Journal of Applied Pharmaceutical Science Vol. 11(06), pp 111-117, June, 2021
Available online at http://www.japsonline.com
DOI: 10.7324/JAPS.2021.110613-1
ISSN 2231-3354

Assessment of risk of depression and diabetes among overweight and obese subjects with unsuccessful efforts to reduce body weight: Observation from clinical trial participants of weight loss intervention

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ARTICLE INFO

Received on: 15/02/2021
Accepted on: 29/03/2021
Available online: 05/06/2021

Key words:
Depression, diabetic risk, overweight, obesity.

ABSTRACT

Paucity of data in context to depression and diabetes among obesity (OB) or overweight (OW) subjects with unsuccessful efforts to reduce body weight is unclear. Considering this, we evaluated the relationship between depression and diabetes risk among those populations. The vital and biochemical parameters, including lipid profile, homeostatic model assessment, were measured for eligible screened subjects who participated in the trial of weight loss intervention at first visit. Risk associated with depression and type-2 diabetes was assessed by self-reported Patient Health Questionnaire scale and American Diabetes Association diabetic risk score respectively. In our study, out of 165 individuals, 59 (35.75%) were OW and 106 (64.25%) were OB, as per the World Health Organization criteria. The OW and obesity males have greater risk of pre-diabetes or diabetes (odds ratio: 4.55% and 3.15%, 95% confidence intervals: 1.45–14.21 and 1.33–7.52) (p = 0.009 and 0.008). The body mass index (BMI) is strongly associated with depression and diabetes (p = 0.0001*). Insignificant association was observed between insulin resistance/diabetic among the depressive obese subjects ($p > 0.05$). Obesity or OW were found to link with risk of depression and the abnormal BMI was substantially amplifying the risk of diabetes.

INTRODUCTION

According to the World Health Organization (WHO) statistics, an estimate of 350 and 500 million people are suffering with depression and obesity, respectively, and these statics are alarming (World Health Organization, 2000). Worldwide one among six adults obese and approximately each year 2.8 million persons die because of obesity or over weight (Pradeepa *et al*., 2015). The investigations reported, to achieve and retain weight loss in peoples with obesity or overweight (OW) is arduous; hence, most of the peoples were failure to achieve the goal (Mariman *et al*., 2012; Rosenbaum *et al*., 2010; Sumithran *et al*., 2013). In addition, obesity and depression had contributed to the burden to the public including rise in the healthcare costs, morbidity and mortality (Chapman *et al*., 2005).

The conflicting outcomes between among obesity (OB) and depression (De Wit *et al*., 2010; Fabricatore *et al*., 2011), but some have not supported this conclusion in all subjects (Bin Li *et al*., 2004; Chang *et al*., 2012). The management of obesity in patients with depression is a difficult task. However, a moderate decrease in the body weight had contribution positively to improve the depressive symptoms (Jantaratnotai *et al*., 2011). The aim of this work was to investigate the burden of depression and type-2 diabetes between OW and obese subjects from the Clinical trial of weight loss intervention.

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METHODOLOGY

Study population

It was an observational study, the participants were enrolled after taking the informed consent form, and the study was enrolled in clinical trial registry, Reg. No. CTRI/2020/02/023329. Totally 165 subjects of either sex, with aged range from ≥19 years and less than 65 years with non-diabetic OB or OW data were collected at the first visit. The participants were screened for vital and medical examinations and biochemical parameters, such as lipid profile, homeostatic model assessment for insulin resistance (HOMA-IR) were measured at the Department of Endocrinology and Metabolism, India. Before data collection, all participants given informed consent, and the trial protocol was approved by the Institutional Ethics Committee of Endo-Life Specialty Hospital, Guntur, India.

Measurements

Anthropometric measurements

The height and weight of the subjects was measured in centimeters and kilograms using a digital scale. The body mass index (BMI) of the subjects was calculated as the weight of the person in kilograms divided by the square of the height. The OW and obesity subjects were categorized as Class-I, II, and III according to WHO standards (World Health Organization, 2000) as follows: OW (BMI kg/m^2 between 25.0and 29.9), and obese (BMI >30.0), obese class-I (30.0–34.9), obese class-II (35.0–39.9) and obese class-III (≥40.0). The waist circumference was measured by using normal conventional (Non-Elastic) measuring tape.

