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Effectiveness of Triple Package Intervention on Level of Awareness, Diet Pattern and Selected Biophysiological Parameters of Breast Cancer Among High Risk Women- Pilot RCT

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Abstract

Background of the Study: In developing countries like India, noncommunicable diseases such as cancer, diabetes mellitus, and hypertension are growing exponentially day by day. The prevalence and incidence of cancer, especially breast cancer, are increasing on a larger scale.

Objectives of the study: The aim of the study was to assess the effectiveness of triple package interventionon level of awareness, dietary pattern and selected biophysiological parameters of breast cancer among women.

Research Methodology: We conducted a two-group parallel pilot RCT with 32 high-risk women aged 30–45 years, regular menstrual cycle and obese / overweight as per WHO guidelines. For both the control arm and experimental arm, a face-to-face interview technique was used to ascertain information about socio-demographic, gynecological and lifestyle variables. The level of awareness was assessed using structured knowledge questionnaire prepared by the Investigators.

Results: The results obtained showed that the level of knowledge among women in the experimental arm was statistically significantly better than the control arm, and the post-test scores in knowledge were significantly higher than before ($p < 0.001$).

Conclusion: The researchers conclude that the triple package intervention was successful in raising awareness and knowledge in high-risk women, but this was not translated into meaningful changes in diet or biophysiology. These results suggest that there is a necessity of a multi-faceted, behavioural, and context-driven approach to determining lasting lifestyle and health changes.

INTRODUCTION

Breast cancer accounts for the most common cancer in Asia especially targeting developing countries. Over the past decade the incidence of breast cancer has exponentially increased targeting one in four of all cancers among women [1]. Global Cancer Observatory reported that number of new cases affected with Breast cancer is 23.8%. Breast cancer stands out first with 46.78% incidence and 12.7% mortality. In South East Asia the mortality rate is expected to increase to 61.7% by 2040. India has a low 5-year survival rate compared to Western and developed countries [2]. Non-modifiable risk factors include age, being female, genetic characteristics, specific racial or ethnic characteristics, family history, altered immunological biomarkers and delayed menopause. Modifiable risk factors are consumption of alcohol, smoking, increased body mass index, lack of physical activity, intake of high fat and fiber. These factors are mostly preventable and therefore immediate attention has to be provided to the women specifically with high risk factors [3].

A study in Tanzania on bread awareness showed that 92.38% heard about breast cancer, 39% have identified risk factors and 48.65% practices Breast self -examination[4]. A systematic review also identified that customized education programs are highly effective in enhancing knowledge about breast

cancer and the advantages of screening practices in diverse populations, including women in rural and underserved groups [5]. These interventions are important in highlighting the importance of awareness in the formation of health seeking behaviour, particularly in relation to routine screening that may result in early diagnosis and resulting better survival [6, 7].

Eating habits of the women, especially those that are characterized as being at a high risk of developing breast cancer also goes a long way in the management of the disease. Research associates obesity and poor dietary habits with an increased likelihood of breast cancer coming back and dying. Nutritional programs that promote the change to a more healthy diet, such as the intake of more fruits and vegetables and the intake of less calories, are demonstrated to bring good health results to breast cancer patients [8, 9]. The diet breast cancer association is also complicated by the presence of modifiable risk factors including alcohol consumption and sedentary lifestyles that had been found to contribute substantially to breast cancer risks by various studies [10, 11].

It’s the need of the hour to indulge in approaches that focus on breast cancer prevention: community-based interventions to reduce risk factors for individuals and identifying the women with high risk for developing breast caner and also provide them a personalized -interventional strategies. The awareness programs may increase the women’s knowledge during the stipulated time whereas that is not sufficient for a sustained behavioral change. A group of proactive interventions aiming at improving women’s awareness, early detection strategies, dietary modifications and lifestyle changes can bring about a drastic change in the life of women.

AIM OF THE STUDY

The study aimed to evaluate the effectiveness of triple package intervention on dietary pattern among women within and between the control and experimental arm.

RESEARCH METHODOLOGY

A Quantitative approach with two-group parallel Randomized Control trial was adopted for the study. Simple Random Sampling technique (lottery method) was used to collect data from 32 high risk women of age 30–45 years, regular menstrual cycle and obese / overweight as per WHO guidelines. Allocation to control and experimental arm was done using computer generated table. 16 samples were allotted in each arm. Pilot trial was done with 10% of main study sample size along with considering 10% attrition. All the obtained data was kept anonymous.

