

# Chapter – 6

# RESULTS

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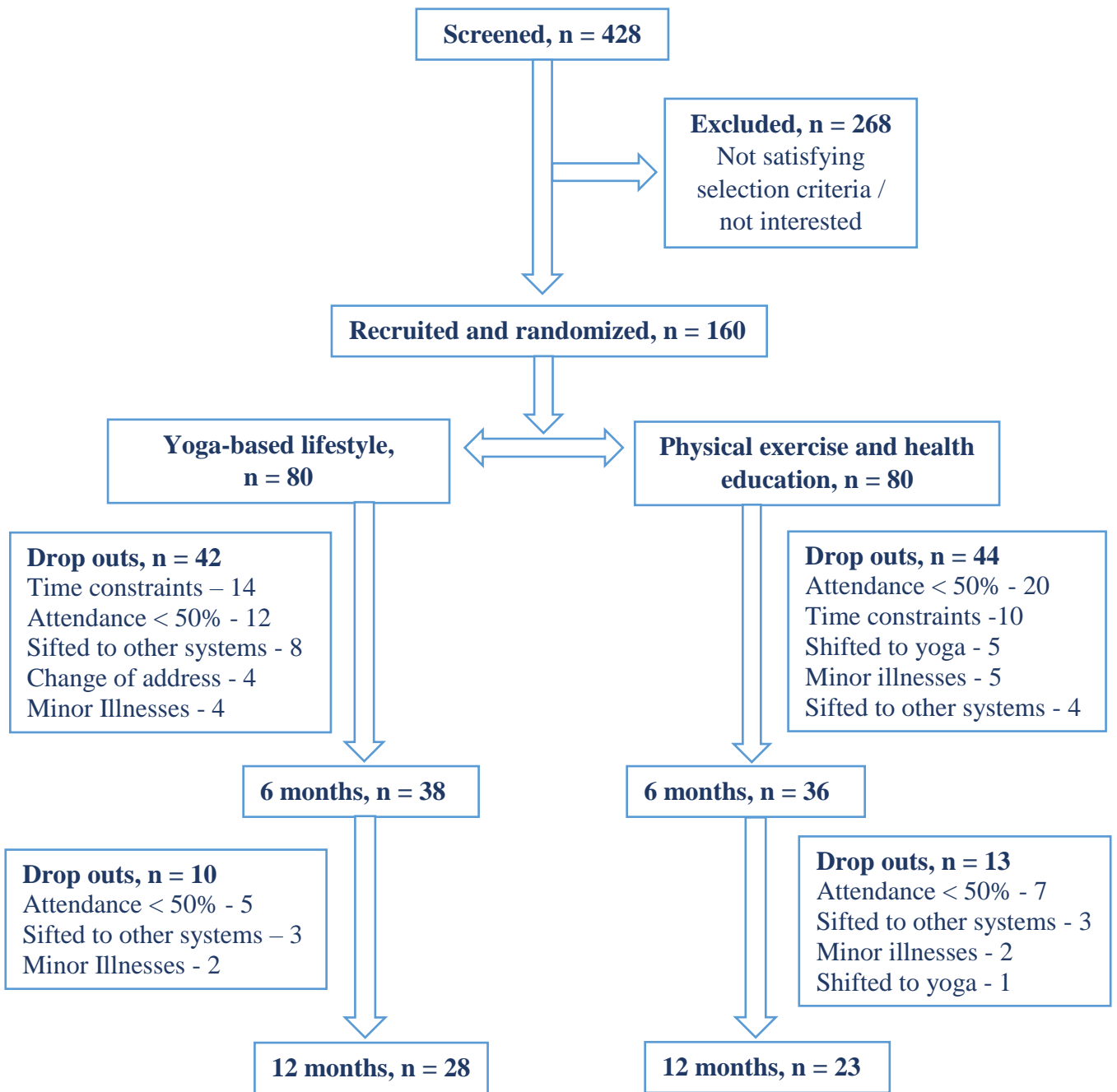
## 6 RESULTS

Out of 428 screened, 160 subjects satisfying study selection criteria were randomized into two groups (80 in YBL group and 80 in PHE group). Thirty eight participants in the YBL group and thirty six participants in the PHE group completed the 6 months follow-up. At the end of 1 year, 51 subjects (28 in YBL group and 23 in PHE group) completed the study. *Figure 1* provides the profile of the study and includes the reasons for the drop out. It is important to note that COVID-19 pandemic started when the first follow-up (6 months after start of the intervention) of the participants was ongoing and continued till the completion of the trial. We anticipate it to be a major factor to affect the adherence of the participants to the study (*see figure 1*).

### 6.1 DEMOGRAPHIC DATA

The demographic variables assessed for the study were age, gender, socioeconomic class, habit of smoking, habit of tobacco chewing, habit of alcohol consumption, metabolic equivalent, duration of type 2 diabetes mellitus, family history type 2 diabetes mellitus, mode of treatment, comorbidities, and history of surgery in the past. There were no differences in the demographic variables between YBL group and PHE group at baseline (*see Table 3*). Similarly there was no any significant difference in demographic variables between the completers and drop-outs in the study (*see table 4*)

**Figure 2: Trial profile**



**Table 3: Demographic data; YBL vs. PHE**

SN	Variable	YBL Group (n = 80)	PHE Group (n = 80)	p value
1	Age (Mean±SD)	53.74±9.25	52.94±8.73	0.57 <sup>a</sup>
2	Gender (n)			0.44 <sup>b</sup>
	a) Male	43	41	
	b) Female	37	39	
2	Socioeconomic Class (n)			0.86 <sup>b</sup>
	a) Upper	13	14	
	b) Upper Middle	8	11	
	c) Lower Middle	14	12	
	d) Upper Lower	30	32	
	e) Lower	15	11	
4	Habits			
	a) Smoking (n)	23	26	0.61 <sup>b</sup>
	b) Tobacco Chewing (n)	22	18	0.46 <sup>b</sup>
	c) Alcohol Consumption (n)	14	12	0.67 <sup>b</sup>
	d) MET (Mean±SD)	70.82±26.78	68.11±21.56	0.48 <sup>a</sup>
5	Duration of T2DM (Mean±SD)	6.23±5.79	6.69±4.24	0.56 <sup>a</sup>
6	Family History of T2DM (n)	44	45	0.50 <sup>b</sup>
7	Comorbidities (n)			
	a) Disk Prolapse	2	2	1.00 <sup>b</sup>
	b) Back Pain	8	12	0.34 <sup>b</sup>
	c) Hypertension	28	23	0.40 <sup>b</sup>
	d) Dyslipidaemia	11	14	0.51 <sup>b</sup>
8	History of Surgery in the past (n)	15	13	0.68 <sup>b</sup>
9	Mode of Treatment (n)			0.41 <sup>b</sup>
	a) Oral Medication	56	63	
	b) Insulin	14	11	

<sup>a</sup>Independent t test, <sup>b</sup>Chi square test, <sup>c</sup>Kuppuswami socioeconomic scale 2020

Abbreviations: MET: Metabolic Equivalents; T2DM: Type 2 Diabetes Mellitus SD; Standard Deviation

**Table 4: Demographic Data; Completers vs. Drop-outs**

SN	Variable	Completers (n = 51)	Drop-outs (n = 109)	p value
1	Age (Mean±SD)	53.22±9.35	53.39±8.83	0.91 <sup>a</sup>
2	Gender (n)			0.67 <sup>b</sup>
	c) Male	28	56	
	d) Female	23	53	
3	Socioeconomic Class <sup>c</sup> (n)			0.62 <sup>b</sup>
	f) Upper	8	19	
	g) Upper Middle	8	11	
	h) Lower Middle	9	17	
	i) Upper Lower	16	48	
	j) Lower	10	16	
4	Habits			
	e) Smoking (n)	15	34	0.82 <sup>b</sup>
	f) Tobacco Chewing (n)	14	26	0.62 <sup>b</sup>
	g) Alcohol Consumption (n)	8	18	0.89 <sup>b</sup>
	h) MET (Mean±SD)	68.35±25.63	68.65±26.19	0.94 <sup>a</sup>
5	Duration of T2DM (Mean±SD)	6.82±4.59	6.63±4.62	0.81 <sup>a</sup>
6	Family History of T2DM (n)	28	61	0.90 <sup>b</sup>
7	Comorbidities (n)			
	e) Disk Prolapse	2	4	0.93 <sup>b</sup>
	f) Back Pain	6	12	0.88 <sup>b</sup>
	g) Hypertension	16	34	0.98 <sup>b</sup>
	h) Dyslipidaemia	7	14	0.87 <sup>b</sup>
8	History of Surgery in the past (n)	10	17	0.53 <sup>b</sup>
9	Mode of Treatment (n)			
	c) Oral Medication	37	76	0.71 <sup>b</sup>
	d) Insulin	8	17	0.98 <sup>b</sup>

<sup>a</sup>Independent t test, <sup>b</sup>Chi square test, <sup>c</sup>Kuppuswami socioeconomic scale 2020

Abbreviations: MET: Metabolic Equivalents; T2DM: Type 2 Diabetes Mellitus SD; Standard Deviation,

## 6.2 PER PROTOCOL ANALYSIS

*Table 5: Per protocol analysis results showing between-group differences in study variables*

SN	Variables	Group	Baseline			6 Months			1 year		
			Mean±SD	F value	P <sup>a</sup> value	Mean±SD	F value	p <sup>a</sup> value	Mean±SD	F value	p <sup>a</sup> value
1	HbA1C (%)	YBL	8.10±1.50	0.70	0.40	7.34±1.17	5.95	0.01*	6.60±0.75	22.08	<0.001*
		PHE	8.52±2.08	(1,49)		8.40±1.90	(1,49)		8.15±1.55	(1,49)	
2	FBS (mg %)	YBL	142.54±46.01	2.08	0.15	128.86±36.28	4.54	0.03*	119.36±25.46	8.83	0.005*
		PHE	163.61±58.37	(1,49)		157.70±59.47	(1,49)		151.22±49.35	(1,49)	
3	PPBS (mg %)	YBL	202.89±62.48	2.06	0.15	186.50±63.35	2.91	0.09	170.93±48.38	9.29	0.01*
		PHE	234.43±93.47	(1,49)		210.74±87.60	(1,49)		210.00±48.97	(1,49)	
4	BMI (Kg/m <sup>2</sup> )	YBL	26.63±3.31	0.313	0.57	26.25±3.05	0.06	0.79	25.27±3.10	0.24	0.62
		PHE	26.06±4.01	(1,49)		25.98±4.07	(1,49)		25.78±4.31	(1,49)	
5	Waist-Hip Ratio	YBL	0.960±0.049	0.655	0.42	0.942±0.067	0.53	0.46	0.929±0.06	0.51	0.48
		PHE	0.949±0.045	(1,49)		0.929±0.063	(1,49)		0.916±0.06	(1,49)	
6	Medication Score	YBL	2.33±1.96	0.741	0.39	1.95±2.04	0.14	0.52	1.75±1.75	0.61	0.48
		PHE	1.90±1.55	(1,49)		1.75±1.59	(1,49)		2.13±1.68	(1,49)	
7	Systolic BP (mm Hg)	YBL	128.64±14.67	(1,49)	2.29	124.25±16.53	(1,49)	0.95	120.82±11.32	(1,49)	0.12
		PHE	123.87±17.50	1.123		123.96±16.96	0.004		125.96±12.05	2.45	
8	Diastolic BP (mm Hg)	YBL	82.43±10.13	(1,49)	0.08	80.07±8.91	(1,49)	0.97	78.50±5.87	(1,49)	0.26
		PHE	77.57±9.08	3.19		80.17±9.31	0.002		80.48±6.56	1.29	
9	DASS Depression	YBL	4.57±4.45	0.01	0.92	3.46±4.16	0.11	0.74	2.00±1.82	5.45	0.02*
		PHE	4.70±4.57	(1,49)		3.78±2.15	(1,49)		3.39±2.42	(1,49)	
10	DASS Anxiety	YBL	3.32±4.56	0.11	0.73	2.61±4.42	0.03	0.85	2.04±2.67	0.14	0.71
		PHE	2.91±3.96	(1,49)		2.39±3.99	(1,49)		2.30±2.40	(1,49)	
11	DASS Stress	YBL	6.50±6.58	0.390	0.53	2.58±0.33	19.16	0.01*	3.96±4.38	0.15	0.69
		PHE	5.43±5.36	(1,49)		3.04±0.42	(1,49)		4.43±4.11	(1,49)	

*Abbreviations:* FBS: fasting blood sugar; PPBS: Postprandial blood sugar; DASS: Depression Anxiety Stress Scale -42; BMI: body Mass Index; YBL: Yoga Based Lifestyle;

PHE: Physical Education and Health Education Programme

<sup>a</sup> Repeated Measures ANOVA with Bonferroni's Correction

\*p < 0.05

**Table 6: Per protocol analysis results showing within-group changes in study variables**

SN	Variables	Group	Baseline (1) Mean±SD	6 months (2) Mean±SD	1 year (3) Mean±SD	P <sup>a</sup> value 1 vs. 2	P <sup>a</sup> value 1 vs. 3	F value
1	HbA1C (%)	YBL	8.10±1.50	7.34±1.17	6.60±0.75	0.01*	<0.001*	27.66 (2,48)
		PHE	8.52±2.08	8.40±1.90	8.15±1.55	1.00	0.55	1.89 (2,48)
2	FBS (mg %)	YBL	142.54±46.01	128.86±36.28	119.36±25.46	0.25	0.01*	4.68 (2,48)
		PHE	163.61±58.37	157.70±59.47	151.22±49.35	1.00	0.43	1.17 (2,48)
3	PPBS (mg %)	YBL	202.89±62.48	186.50±63.35	170.93±48.38	0.82	0.06	2.99 (2,48)
		PHE	234.43±93.47	210.74±87.60	210.00±48.97	0.46	0.33	1.39 (2,48)
4	BMI (Kg/m <sup>2</sup> )	YBL	26.63±3.31	26.25±3.05	25.27±3.10	0.26	<0.001*	25.53 (2,48)
		PHE	26.06±4.01	25.98±4.07	25.78±4.31	1.00	1.00	0.92 (2,48)
5	Waist-Hip Ratio	YBL	0.960±0.049	0.942±0.067	0.929±0.06	0.16	0.15	3.76 (2,48)
		PHE	0.949±0.045	0.929±0.063	0.916±0.06	0.14	0.24	3.80 (2,48)
6	Medication Score	YBL	2.33±1.96	1.95±2.04	1.75±1.75	0.03*	0.003*	6.47 (2,48)
		PHE	1.90±1.55	1.75±1.59	2.13±1.68	1.00	0.62	2.91 (2,48)
7	Systolic BP (mm Hg)	YBL	128.64±14.67	124.25±16.53	120.82±11.32	0.02*	<0.001*	10.50 (2,48)
		PHE	123.87±17.50	123.96±16.96	125.96±12.05	1.00	0.57	1.01 (2,48)
8	Diastolic BP (mm Hg)	YBL	82.43±10.13	80.07±8.91	78.50±5.87	0.11	0.01*	4.81 (2,48)
		PHE	77.57±9.08	80.17±9.31	80.48±6.56	1.10	1.12	2.55 (2,48)
9	DASS Depression	YBL	4.57±4.45	3.46±4.16	2.00±1.82	0.21	0.001*	8.45 (2,48)
		PHE	4.70±4.57	3.78±2.15	3.39±2.42	0.66	0.75	1.50 (2,48)
10	DASS Anxiety	YBL	3.32±4.56	2.61±4.42	2.04±2.67	0.89	0.13	2.64 (2,48)
		PHE	2.91±3.96	2.39±3.99	2.30±2.40	1.00	1.00	0.39 (2,48)
11	DASS Stress	YBL	6.50±6.58	2.58±0.33	3.96±4.38	0.004*	0.026*	5.78 (2,48)
		PHE	5.43±5.36	3.04±0.42	4.43±4.11	0.19	0.99	1.89 (2,48)

*Abbreviations:* FBS: fasting blood sugar; PPBS: Postprandial blood sugar; DASS: Depression Anxiety Stress Scale -42; BMI: body Mass Index; YBL: Yoga Based Lifestyle; PHE: Physical Education and Health Education Programme

<sup>a</sup> Repeated Measures ANOVA with Bonferroni's Correction

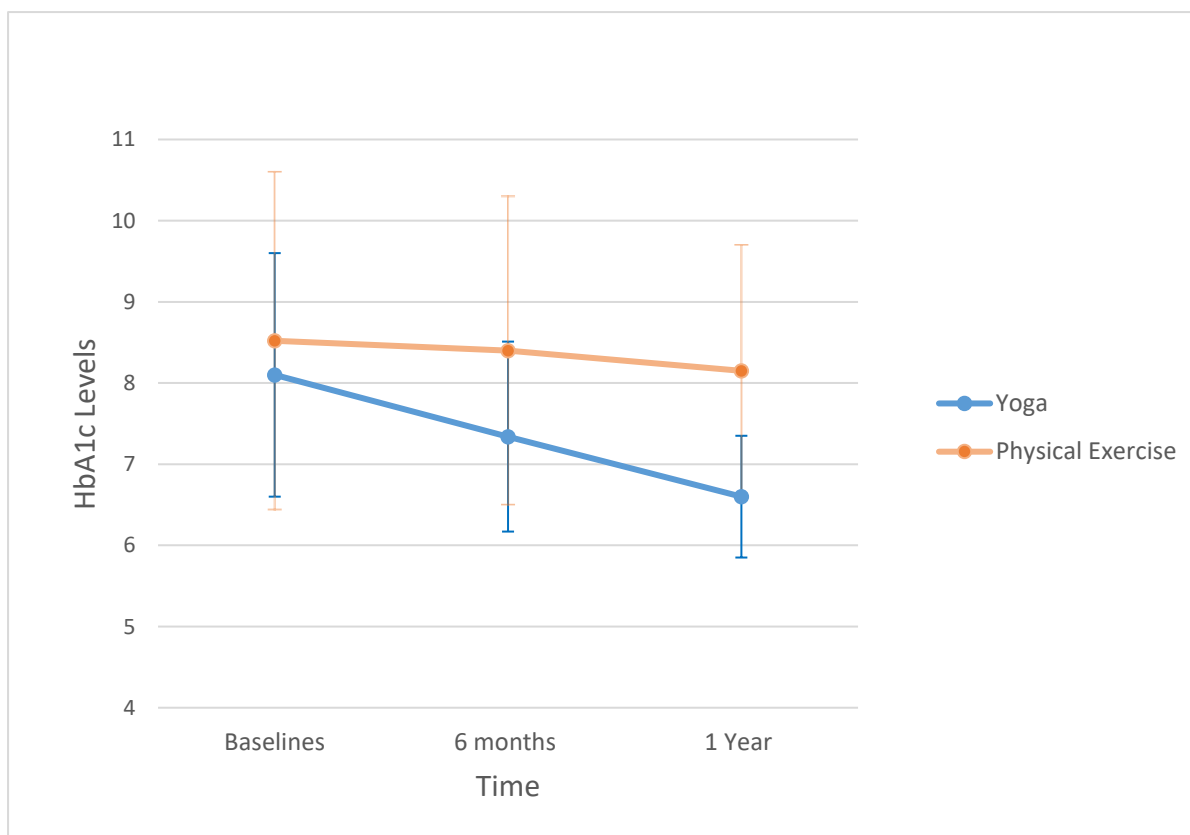
\*p < 0.05

## 6.2.1 Biochemical Variables

### 6.2.1.1 HbA1c level

There was a significant group\*time interaction effect for HbA1c favouring YBL group at 6 months as well as at 1 year. The HbA1c reduced significantly at 6 months ( $p=0.01$ ) as well as at 1 year ( $p<0.001$ ) as compared to PHE group. The significant within-group reduction in HbA1c was found only in YBL group at 6 months ( $p=0.01$ ) as well as 1 year ( $p<0.001$ ). The mean HbA1c reduced by 0.76 in 6 months and by 1.5 in 1 year in YBL group. *Table 5, Table 6 and Figure 2* provide the details of changes in HbA1c.

