International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 3 May–June 2025, pp: 182-188 www.ijprajournal.com ISSN: 2456-4494

A Non-Interventional Data Collection to Determine the Impact of Obesity on Thyroid Levels in Healthy Volunteers Compared in Type-2 Dm Patients

V raja Rajeswari Kola[1], Devarapalli Reni Jessica[2], Shaik Jani Basha[3], Shaik Tamseel[4], T.Sukanya[5], Navajis Ali[6].

Associate Professor, Nimra College of Pharmacy, Jupudi, Ibrahimpatnam, Vijayawada [1].
5th Year Pharm D Students, Nimra College of Pharmacy, Jupudi, Ibrahipatnam, Vijayawada [2,3,4,5]

Date of Submission: 01-05-2025 Date of Acceptance: 10-05-2025

I. INTRODUCTION:

Overweight and obesity are defined as abnormal or excessive fat accumulation that presents a risk to health. A body mass index (BMI) over 25 is considered overweight, and over 30 is obese. In 2019, an estimated 5 million noncommunicable disease (NCD) deaths were caused by higher-than-optimal BMI.

Rates of overweight and obesity continue to grow in adults and children. From 1990 to 2022, the percentage of children and adolescents aged 5–19 years living with obesity increased four-fold from 2% to 8% globally, while the percentage of adults 18 years of age and older living with obesity more than doubled from 7% to 16%.

Obesity is one side of the double burden of malnutrition, and today more people are obese than underweight in every region except the South-East Asia Region. Once considered a problem only in high-income countries, today some middle-income countries have among the highest prevalence of overweight and obesity worldwide.

Overweight and obesity are major risk factors for a number of chronic diseases, including cardiovascular diseases such as heart disease and stroke, which are the leading causes of death worldwide. Being overweight can also lead to diabetes and its associated conditions, including blindness, limb amputations, and the need for dialysis. Rates of diabetes have quadrupled since around the world since 1980. Carrying excess weight can lead to musculoskeletal disorders including osteoarthritis. Obesity is also associated with some cancers, including endometrial, breast, ovarian, prostate, liver, gallbladder, kidney and colon. The risk of these noncommunicable diseases increases even when a person is only slightly overweight and grows more serious as the body mass index (BMI) climbs.

Obesity in childhood is associated with a wide range of serious health complications and an increased risk of premature onset of related illnesses. Studies have found that without intervention, children and adolescents with obesity will likely continue to be obese into adulthood. [1]

II. THYROID DISEASE TYPES AND CAUSES

There are two main types of thyroid disease: hyperthyroidism and hypothyroidism. Both conditions can be caused by other diseases that impact the way the thyroid gland works.

2.1.Hyperthyroidism vs. hypothyroidism

All types of hyperthyroidism are due to an overproduction of thyroid hormones, but the condition can occur in several ways:

2.2.Gravesdisease: The production of too much thyroid hormone.

2.3.Toxic adenomas: Nodules that form in the thyroid gland and upset the body's chemical balance by making thyroid hormones. Some goiters may contain several of these nodules.

2.4. Subacute thyroiditis: Inflammation of the thyroid that causes the gland to "leak" excess hormones. This leads to temporary hyperthyroidism that generally lasts a few weeks but may persist for months.

2.5. Pituitary gland malfunctions or cancerous growths in the thyroid gland: In rare cases, these can cause hyperthyroidism.

2.6.Hypothyroidism, by contrast, stems from an underproduction of thyroid hormones. As your body needs certain amounts of thyroid hormones to make energy, a drop in hormone production leads to lower energy levels. Causes of hypothyroidism include:

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 3 May–June 2025, pp: 182-188 www.ijprajournal.com ISSN: 2456-4494

2.7. Hashimoto's thyroiditis: In this autoimmune disorder, the body attacks thyroid tissue. The tissue eventually dies and stops producing hormones.
2.8. Postpartum thyroiditis: This can happen anytime in the year after you give birth, or have a miscarriage or abortion. It's not common, occurring in 5% to 9% of those situations. It's usually a temporary condition.
2.9. Iodine deficiency: Iodine is used by the thyroid to produce hormones. An iodine deficiency is an issue that affects several million people around the world.
2.10. Removal of your thyroid gland: Your thyroid may have been surgically removed or chemically destroyed.
2.11. Exposure to excessive amounts of iodine: Cold and sinus medicines, the heart medicine amiodarone, or certain contrast dyes given before some X-rays may expose you to too much iodine.
2.12. Past thyroid issues: You may be at greater risk for hypothyroidism if you have had thyroid problems in the past.
Lithium: This drug is also linked to hypothyroidism.[2]