Tool instruments

A face-to-face interview technique was used to ascertain information about socio-demographic, gynecological and lifestyle variables from the selected samples. Socio-demographic variables consisted of age, type of family, religion, educational status, occupation, heard about breast caner and source of

information. Gynecological variables inquired about pattern and duration of menstrual cycle, premenstrual symptoms, age at marriage, GPLA score, history of hormone treatment and family history of breast cancer. Information on type of diet consumed often in a week, its frequency, personal habit of betel nuts, tobacco chewing, active and passive smoking were obtained for lifestyle variables. The level of awareness was assessed using a structured knowledge questionnaire. A 24-hour recall of one weekday and a weekend was collected using the ICMR format. It was calculated using the standard formula. Amount of food consumed / total amount required * 100. Food deficit was calculated by subtracting 100 from the obtained value [11]. The obtained data was interpreted in terms of Kilocalories, fat and protein.

In the next phase, samples were assessed for biophysiological parameters. The equipment's were pre calibrated before the assessment phase. Blood pressure was assessed using Omron digital BP apparatus was categorized as per American Heart Association guidelines. Weight was assessed using the Omron body composition monitor and height was measured using portable wall mounted growth stature. Body Mass Index (BMI) was calculated using the standard formula. Weight in Kg/ Height in m^2 and the obtained values were categorized as per WHO guidelines [13] Fasting blood glucose (FBS) was assessed from the samples following 8–10 hours of fasting overnight. It was checked using one touch glucometer. It was interpreted using American Diabetes Association. The data was collected for both the arms at the initial phase of data collection and at the end of the study.

Ethical clearance permission

Prior to execution of data collection procedure, the study purpose, criteria for consent (voluntary participation, confidentiality) was outlined and the samples were provided contact details of the Principal Investigator and IRB details for clarification or withdrawal from the study. The study was approved by the IRB committee (8787/IEC/2024). Informed consent was obtained from all participants. The authors confirm that all experiments were performed in accordance with relevant guidelines and regulations. CTRI registration was done for the study. [14]

Procedure of data collection

Pilot study was conducted for 8 weeks from 20.08.2024 to 14.10.2024. Ethical clearance was obtained from Institutional Ethical Committee. After obtaining formal permission from Medical Officer, Health & Wellness Centre Villianur, women in the selected area were approached. An initial survey was done among 82 women to categorize them as high risk using snehita Breast cancer online calculator [15] Among them 32 samples were recruited for the study as per the inclusion criteria by using simple random sampling technique. Computer generated table was used to allocate women to control and experimental arm. Informed consent was obtained. Women in control arm received routine care and followed routine practice whereas women in experimental arm received interventional strategies pertaining to breast cancer primary prevention.

Teaching session on breast cancer- The session started by assessing the women's previous knowledge on Breast cancer. Teaching was given to the high-risk women by the researcher individually by using PowerPoint presentation for about 20 minutes related to Breast cancer- definition, causes, risk factors, diagnosis, prevention and management.

Training session on breast cancer

After ensuring adequate privacy, Clinical breast examination (CBE) was performed by the Investigator. Women were taught about the steps to perform Breast Self -Examination using breast model and return demonstration was done by them. Doubts were clarified by the researcher at the end of the session.

Nutritional education

The session started by collecting the two days 24 hours recall from the women. One weekday and one weekend recall was collected using ICMR format by the Investigator. The session started by making 3–4 women in a group. They were made to sit in a comfortable environment. The researcher educated them about Nutrition, healthy food, the importance of nutrition for cancer prevention, recommended foods for breast cancer prevention, Food pyramid for balanced diet-2000 Kcal, menu plan for sedentary women and about adopting healthy lifestyle pattern using flash card for about 10–15 minutes. Group members actively participated and doubts were clarified by the researcher at the end of the session.

Physical activity

Women were encouraged to do moderate intensity brisk walking for 3 days alternatively in a week for about one hour per session. A total of 24 sessions were performed by the women. The one hour session was divided to warm up period (10 minutes), followed by 45 minutes of brisk walking and cooling down session (5 minutes).

Women were reinforced through telecommunication (Whatsapp group), home visit and follow up protocol chart to ensure the compliance of interventions.

