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Garlic- Infused Honey on Lipid Levels: A participant blinded randomized control clinical trial

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Abstract:
Background*: Noncommunicable diseases (NCDs) are more prevailing across the globe, it causes 41 million deaths all over the world which is 71% of all deaths (WHO).[1] The common NCDs are cardiovascular diseases, diabetes mellitus and cancers, among these cardiovascular diseases are responsible for more deaths.[2] The lifestyle changes include physical inactivity, poor dietary pattern, harmful consumption of alcohol and tobacco use are the responsible for developing non communicable diseases, the 90% of cardiovascular diseases are preventable if the atherosclerosis been reduced.[3] The 10mg/dl reduction of serum cholesterol can reduce 20% of occurrence of heart disease in 5 years.[4] In the current study we tested the hypothesis that there is a significant reduction in the lipid levels among cardiac risk adults before and after the intake of Garlic – Infused Honey for a period of four weeks.*
Materials and Methods*: A participant blinded randomized control clinical trial was done among urban population, door to door survey were conducted to identify the cardiac risk adults using modified STEP tool and physiological measures to find out eligible Cardiac risk adults. 232 Cardiac risk adults were screened for hyperlipidemia and 52 eligible cardiac risk adults were identified and enrolled for the study. Approval got from the institutional review board, ICMR-CTRI and Informed consent was obtained from all the cardiac risk adults prior to risk assessment.*
Results*: The Four week of Intervention result shows there was significant decreases in total cholesterol by 49.19 mg/dl (p<0.001) in Experimental Group, whereas 24 mg/dl (p<0.001) in Control Group and there were significant differences observed between experimental and control groups in posttest with mean total cholesterol deference of 17.4 mg/dl (p=0.013).*
Conclusion: *The present study concludes that Garlic – Infused Honey is effective in reducing total cholesterol in 4 weeks.*
Key Word*: Garlic – infused Honey, Lipid levels, Total Cholesterol, Cardiac risk, Urban areas, Adults.*

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I. Introduction

Noncommunicable diseases (NCDs) are more prevailing across the globe, it causes 41 million deaths all over the world which is 71% of all deaths (WHO).[1] The common NCDs are cardiovascular diseases, diabetes mellitus and cancers, among cardiovascular diseases are responsible for more deaths.[2] Increased cholesterol level will leads to risk of developing cardiovascular problems, the third leading cause for ischemic heart diseases is high blood cholesterol.[4] Low and middle income countries are suffering from 77% of deaths due to all NCDs.[1] The lifestyle changes include physical inactivity, poor dietary pattern, harmful consumption of alcohol and tobacco use are the responsible for developing non communicable diseases[3]. All the age groups are vulnerable to NCDs, however age between 30-69 are dying more in number.[1] The 90% of cardiovascular diseases are preventable if the atherosclerosis been reduced.[3] The 10mg/dl reduction of serum cholesterol can reduce 20% of occurrence of heart disease in 5 years.[4] In the current study we tested the hypothesis that there is a significant reduction in the lipid levels among cardiac risk adults before and after the intake of Garlic – Infused Honey for a period of four weeks.

II. Material And Methods

Community based door to door, participant blinded, randomized control clinical trial was conducted from December 2017 to January 2018 in urban areas of Puducherry. Cardiac risk assessment was done to the adult male and female who are age between 20 to 60 years using modified STEP Tool check list and Physiological measures include Blood Pressure and BMI to identify the cardiac risk. The primary outcome of this study was lipid profile which was measured with total cholesterol level in the serum among 232 identified cardiac risk adults after excluding the adults who had a history of co-morbid conditions such as hypertension, diabetes and stroke. The blood was collected at the empty stomach which was stored in 8^{o}C ice box for the maximum of 40 minutes and serum was separated using centrifugation at 3000RPM for ten minutes and analyzed with Roche Cobas C 311 Gen.2 fully automated analyzer. Baseline total cholesterol levels were obtained to identify the eligibility.

Study Design: True Experimental research design

Study Location: This study was done in the urban area of Muthialpet, UT of Puducherry, India.

Study Duration: December 2017 to January 2018.

Sample size: 52 cardiac risk adults.

Sample size calculation: Sample size was estimated using power analysis of previous research study and required sample size for this study was 25 in each group (Control and Experimental) to get reduction of Total cholesterol 22.1 mg/dl, 90% power of the study, 5% significant level and 10% dropout.

Subjects & selection method: 52 eligible cardiac risk adults were identified from the urban area of muthialpet, UT of Puducherry, India. Enrolled cardiac risk adults were randomly assigned into Experimental Group (n=35) and Control Group (n=35) by computer generated random number by random technique as follow:

Experimental group (N=26 cardiac risk adults) -Tablet Atorvaststin 10mg daily at night after meal and 10g of Garlic – infused honey with a glass of water in an empty stomach daily for a period of four weeks;

Control group (N=26 cardiac risk adults) – Tablet Atorvaststin 10mg daily at night after meal.

Inclusion criteria:

1. Cardiac risk adults age 20 - 60 years.
2. Newly diagnosed Cardiac risk Adults who are having elevated Total cholesterol >200 mg/dl.
3. Adults who are willing to participate.

Exclusion criteria:

1. Adults who are already on any other AYUSH drugs.
2. Adults who are already taking Garlic drug
3. The adults who had a history of co-morbid conditions such as hypertension, diabetes and stroke.