**Figure 3: Changes in HbA1c levels**

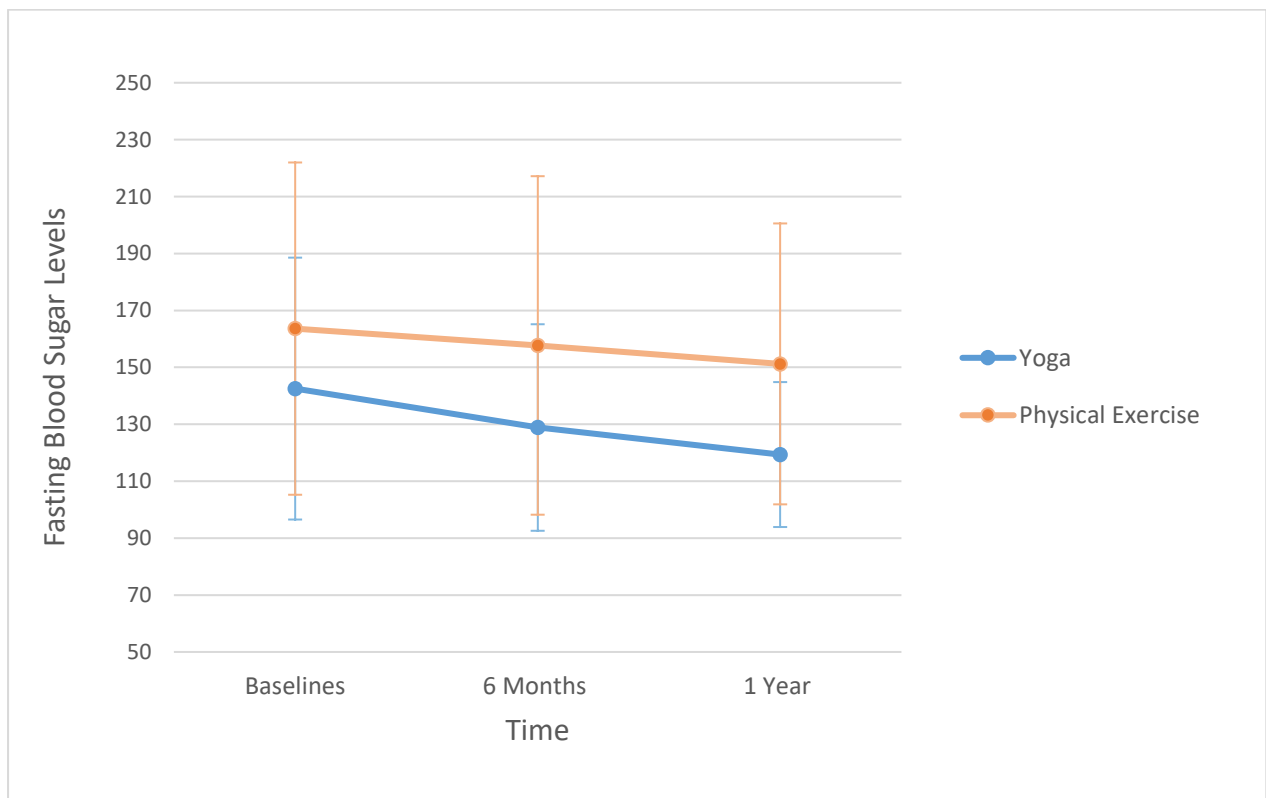




### 6.2.1.2 Fasting Blood Sugar (FBS)

There was a significant group\*time interaction effect for Fasting Blood Sugar level favouring YBL group at 6 months as well as at 1 year. The Fasting Blood Sugar level reduced significantly at 6 months ( $p=0.03$ ) as well as at 1 year ( $p=0.005$ ) as compared to PHE group. The significant within-group reduction in Fasting Blood Sugar level was found only in YBL group at 1 year ( $p<0.01$ ). The mean Fasting Blood Sugar reduced by 13.68 in 6 months and by 23.18 in 1 year in YBL group. *Table 5, Table 6 and Figure 3* provide the details of changes in Fasting Blood Sugar.

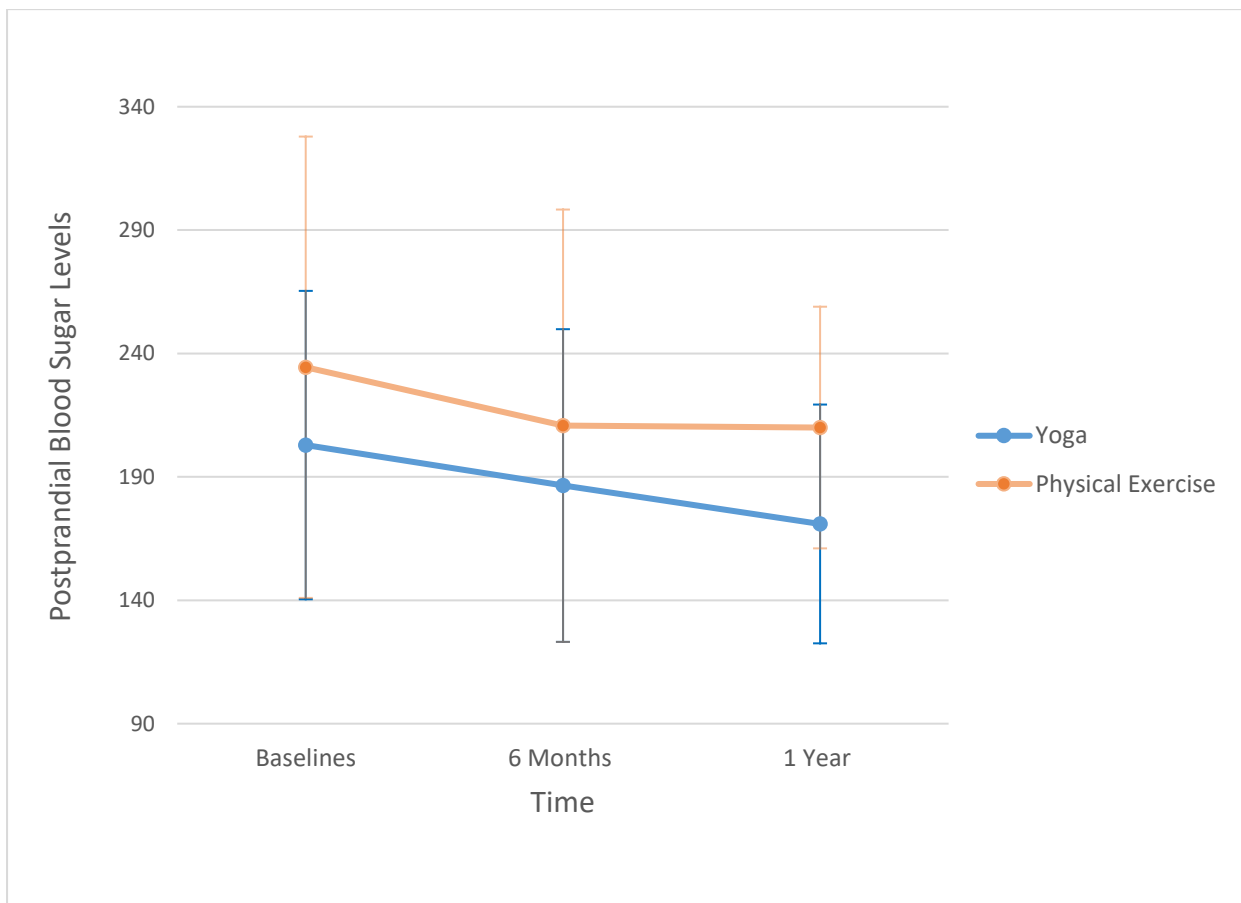
**Figure 4: Changes in FBS levels**



### 6.2.1.3 Postprandial Blood Sugar (PPBS)

There was a significant group\*time interaction effect for Postprandial Blood Sugar level favouring YBL group at 1 year. The Postprandial Blood Sugar reduced significantly at 1 year ( $p=0.01$ ) as compared to PHE group. The mean Postprandial Blood Sugar reduced by 31.96 in 1 year in YBL group. *Table 5, Table 6 and Figure 4* provide the details of changes in Postprandial Blood Sugar level.

**Figure 5: Changes PPBS levels**

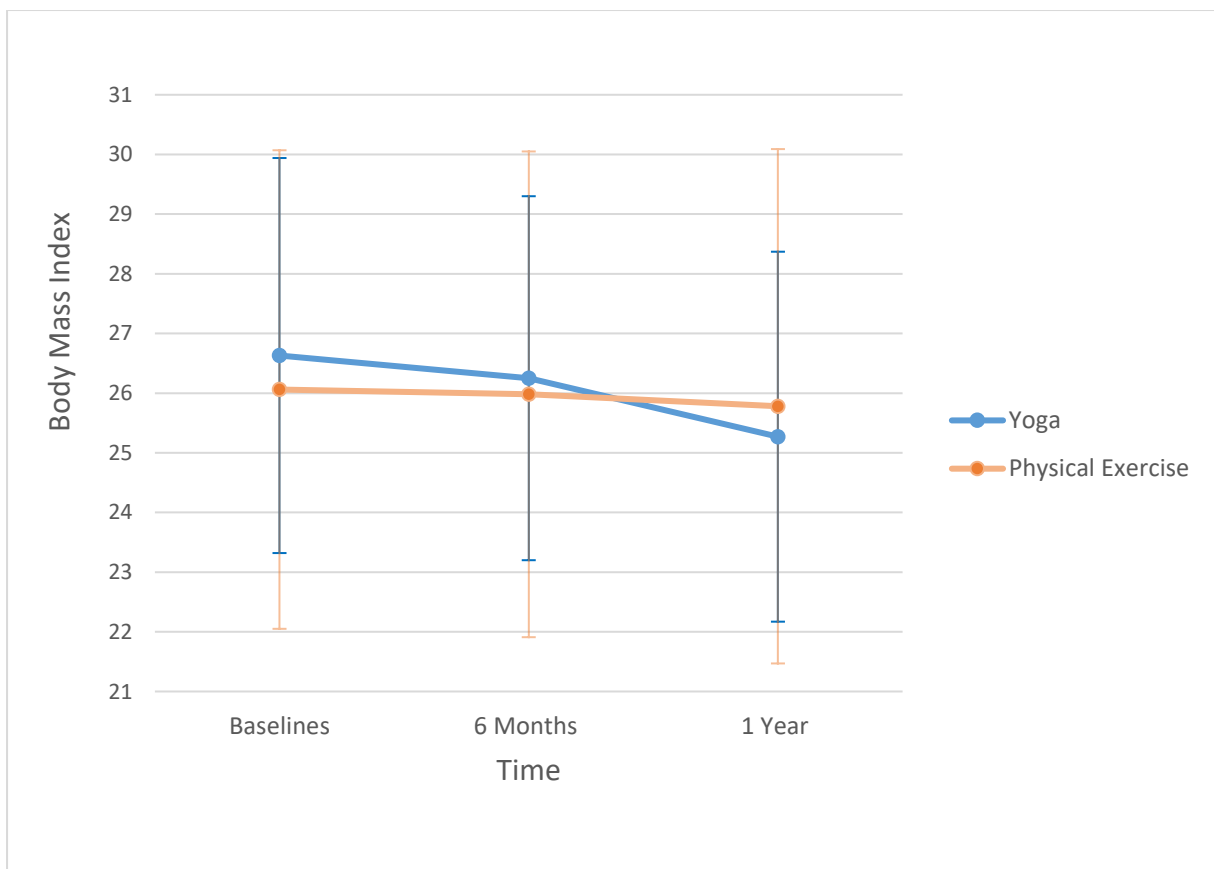


## 6.2.1 Anthropometric Variables

### 6.2.2.1 Body Mass Index (BMI)

There was no significant group\*time interaction effect for Body Mass Index at 6 months as well as at 1 year. Although, there was a trend towards greater reduction in the YBL group compared to PHE group. The significant within-group reduction in Body Mass Index was found only in YBL group at 1 year ( $p < 0.001$ ). The mean Body Mass Index reduced by 1.36 in 1 year in YBL group. *Table 5, Table 6 and Figure 5* provide the details of changes in Body Mass Index.

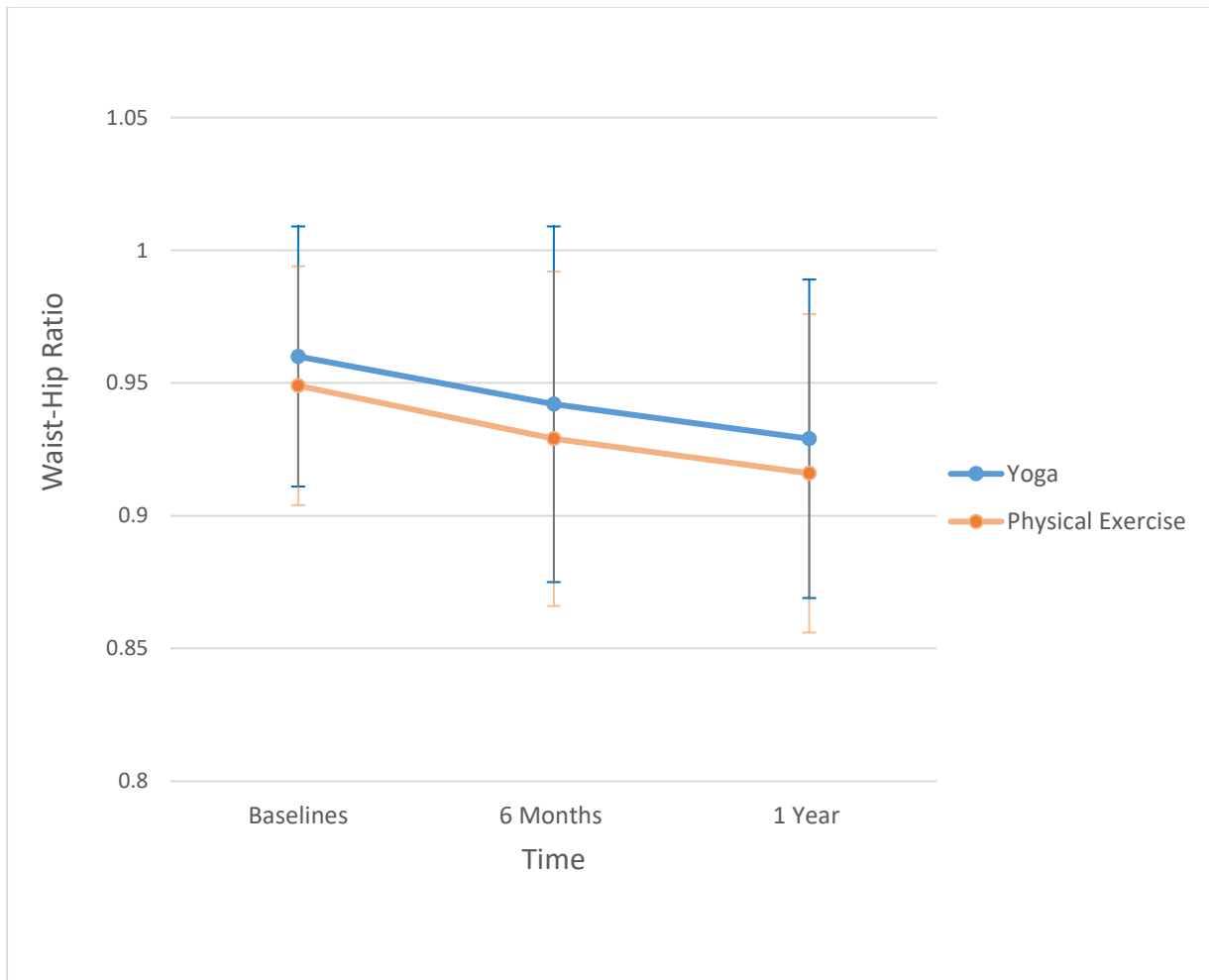
**Figure 6: Changes in Body Mass Index**



### 6.2.2.2 Waist-hip Ratio

There was no significant group\*time interaction effect for Waist-hip Ratio at 6 months as well as at 1 year. We did not find any significant within-group reduction in Waist-hip Ratio in both YBL and PHE group. Although, there was a trend towards reduction in both YBL group and PHE group. *Table 5, Table 6 and Figure 6* provide the details of changes in Waist-hip Ratio in both YBL group and PHE group.

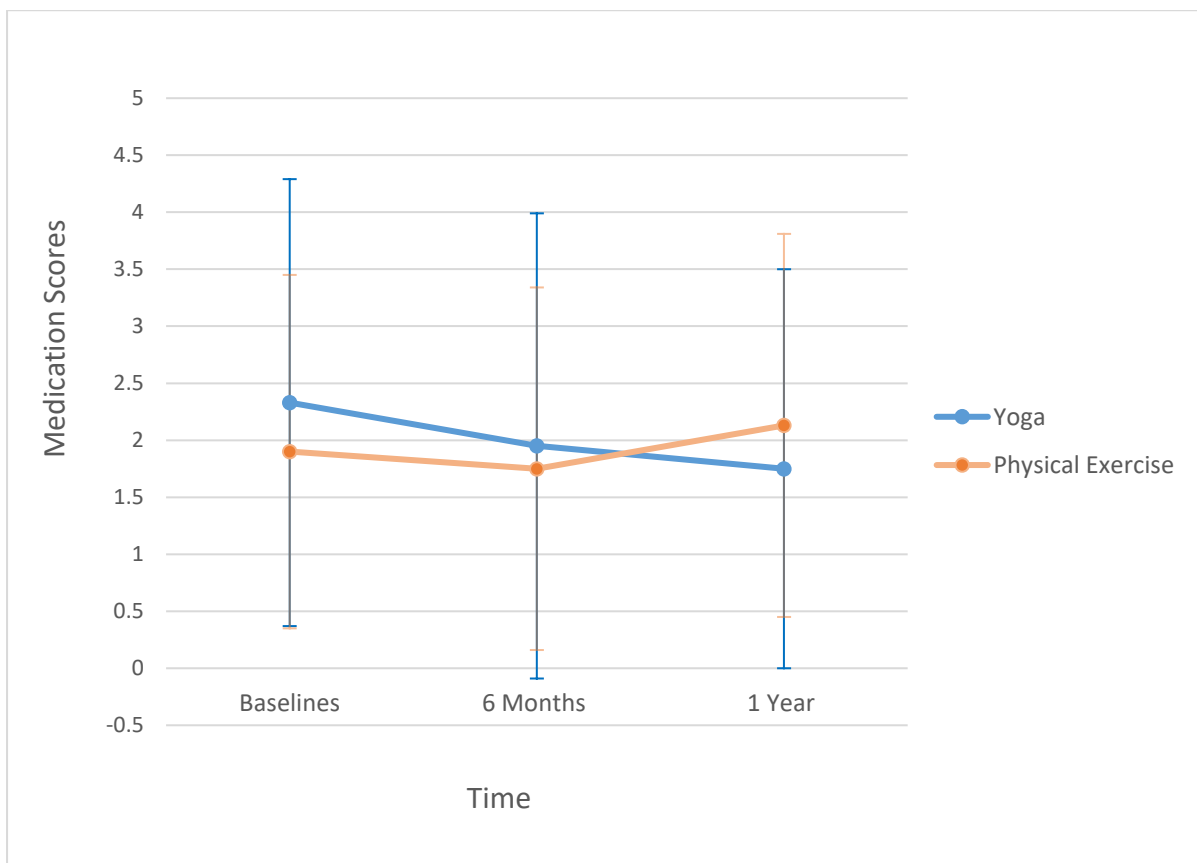
**Figure 7: Changes in Waist-hip Ratio**



### 6.2.3 Medication Score

There was no significant group\*time interaction effect for Medication Score at 6 months as well as at 1 year. Although, there was a trend towards greater reduction in the YBL group compared to PHE group. The significant within-group reduction in Medication Score was found only in YBL group at 6 months ( $p=0.03$ ) as well as at 1 year ( $p=0.003$ ). The mean Medication Score reduced by 0.58 in 1 year in YBL group. *Table 5, Table 6 and Figure 7* provide the details of changes in Medication Score.