Depression outcomes

In our study, the screening of depression was carried out by Patient Health Questionnaire (PHQ-9) scale. The PHQ-9 scale was used to screen the depressive symptoms (Maurer, 2012), and it is validated (Nease, 2003) and easy to complete by the individuals. Responses are scored from 0 to 3, representing "not at all," "several days," "more than half the days," and "nearly every day," respectively, with total scores ranging from 0 to 27. Scores ≥ 10 are usually used to describe the depression in clinical studies.

Diabetic risk outcomes

Assessment of diabetic risk was carried out by using a patient self-assessment diabetes screening score which contains total seven questionnaires. If the total score is greater than or equal to five, the subjects are at increased risk for having type-2 diabetes mellitus (T2DM) (American Diabetic Association, 2008). Insulin resistance (IR) was measured with HOMA-IR. This method is used for not only for assessing β-cell function but also for IR from basal (fasting) glucose and insulin. HOMA-IR was calculated using the following formula (Matthews *et al*., 1985). HOMA-IR = fasting plasma glucose (mg/dl) × fasting insulin (μU/ml)/405. Based on literature (Aydin, 2014; Calori *et al*., 2011) a cutoff value of ≥2.5 was selected for HOMA-IR to find IR.

Statistical analysis

Statistical Package for the Social Sciences (SPSS) version 22 (IBM Corporation, Chicago, IL) was used for conducting data entry and statistical analysis whereas the frequencies and percentages were determined using descriptive analysis for categorical variables. Central tendency and dispersion were calculated for quantitative variables. Independent sample *t*-test and Chi-square test or Fisher's exact test were employed for comparing continuous variables and categorical variables. The results of risk were expressed in 95% confidence intervals (CI) and odds ratio (OR). The level of significance was fixed at $p < 0.05$ for all the analysis.

RESULTS

The characteristics of the 165 participants (63, male and 103 women) and the participants were stratified by presence of OW (<30 kg/m^2) and obesity (≥ 30 kg/m^2). Participants of gender, age, height and lipid profile were not significant ($p < 0.05$) among OW subjects as compared to OB. (Table 1). The continuous variables (Supplementary Table S1) are statistically non-significant and the mean values were nearly equivocal among the both genders, but the mean values of low density lipoprotein (LDL), T2DM risk score was high in males. Table 2 depicts the participants with PHQ-9 score were stratified by moderate to severe depression (≥10) and the non depression to mid depression (<10). Except alcoholics ($p < 0.05$), remaining all characteristics were significantly ($p > 0.05$) associated with depressive subjects (PHQ-9 score ≥ 10). The odds of depression were 3–5 times more among the subjects with obesity, hypertension, unmerited status, and smokers, respectively.

Table 3 represents the risk of T2DM, the subjects with low income and alcoholics were not have significant association with T2DM ($p < 0.05$), remaining all parameters were associated

Table 1. Characteristic of the OW and obese trial participants.

Characteristics	Over weight (n = 59)	Obese (n = 106)	Total	p value
Male	23 (39%)	39 (38%)	62	0.782
Female	36 (61%)	67 (62%)	103	
Age (years)	38 ± 8.2	36.4 ± 10.8	36.86 ± 9.66	0.10
BMI (kg/m^2)	27.62 ± 1.27	32.9 ± 2.46	31.01 ± 3.30	0.0001*
Height (cm)	160 ± 6.7	160 ± 5.86	160.29 ± 6.14	1.0
Weight (kg)	70.9 ± 5.8	84.5 ± 7.21	79.67 ± 9.40	0.0001*
systolic bold pressure (SBP) (mm of Hg)	128 ± 12	136 ± 11.73	133.01 ± 12.34	0.0001*
diastolic bold pressure (DBP) (mm of Hg)	82 ± 6	86 ± 6.94	84.55 ± 6.82	0.0003*
TC (mg/dl)	199.14 ± 21.51	200.27 ± 24.49	199.70 ± 46	0.767
high density lipoprotein (HDL) (mg/dl)	37.91 ± 10.57	35.49 ± 9.24	36.7 ± 9.9	0.127
LDL (mg/dl)	100.41 ± 15.97	104.47 ± 21.48	100.44 ± 18.72	0.206
TG (mg/dl)	160.81 ± 31.53	170.67 ± 40.14	165.74 ± 35.83	0.105
very low density lipoprotein (VLDL) (mg/dl)	32.16 ± 6.33	34.13 ± 8.03	33.14 ± 7.18	0.106
fasting plasma glucose (FPG) (mg/dl)	80 ± 7	93.29 ± 9.89	88.67± 10.92	0.0001*
HOMA-IR	1.33 ± 0.38	1.83 ± 0.71	1.83 ± 0.71	0.0001*
PHQ-9 Score	5 ± 1	9.16 ± 1.83	8 ± 2.59	0.0001*
DM Risk Score	3 ± 1	4.8 ± 1.23	4.04 ± 1.54	0.001*