RESULTS

Table 1 indicates that 43.8% of women in the control group were between the ages of 30-35 and 43.8% were between the ages of 35-40 years and in the experimental group 56.3% were in the 35-40 years age group. There were more nuclear families, which was 62.5 in the control group and 56.3 in the experimental group. The majority of the participants were Hindus (93.8 percent of the control group and 75.0 percent of the experimental group). About fifty percent of the control group reported primary education and secondary education was most prevalent in the experimental group with a figure of 43.8. The largest occupational group was homemakers which made 68.8 percent occupational group in the control and 50 percent in the experimental group. Both groups had heard about breast cancer through media and health professionals, with all the women having heard about breast cancer.

Table 2 shows that age at menarche was most frequently 12 years in the control group of 31.3 years at 31.3 years whereas in the experimental group the age at menarche was 13 years at 31.3 years. The menstrual cycles of most of the women were after every 28-32 days, which covered 75.0% of the women in the control group and 62.5% of the experimental group, and a period of the menstrual cycle was 3-4 days in 56.3% of women in the control group and 62.5% in the experimental group. Forty-three-point eight percent of women in both groups always had premenstrual symptoms. The control group had the highest age at marriage (usually 26 years) and most of its women had two children which represented 75.0% and 62.5% of the control and experimental group respectively. No one had a history of hormone treatment and 12.5 per cent in all groups reported a family history of cancer.

Table 3 indicates that 50.0 percent of women in the control group and 56.3 percent in the experimental group did follow a mixed diet with non- vegetarian diet being followed by 43.8 percent of each group. In the experimental group, 93.8% of all women, and in all the women in the control group, there were no personal habits. According to both groups, 18.8% of women were reported to be passive smokers, with most of them reporting not being exposed at all.

Table 4 illustrates that experimental arm had a significant increase in post-test knowledge score over the control arm. The knowledge score mean in the experimental arm rose by 10.19 to 22.50, and the same showed a slight change in the control arm by 11.25 to 11.44. This was statistically significant with the p value of less than 0.001 and therefore showed that the intervention was effective in knowledge.

Table 5 indicates that the control and experimental arm did not have a statistically significant difference in terms of energy intake, protein intake and fat intake, where the values of the p were 0.197 with energy, 0.008 with protein and 0.775 with fat, all of which is greater than the level of statistical significance. These results show that no significant effect on the energy, protein and fat parameters was observed between the two groups as a result of the applied interventional strategies.

Table 6 indicates no statistically significant difference existed between pre- and post-test scores in knowledge, energy, protein, and fat in the control arm because all the p values exceeded 0.05. Conversely, in the experimental arm there was a statistically significant increase in knowledge with p value of 0.010, in energy with p value of 0.020 and in protein with p value of 0.051, but change in fat was not statistically significant with p value of 0.061. Table 7 shows that there was no statistically significant difference between the control arm and experimental arm in post-test biophysiological parameters.

Table 1 : Socio demographic variables among high risk women n=32

Socio Demographic variables		Group			
		Control arm		Experimental arm	
		F	%	f	%
Age	30-35	7	43.8%	4	25.0%
	35-40	7	43.8%	9	56.3%
	40-45	2	12.5%	3	18.8%
Type of family	Joint family	6	37.5%	7	43.8%
	Nuclear family	10	62.5%	9	56.3%
Religion	Christian	0	0.0%	3	18.8%
	Hindu	15	93.8%	12	75.0%
	Muslim	1	6.3%	1	6.3%
Edn.status	Primary education	8	50.0%	4	25.0%
	Secondary education	4	25.0%	7	43.8%
	University or Higher	4	25.0%	5	31.3%
Occupation	Homemaker	11	68.8%	8	50.0%
	Sedentary worker	3	18.8%	2	12.5%
	Professional	2	12.5%	3	18.8%
	Others	0	0.0%	3	18.8%
Heard abt B.CA	Yes	16	100.0%	16	100.0%
Source of Inf.	Family	2	12.5%	0	0.0%
	Media	7	43.8%	7	43.8%
	Health Professionals	7	43.8%	8	50.0%
	Others	0	0.0%	1	6.3%

Table 2: Gynecological variables in control group and experimental group among high risk women. n=32