**Figure 8: Changes in Medication Score**

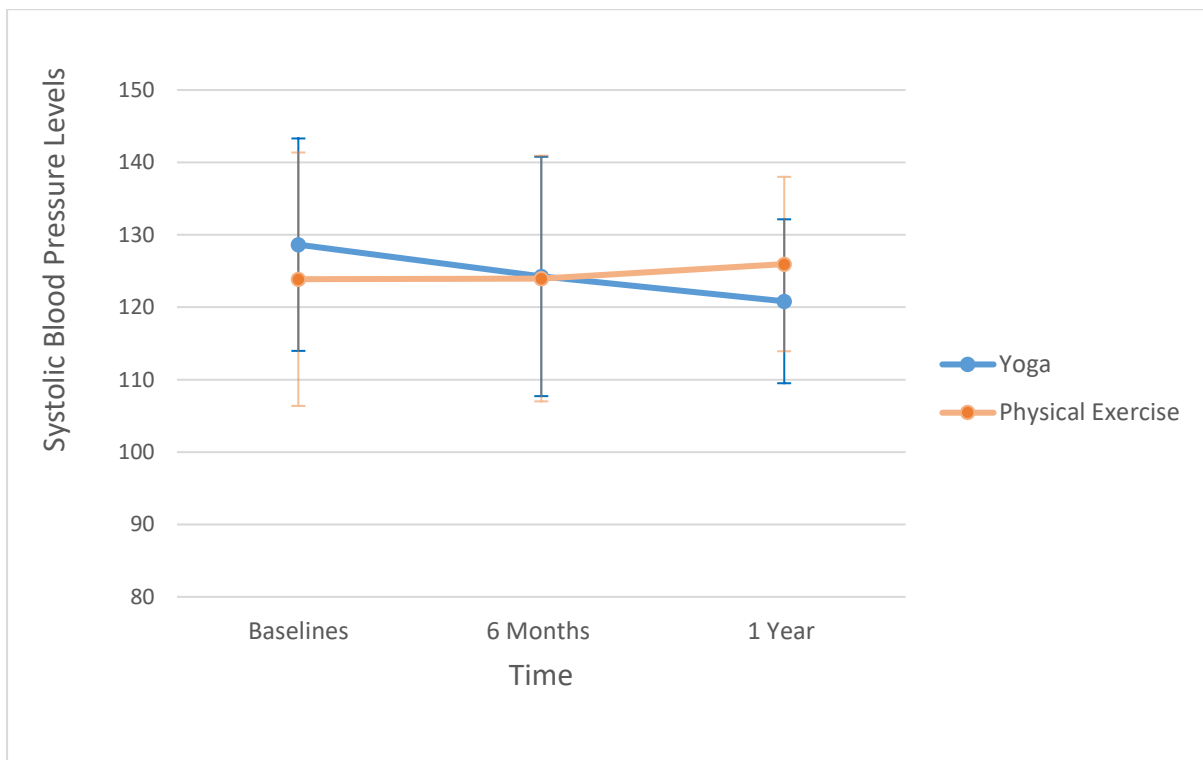


## 6.2.4 Blood Pressure

### 6.3.4.1 Systolic Blood Pressure

There was no significant group\*time interaction effect for Systolic Blood Pressure at 6 months as well as at 1 year. Although, there was a trend towards greater reduction in the YBL group compared to PHE group. The significant within-group reduction in Systolic Blood Pressure was found only in YBL group at 6 months ( $p=0.02$ ) as well as at 1 year ( $p<0.001$ ). The mean Systolic Blood Pressure reduced by 7.72 in 1 year in YBL group. *Table 5, Table 6 and Figure 8* provide the details of changes in systolic Blood Pressure. The separate analysis of the subjects having high blood pressure (Blood Pressure  $>140/90$ ) showed that the Systolic Blood Pressure reduced by 13.42 in YBL group and it reduced by 6.2 in PHE group in 1 year.

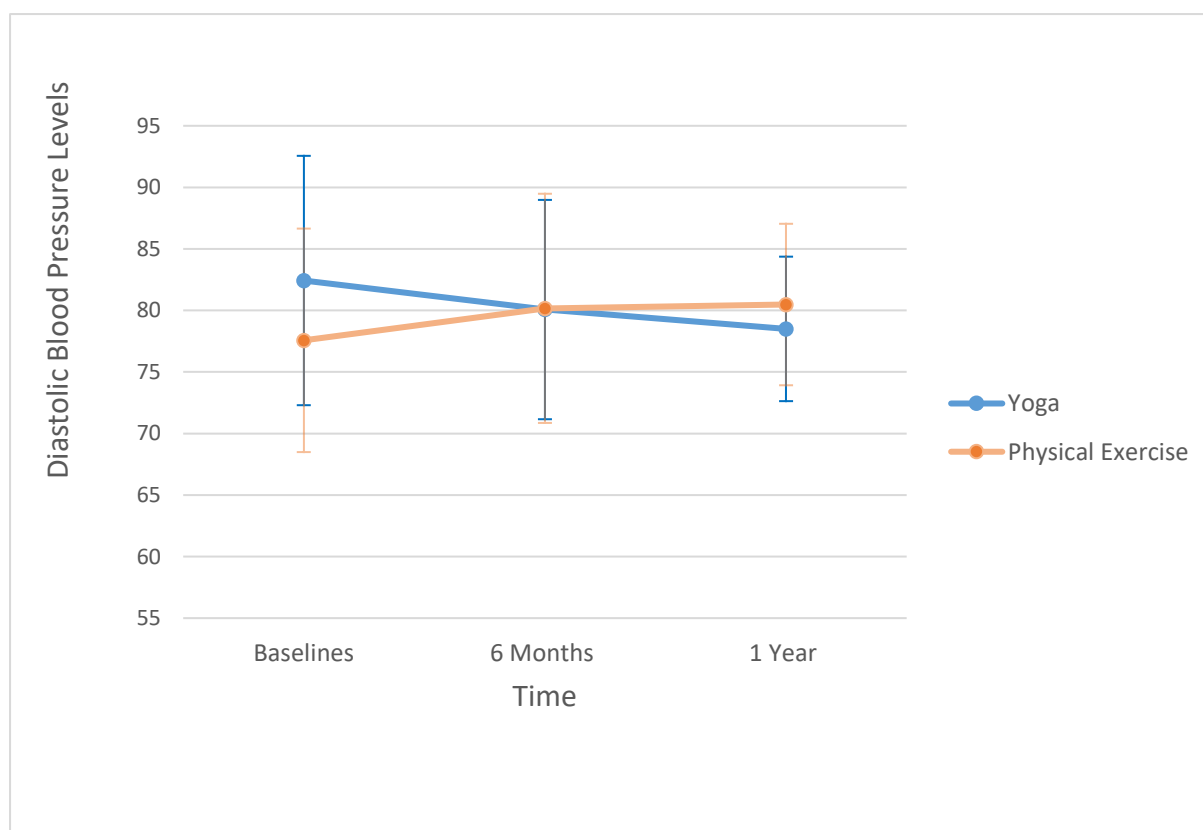
**Figure 9: Changes in Systolic Blood Pressure**



### 6.2.4.2 Diastolic Blood Pressure

There was no significant group\*time interaction effect for Diastolic Blood Pressure at 6 months as well as at 1 year. Although, there was a trend towards greater reduction in the YBL group compared to PHE group. The significant within-group reduction in Diastolic Blood Pressure was found only in YBL group at 1 year ( $p < 0.01$ ). The mean Diastolic Blood Pressure reduced by 9.93 in 1 year in YBL group. *Table 5, Table 6 and Figure 9* provide the details of changes in Diastolic Blood Pressure. The separate analysis of the subjects having high blood pressure (Blood Pressure  $> 140/80$ ) showed that the Diastolic Blood Pressure reduced by 8.43 in YBL group and it reduced by 2.20 in PHE group in 1 year.

**Figure 10: Changes in Diastolic Blood Pressure**

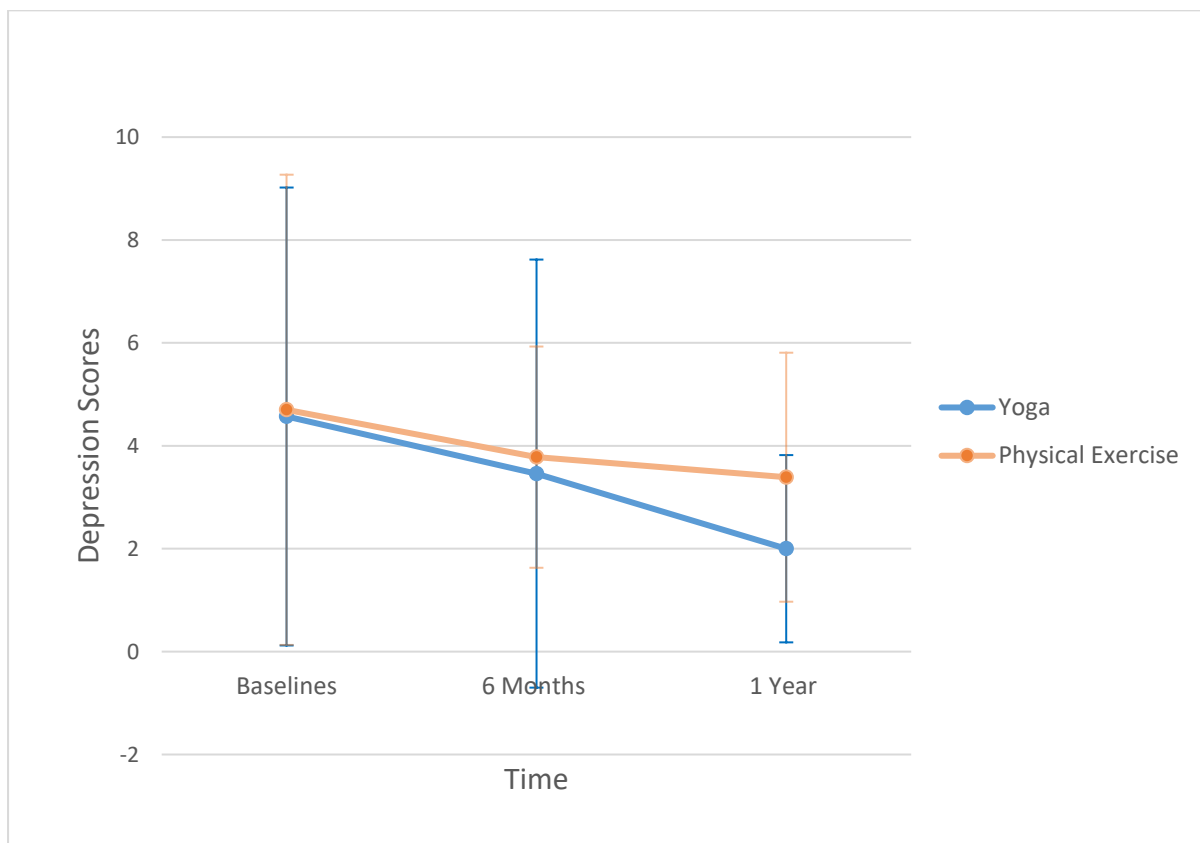


## 6.2.5 Psychological Variables

### 6.2.5.1 Depression

There was a significant group\*time interaction effect for DASS Depression Score favouring YBL group at 1 year. The DASS Depression Score reduced significantly at 1 year as compared to PHE group ( $p=0.02$ ). The significant within-group reduction in DASS Depression Score was found only in YBL group at 1 year ( $p<0.001$ ). The mean DASS Depression Score reduced by 2.57 in 1 year in YBL group. *Table 5, Table 6 and Figure 10* provide the details of changes in DASS Depression Score.

**Figure 11: Changes in DASS Depression Scores**

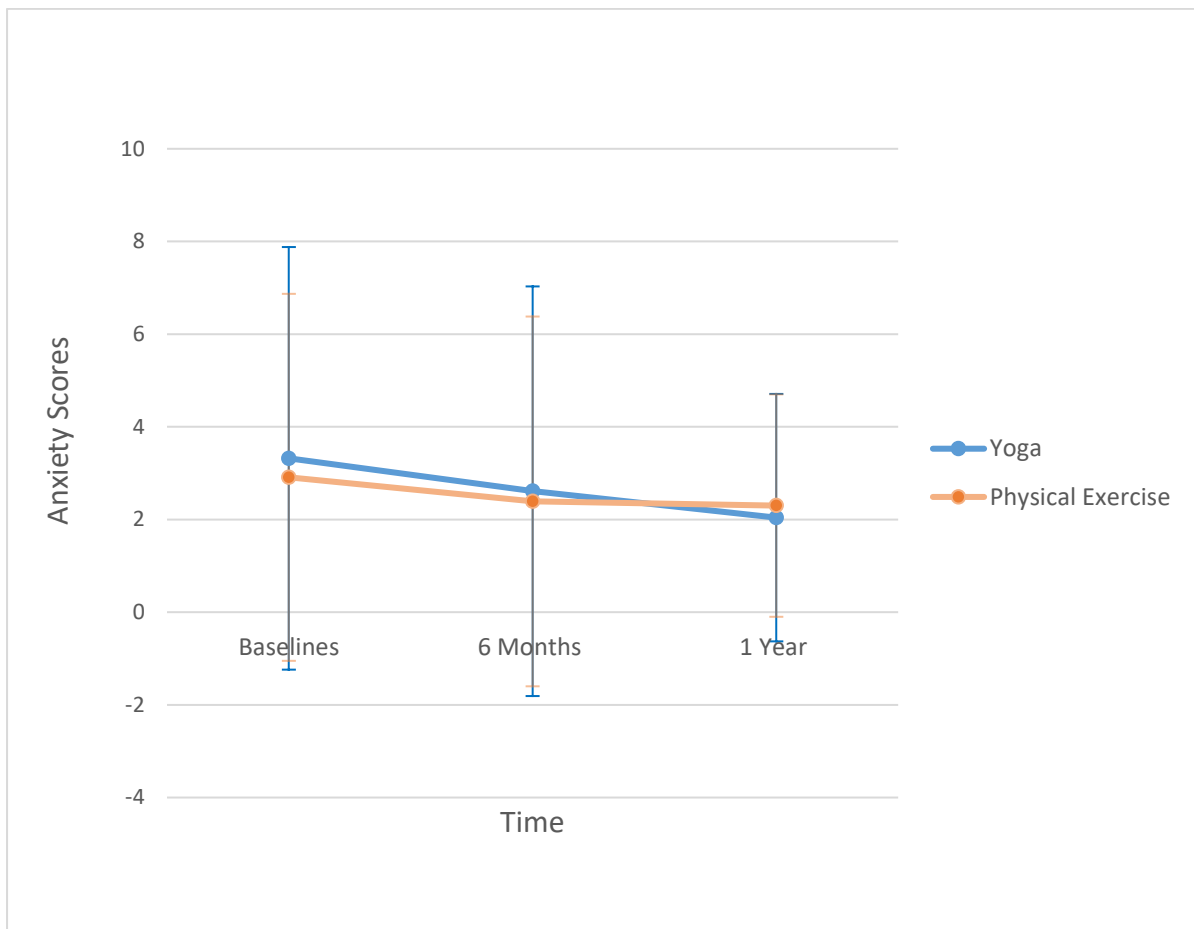




### 6.2.5.2 Anxiety

There was no significant group\*time interaction effect for DASS Anxiety Score at 6 months as well as at 1 year. We did not find any significant within-group reduction in DASS Anxiety Score in both YBL and PHE group. Although, there was a trend towards reduction in both YBL group and PHE group. There was a trend towards greater reduction in the YBL group compared to PHE group. *Table 5, Table 6 and Figure 11* provide the details of changes in DASS Anxiety Score in both YBL group and PHE group.

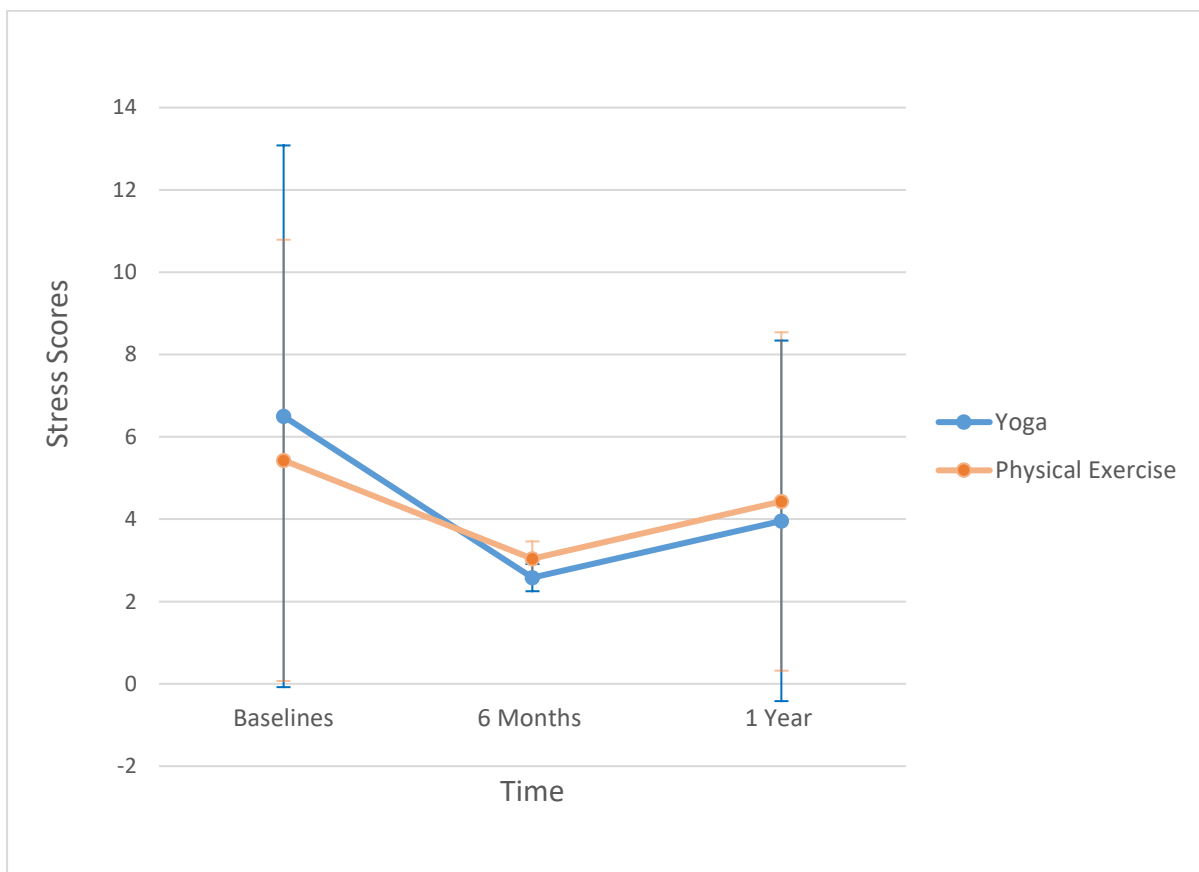
**Figure 12: Changes in DASS Anxiety Scores**



### 6.2.5.3 Stress

There was a significant group\*time interaction effect for DASS Stress Score favouring YBL group at 6 months. The DASS Stress Score reduced significantly at 6 months as compared to PHE group ( $p=0.01$ ). The significant within-group reduction in DASS Stress Score was found only in YBL group at 6 months ( $p=0.004$ ) as well as at 1 year ( $p<0.026$ ). The mean DASS Stress Score reduced by 3.92 in 6 months and by 2.54 in 1 year in YBL group. *Table 5, Table 6 and Figure 12* provide the details of changes in DASS Stress Score.