Procedure methodology

The investigator obtained formal permission from institutional review board of College of Nursing, PIMS and Health and Family Welfare Services, Puducherry. After obtaining informed consent the investigator assessed the Cardiac risk for selected population using modified STEP Tool check list and Physiological measures include Blood Pressure and BMI. After Cardiac risk assessment those who are in mild to high risk were taken pretest blood samples for total cholesterol. 232 Cardiac risk adults were screened for hypercholesterolemia among them 52 eligible Cardiac risk adults those who are having elevated total cholesterol >200 mg/dl without co-morbid conditions such as hypertension, Diabetes and stroke and also those who are willing to participate in this study was included in the study. Selected Cardiac risk adults were divided into two groups such as Experimental Group and Control Group using Random Sampling method. The Experimental group was treated with 10mg of tablet Atorvastatin daily at night along with 10g of Garlic – Infused Honey with glass of water for the period of 4 weeks daily at empty stomach and Control group was treated only with 10mg of tablet Atorvastatin daily at night for the same period. The Cardiac risk adults were not reported any complications during study period. After the 4 weeks of intervention post-test blood samples were collected for Total cholesterol in both Experimental Group and the Control Group after three days on completion of intervention.

Statistical analysis

The collected data of 52 Cardiac risk adults (26 experimental group and 26 control group) was entered in Microsoft Excel 2010 and it was analyzed using SPSS 22.0. Frequency, percentage, mean, and SD were used to describe the study variables. Independent t-test used to evaluate the effectiveness. Chi-square test was used to identify association between variables. Any p value less than 0.05 considered statistically significant.

III. Result

The Four week of Intervention result shows there was significant decreases in total cholesterol by 49.19 mg/dl (p<0.001) in Experimental Group, whereas 24 mg/dl (p<0.001) in Control Group and there were significant differences observed between experimental and control groups in posttest with mean total cholesterol deference of 17.4 mg/dl (p=0.013).

Table 1 Shows that the study variables of cardiac risk adults in pre-test level both experimental and control group was distributed equally, there was no statistical differences was observed among study variables

Study Variable	**categories**	**Experimental group (n=26)**	**Control group (n=26)**	**p value**
Age in Years	20-30	6 (23.1)	7 (26.9)	0.748
	31-40	20 (76.9)	19 (73.1)	
Sex	Male	12 (46.2)	13 (50.0)	0.781
	Female	14 (53.8)	13 (50.0)	
Food Habit	Non-Vegetarian	25 (96.2)	26 (100.0)	-
	Vegetarian	1 (3.8)	0 (0.0)	
Family history of cardio vascular disease (CVD)	Yes	13 (50.0)	7 (26.9)	0.087
	No	13 (50.0)	19 (73.1)	
BMI	Normal range (18.51-24.99)	10 (38.46)	14 (53.85)	0.265
	Over weight (>25.00)	16 (61.54)	12 (4615)	

Table 2 revealed that in pre-test mean of experimental group was 237.6 ± 25.8 and in control group was 229.8 ± 21.9, the calculated p = 0.248, there were no significant differences observed in mean total cholesterol level in both experimental and control groups which means both groups are statistically equal at pre-test level

Variable	**Experimental group (n=26) Mean ±SD**	**Control group (n=26) Mean ± SD**	**t-Value**	**p-Value**
Total Cholesterol	237.6 ± 25.8	229.8 ± 21.9	1.168	0.248

Table 3 shows the post interventional comparison of total cholesterol of cardiac risk adults in experimental group and control group, the significant difference was observed (p = 0.013) in post-test level between the experimental and control group

Variable	**Experimental group (n=26) Mean ±SD**	**Control group (n=26) Mean ± SD**	**t-Value**	**p-Value**
Total Cholesterol	188.4 ± 28.3	205.8 ± 19.5	-2.577	0.013

Table 4 shows that the pretest and post interventional comparison of total cholesterol of cardiac risk adults within the experimental group, there was statistically significant differences observed at p = <0.001 level after the intervention.

Variable	**Baseline (n=26) Mean ±SD**	**After intervention (n=26) Mean ± SD**	**t-Value**	**p-Value**
Total Cholesterol	237.6 ± 25.8	188.4 ± 28.3	7.725	<0.001

Table 5 shows that the pretest and post interventional comparison of total cholesterol level of cardiac risk adults within the control group, there was statistically significant differences observed at p = <0.001 level after the atorvastatin.

Variable	**Baseline (n=26) Mean ±SD**	**After atorvastatin (n=26) Mean ± SD**	**t-Value**	**p-Value**
Total Cholesterol	229.8 ± 21.9	205.8 ± 19.5	8.071	<0.001

This was community-based door to door, participant blinded, randomized control clinical trial to evaluate the effectiveness of the Garlic – infused honey on lipid levels as primary outcome. As the main finding of this study shows that garlic – infused honey is effective in reducing total cholesterol level in cardiac risk adults. We observed that the total cholesterol level was significantly decreased after the four weeks of intervention in both experimental and control group. The mean Lipid levels difference of Experimental Group was 49.19 ± 32.47 mg/dl and Control Group was 24.00 ± 15.16 mg/dl. This study reveals that 10mg of atorvastatin can reduce 24 mg/dl of serum total cholesterol and Garlic – infused honey with 10mg of atorvastatin can reduce 49 mg/dl of serum total cholesterol and this study is similar to Javad Kojuri et.al study titled "Effects of anethum graveolens and garlic on lipid profile in hyperlipidemic patients" the result revealed that total cholesterol decreased by 26.82 mg/dl in six weeks of enteric-coated garlic powder tablet intervention[8]

IV. Conclusion

Garlic and honey are commonly available kitchen items all over the world. Garlic-infused honey can be prepared easily at the home. This study proves that the 10g of garlic-infused honey is effective in reducing the total cholesterol level, hence it can prevent the development of cardio vascular diseases in future. We observed only the total cholesterol level in lipid profile since other parameters of lipid profile can be evaluated with the same intervention to identify the same.

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Conflict of interest

There is no conflict of interest.

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