Gynecological variables		Group			
		Control arm		Experimental arm	
		f	%	F	%
Age of menarche	11	4	25.0%	4	25.0%
	12	5	31.3%	4	25.0%
	13	3	18.8%	5	31.3%
	14	4	25.0%	2	12.5%
	17	0	0.0%	1	6.3%
pattern of cycle	Once in 28 days	4	25.0%	6	37.5%
	Once in 28-32 days	12	75.0%	10	62.5%
duration of cycle	1-2 days	3	18.8%	0	0.0%
	3-4 days	9	56.3%	10	62.5%
	5-6 days	4	25.0%	6	37.5%
PMS	Always present	7	43.8%	7	43.8%
	Rarely present	6	37.5%	5	31.3%
	Not present	3	18.8%	4	25.0%
Age at marriage	23	1	6.3%	3	18.8%
	24	2	12.5%	1	6.3%
	25	2	12.5%	2	12.5%
	26	6	37.5%	3	18.8%
	27	2	12.5%	2	12.5%
	28	1	6.3%	0	0.0%
	29	1	6.3%	3	18.8%
	30	1	6.3%	0	0.0%
	31	0	0.0%	1	6.3%
	37	0	0.0%	1	6.3%
No.of children	1	4	25.0%	6	37.5%
	2	12	75.0%	10	62.5%

H/O hormone treatment	No		16	100.0%	16	100.0%
Family history of CA	Yes		2	12.5%	2	12.5%
	No		14	87.5%	14	87.5%
	Type of diet	Lacto-ovo-vegetarian	1	6.3%	0	0.0%
		Non-vegetarian	7	43.8%	7	43.8%
		Mixed diet	8	50.0%	9	56.3%
	H/o personal habits	Yes	0	0.0%	1	6.3%
		No	16	100.0%	15	93.8%
	Passive smoking	Yes	3	18.8%	3	18.8%
		No	13	81.3%	13	81.3%

Table 3: Gynecological variables in control group and experimental group among high risk women. n=32

Gynecological variables		Group			
Life style history		Control group		Experimental group	
		f	%	F	%
Type of diet	Lacto-ovo-vegetarian	1	6.3%	0	0.0%
	Non-vegetarian	7	43.8%	7	43.8%
	Mixed diet	8	50.0%	9	56.3%
H/o personal habits	Yes	0	0.0%	1	6.3%
	No	16	100.0%	15	93.8%
Passive smoking	Yes	3	18.8%	3	18.8%
	No	13	81.3%	13	81.3%

Table 4: Effectiveness of Interventional strategies on level of knowledge between the control arm and experimental arm.

Level of Knowledge	Pre test		Post test		p value
	Mean	Standard Deviation	Mean	Standard Deviation	<.001*
Control arm	11.25	3.94	11.44	3.68	
Experimental arm	10.19	3.48	22.50	3.26	

*Significant at $p < 0.05$

Table 5: Effectiveness of Interventional strategies on energy, protein and fat between the control arm and experimental arm.

Energy (Kcal)	Pre test		Post test		p value
	Mean	Standard Deviation	Mean	Standard Deviation	
Control arm	-13.87	10.70	-10.25	6.82	0.197
Experimental arm	-10.62	5.03	-7.25	2.59	NS
Protein (g)					
Control arm	-42.56	9.32	-44.44	7.81	0.008
Experimental arm	-38.56	11.62	-34.56	10.50	NS
Fat (g)					
Control arm	-29.19	15.83	-32.44	17.18	0.775
Experimental arm	-35.62	8.37	-31.00	10.08	NS

*Significant at $p < 0.05$

Table 6: Effectiveness of Interventional strategies on energy, protein and fat within the control arm and experimental arm.

Arm	Parameter	Pre-test	Post-test	Test value	p value	Result
Control arm	Knowledge (Mean rank)	3.75	3.00	z = −1.000	0.317	NS
	Energy (Mean rank)	7.36	5.30	z = −0.985	0.325	NS
	Protein (Mean ± SD)	1.875 ± 9.032	—	t = 0.830	0.419	NS
	Fat (Mean ± SD)	3.250 ± 15.524	—	t = 0.837	0.416	NS
Experimental arm	Knowledge (Mean rank)	8.50	0.00	z = −3.527	0.010	*S
	Energy (Mean ± SD)	3.375 ± 5.201	—	—	0.020	*S
	Fat (Mean ± SD)	−4.625 ± 9.150	—	—	0.061	NS
	Protein (Mean rank)	7.59	7.17	z = −1.949	0.051	*S