**Figure 13: Changes in DASS Stress Scores**



## 6.2.6 Thermal Imaging Parameters

### 6.2.6.1 Correlation between HbA1c and Thermal Imaging Variables

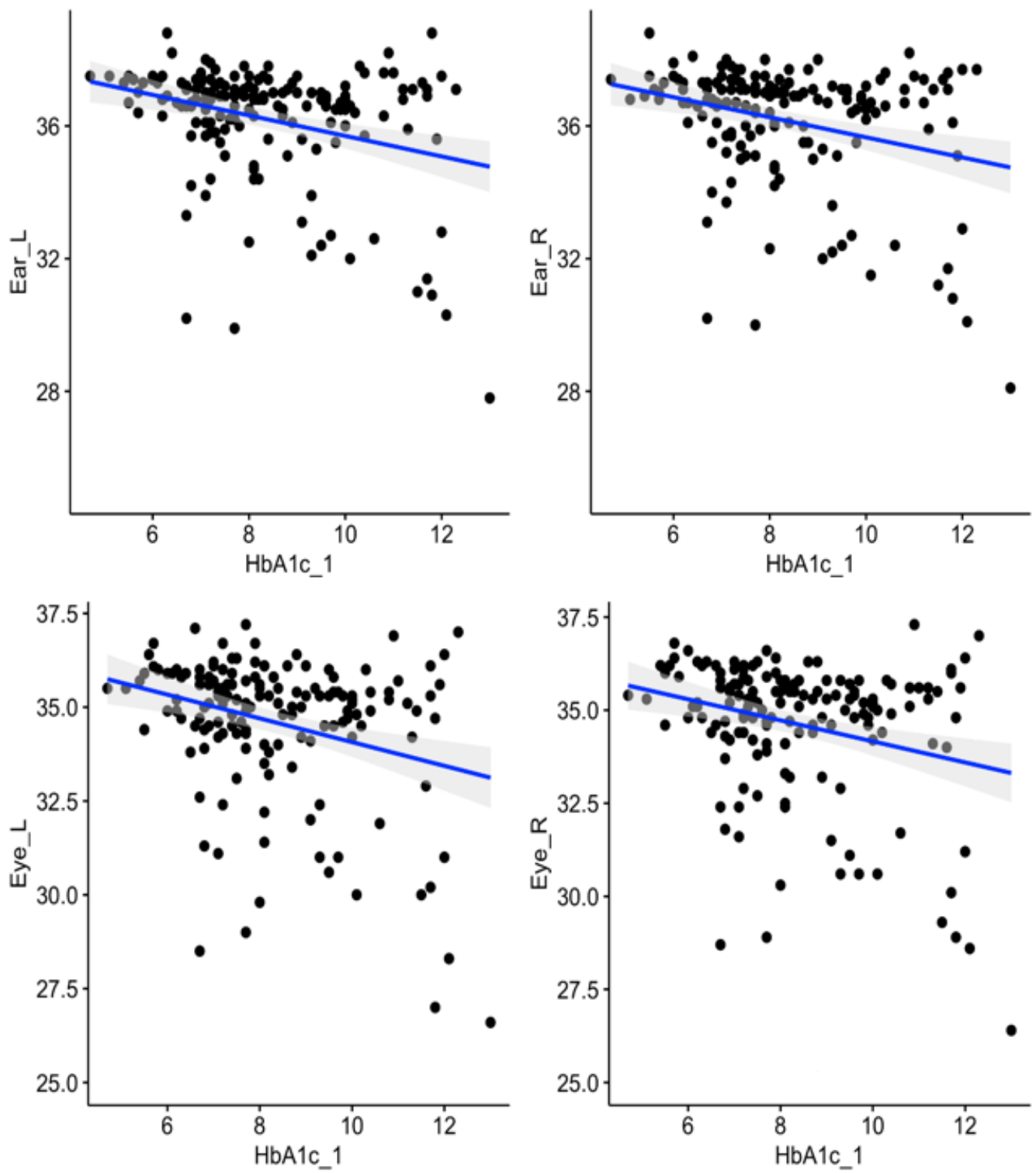
All the 59 thermal imaging variables selected for the study showed negative correlation with HbA1c level. Out of those 59 variables, 29 showed the significant correlation with the HbA1c level. We observed that especially the areas in the face: left ear, right ear, left eye, right eye, centre of eyebrows showed stronger negative correlation with HbA1c. Similarly knees, ankles and shins also shows strong correlation with HbA1c levels (*see Table 7 & Figure 13*).

**Table 7: Thermal imaging variables showing significant correlation with HbA1c at baseline (n=160)**

SN	Thermography Variables	Correlation with HbA1c (r)	P <sup>a</sup> value
1	Dorsum of Right 1 <sup>st</sup> Toe	-0.159	0.045*
2	Dorsum of Right 3 <sup>rd</sup> Toe	-0.156	0.049*
3	Dorsum of Right 5 <sup>th</sup> Toe	-0.186	0.019*
4	Dorsum of Left 1 <sup>st</sup> Toe	-0.156	0.049*
5	Dorsum of Left 5 <sup>th</sup> Toe	-0.169	0.033*
6	Right Knee	-0.254	0.001*
7	Right Ankle	-0.223	0.005*
8	Left Knee	-0.278	<0.001*
9	Left Ankle	-0.252	0.001*
10	Right Shin Average	-0.256	0.001*
11	Left Shin Average	-0.224	0.004*
12	Centre of Eyebrows	-0.250	0.002*
13	Right Eye	-0.269	0.001*
14	Left Eye	-0.316	<0.001*
15	Right Ear	-0.269	0.001*
16	Left Ear	-0.316	<0.001*
17	Right Heel	-0.160	0.044*
18	Plantar of Left 5 <sup>th</sup> Toe	-0.164	0.039*
19	Left Heel	-0.164	0.039*
20	Plantar of Right Foot Average	-0.214	0.007*
21	Plantar of Left Foot Average	-0.237	0.003*
22	Dorsum of Right 1 <sup>st</sup> Finger	-0.164	0.039*
23	Dorsum of Left 1 <sup>st</sup> Finger	-0.161	0.042*
24	Dorsum of Right Hand Average	-0.223	0.005*
25	Dorsum of Left Hand Average	-0.219	0.005*
26	Palmar of Right 1 <sup>st</sup> Finger	-0.159	0.045*
27	Palmar of Left 1 <sup>st</sup> Finger	-0.158	0.047*
28	Palmar of Right Hand Average	-0.231	0.003*
29	Palmar of Left Hand Average	-0.233	0.003*

<sup>a</sup> Pearson's Correlation Coefficient Test, \*p < 0.05

Figure 14: Correlation between individual thermal imaging variables and HbA1c



### 6.2.6.2 Changes on Thermal Imaging Parameters after Intervention

**Table 8: Per protocol analysis results showing significant between-group differences in thermal imaging variables**

SN	Variables	Group	Baseline			6 Months			1 year		
			Mean±SD	F value	P <sup>a</sup> value	Mean±SD	F value	p <sup>a</sup> value	Mean±SD	F value	p <sup>a</sup> value
1	Right Knee	YBL	30.29±1.58	2.97 (1,49)	0.09	31.74±1.57	0.79 (1,49)	0.38	32.58±1.55	8.45 (1,49)	0.005*
		PHE	29.47±1.86			31.34±1.58			31.29±1.28		
2	Right Ankle	YBL	29.89±1.96	1.26 (1,49)	0.27	31.26±1.70	0.04 (1,49)	0.84	32.25±1.42	5.65 (1,49)	0.02*
		PHE	29.19±1.49			31.16±1.81			31.19±1.74		
3	Left Knee	YBL	30.15±1.67	2.73 (1,49)	0.11	31.54±1.59	1.30 (1,49)	0.26	32.31±1.65	8.61 (1,49)	0.005*
		PHE	29.31±1.97			31.03±1.97			30.98±1.56		
4	Left Ankle	YBL	29.92±1.89	1.34 (1,49)	0.25	31.47±1.75	0.03 (1,49)	0.85	32.50±1.60	6.21 (1,49)	0.01*
		PHE	29.23±2.40			31.56±1.52			31.40±1.52		
5	Right Shin Average	YBL	31.14±1.75	0.37 (1,49)	0.54	32.83±1.48	0.91 (1,49)	0.34	33.48±1.55	6.73 (1,49)	0.01*
		PHE	30.83±1.90			32.42±1.55			32.36±1.50		
6	Left Shin Average	YBL	31.27±1.66	0.59 (1,49)	0.45	32.61±1.55	0.002 (1,49)	0.96	33.41±1.53	5.14 (1,49)	0.03*
		PHE	30.88±2.01			32.60±1.31			32.50±1.29		
7	Centre of Eyebrows	YBL	33.08±1.65	0.11 (1,49)	0.74	34.66±1.97	1.86 (1,49)	0.18	34.94±1.66	5.90 (1,49)	0.01*
		PHE	33.24±1.75			34.11±1.22			33.89±1.35		
8	Right Eye	YBL	34.87±1.60	0.004 (1,49)	0.95	36.10±1.21	3.14 (1,49)	0.08	36.13±1.40	5.28 (1,49)	0.02*
		PHE	34.84±1.85			35.56±0.89			35.31±1.08		

Abbreviations: YBL: Yoga Based Lifestyle; PHE: Physical Education and Health Education Programme

<sup>a</sup> Repeated Measures ANOVA with Bonferroni's Correction

\*p < 0.05

**Table 9: Per protocol analysis results showing significant within-group changes in thermal imaging variables**

SN	Variables	Group	Baseline (1) Mean±SD	6 months (2) Mean±SD	1 year (3) Mean±SD	P <sup>a</sup> value 1 vs. 2	P <sup>a</sup> value 1 vs. 3	F value
1	Dorsum of Right 1 <sup>st</sup> Toe	YBL	25.94±3.21	28.20±3.13	29.18±2.96	0.005*	<0.001*	11.51 (2,48)
		PHE	25.93±2.92	29.21±4.17	28.50±3.60	<0.001*	0.001*	11.90 (2,48)
2	Dorsum of Right 3 <sup>rd</sup> Toe	YBL	25.65±3.34	27.89±3.05	28.95±2.78	0.004*	<0.001*	12.36 (2,48)
		PHE	24.97±2.79	28.82±4.31	28.49±3.95	<0.001*	<0.001*	13.88 (2,48)
3	Dorsum of Right 5 <sup>th</sup> Toe	YBL	26.09±3.07	28.15±3.13	29.07±2.79	0.007*	<0.001*	10.02 (2,48)
		PHE	26.05±3.51	29.05±3.76	28.65±3.54	<0.001*	0.004*	9.26 (2,48)
4	Dorsum of Left 1 <sup>st</sup> Toe	YBL	26.16±3.41	28.59±3.15	29.62±2.91	0.002*	<0.001*	13.89 (2,48)
		PHE	25.52±2.88	29.16±4.08	28.77±3.75	<0.001*	<0.001*	11.46 (2,48)
5	Dorsum of Left 5 <sup>th</sup> Toe	YBL	25.26±3.23	27.92±3.05	28.76±2.89	<0.001*	<0.001*	14.15 (2,48)
		PHE	24.71±2.58	28.34±3.66	27.96±3.56	<0.001*	<0.001*	15.16 (2,48)
6	Right Knee	YBL	30.29±1.58	31.74±1.57	32.58±1.55	0.001*	<0.001*	18.41 (2,48)
		PHE	29.47±1.86	31.34±1.58	31.29±1.28	<0.001*	0.001*	10.18 (2,48)
7	Right Ankle	YBL	29.89±1.96	31.26±1.70	32.25±1.42	0.019*	<0.001*	17.27 (2,48)
		PHE	29.19±1.49	31.16±1.81	31.19±1.74	0.002*	0.001*	7.24 (2,48)
8	Left Knee	YBL	30.15±1.67	31.54±1.59	32.31±1.65	0.001*	<0.001*	17.51 (2,48)
		PHE	29.31±1.97	31.03±1.97	30.98±1.56	<0.001*	0.001*	8.70 (2,48)
9	Left Ankle	YBL	29.92±1.89	31.47±1.75	32.50±1.60	0.002*	<0.001*	22.15 (2,48)
		PHE	29.23±2.40	31.56±1.52	31.40±1.52	<0.001*	<0.001*	12.49 (2,48)
10	Right Shin Average	YBL	31.14±1.75	32.83±1.48	33.48±1.55	<0.001*	<0.001*	16.65 (2,48)
		PHE	30.83±1.90	32.42±1.55	32.36±1.50	0.001*	0.004*	7.08 (2,48)
11	Left Shin Average	YBL	31.27±1.66	32.61±1.55	33.41±1.53	0.003*	<0.001*	16.26 (2,48)
		PHE	30.88±2.01	32.60±1.31	32.50±1.29	0.001*	0.002*	7.99 (2,48)
12	Centre of Eyebrows	YBL	33.08±1.65	34.66±1.97	34.94±1.66	<0.001*	<0.001*	11.86 (2,48)
		PHE	33.24±1.75	34.11±1.22	33.89±1.35	0.07	0.41	2.97 (2,48)

SN	Variables	Group	Baseline (1) Mean±SD	6 months (2) Mean±SD	1 year (3) Mean±SD	P <sup>a</sup> value 1 vs. 2	P <sup>a</sup> value 1 vs. 3	F value
13	Right Eye	YBL	34.87±1.60	36.10±1.21	36.13±1.40	0.001*	0.002*	8.00 (2,48)
		PHE	34.84±1.85	35.56±0.89	35.31±1.08	0.11	0.68	2.59 (2,48)
14	Left Eye	YBL	34.69±1.90	35.81±1.26	35.91±1.33	0.003*	0.005*	6.18 (2,48)
		PHE	34.97±1.69	35.66±0.83	35.34±1.07	0.19	1.00	2.54 (2,48)
15	Right Heel	YBL	27.28±2.34	28.69±2.77	29.68±2.40	0.51	0.001*	10.55 (2,48)
		PHE	27.24±1.85	29.02±2.74	28.96±2.55	0.21	0.39	3.90 (2,48)
16	Plantar of Left 5 <sup>th</sup> Toe	YBL	25.03±3.20	27.19±2.99	28.24±2.71	0.001*	<0.001*	15.26 (2,48)
		PHE	24.25±2.02	27.67±3.47	27.34±3.40	<0.001*	<0.001*	15.35 (2,48)
17	Left Heel	YBL	27.22±2.34	28.66±2.56	29.56±2.32	0.03*	0.001*	9.93 (2,48)
		PHE	27.04±1.82	28.56±2.64	28.53±2.54	0.04*	0.07	3.14 (2,48)
18	Plantar of Right Foot Average	YBL	28.25±2.18	29.46±2.22	30.51±2.02	0.04*	<0.001*	13.20 (2,48)
		PHE	28.03±1.79	29.88±2.31	29.67±2.26	0.003*	0.02*	6.20 (2,48)
19	Plantar of Left Foot Average	YBL	28.19±2.10	29.46±2.24	30.40±1.98	0.03*	<0.001*	11.56 (2,48)
		PHE	27.77±1.89	29.35±2.36	29.29±2.22	0.017*	0.03*	4.16 (2,48)
20	Dorsum of Right 1 <sup>st</sup> Finger	YBL	31.59±2.94	33.19±2.27	33.63±2.63	0.015*	0.007*	5.06 (2,48)
		PHE	31.52±2.74	32.78±2.45	32.75±2.44	0.12	0.26	2.24 (2,48)
21	Dorsum of Left 1 <sup>st</sup> Finger	YBL	31.41±2.91	32.42±2.40	33.46±2.43	0.03*	0.003*	6.83 (2,48)
		PHE	31.49±2.50	32.80±2.30	32.70±2.09	0.08	0.21	2.67 (2,48)
22	Dorsum of Right Hand Average	YBL	31.69±2.04	33.02±1.93	33.62±2.08	0.017*	0.001*	8.17 (2,48)
		PHE	31.01±1.73	32.87±2.12	32.81±1.97	0.28	0.45	1.43 (2,48)
23	Dorsum of Left Hand Average	YBL	31.52±1.98	32.38±2.38	33.08±2.47	0.30	0.02*	6.57 (2,48)
		PHE	31.83±1.77	32.66±1.94	32.64±1.83	0.45	0.54	1.05 (2,48)
24	Palmar of Right Hand Average	YBL	32.01±3.39	33.36±2.05	33.94±2.20	0.01*	0.001*	8.51 (2,48)
		PHE	32.55±1.78	33.50±1.71	33.36±1.73	0.17	0.39	1.98 (2,48)
25	Palmar of Left Hand Average	YBL	31.96±2.23	33.18±1.88	33.66±2.11	0.016*	0.002*	7.01 (2,48)
		PHE	32.50±1.70	33.65±1.42	33.42±1.50	0.04*	0.24	3.87 (2,48)

Abbreviations: YBL: Yoga Based Lifestyle; PHE: Physical Education and Health Education Programme

<sup>a</sup> Repeated Measures ANOVA with Bonferroni's Correction

\*p < 0.05

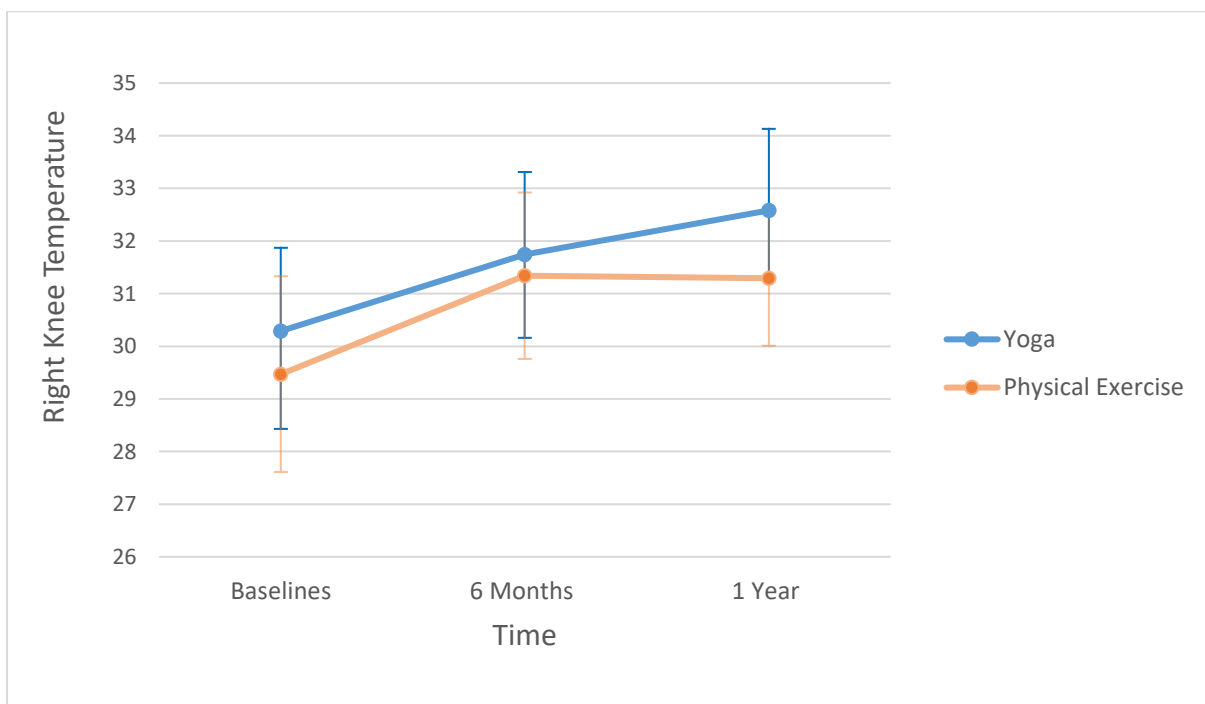
All the 29 thermal imaging variables correlated with HbA1c showed the trend of increase in temperature within both YBL and PHE group. However, 25 variables in YBL group and 14 variables in PHE group showed significant time interaction effects after intervention. *Table 9* provides the details of within-group changes in thermal imaging variables.

Eight thermal imaging variables having stronger correlation with HbA1c (Right Knee, Left Knee, Right Ankle, Left Ankle, Right Shin Average, Left Shin Average, Centre of Eyebrows, Right Eye) showed significant Group\*time interaction effects favouring YBL group (*see Table 8*).

### 1) Right Knee

There was a significant group\*time interaction effect for the temperature of Right Knee favouring YBL group at 1 year. The temperature of Right Knee increased significantly at 1 year as compared to PHE group ( $p=0.005$ ). The mean temperature of Right Knee increased by 2.29 in 1 year in YBL group. *Table 8*, *Table 9* and *Figure 14* provide the details of changes in the temperature of Right Knee.

