the end of the intervention period (6 months), post intervention data regarding STEP 1 and STEP 2 as well as KAP (same parameters as those assessed at baseline) was collected from the subjects who consented to participate in the last phase of the study. For this, the same questionnaire as those used as baseline were used with certain additional questions pertaining to feedback of intervention (Appendix 9 & 10).

The post-intervention data for STEP 1 and STEP 2 as well as blood test was communicated to the Admin. & Personnel Head as well as the participating employees. Photo copy of post intervention blood test report was given to all the respective employees.

Statistical Analysis

The data was entered in a computer using an excel spreadsheet. The data was cleaned and verified after which it was subjected to appropriate statistical analysis. Frequency distribution, mean, standard deviation as well as t-test, ANOVA and chi-square analysis was performed for the data using SPSS statistical software. Results have been presented in tabular and/or graphical form.