Table 7: Effectiveness of Interventional strategies on selected biophysiological parameters within the control arm and experimental arm: n=32

Post test clinical parameters		Group				Chi-square value	p value
		Control		Experimental			
		f	%	f	%		
SBP	Normal	7	43.8%	9	56.3%	1.317	0.518
	Elevated	8	50.0%	7	43.8%		NS
	BP stage I	1	6.3%	0	0.0%		
DBP	Normal	6	37.5%	11	68.8%	3.613	0.164
	Elevated	1	6.3%	0	0.0%		NS
	BP stage I	9	56.3%	5	31.3%		
BMI	Normal	0	0.0%	2	12.5%	2.4	0.301
	Overweight	10	62.5%	10	62.5%		NS
	Obese	6	37.5%	4	25.0%		
Body fat	Normal	1	6.3%	6	37.5%	4.571	0.102
	High	9	56.3%	6	37.5%		NS
	Very high	6	37.5%	4	25.0%		
Visceral fat	Normal	5	31.3%	5	31.3%	0.259	0.879
	High	8	50.0%	9	56.3%		NS
	Very high	3	18.8%	2	12.5%		
Skeletal muscle	Low	6	37.5%	6	37.5%	0.202	0.904
	Normal	5	31.3%	4	25.0%		NS
	High	5	31.3%	6	37.5%		
WHR	Normal	0	0.0%	1	6.3%	2.333	0.311
	Central adiposity	1	6.3%	3	18.8%		NS
	High central adiposity	15	93.8%	12	75.0%		
FBS	Normal	3	18.8%	4	25.0%	0.543	0.762
	Pre DM	11	68.8%	9	56.3%		NS
	DM	2	12.5%	3	18.8%		

DISCUSSION

The results of the current study indicate that the increase in the level of knowledge in women in the experimental arm is statistically significant when compared to the control arm, which proves that the educational intervention is effective. This is substantiated by the evidence that structured nutrition education is highly effective towards improving dietary knowledge and compliance to healthy practices in pregnancy [12, 13].

The appearance of the great increase of the post-test knowledge scores in the experimental group ($p < 0.001$) also indicates the effectiveness of the intervention. Other previous studies have found similar improvements in pregnancy-specific dietary knowledge after nutrition education [14]. Nonetheless, empirical studies indicate that, in spite of the efficacy of educational interventions to enhance knowledge, these interventions do not necessarily lead to a similar change in diet or health [15].

The current research did not present statistically significant differences in energy, protein and fat intake in the control and experimental arm though there was an improvement in the knowledge ($p > 0.05$). This observation is similar to those who have found beneficial effects of knowledge without a significant alteration in actual dietary consumption, mostly because of socio-economic and environmental factors [16, 17].

The Within-group analysis found that the experimental arm experienced substantial gains in knowledge and small gains in energy and protein intake whereas no substantial gains had been observed in the control arm. The results of this study are consistent with the existing research that showed that the dietary awareness and specific attributes of dietary behavior could be positively impacted by repeated and intensive educational intervention [18, 19].

The analysis of the post-tests revealed that there was no statistically significant difference between the control and experimental arm in terms of parameters of the biophysiological parameters like body mass index and fasting blood sugar. There are other previous studies that have reported similar findings, and indicated that enhancement of knowledge alone may be inadequate in creating short-term clinical outcomes without prolonged modifications in behavior and facilitative settings [20, 21].

CONCLUSION

The study results indicate that the educational intervention had a positive impact on the nutritional knowledge in the experimental group of women since the level of such knowledge was significantly increased in the study. Nevertheless, this increase in the level of knowledge did not make significant shifts in the dietary intake and biophysiological parameters. These findings point out that knowledge improvement is not enough to initiate any significant changes in behavior and physiological mechanisms. As such, there are a need to have comprehensive intervention plans that would be inclusive of behavioral support, practical and skills-based and an understanding of the environmental and socio-cultural factors. The future research would be aimed at combining practical and supportive methods to help the effective use of the knowledge about nutrition into everyday activities, hence, supporting the long-term enhancement of both a diet and health.