**Figure 15: Changes in Right Knee Temperature**

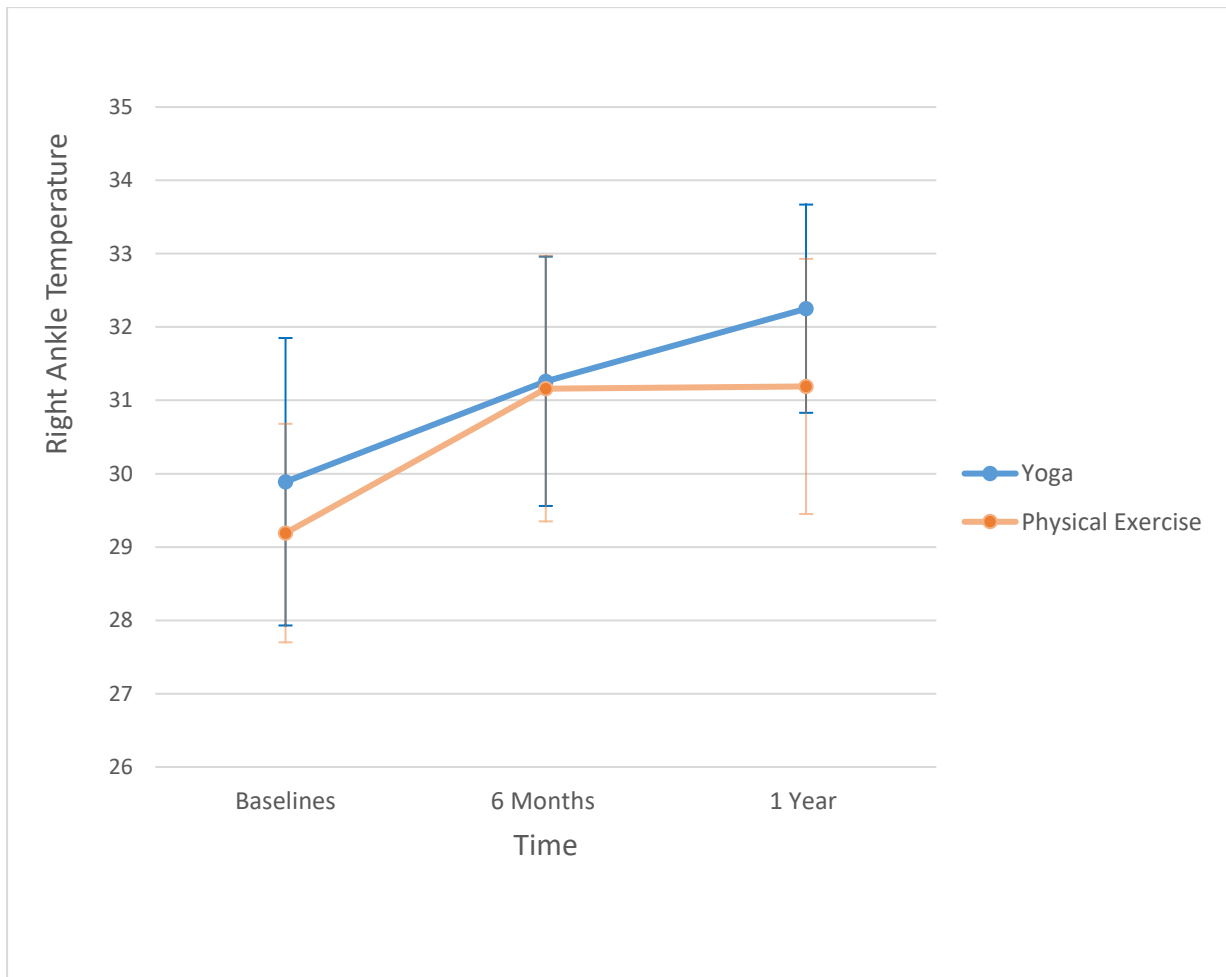




## 2) Right Ankle

There was a significant group\*time interaction effect for the temperature of Right Ankle favouring YBL group at 1 year. The temperature of Right Ankle increased significantly at 1 year as compared to PHE group ( $p=0.02$ ). The mean temperature of Right Ankle increased by 2.36 in 1 year in YBL group. *Table 8, Table 9* and *Figure 15* provide the details of changes in the temperature of Right Knee

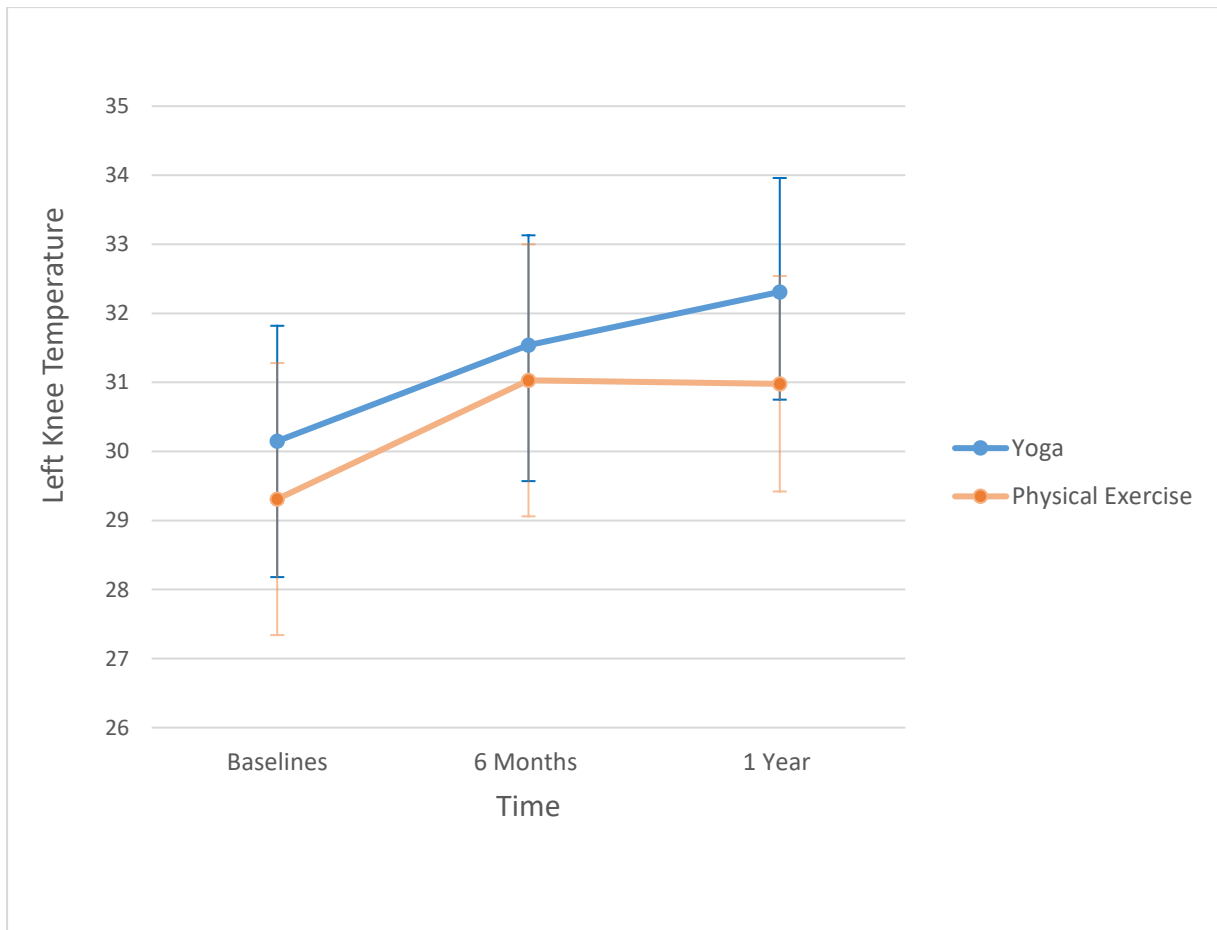
**Figure 16: Changes in Right Ankle Temperature**



### 3) Left Knee

There was a significant group\*time interaction effect for the temperature of Left Knee favouring YBL group at 1 year. The temperature of Left Knee increased significantly at 1 year as compared to PHE group ( $p=0.005$ ). The mean temperature of Left Knee increased by 2.16 in 1 year in YBL group. *Table 8, Table 9 and Figure 16* provide the details of changes in the temperature of Left Knee.

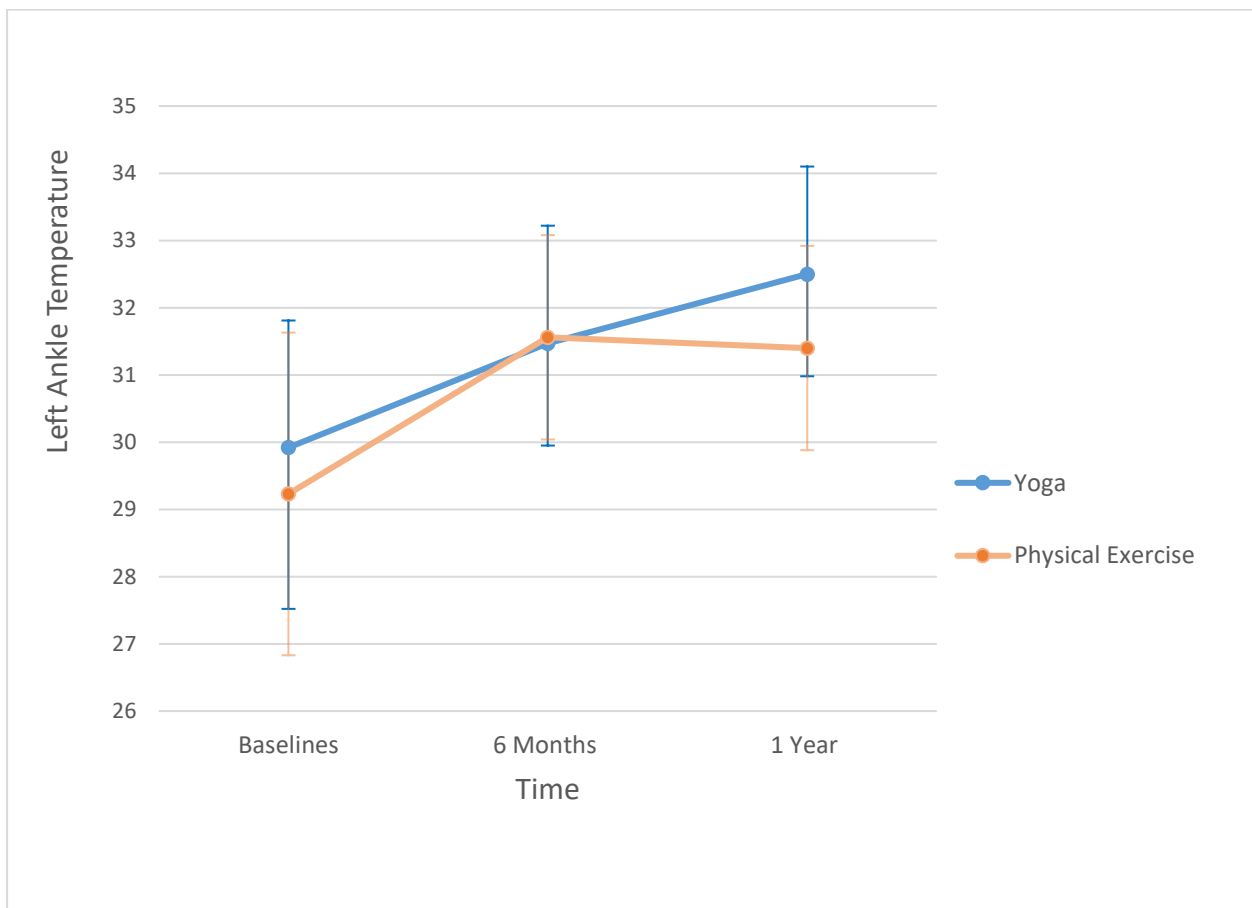
**Figure 17: Changes in Left Knee Temperature**



#### 4) Left Ankle

There was a significant group\*time interaction effect for the temperature of Left Ankle favouring YBL group at 1 year. The temperature of Left Ankle increased significantly at 1 year as compared to PHE group ( $p=0.01$ ). The mean temperature of Left Ankle increased by 2.58 in 1 year in YBL group. *Table 8, Table 9 and Figure 17* provide the details of changes in the temperature of Left Ankle.

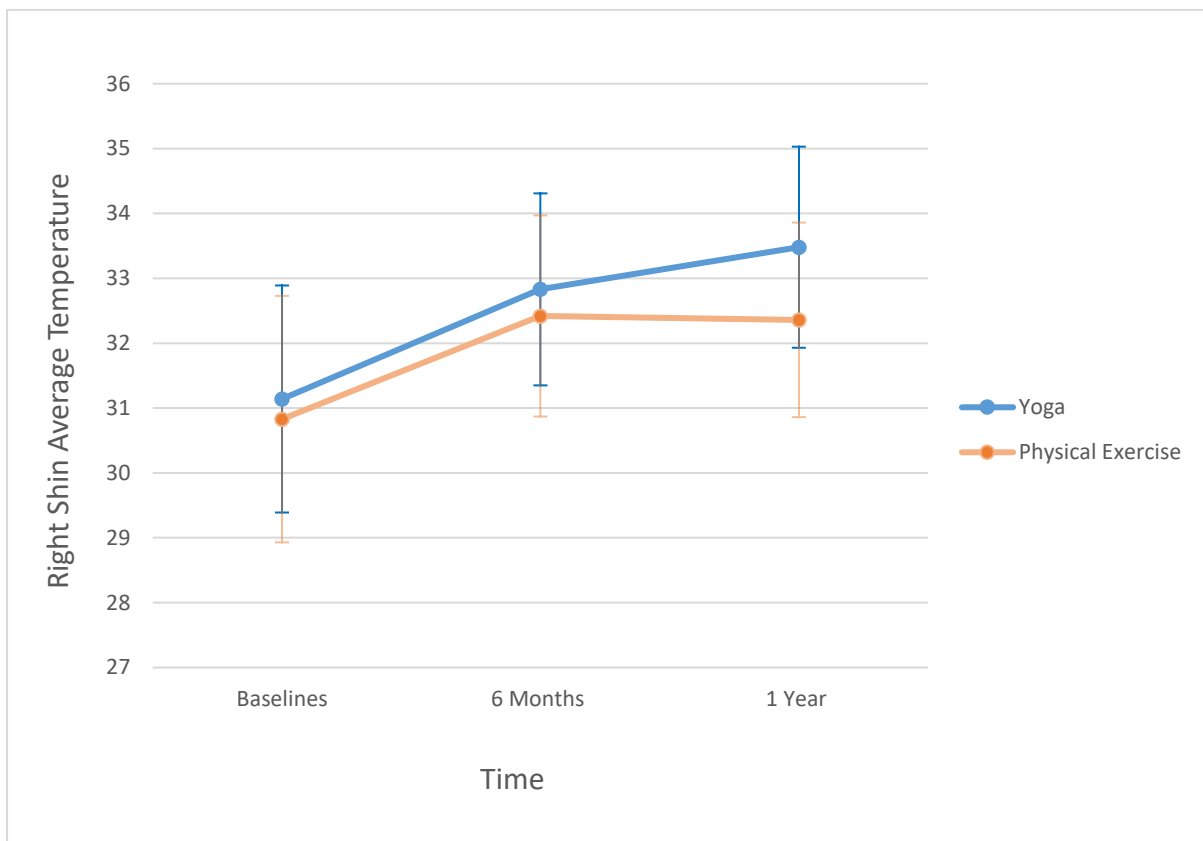
**Figure 18: Changes in Left Ankle Temperature**



### 5) Right Shin Average

There was a significant group\*time interaction effect for the average temperature of Right Shin favouring YBL group at 1 year. The average temperature of Right Shin increased significantly at 1 year as compared to PHE group ( $p=0.01$ ). The average temperature of Right Shin increased by 2.34 in 1 year in YBL group. *Table 8, Table 9 and Figure 18* provide the details of changes in the average temperature of Right Shin.

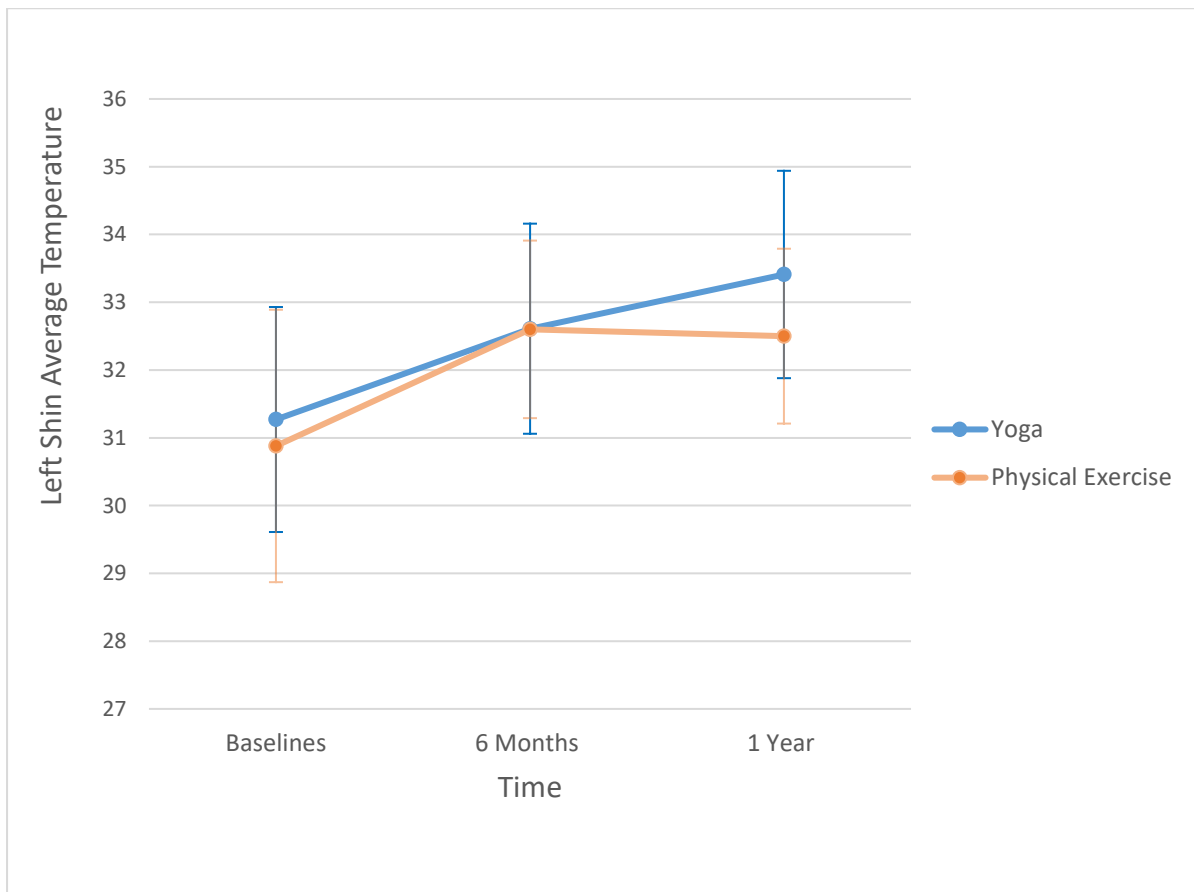
**Figure 19: Changes in Right Shin Temperature**



## 6) Left Shin Average

There was a significant group\*time interaction effect for the average temperature of Left Shin favouring YBL group at 1 year. The average temperature of Left Shin increased significantly at 1 year as compared to PHE group ( $p=0.03$ ). The average temperature of Left Shin increased by 2.04 in 1 year in YBL group. *Table 8, Table 9 and Figure 19* provide the details of changes in the average temperature of Left Shin.