*The p value <0.05 were considered to be statistically significant.

Table S1. Risk factors among male and females.

Characteristics	Male (n = 62)	Female (n = 103)	p value
Age (years)	35 ± 10	38 ± 9.8	0.06
SBP (mm of Hg)	132 ± 12	134 ± 9.8	0.24
DBP (mm of Hg)	84 ± 6.4	85 ± 7.1	0.36
BMI (kg/m^2)	30.7 ± 2.99	31.2 ± 3.47	0.25
Hight (cm)	159 ± 9.27	160.52 ± 5.96	0.31
Weight (kg)	78.59 ± 9.27	80.32 ± 9.42	0.25
total cholesterol (TC) (mg/dl)	195.89 ± 24.30	202 ± 22.35	0.10
HDL (mg/dl)	35 ± 9.77	37 ± 9.76	0.20
LDL (mg/dl)	106.23 ± 19	101.56 ± 20.37	0.14
TG (mg/dl)	166.31 ± 32.25	167.83 ± 40.21	0.80
VLDL (mg/dl)	33.26 ± 6.45	33.57 ± 8.04	0.79
FPG (mg/dl)	88 ± 9.9	89 ± 11	0.55
HOMA-IR	1.78 ± 0.62	1.87 ± 0.75	0.42
PHQ-9 Score	7.55 ± 2.45	7.79 ± 2.57	0.55
DM Risk Score	4.31 ± 1.50	3.9 ±1.50	0.09

Table 2. Estimated ORs of depression among study the study subjects.

Demographics	N	Moderate to severe depression [n = 78 (%)[a]]	Mild depression [n = 87 (%)[b]]	OR	95% CI	p value
Body weight						
Obese	105	65 (62)	41 (38)	3.13	1.66-6.01	0.0005*
Over weight	59	13 (22)	46 (88)			Reference
Hypertension						
Yes	95	43 (45.26)	52 (54.74)	0.82	0.44-1.53	0.60
No	70	35 (50)	35 (50)			Reference
Marital status						
Unmarried	40	29 (72.5)	11 (27.5)	4.08	1.87-8.93	0.0004*
Married	115	49 (42.60)	76 (57.40)			Reference
Literacy levels						
Below secondary school	35	06 (17.14)	29 (82.86)	0.16	0.06-0.42	0.0002*
Above secondary school	130	72 (55.38)	58 (44.62)			Reference
Annual income						
<2 lochs (Rs.)	24	16 (66.67)	08 (33.33)	2.54	1.02-6.34	0.044*
>2 lakhs (Rs.)	141	62 (43.98)	79 (56.02)			Reference
Smoking						
Yes	25	18 (72)	06 (28)	3.60	1.02-6.34	0.0117*
No	140	60 (42.85)	81 (57.15)			Reference
Alcohol consumption						
Yes	16	10 (62.5)	06 (37.5)	1.98	0.68-5.74	0.205
No	149	68 (45.64)	81 (54.36)			Reference

[a]PHQ-9 score (0–9) = Moderate to severe depression.

[b]PHQ-9 score (0–9 = No/Mild depression.

*The p value < 0.05 were considered to be statistically significant.

($p > 0.05$) with T2DM. The proportionate analysis (Chi square test) explains the highest significant association between BMI and depression ($p < 0.05$) and significant association between BMI and T2DM ($p > 0.05$) (Tables 4 and 5). We were also analyzed the prediction of risk of diabetes among the obese subjects with depression (Table 6). The subjects were stratified into PHQ-9 <10 score and ≥10 score respectively. The IR and DM risk (≥ 5) score were not statistically associated with depression.