III. DIABETES MELLITUS:

Diabetes Mellitus, disorder of carbohydrate metabolism characterized by impaired ability of the body to produce or respond to insulin and thereby maintain proper levels of sugar (glucose) in the blood.
Diabetes Self-testing glucose meter for measuring blood glucose levels in patients with diabetes mellitus.

Diabetes is a major cause of morbidity and mortality, though these outcomes are not due to the immediate effects of the disorder. They are instead related to the diseases that develop as a result of chronic diabetes mellitus.

These include diseases of large blood vessels (macrovascular disease, including coronary heart disease and peripheral arterial disease) and small blood vessels (microvascular disease, including retinal and renal vascular disease), as well as diseases of the nerves.[3]
Collecting Comparing T3,T4,TSH Levels in Healthy obese with Type 2 DM Subjects.

3.1.Causes and types

Langerhans The islets of Langerhans are responsible for the endocrine function of the pancreas. Each islet contains beta, alpha, delta, and pancreatic polypeptide (PP) cells that are responsible for the secretion of pancreatic hormones. Beta cells secrete insulin, a well-characterized hormone that plays an important role in regulating glucose metabolism.

Insulin is a hormone secreted by beta cells, which are located within clusters of cells in the pancreas called the islets of Langerhans. Insulin's role in the body is to trigger cells to take up glucose so that the cells can use this energy-yielding sugar. Patients with diabetes may have dysfunctional beta cells, resulting in decreased insulin secretion, or their muscle and adipose cells may be resistant to the effects of insulin, resulting in a decreased ability of these cells to take up and metabolize glucose. In both cases, the levels of glucose in the blood increase, causing hyperglycemia (high blood sugar). As glucose accumulates in the blood, excess levels of this sugar are excreted in the urine. Because of greater amounts of glucose in the urine, more water is excreted with it, causing an increase in urinary volume and frequency of urination as well as thirst. (The name diabetes mellitus refers to these symptoms: diabetes, from the Greek diabainein, meaning "to pass through," describes the copious urination, and mellitus, from the Latin meaning "sweetened with honey," refers to sugar in the urine.) Other symptoms of diabetes include itching, hunger, weight loss, and weakness.

There are two major forms of the disease. Type 1 diabetes, formerly referred to as insulin-dependent diabetes mellitus (IDDM) or juvenile-onset diabetes, usually arises in childhood. Type 2 diabetes, formerly called non-insulin-dependent diabetes mellitus (NIDDM) or adult-onset diabetes, usually occurs after age 40 and becomes more common with increasing age.

IV. AIM:

The aim of the study is todetermine the Impact of obesity on Thyroid levels in healthy volunteers compared in Type-2 DM Patients.[4]

V. OBJECTIVES:

To compare thyroid levels between healthy overweight individuals and overweight patients with type-2 diabetes.

Main Inclusion Criteria
•Both Male & Female Patients of age 18 to 60 years old
•Patients who are willing to sign the written informed consent
•Patients who are diagnosed with Type -2 DM (50% of study Population)

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 3 May–June 2025, pp: 182-188 www.ijprajournal.com ISSN: 2456-4494

•Participants who are Healthy with Abnormal BMI& Undiagnosed with Type -2 DM (50% of study Population) Patients who are willing to follow the study procedures

Main Exclusion Criteria
•Pregnant women
•Underlying or diagnosed with serious diseases or deemed unsuitable for this clinical study by the study's clinician
•Being treated with a high dose of steroids or immunosuppressant therapy or systemic antibiotics
•Presenting a progressive neoplastic lesion treated with radiotherapy or chemotherapy
•Subjects included in clinical study at present or during the past 30 days

Ethical Considerations:

Informed consent must be obtained from all participants.

The study must be conducted in compliance with ethical guidelines and approved by an Institutional Review Board (IRB).