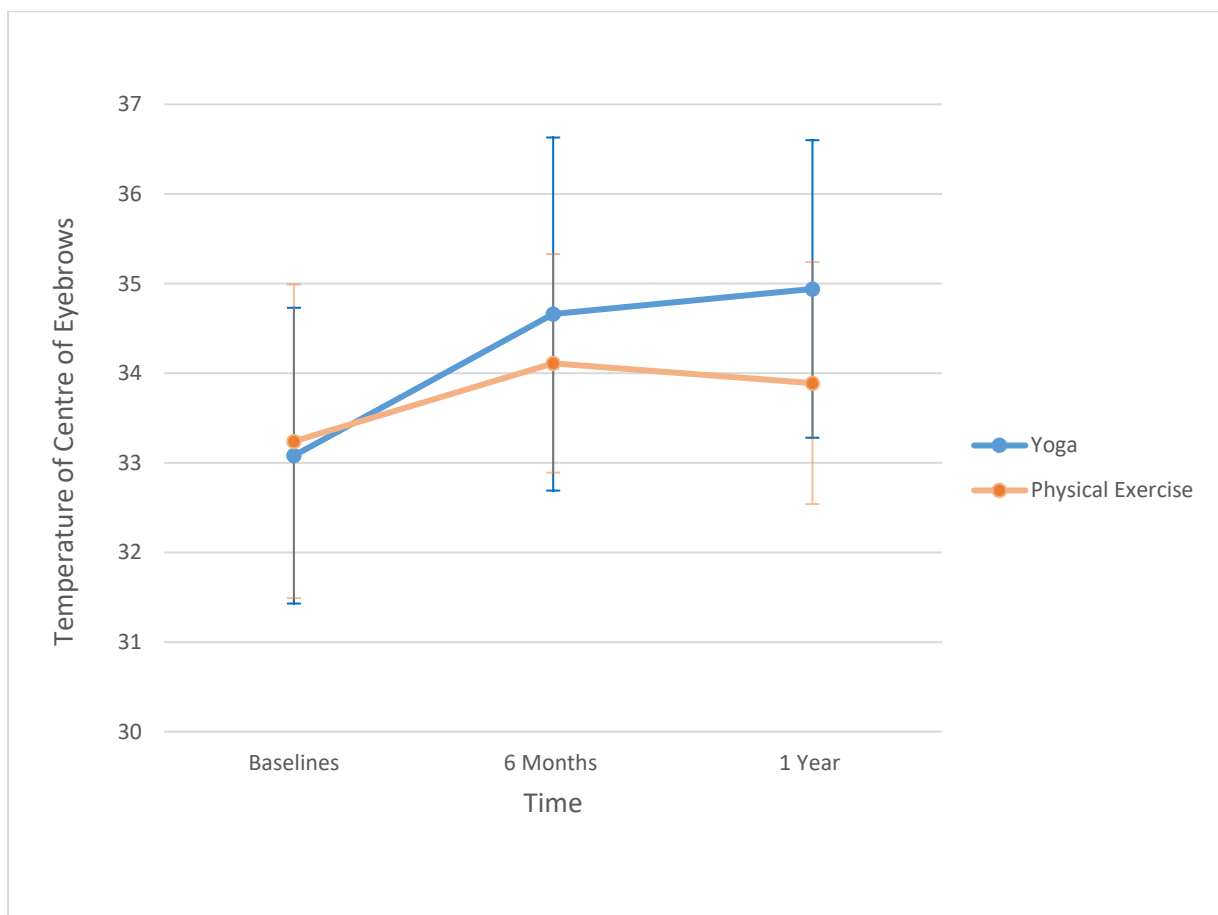
**Figure 20: Changes in Left Shin Temperature**



## 7) Centre of Eyebrows

There was a significant group\*time interaction effect for the temperature of Centre of Eyebrows favouring YBL group at 1 year. The temperature of Centre of Eyebrows increased significantly at 1 year as compared to PHE group ( $p=0.01$ ). The mean temperature of Centre of Eyebrows increased by 1.96 in 1 year in YBL group. *Table 8, Table 9* and *Figure 20* provide the details of changes in the temperature of Centre of Eyebrows.

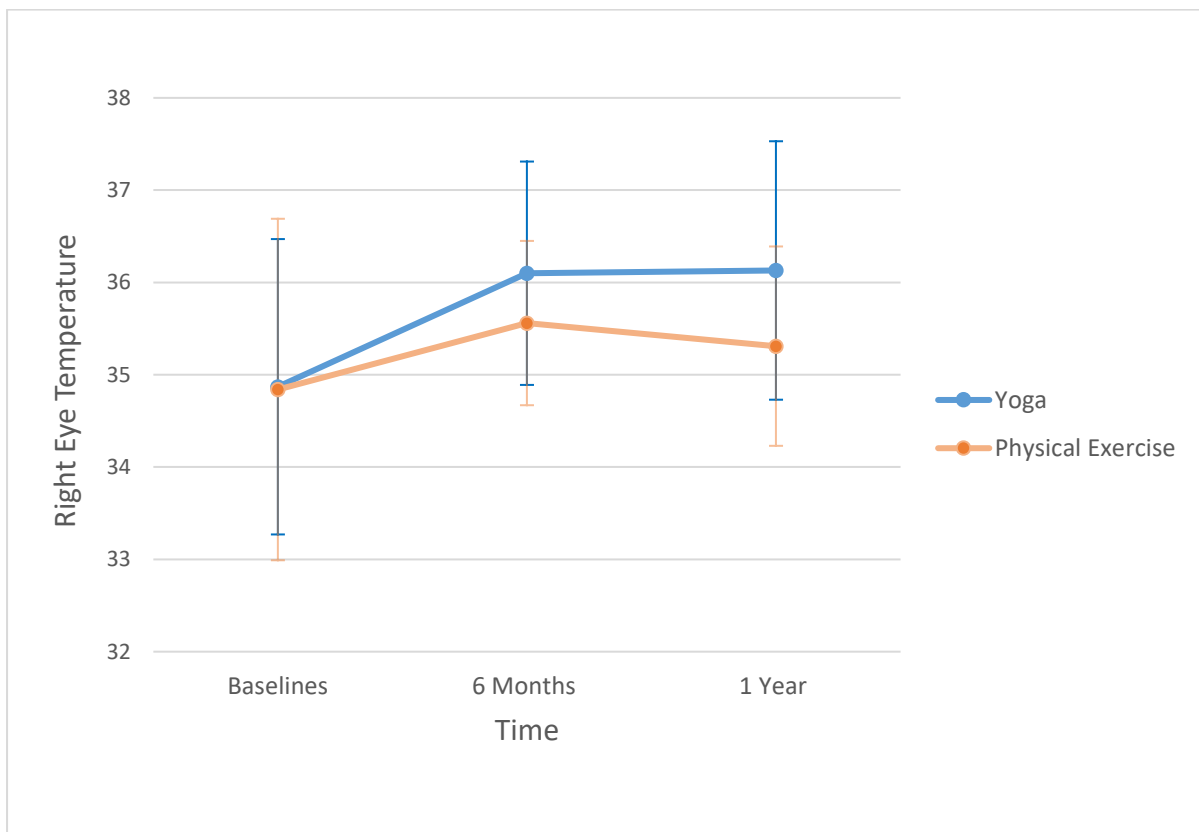
**Figure 21: Changes in temperature of Centre of Eyebrows**

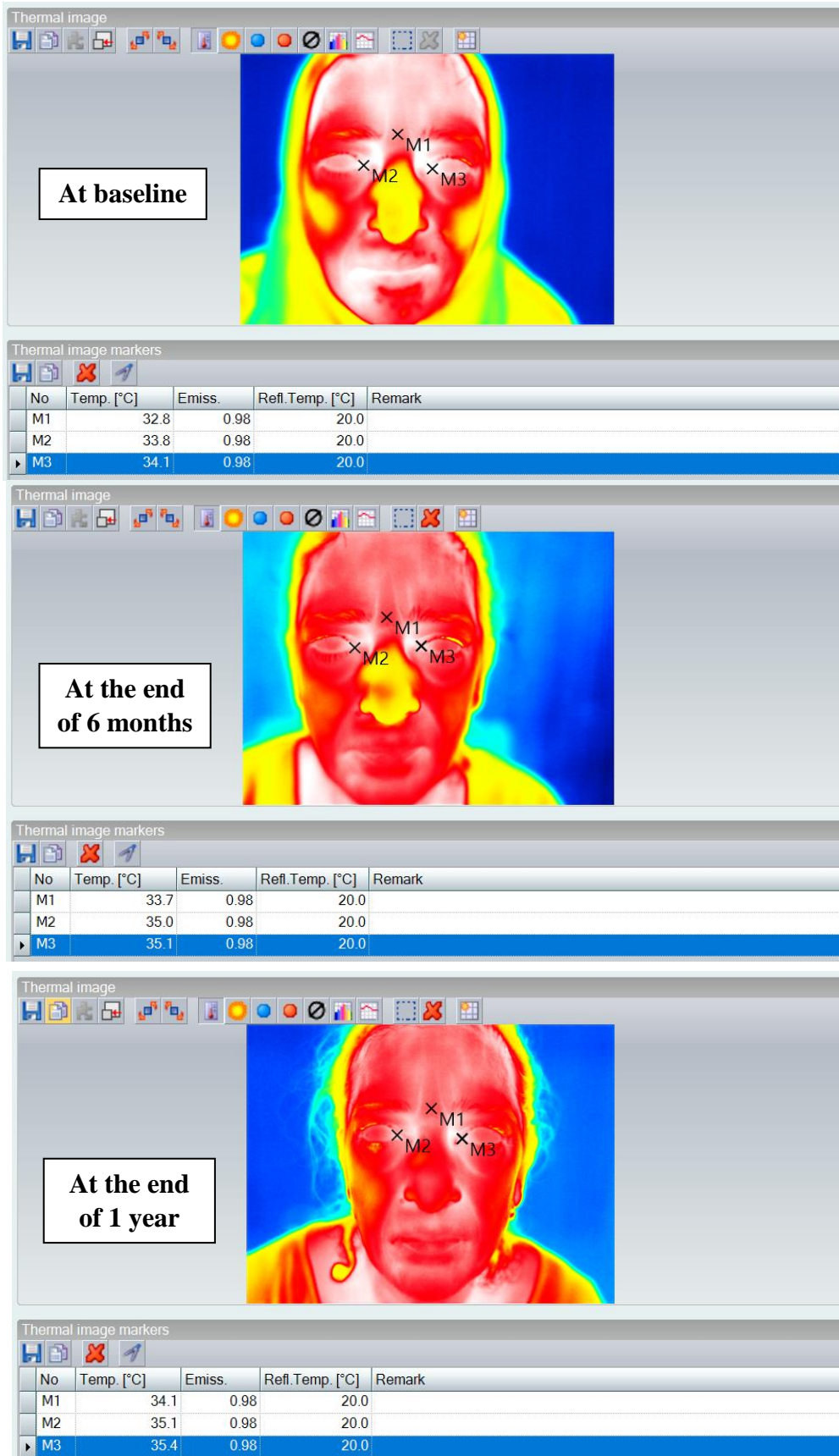


## 8) Right Eye

There was a significant group\*time interaction effect for the temperature of Right Eye favoring YBL group at 1 year. The temperature of Right Eye increased significantly at 1 year as compared to PHE group ( $p=0.02$ ). The mean temperature of Right Eye increased by 1.26 in 1 year in YBL group. *Table 8, Table 9* and *Figure 21* provide the details of changes in the temperature of Right Eye.

**Figure 22: changes in Right Eye temperature**





**Plate 24: Changes in body temperature of a female T2DM subject after YBL intervention**



## 6.2.7 Electro-photonic Imaging Parameters

### 6.2.7.1 Correlation between HbA1c and EPI Variables

Out of 89 EPI variables, 11 variables showed both positive and negative correlations with HbA1c. Especially energy balance (Balance, Organs balance right, Organs balance left, Kidneys balance, Digestive system balance, Adrenals balance, Cerebral zone vessels balance, Cerebral zone cortex balance, Liver balance and Lumber spine balance) showed significant negative correlation and EPI Stress variable showed significant positive correlation with HbA1C levels. *Table 10* and *Graph 22* provides the details of the correlation between EPI variables and HbA1c level.

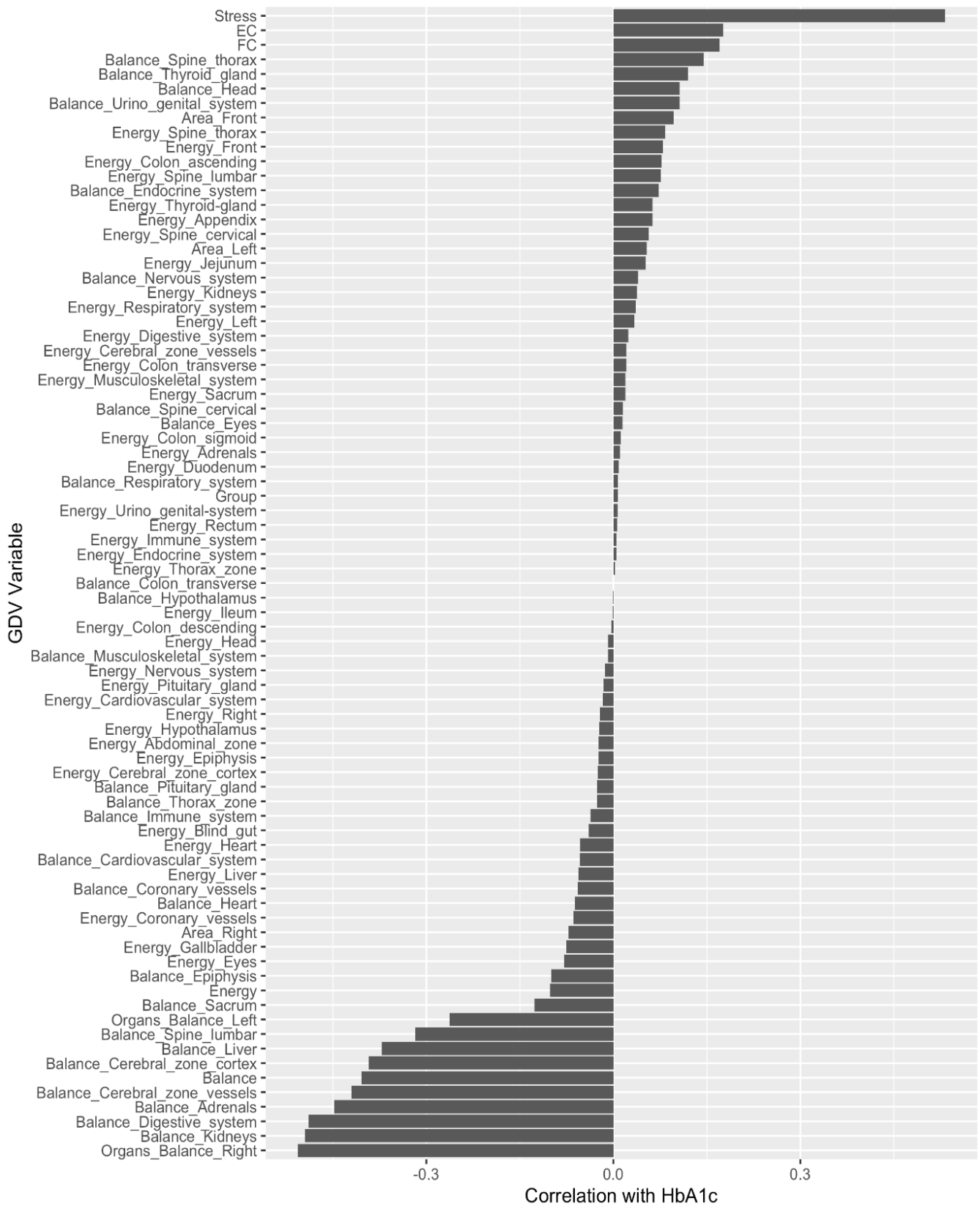
**Table 10: EPI variables showing significant correlation with HbA1c at baseline (n=160)**

SN	GDV Variables	Correlation with HbA1c (r)	P value
1	EPI Stress	0.422	<0.001*
2	Balance	-0.405	<0.001*
3	Organs balance left	-0.259	0.001*
4	Organs balance right	-0.505	<0.001*
5	Cerebral zone cortex balance	-0.394	<0.001*
6	Cerebral zone vessels balance	-0.420	<0.001*
7	Adrenals balance	-0.449	<0.001*
8	Lumber spine balance	-0.318	<0.001*
9	Digestive system balance	-0.491	<0.001*
10	Liver balance	-0.371	<0.001*
11	Kidneys balance	-0.496	<0.001*

<sup>a</sup>Pearson's Correlation Coefficient Test

\*p < 0.05

**Figure 23: Correlation between EPI variables and HbA1c level**



### 6.2.7.2 Changes on EPI Variables after Intervention

**Table 11: Per protocol analysis results showing significant between-group differences in EPI variables**

SN	Variables	Group	Baseline			6 Months			1 year		
			Mean±SD	F value	P <sup>a</sup> value	Mean±SD	F value	p <sup>a</sup> value	Mean±SD	F value	p <sup>a</sup> value
1	EPI Stress	YBL	3.10±0.09	0.34	0.56	2.58±0.07	19.16	<0.001*	2.34±0.06	43.52	<0.001*
		PHE	3.18±0.10	(1,49)		3.04±0.08	(1,49)		2.97±0.07	(1,49)	
2	Balance	YBL	85.64±8.11	1.13	0.29	95.51±3.66	15.09	<0.001*	98.35±1.58	66.63	<0.001*
		PHE	88.03±7.80	(1,49)		92.19±2.04	(1,49)		92.66±3.25	(1,49)	
3	Organs Balance Left	YBL	82.21±10.14	1.85	0.18	92.95±7.87	1.21	0.28	97.75±3.54	15.65	<0.001*
		PHE	85.94±9.23	(1,49)		90.63±6.99	(1,49)		90.47±8.94	(1,49)	
4	Organs Balance Right	YBL	85.14±8.34	0.07	0.79	94.41±5.85	7.17	0.01*	98.68±4.56	31.55	<0.001*
		PHE	85.80±9.84	(1,49)		90.55±4.01	(1,49)		89.15±7.45	(1,49)	
5	Cerebral Zone Cortex Balance	YBL	84.42±8.67	0.05	0.82	92.21±7.21	10.80	0.002*	95.83±4.58	27.70	<0.001*
		PHE	83.78±11.30	(1,49)		85.49±7.35	(1,49)		86.09±8.40	(1,49)	
6	Adrenals Balance	YBL	82.27±12.86	0.011	0.74	92.79±11.61	6.72	0.013*	92.52±10.87	7.61	0.008*
		PHE	81.06±13.31	(1,49)		83.63±13.65	(1,49)		83.90±11.39	(1,49)	
7	Digestive System Balance	YBL	83.44±9.48	1.18	0.28	89.84±5.71	13.98	<0.001*	94.67±6.20	36.82	<0.001*
		PHE	80.19±11.88	(1,49)		84.43±4.34	(1,49)		82.61±7.99	(1,49)	

Abbreviations: YBL: Yoga Based Lifestyle; PHE: Physical Education and Health Education Programme

<sup>a</sup> Repeated Measures ANOVA with Bonferroni's Correction

\*p < 0.05

**Table 12: Per protocol analysis results showing significant within-group changes in EPI variables**

SN	Variables	Group	Baseline (1) Mean±SD	6 months (2) Mean±SD	1 year (3) Mean±SD	P <sup>a</sup> value 1 vs. 2	P <sup>a</sup> value 1 vs. 3	F value
1	EPI Stress	YBL	3.10±0.09	2.58±0.07	2.34±0.06	<0.001*	<0.001*	29.60 (2,48)
		PHE	3.18±0.10	3.04±0.08	2.97±0.07	0.75*	0.25	1.94 (2,48)
2	Balance	YBL	85.64±8.11	95.51±3.66	98.35±1.58	<0.001*	<0.001*	35.82 (2,48)
		PHE	88.03±7.80	92.19±2.04	92.66±3.25	0.09	0.04*	3.34 (2,48)
3	Organs Balance Left	YBL	82.21±10.14	92.95±7.87	97.75±3.54	<0.001*	<0.001*	25.91 (2,48)
		PHE	85.94±9.23	90.63±6.99	90.47±8.94	0.08	0.19	2.67 (2,48)
4	Organs Balance Right	YBL	85.14±8.34	94.41±5.85	98.68±4.56	<0.001*	<0.001*	23.92 (2,48)
		PHE	85.80±9.84	90.55±4.01	89.15±7.45	0.09	0.38	2.44 (2,48)
5	Cerebral Zone Cortex Balance	YBL	84.42±8.67	92.21±7.21	95.83±4.58	0.004*	<0.001*	14.43 (2,48)
		PHE	83.78±11.30	85.49±7.35	86.09±8.40	1.00	0.97	0.48 (2,48)
6	Adrenals Balance	YBL	82.27±12.86	92.79±11.61	92.52±10.87	0.17	0.01*	5.55 (2,48)
		PHE	81.06±13.31	83.63±13.65	83.90±11.39	1.00	1.00	0.32 (2,48)
7	Lumbar Spine Balance	YBL	82.27±10.74	88.81±6.33	88.57±10.36	0.046*	0.07	3.40 (2,48)
		PHE	82.55±10.91	86.94±7.45	89.41±9.21	0.40	0.08	2.54 (2,48)
8	Digestive System Balance	YBL	83.44±9.48	89.84±5.71	94.67±6.20	0.02*	<0.001*	10.89 (2,48)
		PHE	80.19±11.88	84.43±4.34	82.61±7.99	0.29	1.00	1.53 (2,48)
9	Liver Balance	YBL	78.89±18.14	88.55±11.50	83.13±15.19	0.012*	0.89	5.15 (2,48)
		PHE	79.01±12.84	88.95±7.15	82.77±14.44	0.021*	1.00	4.68 (2,48)
10	Kidneys Balance	YBL	84.70±9.78	84.63±9.20	87.79±8.29	1.00	0.73	1.07 (2,48)
		PHE	80.03±12.88	85.11±8.28	90.45±7,87	0.24	0.002*	6.46 (2,48)

Abbreviations: YBL: Yoga Based Lifestyle; PHE: Physical Education and Health Education Programme

<sup>a</sup> Repeated Measures ANOVA with Bonferroni's Correction

\*p < 0.05

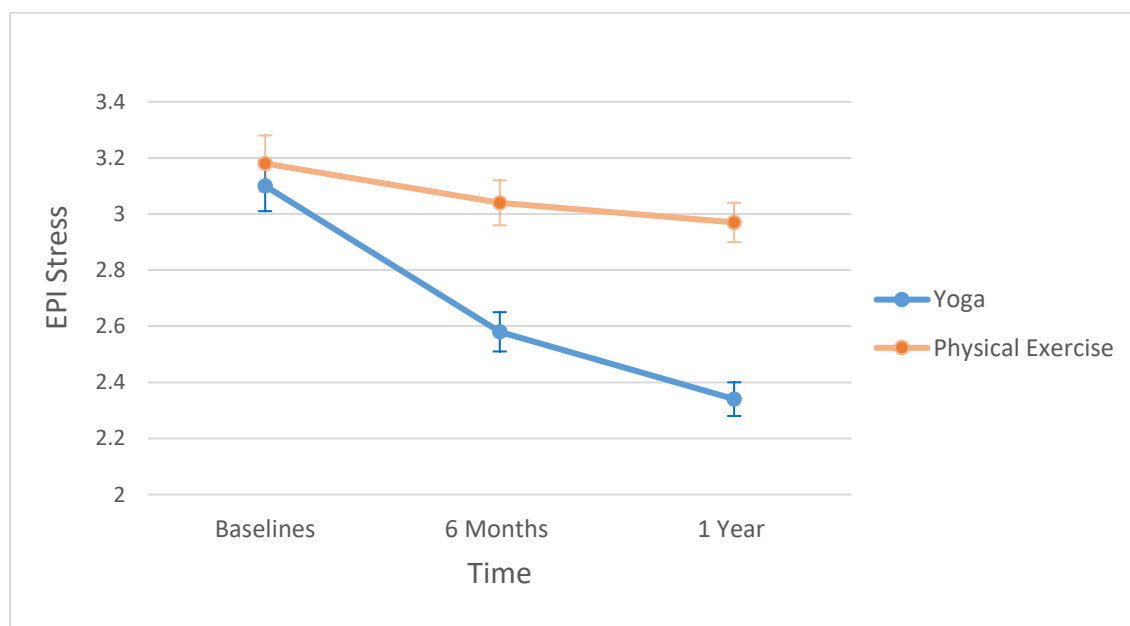
All 11 electro-photonic imaging variables correlated with HbA1c showed the trend of improvement within both YBL and PHE group. However, 9 variables in YBL group and 4 variables in PHE group showed significant time interaction effects after intervention. *Table 12* provides the details of within-group changes in thermal imaging variables.