DISCUSSION

OB and OW are common morbidities with overlapping pathophysiology whose co-existence is associated with adverse

Table 3. Estimated ORs of T2DM among study the study subjects.

Demographics	*N*	T2DM risk(*n* = 82)[a]	No T2DM risk(*n* = 83)[b]	OR	95% CI	*p* value
Body weight						
Obese	106	61 (57.55)	45 (42.45)	2.45	1.27–4.73	0.007*
Over weight	59	21 (35.60)	38 (64.40)			Reference
Hypertension						
Yes	95	58 (61.05)	37 (38.95)	3.00	1.57–5.71	0.0008*
No	70	24 (34.28)	46 (65.72)			Reference
Marital status						
Unmarried	40	14 (35)	26 (65)	0.45	0.21–0.94	0.03*
Married	115	68 (59.13)	57 (40.87)			Reference
Literacy levels						
Below secondary school	35	22 (62.85)	13 (37.15)	1.97	0.91–4.25	0.08
Above secondary school	130	60 (46.15)	70 (53.85)			Reference
Annual income						
< 2 lakhs (Rs.)	24	15 (62.5)	09 (37.5)	1.84	0.75–4.48	0.17
>2 lakhs (Rs.)	141	67 (47.52)	74 (52.48)			Reference
Smoking						
Yes	25	18 (72)	07 (28)	3.05	1.19–7.77	0.01*
No	140	64 (44.28)	76 (55.72)			Reference
Alcohol consumption						
Yes	16	09 (56.25)	07 (43.75)	1.33	0.47–3.78	0.58
No	149	73 (49)	76 (51)			Reference
Knowledge on DM						
Poor	42	35 (83.33)	07 (11.67)	8.08	3.32–19.67	0.0001*
Good	123	47 (38.21)	76 (61.79)			Reference

[a]ADA DM risk score (≥5) = T2DM risk.

[b]ADA DM risk score (≤4) = No T2DM risk.

*The *p* value < 0.05 were considered to be statistically significant.

Table 4. Association between BMI and PHQ-9 score.

BMI kg/m^2	PHQ-9 score				*n* (%)	*p* value
	1–4	5–19	10–14	15–19		
25–29.9 (Over weight)	16	43	00	00	59 (35.75)	
30–34.9 (Obese Grade-I)	00	55	28	01	84 (50.90)	0.001*
35–39.9 (Obese Grade-II)	00	04	15	00	19 (11.50)	
>40 (Obese Grade-III)	00	01	02	00	3 (1.85)	

*The *p* value <0.05 were considered to be statistically significant.

health outcomes. In fact, depression was improved with successful intervention in many OB or OW subjects after reducing their weight (Jantaratnotai *et al*., 2017). Present study demonstrates the risk of depression and type-2 diabetes among OW and obese subjects, especially pronounced in the subjects with unsuccessful efforts to reduce their body weight. Additionally we examined, weather the obesity and depression additively associated with risk of diabetes.

The mean score of HOMA-IR and PHQ-9 score were significantly high in obese subjects (Table 1) and OW, OB, hypertension, and alcohol consumption were not risk factors for depression in our study subjects (Table 2). The large number 103 (62.43%) of subjects has mild risk of depression and 46 (27.97%) had moderate depression (Supplementary Table S3). The mean PHQ-9 scale was found to be 7.55 ± 2.45 in males and 7.79 ± 2.57 were observed in females (Supplementary Table S1). The similar results were observed in (Cui *et al*., 2018; Rathee, 2017; Stunkard *et al*., 2003). The number of subjects with PHQ-9 score (depression severity score) <10 was observed in 44 (37.28%) males and 18 females (38.30%). The depression severity score ≥10 was observed 74 (62.72) in females and 29 (61.70) in males, which indicates the high risk of depression in females. The subjects with <10 PHQ-9 score have the mean BMI of 29.9 ± 2.7 and ≥10 had 33.90 ± 2.88 BMI, respectively. These results suggest, the likely hood of depression was more common in OB individuals (Supplementary Table S2). Similarly, being OW (OR: 1.39. 95% CI: 1.03–1.87) is a noticeable risk factor for depression (Smarr *et al*., 2011). The chi-square analysis shown in Table 4 has significant association between BMI and depression score (*p* =

Table 5. Association between BMI and DM risk score.