Confidentiality and privacy of participant data must be maintained at all times.[6]

Statistical methods and planned analysis:
Subject Population(s) for Analysis: Parents of Participants who have signed an Informed Consent Form indicating that they understand the purpose of and the procedures required for the study and are of age 18 to 60 years and above will be included in the statistical analysis. Participants who have complied with the study procedures followed the study instructions and completed the clinical study will be included in the statistical analysis.[7]

Data Analysis Plan:
Descriptive Statistics:

Demographics and baseline characteristics: Use descriptive statistics (mean, standard deviation, range) to summarize continuous variables (e.g., age, BMI, thyroid levels).
For categorical variables (e.g., gender, diabetes status), report frequencies and percentages.[8]

Comparison of characteristics between the two groups:

Healthy volunteers vs. type 2 diabetes patients: Compare basic characteristics (age, gender, BMI, thyroid levels) using t-tests (for continuous variables) or chi-square tests (for categorical variables).

Comparative Analysis: Between-group comparison (healthy volunteers vs. type 2 diabetes patients):Use independent t-tests (for continuous variables like thyroid hormone levels) [9] or Mann-Whitney U tests (for non-normally distributed variables) to compare thyroid hormone levels between the two groups.Chi-square tests or Fisher's Exact Test for categorical outcomes [10] like the prevalence of thyroid dysfunction. Effect of obesity on thyroid levels:

Correlational analysis: Perform Pearson's correlation or Spearman's rank correlation to assess the relationship between BMI (or waist circumference) and thyroid hormone levels (TSH, T3, T4).

Multivariate linear regression (if data allows): Model the relationship between obesity and thyroid hormone levels, adjusting for confounders like age, sex, and diabetes status

VI. METHODOLOGY:

Clinical Phase: Non interventional
Type of Research: Academic Research
Study Sites: Single site
Study Period

Planned Enrolment Duration: Approximately 3 months.
Planned Total Duration of the Study: 6 months.
Study Visits: Single visit study
Study Population Both Male & Female population.

Study Objectives:

The objective of this study is to determine the impact of obesity on thyroid levels in healthy volunteers compared with Type 2 Diabetic Patients.
Study Design:A Non interventional cross-sectional pilot study.
Number of Subjects:100 subjects.

Study End Points:

The End Point is find impact of obesity on thyroid levels in healthy volunteers compared with Type 2 Diabetic Patient byStratified analysis: Stratify the groups (healthy volunteers and type 2 diabetes patients) based on BMI categories (e.g., normal weight, overweight, obese) and assess differences in thyroid function.

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 3 May–June 2025, pp: 182-188 www.ijprajournal.com ISSN: 2456-4494

VII. RESULTS

TABLE-1 (SUMMARY STATSTICS OF DEMOGRAPHICS)		
Total No of Patients (n=100)		
Parameter	**Non-Diabetic (n=47)**	**Diabetic (n=53)**
	Mean ± SD	**Mean ± SD**
Age (Yrs)	39.61 ± 10.24	38.94 ± 11.27
Height (Mts)	1.60 ± 0.09	1.61 ±1.61
Weight (Kgs)	79.91 ± 14.13	71.30 ± 13.80
BMI (kg/m$^{2)}$	38.19 ± 8.76	33.84 ± 10.16