Declarations

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Author Contribution

Mrs.Catherine.K- Tool preparation , data collection, administration of Intervention package, data coding, data presentation, Interpretation of resultsDr.Sajeetha Kumari.R- Tool preparation, data presentation, administration of Intervention package, Interpretation of resultsDr.Helen Shaji J.C- Tool preparation, data presentation, Interpretation of resultsDr.Rajeswari.D- Tool preparation, data codingDr.Jayasankari.S-Tool preparation, data collection, Interpretation of resultsDr.Ravichandran.K- Data analysis, Data presentation

Data Availability

The authors have used data from the human subjects for the present study

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Figures

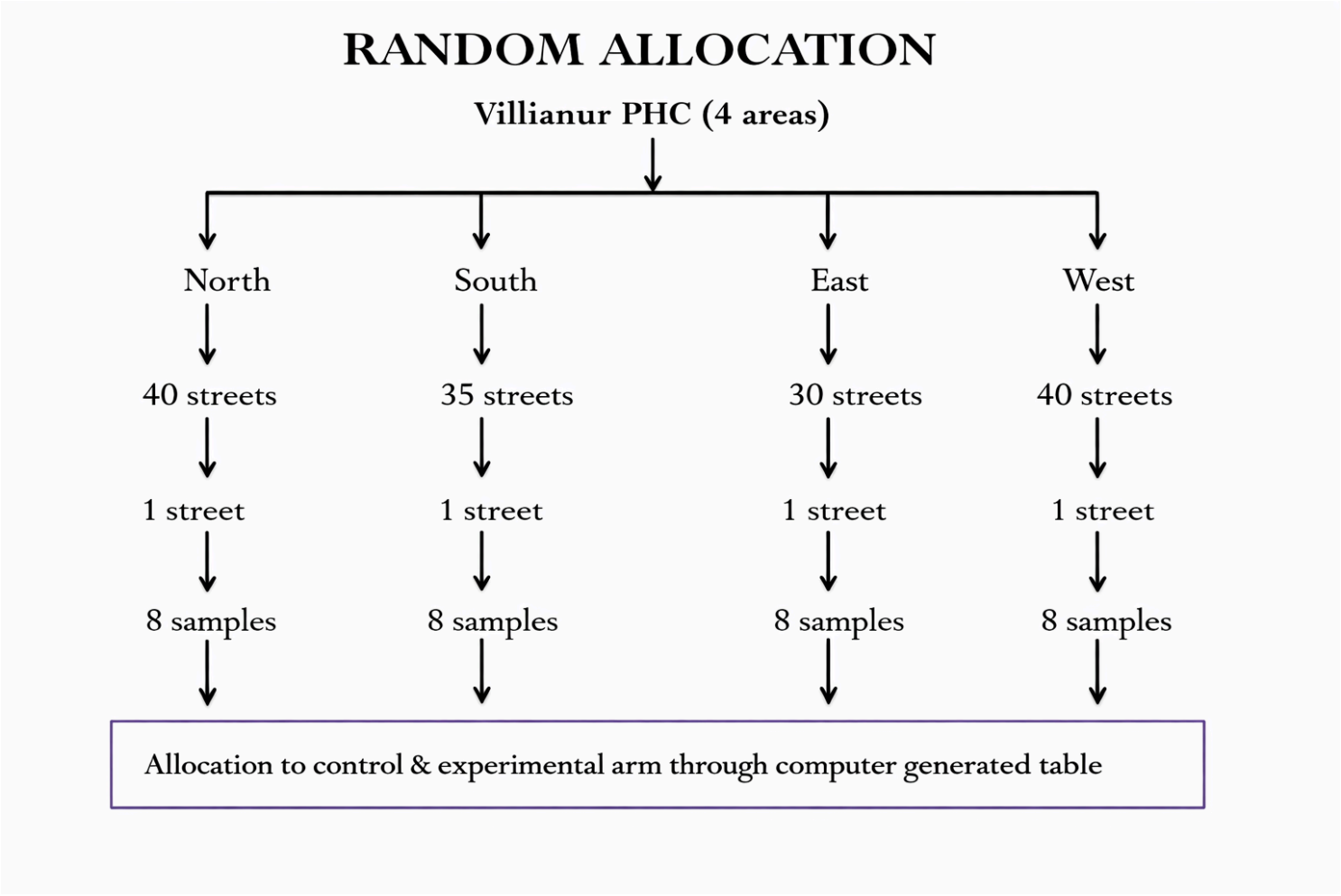


Figure 1

Random Allocation