BMI kg/m²	DM risk score		*n* (%)	*p* value
	≤4	≥5		
25–29.9	59	00	59 (35.75)	0.001*
(Over weight)				
30–34.9 (Obese Grade-I)	60	24	84 (50.90)	
35–39.9 (Obese Grade-II)	15	04	19 (11.50)	
≥ 40 (Obese Grade-III)	02	01	03 (01.85)	

*The *p* value <0.05 were considered to be statistically significant.

Table 6. Predicting the risk of diabetes among obese subjects with depression.

Parameter	Number of obesity subjects (*n* = 106)		*p* value
	PHQ-9 ≥ 10 (*n* = 46) (%)	PHQ-9 < 10 (*n* = 60) (%)	
HOMA-IR			
≥2.5	11 (23.90)	15 (25)	0.89
<2.5	35 (70.10)	45 (75)	
DM risk score			
≥5	27 (58.70)	32 (53.33)	0.58
≤4	19 (41.30)	28 (46.67)	

*The *p* value <0.05 were considered to be statistically significant.

Table S2. Comparison of variables among the subjects with PHQ-9 Score <10 and ≥ 10.

Characteristics	PHQ-9 Score ≤ 9 (*n* = 118)	PHQ-9 Score ≥ 10 (*n* = 47)	*p* value
Male	44 (37.28)	18 (38.30)	
Female	74 (62.72)	29 (61.70)	0.903
Age (years)	37 ± 9.3	35 ± 12	0.25
BMI (kg/m²)	29.9 ± 2.7	33.90 ± 2.88	0.0001
Hight (cm)	160.4 ± 6.2	160.40 ± 6.29	1.00
Weight (kg)	76.9 ± 8.2	87.18 ± 8.30	0.0001
SBP (mm of Hg)	131 ± 11.5	138 ± 13	0.0009
DBP (mm of Hg)	83.5 ± 6.2	87 ± 7.5	0.0024
FPG (mg/dl)	86.8 ± 10.4	93.70 ± 10.63	0.0010
HOMA-IR	1.7 ± 0.7	2.11 ± 0.74	0.0002
TC (mg/dl)	199.78 ± 23.66	199.65 ± 22.7	0.974
HDL (mg/dl)	36.67 ± 10	35.70 ± 9.2	0.566
LDL (mg/dl)	100.67 ± 17.2	110.15 ± 24.6	0.0056
TG (mg/dl)	161.92 ± 32.8	181.07 ± 44.5	0.0027
VLDL (mg/dl)	32.38 ± 6.6	36.21 ± 8.9	0.0001

Table S3. Severity of depression and DM risk among the study subjects.

Likelihood of depression*	Male (*n* = 62) %	Female (*n* = 103)%	Total (*n* = 165)%
No risk	05 (33.95)	10 (09.70)	15 (09.11)
Mild risk	40 (64.51)	63 (61.17)	103 (62.40)
Moderate risk	17 (27.41)	29 (28.16)	46 (27.88)
Severe risk	0 (0)	01 (00.97)	01 (00.60)
Likelihood of diabetes*			
<4	21 (33.87)	45 (43.69)	66 (40.00)
≥4	10 (16.13)	24 (23.30)	34 (20.60)
≥5	31 (50.00)	34 (33.01)	65 (39.40)

*PHQ Score (0–4) = No risk; (5–9) = Moderate risk; (10–14) moderate risk, (>15) = Severe risk (16) (Spitzer *et al*., 1999).

*DM risk score (<4) = no risk; DM risk score (=4) = high risk for undiagnosed/pre-diabetes; DM risk score (≥5) high risk for undiagnosed diabetes (17) (Bang *et al*., 2009).

Table S4. Association between HOMA-IR versus PHQ-9 score.

HOMA-IR	PHQ-9 Score				*n* (%)	*p* value
	1–4	5–9	10–14	15–19		
<1	1	6	0	0	07 (04.24)	0.31
1–1.9	12	59	21	1	93 (56.36)	
2–2.9	3	30	17	0	50 (30.30)	
>2.9	0	7	8	0	15 (9.10)	

The *p* value < 0.05 were considered to be statistically significant.

Table S5. Association between HOMA-IR versus DM risk score.