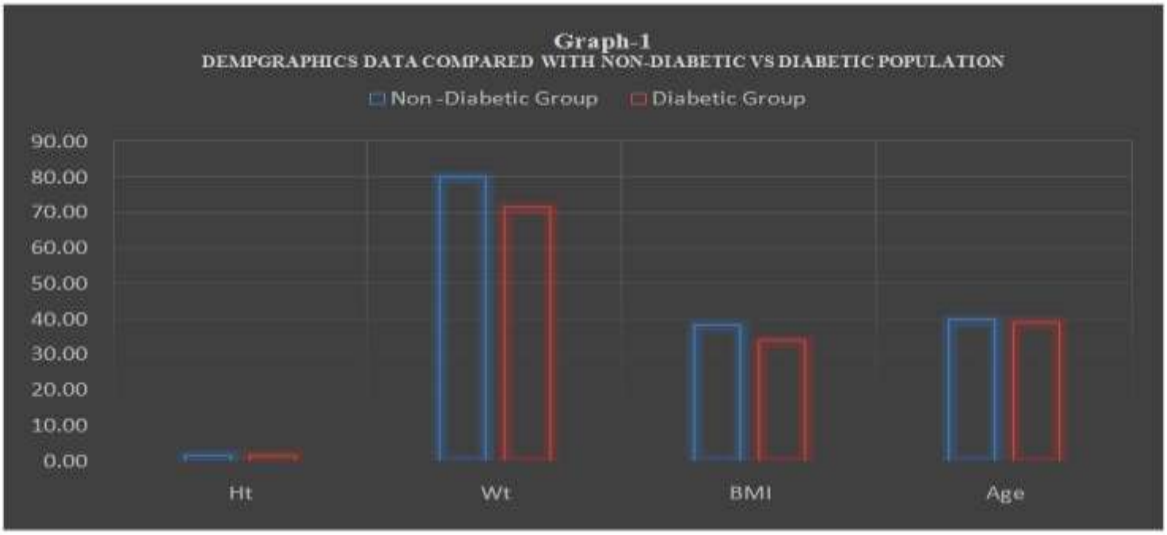


TABLE-2 (SUMMARY STATSTICS OF VITAL SIGNS)		
Total No of Patients (n=100)		
Parameter	**Non-Diabetic (n=47)**	**Diabetic (n=53)**
	Mean ± SD	Mean ± SD
Pulse Rate	91.17 ± 6.22	89.64 ± 6.09
SBP	110.11 ± 8.72	107.00 ± 7.81
DBP	82.74 ± 6.97	79.57 ± 6.31
Respiratory Rate	18.89 ± 2.91	18.13 ± 3.04
Body Temperature	98.34 ± 0.70	98.46 ± 0.79

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 3 May–June 2025, pp: 182-188 www.ijprajournal.com ISSN: 2456-4494

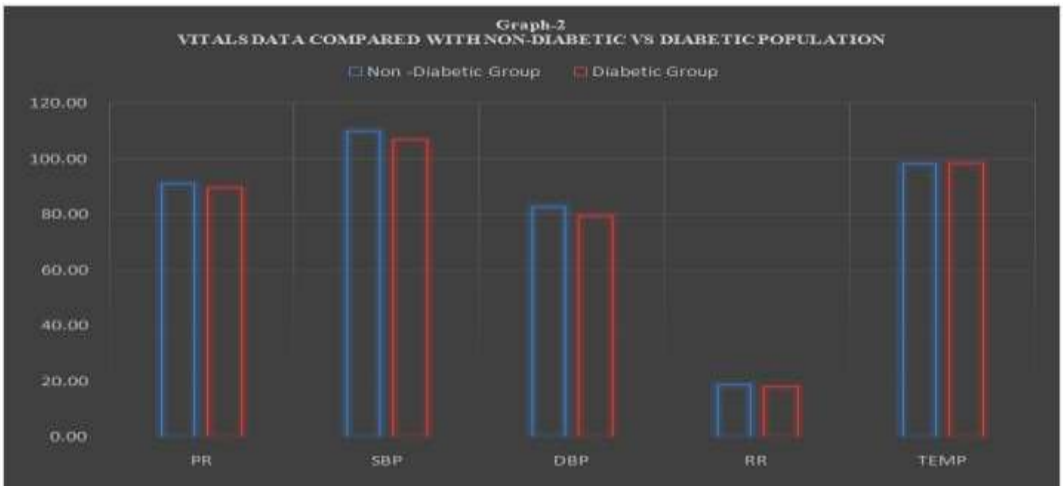
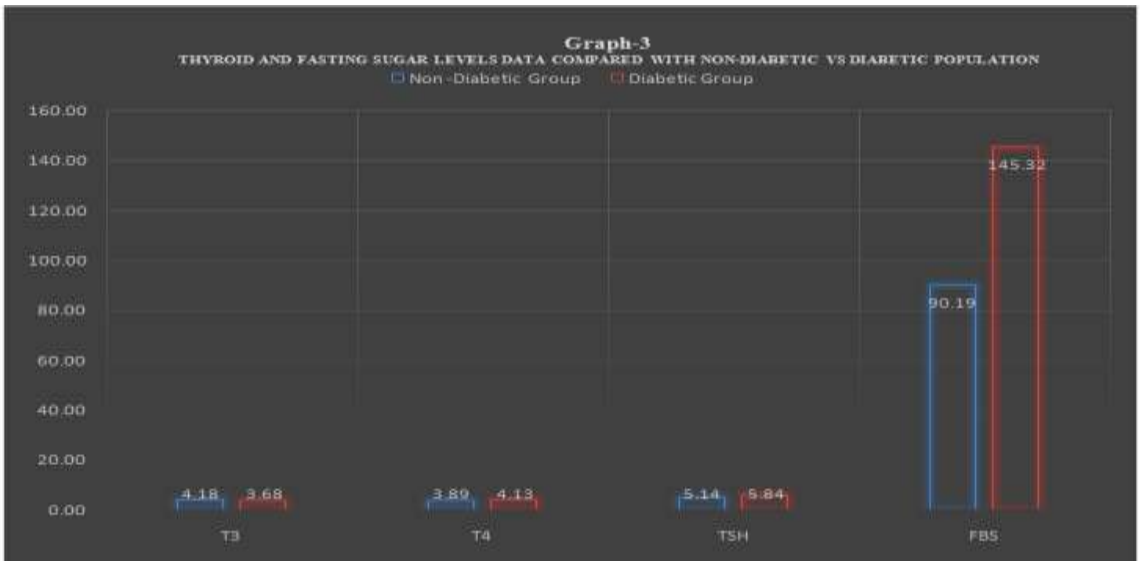