Seven variables (EPI Stress, Balance, Organs Balance Right, Organs Balance Left, Digestive System Balance, Adrenals Balance, and Cerebral Zone Cortex Balance) showed significant Group\*time interaction effects favouring YBL group at 1 year (*see Table 11*).

### 1) EPI Stress

There was a significant group\*time interaction effect for EPI Stress favouring YBL group at 6 months as well as at 1 year. The EPI Stress reduced significantly at 6 months ( $p < 0.001$ ) as well as at 1 year ( $p < 0.001$ ) as compared to PHE group. The mean EPI Stress reduced by 0.52 in 6 months and by 0.76 in 1 year in YBL group. *Table 11, Table 12* and *Graph 23* provide the details of changes in EPI Stress.

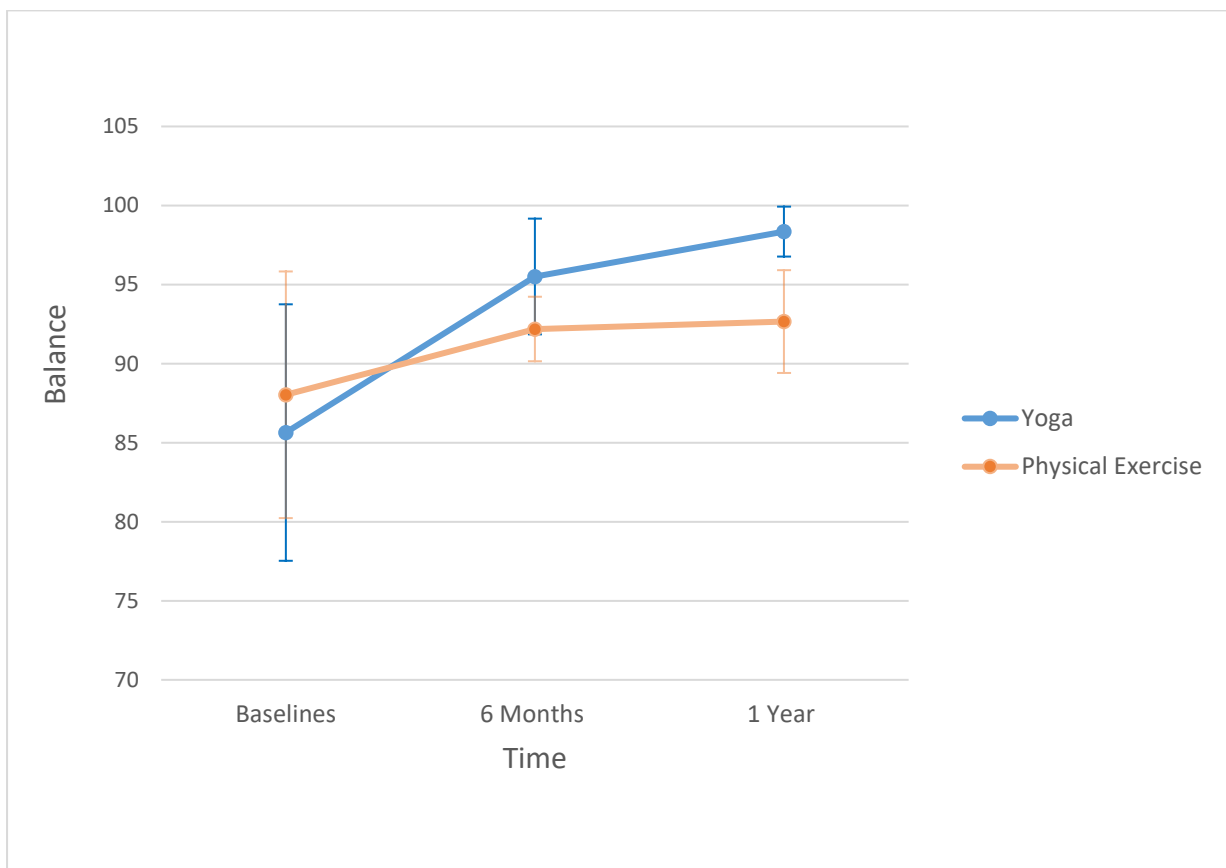
**Figure 24: Changes in GDV Stress**



## 2) Balance

There was a significant group\*time interaction effect for Balance (Overall Energy Balance) favouring YBL group at 6 months as well as at 1 year. The Balance increased significantly at 6 months ( $p<0.001$ ) as well as at 1 year ( $p<0.001$ ) as compared to PHE group. The mean Balance increased by 9.87 in 6 months and by 12.71 in 1 year in YBL group. *Table 11, Table 12 and Graph 24* provide the details of changes in Balance.

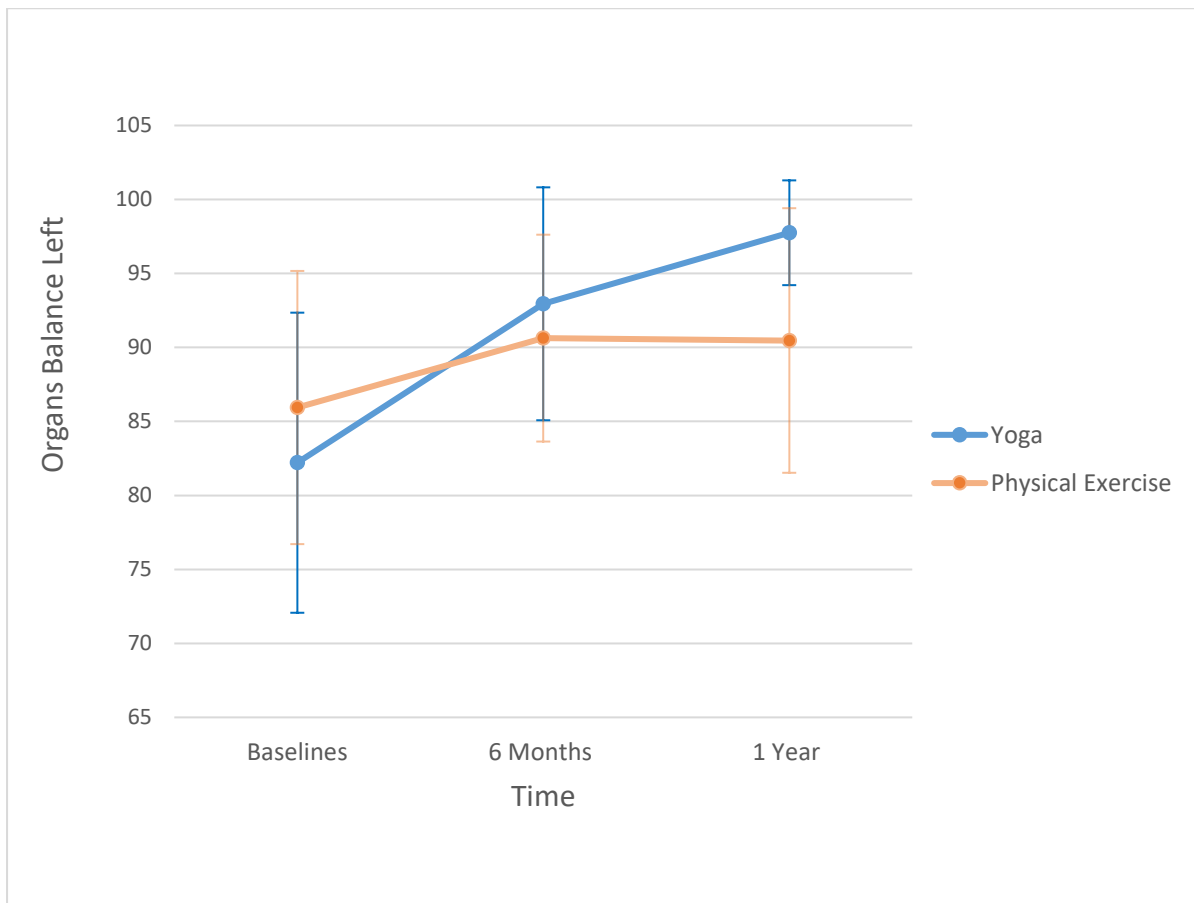
**Figure 25: Changes in Energy Balance**



### 3) Organs Balance Left

There was a significant group\*time interaction effect for Organs Balance Left (Organs Energy Balance Left) favouring YBL group at 6 months as well as at 1 year. The Organs Balance Left increased significantly at 1 year ( $p < 0.001$ ) as compared to PHE group. The mean Organs Balance Left increased by 15.54 in 1 year in YBL group. *Table 11, Table 12 and Graph 25* provide the details of changes in Organs Balance Left.

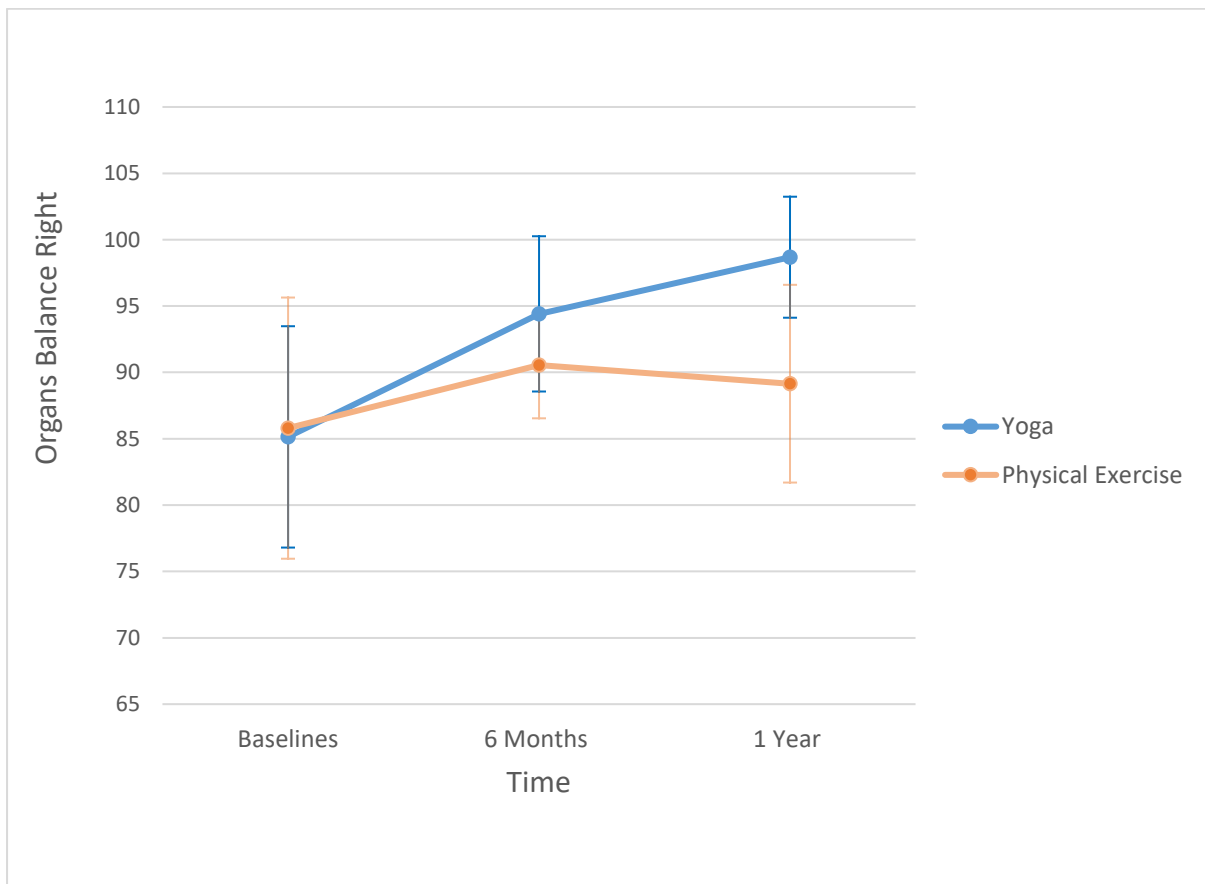
**Figure 26: Changes in Organs Balance Left**



#### 4) Organs Balance Right

There was a significant group\*time interaction effect for Organs Balance Right (Organs Energy Balance Right) favouring YBL group at 6 months as well as at 1 year. The Organs Balance Right increased significantly at 6 months ( $p=0.01$ ) as well as at 1 year ( $p<0.001$ ) as compared to PHE group. The mean Organs Balance Right increased by 9.27 in 6 months and by 13.54 in 1 year in YBL group. *Table 11, Table 12 and Graph 26* provide the details of changes in Organs Balance Right.

**Figure 27: Changes in Organs Balance Right**

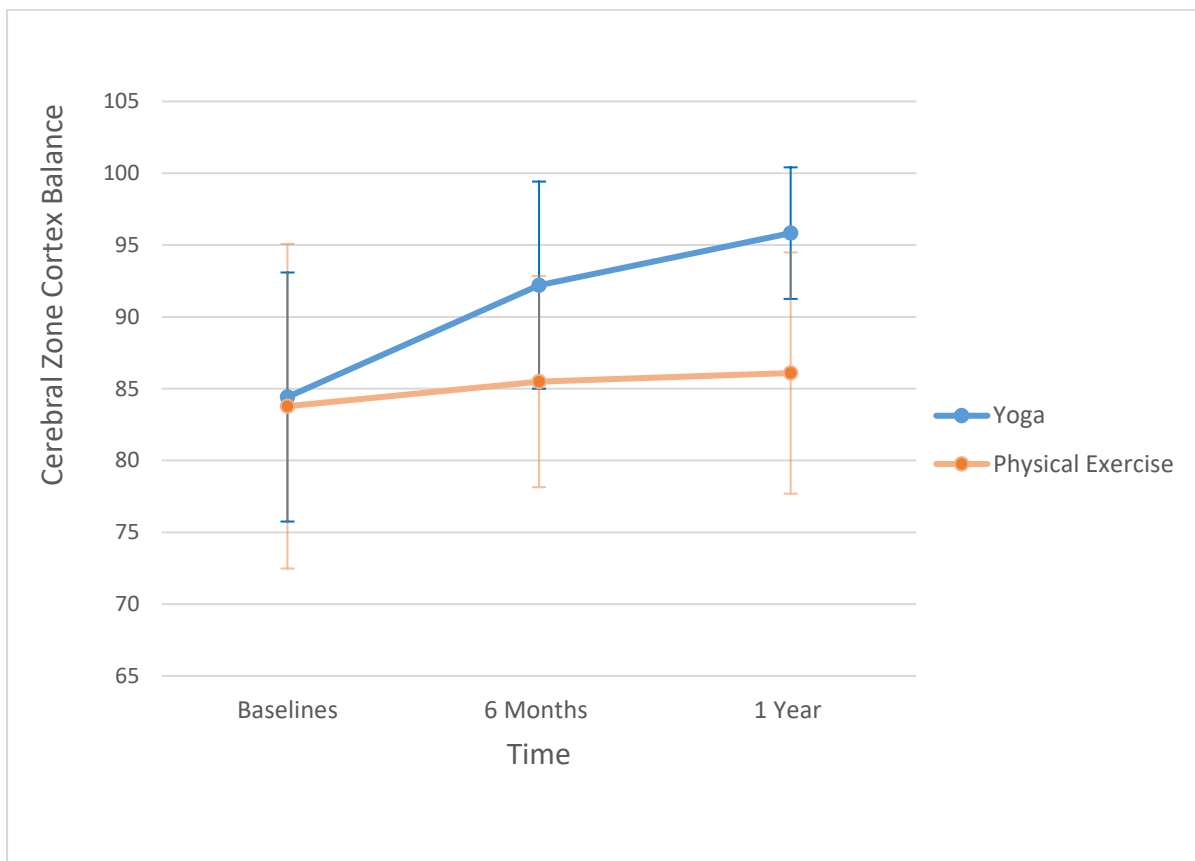




## 5) Cerebral Zone Cortex Balance

There was a significant group\*time interaction effect for Cerebral Zone Cortex Balance (Cerebral Zone Cortex Energy Balance) favouring YBL group at 6 months as well as at 1 year. The Cerebral Zone Cortex Balance increased significantly at 6 months ( $p=0.002$ ) as well as at 1 year ( $p<0.001$ ) as compared to PHE group. The mean Cerebral Zone Cortex Balance increased by 7.79 in 6 months and by 11.14 in 1 year in YBL group. *Table 11, Table 12 and Graph 27* provide the details of changes in Cerebral Zone Cortex Balance.