HOMA-IR	DM risk score		*n* (%)	*p* value
	≥4	≥5		
<1	07	00	07 (04.24)	0.35
1–1.9	78	15	93 (56.36)	
2–2.9	38	12	50 (30.30)	
>2.9	13	02	15 (09.10)	

The *p* value < 0.05 were considered to be statistically significant.

Table S6. Association between PHQ-9 score versus DM risk score.

PHQ-9 score	DM risk score		*n* (%)	*p* value
	<5	≥5		
1–4	18	00	16 (09.70)	0.048*
5–9	87	16	103 (62.43)	
10–14	32	13	45 (27.27)	
15–19	01	00	01 (00.60)	

The *p* value < 0.05 were considered to be statistically significant.

0.001). Significant relation ($p = 0.048$) was observed in between PHQ-9 score and DM risk score, and inverse relation with HOMA-IR (Supplementary Tables S6 and S5). The mean FPG value is high 93.70 ± 10.63 among the subjects with ≥10 PHQ-9 score. The similar study conducted in rural China, reported depressive symptoms were negatively associated with metabolic syndrome (MetS) (Yu *et al*., 2017). The BMI verses PHQ-9 and DM risk were statistically significant ($p = 0.0001$) (Tables 4 and 5) among our subjects. Recent research indicates that there is a longitudinal association between obesity and depression reported that a higher BMI tended to cause depression and vice versa (Konttinen *et al*., 2014). The insignificant relation between HOMA-IR and PHQ-9 score ($p = 0.31$) was showed in (Supplementary Table S4), but the mean value of HOMA-IR was high in ≥10 PHQ-9 score group, which indicates IR is likelihood to associated for depression. The mean HOMA-IR values were equivocal in both genders (Supplementary Tables S1 and S2). In Indian adolescents, the IR was amplified gradually from normal weight to obese in both genders (Singh *et al*., 2013). There is an inverse relationship of the female gender with obesity and they were more likely to develop MetS of the atherosclerotic risk in community study (Bradshaw *et al*., 2013).

A strict lifestyle intervention such as regular physical exercise with low carbohydrate and hypo-caloric diet are the cornerstone recommendation to reverse the metabolic complications. Our results have noteworthy implications and may be used for policy formulation as obesity and diabetes has significant health and economic burden. Hence, there is an imperative need to have policies that discourse rising OB and OW prevalence in India.

CONCLUSION

In contrast to our findings, the present study revealed, OW or obesity is jeopardizing to produce pre-diabetic or diabetes, along with sociodemographic risk factors. The gender difference was not significantly associated with depression among the study participants. Therefore, interventions for strengthening the health system through appropriate physical exercise and well-balanced diet and education, would help to reverse the normal BMI but also, overcome depression levels too. Practicing and imbibing such regimen in our daily life style could play crucial role in overcoming metabolic syndrome and their associated complications.

Future perspectives

After end of the trial (CTRI/2020/02/023329), we will further assess the progress of depression, diabetes risk, and vitals parameters.

ACKNOWLEDGMENT

The authors are highly thankful to Endo-life specialty hospital team for providing extensive help and support to acquire the specific data of screened subjects. The authors also extend their appreciation to chairman of Endo-life hospital, Guntur.

AUTHOR CONTRIBUTIONS

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; agreed to submit to the current journal; gave final approval of the version to be published; and agree to be accountable for all aspects of the work. All the authors are eligible to be an author as per the international committee of medical journal editors (ICMJE) requirements/guidelines.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

FUNDING

Self funded study.

COMPLIANCE WITH ETHICAL STANDARDS

The study procedure was approved by the Institutional Ethics Committee, Dated:27.02.2020 (IEC/19/Nov/155/65) of Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Chennai, affiliated Endo-life Specialty Hospital, Guntur, in accordance with the Declaration of Helsinki (Trial registration number: CTRI/2020/02/023329 Dated: 14.02.2020). Informed consent was obtained from all subjects.

PUBLISHER'S NOTE

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How to cite this article:
Pelluri R, Srikanth K, Chimakurthy J, Nagasubramanian V. Assessment of risk of depression and diabetes among overweight and obese subjects with unsuccessful efforts to reduce body weight: Observation from clinical trial participants of weight loss intervention. J Appl Pharm Sci, 2021; 11(06):111–117.