TABLE-3
(SUMMARY STATSTICS OF T3, T4, TSH & FBS)

Total No of Patients (n=100)

Parameter	Non-Diabetic (n=47)	Diabetic (n=53)	t Value	p Value	T-TEST Significance
	Mean ± SD	Mean ± SD			
T3	4.18 ± 3.22	3.68 ± 2.69	0.84279	0.200699	Non-Significant
T4	3.89 ± 3.79	4.13 ± 5.14	0.26018	0.39764	Non-Significant
TSH	5.14 ± 6.28	5.84 ± 10.14	0.41307	0.34023	Non-Significant
FBS	90.19 ± 7.21	145.32 ± 50.57	**7.40271**	**< .00001**	***p < .05.***
BMI ($kg/m^{2)}$	38.19 ± 8.76	33.84 ± 10.16	**0.27878**	**0.012425**	***p < .05.***



International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 3 May–June 2025, pp: 182-188 www.ijprajournal.com ISSN: 2456-4494

VIII. SUMMARY

From Table-1 Summary Statistics of Demographics, it was evident that the mean age group of Non-Diabetic Patient group was 39.61 ± 10.24 yrs and Diabetic Patient group was 38.94 ± 11.27 yrs, when compared with both groups we observed similar age group of patients was enrolled.

It was evident that the mean height of Non-Diabetic Patient group was 1.60 ± 0.09 mts and Diabetic Patient group was 1.61 ±1.61mts, when compared with both groups we observed similar height of patients was enrolled.

It was evident that themeanWeightof Non-Diabetic Patient group was 79.91 ± 14.13 kgs and Diabetic Patient group was 71.30 ± 13.80 kgs,when compared with both groups we concluded that the patients with non-Diabetic was showed higher weight compared to Diabetic Patient group.

It was evident that themean BMI of Non-Diabetic Patient group was 38.19 ± 8.76 kg/m2and Diabetic Patient group was 33.84 ± 10.16kg/m2, when compared with both groups we concluded both groups are Obese, however patients with non-Diabetic showed more Obese than Diabetic Patient group.

From Table-2 Summary Statistics of Vital Signs,it was evident that the mean Pulse rate of Non-Diabetic Patient group was 91.17 ± 6.22 Beats/Min and Diabetic Patient group was 89.64 ± 6.09Beats/Min,when compared with both groups we observed both groups showed normal Pulse Rate.

It was evident that the mean SBP of Non-Diabetic Patient group was 110.11 ± 8.72 mm/hg and Diabetic Patient group was 107.00 ± 7.81 mm/hg, when compared with both groups we observed both groups showed normal Systolic Blood Pressure.

It was evident that the mean DBP of Non-Diabetic Patient group was 82.74 ± 6.97 mm/hg and Diabetic Patient group was 79.57 ± 6.31 mm/hg, when compared with both groups we observed both groups showed normal Diastolic Blood Pressure.

It was evident that the mean Respiratory Rate of Non-Diabetic Patient group was 18.89 ± 2.91 Beats/Min and Diabetic Patient group was 18.13 ± 3.04 Beats/Min, when compared with both groups we observed both groups showed normal Respiratory Rate.

It was evident that the mean Temperature of Non-Diabetic Patient group was 98.34 ± 0.700 F and Diabetic Patient group was 98.46 ± 0.790 F, when compared with both groups we observed both groups showed normal Temperature.

From Table-3 Summary Statistics ofT3, T4, TSH & FBS,it was evident that the T3 Levels of Non-Diabetic Patient group was 4.18 ± 3.22 pg/ml and Diabetic Patient group was 3.68 ± 2.69 pg/ml,when compared with both groups we observed both groups showed normal T3 Levels.

It was evident that the T4 Levels of Non-Diabetic Patient group was 3.89 ± 3.79 ng/dl and Diabetic Patient group was 4.13 ± 5.14 ng/dl,when compared with both groups we observed both groups showed normal T4 Levels.

It was evident that the TSH Levels of Non-Diabetic Patient group was 5.14 ± 6.28 µIU/mland Diabetic Patient group was 5.84 ± 10.14 µIU/mlL,when compared with both groups we observed both groups showed normal TSH Levels.

It was evident that the FBS of Non-Diabetic Patient group was 90.19 ± 7.21 mg/dl and Diabetic Patient group was 145.32 ± 50.57 mg/dl,when compared with both groups we observed Diabetic Patient group showed clinically abnormal values which results highest Fasting Blood Sugar Levels.

It was evident that themean BMI of Non-Diabetic Patient group was 38.19 ± 8.76 kg/m2and Diabetic Patient group was 33.84 ± 10.16kg/m2, when compared with both groups we concluded both groups are Obese, however patients with non-Diabetic showed more Obese than Diabetic Patient group.

IX. CONCULSION

The study titled "A Non-Interventional Data Collection to Determine the Impact of Obesity on Thyroid Levels in Healthy Volunteers Compared with Type 2 Diabetic Patients" involved data collection from 53 diabetic patients and 47 non-diabetic patients. The aim was to assess the effect of obesity on thyroid levels in both groups. The results showed that the mean age of both groups was similar, with both groups being obese. However, the non-diabetic group was more obese than the diabetic group.

Analysis of the vital signs data revealed that both groups had normal pulse rate, respiratory rate, blood pressure, and body temperature.

Regarding the primary and secondary endpoints, we analysed the data for T3, T4, TSH, and FBS. The findings showed normal levels of T3, T4, and TSH in both groups. When investigating the correlation between obesity and thyroid levels, the analysis using a T-test with two independent

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 3 May–June 2025, pp: 182-188 www.ijprajournal.com ISSN: 2456-4494

means at a 0.05 significance level (one-tailed test) indicated no significant impact of obesity on thyroid levels in either group. However, a correlation between the impact of obesity on patients with High Blood Sugar levels and Patients with normal Sugar Levels was observed when comparing the two groups, with a significant p-value of $p < 0.05$.

REFERENCES:

[1]. https://www.who.int/health-topics/obesity#tab=tab_2 [1]
[2]. https://www.webmd.com/women/understanding-thyroid-problems-basics[2]
[3]. https://www.britannica.com/science/diabetes-mellitus[3]
[4]. https://pubmed.ncbi.nlm.nih.gov/22746188/[4]
[5]. https://www.pharmnet-bund.de/PharmNet/EN/Public/Non-interventional-studies/_node.html[5]
[6]. https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/good-clinical-training[6]
[7]. https://www.who.int/groups/research-ethics-review-committee/guidelines-on-suBMItting-research-proposals-for-ethics-review/templates-for-informed-consent-forms[7]
[8]. https://www.investopedia.com/terms/d/descriptive_statistics.asp[8]
[9]. https://statistics.laerd.com/statistical-guides/independent-t-test-statistical-guide.php [9]
[10]. https://pmc.ncbi.nlm.nih.gov/articles/PMC5426219/ [10]