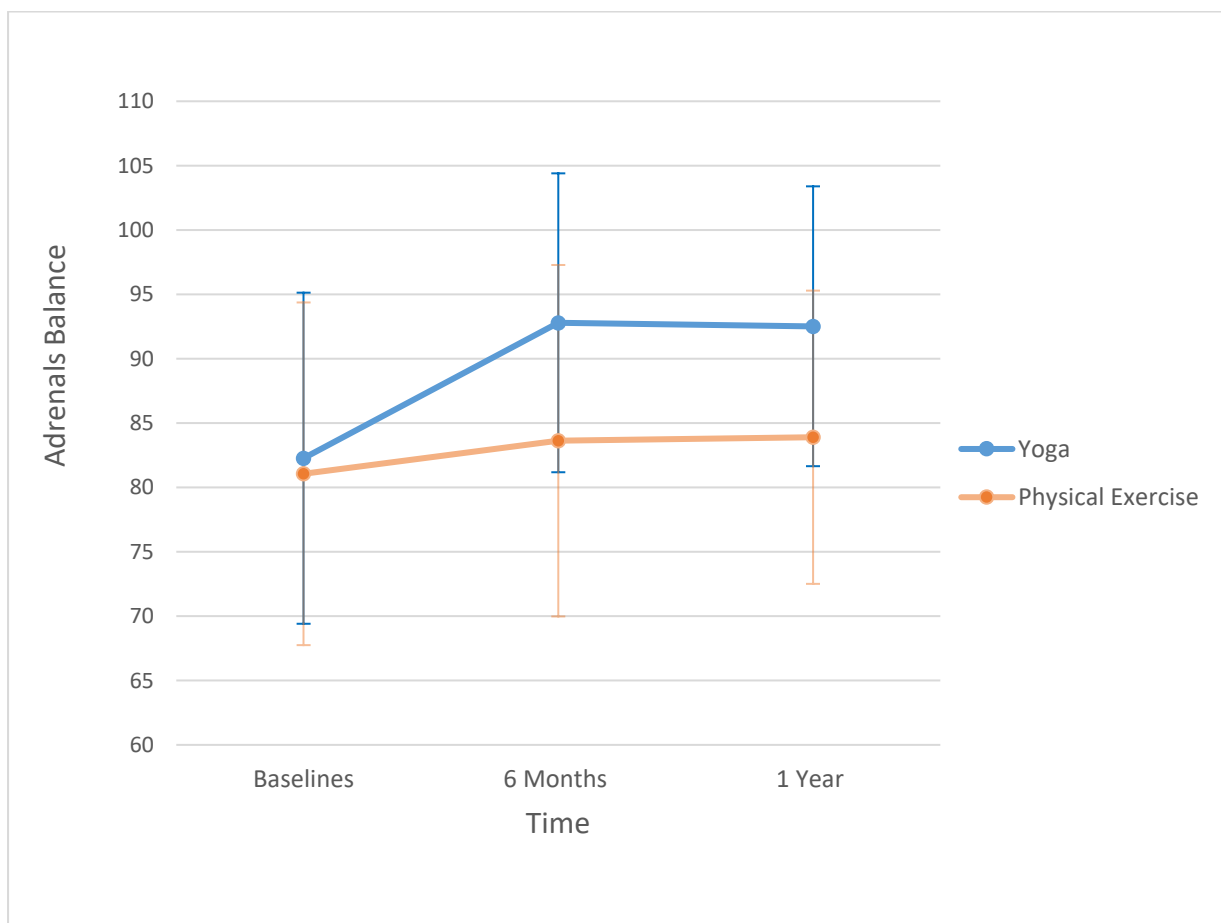
**Figure 28: Changes in Cerebral Zone Cortex Balance**



## 6) Adrenals Balance

There was a significant group\*time interaction effect for Adrenals Balance (Adrenals Energy Balance) favouring YBL group at 6 months as well as at 1 year. The Adrenals Balance increased significantly at 6 months ( $p=0.013$ ) as well as at 1 year ( $p<0.008$ ) as compared to PHE group. The mean Adrenals Balance increased by 10.52 in 6 months and by 10.25 in 1 year in YBL group. *Table 11, Table 12 and Graph 28* provide the details of changes in Adrenals Balance.

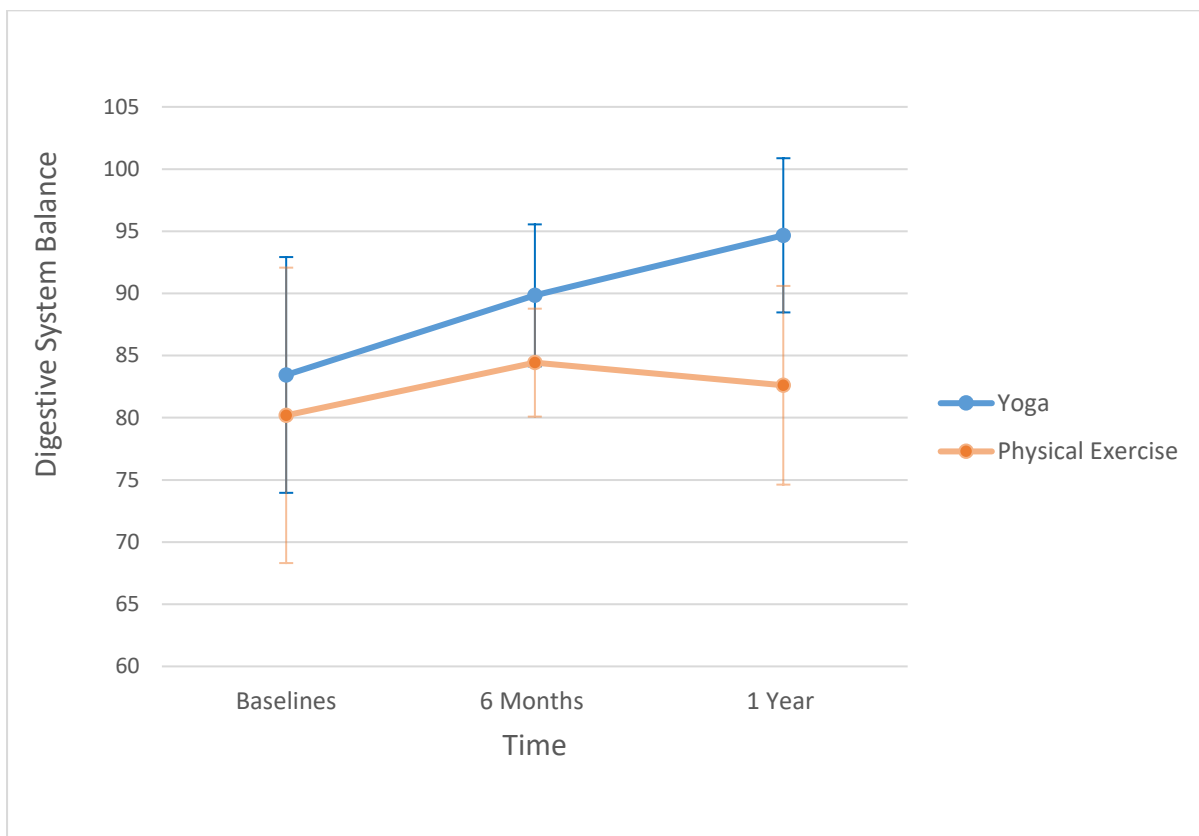
**Figure 29: Changes in Adrenals Balance**



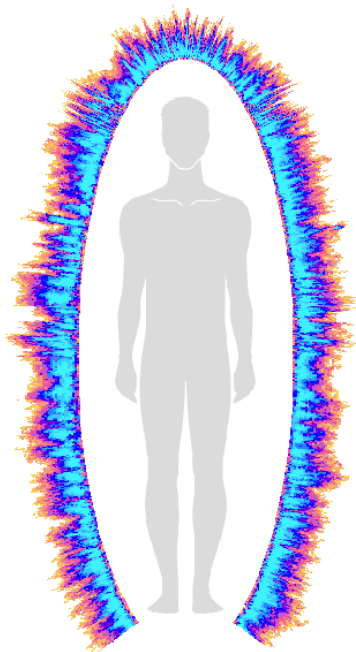
## 7) Digestive System Balance

There was a significant group\*time interaction effect for Digestive System Balance (Digestive System Energy Balance) favouring YBL group at 6 months as well as at 1 year. The Digestive System Balance increased significantly at 6 months ( $p < 0.001$ ) as well as at 1 year ( $p < 0.001$ ) as compared to PHE group. The mean Digestive System Balance increased by 6.4 in 6 months and by 11.32 in 1 year in YBL group. *Table 11, Table 12 and Graph 29* provide the details of changes in Digestive System Balance.

**Figure 30: Changes in Digestive System Balance**

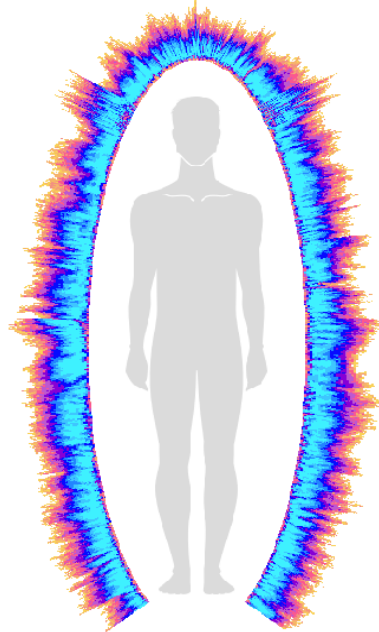


At baseline



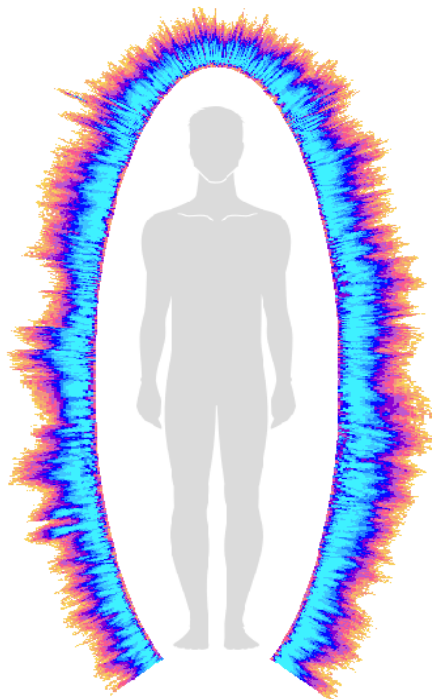
Energy 37 Joules ( $\times 10^{-3}$ )  
Balance: 95%

At the end  
of 6 months



Energy 43 Joules ( $\times 10^{-3}$ )  
Balance: 99%

At the end  
of 1 year



Energy 45 Joules ( $\times 10^{-3}$ )  
Balance: 100%

*Plate 25: Changes in bioenergy pattern of a male T2DM subject after YBL intervention*

### 6.3 INTENTION TO TREAT ANALYSIS

*Table 13: Intention to treat analysis results showing group\*time interaction effect in study variables*

SN	Variables	Time*Group	Std. Beta	Standardized CI	p <sup>a</sup> Value	Time*Group	Std. Beta	Standardized CI	p <sup>a</sup> Value
		6 months (YBL minus PHE)				12 months (YBL minus PHE)			
1	HbA1c	-0.80	-0.47	-0.75 – -0.19	0.001*	-1.25	-0.74	-1.06 – -0.41	<0.001*
2	FBS	-13.28	-0.26	-0.57 – 0.05	0.09	-15.99	-0.32	-0.68 – 0.04	0.08
3	PPBS	-14.01	-0.18	-0.58 – 0.22	0.37	-37.75	-0.49	-0.95 – -0.02	0.04*
4	BMI	-0.19	-0.05	-0.20 – 0.09	0.45	-1.01	-0.28	-0.44 – -0.12	0.001*
5	Waist-Hip Ratio	0.01	0.19	-0.12 – 0.50	0.23	-0.01	-0.12	-0.48 – 0.25	0.532
6	Medication score	-0.39	-0.20	-0.41 – 0.01	0.06	-0.86	-0.45	-0.69 – -0.20	<0.001*
7	Systolic BP	-6.78	-0.42	-0.65 – -0.19	<0.001*	-10.73	-0.66	-0.93 – -0.39	<0.001*
8	Diastolic BP	-5.10	-0.53	-0.81 – -0.25	<0.001*	-7.49	-0.78	-1.10 – -0.45	<0.001*
9	DASS Depression	-0.71	-0.11	-0.31 – 0.08	0.26	-1.45	-0.23	-0.45 – -0.00	0.04*
10	DASS Anxiety	-0.50	-0.13	-0.47 – 0.20	0.44	-0.73	-0.19	-0.59 – 0.20	0.33
11	DASS Stress	-0.84	-0.16	-0.49 – 0.18	0.35	-1.43	-0.27	-0.66 – 0.12	0.17

*Abbreviations:* FBS: Fasting Blood Sugar; PPBS: Postprandial Blood Sugar; DASS: Depression Anxiety Stress Scale -42; BMI: body Mass Index; BP: Blood Pressure; CI: Confidence Interval; Std.: standardized; YBL: Yoga Based Lifestyle; PHE: Physical Education and Health Education Programme

<sup>a</sup> Intention to treat with mixed model approach: Linear mixed-effects (LME) model with Restricted Maximum Likelihood (REML) estimation

\*p < 0.05

**Table 14: Intention to treat analysis results showing time effect in study variables**

SN	Variables	Time effect <i>6 months</i>	Std. Beta	Standardized CI	p <sup>a</sup> Value	Time effect <i>12 months</i>	Std. Beta	Standardized CI	p <sup>a</sup> Value
1	HbA1c	-0.08	-0.05	-0.25 – 0.15	0.64	-0.33	-0.19	-0.44 – 0.05	0.11
2	FBS	-5.06	-0.10	-0.32 – 0.12	0.37	-10.99	-0.22	-0.48 – 0.05	0.10
3	PPBS	-1.50	-0.02	-0.31 – 0.27	0.89	1.66	0.02	-0.32 – 0.36	0.90
4	BMI	-0.32	-0.09	-0.19 – 0.01	0.09	-0.43	-0.12	-0.24 – 0.00	0.054
5	Waist-Hip Ratio	-0.02	-0.35	-0.58 – -0.13	0.002*	-0.02	-0.34	-0.61 – -0.07	0.013*
6	Medication score	-0.20	-0.11	-0.26 – 0.05	0.17	0.19	0.10	-0.08 – 0.28	0.28
7	Systolic BP	1.67	0.10	-0.06 – 0.27	0.22	2.56	0.16	-0.04 – 0.35	0.12
8	Diastolic BP	2.67	0.28	0.08 – 0.48	0.01*	3.60	0.37	0.13 – 0.61	0.002*
9	DASS Depression	-0.37	-0.06	-0.20 – 0.08	0.41	-0.39	-0.06	-0.23 – 0.11	0.46
10	DASS Anxiety	-0.37	-0.10	-0.34 – 0.14	0.42	-0.68	-0.18	-0.47 – 0.11	0.22
11	DASS Stress	-0.53	-0.10	-0.34 – 0.14	0.41	-1.02	-0.19	-0.48 – 0.10	0.19

*Abbreviations:* FBS: Fasting Blood Sugar; PPBS: Postprandial Blood Sugar; DASS: Depression Anxiety Stress Scale -42; BMI: body Mass Index; BP: Blood Pressure; CI: Confidence Interval; Std.: standardized

<sup>a</sup> Intention to treat with mixed model approach: Linear mixed-effects (LME) model with Restricted Maximum Likelihood (REML) estimation

\*p < 0.05

### 6.3.1 Biochemical Variables

#### 6.3.1.1 HbA1c levels

There was a significant group\*time interaction effect for HbA1c at 6 months as well as 12 months favouring YBL group. The estimated decrease in mean HbA1c in YBL group was 0.80 at the end of 6 months and 1.25 at the end of 12 months as compared to PHE group (*see table 13, 14 and 15*).

**Table 15: ITT analysis result showing changes in HbA1c levels before and after intervention (6 month and 12 months)**

Predictors	HbA1c level				
	Estimates	std. Beta	CI	standardized CI	p
(Intercept)	8.37	0.19	8.00 – 8.73	-0.02 – 0.41	<0.001
Time [6]	-0.08	-0.05	-0.42 – 0.26	-0.25 – 0.15	0.646
Time [12]	-0.33	-0.19	-0.74 – 0.08	-0.44 – 0.05	0.114
Group [YOGA]	-0.03	-0.02	-0.55 – 0.49	-0.32 – 0.29	0.921
Time [6] * Group [YOGA]	-0.80	-0.47	-1.28 – -0.32	-0.75 – -0.19	<b>0.001</b>
Time [12] * Group [YOGA]	-1.25	-0.74	-1.81 – -0.69	-1.06 – -0.41	<0.001
<b>Random Effects</b>					
$\sigma^2$	0.59				
$\tau_{00\ SN}$	2.23				
ICC	0.79				
$N_{SN}$	160				
Observations	285				
Marginal $R^2$ / Conditional $R^2$	0.088 / 0.810				

### 6.3.1.2 Fasting Blood Sugar (FBS)

There was no significant group\*time interaction effect for FBS at 6 months as well as 12 months favouring YBL group. Although, there was a trend towards greater reduction in the YBL group. The estimated decrease (insignificant) in mean FBS in YBL group was 13.28 at the end of 6 months and 15.99 at the end of 12 months as compared to PHE group (*see table 13, 14 and 16*).

**Table 16: ITT analysis result showing changes in FBS levels before and after intervention (6 month and 12 months)**

Predictors	Fasting Blood Sugar				
	Estimates	std. Beta	CI	standardized CI	p
(Intercept)	155.94	0.16	144.63 – 167.24	-0.07 – 0.38	<0.001
Time [6]	-5.06	-0.10	-16.28 – 6.16	-0.32 – 0.12	0.377
Time [12]	-10.99	-0.22	-24.43 – 2.45	-0.48 – 0.05	0.109
Group [YOGA]	-0.15	-0.00	-16.14 – 15.84	-0.32 – 0.31	0.985
Time [6] * Group [YOGA]	-13.28	-0.26	-28.95 – 2.40	-0.57 – 0.05	0.097
Time [12] * Group [YOGA]	-15.99	-0.32	-34.24 – 2.26	-0.68 – 0.04	0.086
<b>Random Effects</b>					
$\sigma^2$	631.54				
$\tau_{00}$ SN	2029.49				
ICC	0.76				
N <sub>SN</sub>	160				
Observations	285				
Marginal R <sup>2</sup> / Conditional R <sup>2</sup>	0.031 / 0.770				



### 6.3.1.3 Postprandial Blood Sugar (PPBS)

There was a significant group\*time interaction effect for PPBS at 12 months favouring YBL group (see table 13, 14 and 17). The estimated decrease in mean PPBS in YBL group was 37.75 at the end of 12 months as compared to PHE group (see table 13, 14 and 17).

**Table 17: ITT analysis result showing changes in PPBS levels before and after intervention (6 month and 12 months)**

Postprandial Blood Sugar					
Predictors	Estimates	std. Beta	CI	standardized CI	p
(Intercept)	219.75	0.09	202.85 – 236.65	-0.13 – 0.31	< <b>0.001</b>
Time [6]	-1.50	-0.02	-23.61 – 20.60	-0.31 – 0.27	0.894
Time [12]	1.66	0.02	-24.83 – 28.15	-0.32 – 0.36	0.902
Group [YOGA]	0.14	0.00	-23.76 – 24.03	-0.31 – 0.31	0.991
Time [6] * Group [YOGA]	-14.01	-0.18	-44.90 – 16.87	-0.58 – 0.22	0.374
Time [12] * Group [YOGA]	-37.75	-0.49	-73.74 – -1.76	-0.95 – -0.02	<b>0.040</b>
<b>Random Effects</b>					
$\sigma^2$	2601.84				
$\tau_{00}$ SN	3343.99				
ICC	0.56				
N SN	160				
Observations	285				
Marginal R <sup>2</sup> / Conditional R <sup>2</sup>	0.021 / 0.572				

## 6.3.2 Anthropometric Variables

### 6.3.2.1 Body Mass Index (BMI)

There was a significant group\*time interaction effect for BMI at 12 months favouring YBL group. The estimated decrease in mean BMI in YBL group was 1.01 at the end of 12 months as compared to PHE group (*see table 13, 14 and 18*).

**Table 18: ITT analysis result showing changes in Body Mass Index before and after intervention (6 month and 12 months)**

<i>Predictors</i>	<b>BMI</b>				
	<i>Estimates</i>	<i>std. Beta</i>	<i>CI</i>	<i>standardized CI</i>	<i>p</i>
(Intercept)	27.21	0.17	26.42 – 28.00	-0.05 – 0.39	<b>&lt;0.001</b>
Time [6]	-0.32	-0.09	-0.68 – 0.05	-0.19 – 0.01	0.088
Time [12]	-0.43	-0.12	-0.86 – 0.01	-0.24 – 0.00	0.054
Group [YOGA]	-0.23	-0.06	-1.35 – 0.88	-0.38 – 0.25	0.682
Time [6] * Group [YOGA]	-0.19	-0.05	-0.70 – 0.31	-0.20 – 0.09	0.455
Time [12] * Group [YOGA]	-1.01	-0.28	-1.60 – -0.42	-0.44 – -0.12	<b>0.001</b>
<b>Random Effects</b>					
$\sigma^2$	0.63				
$\tau_{00}$ SN	12.31				
ICC	0.95				
$N_{SN}$	160				
Observations	285				
Marginal $R^2$ / Conditional $R^2$	0.017 / 0.952				

### 6.3.2.2 Waist-hip Ratio

There was a significant time effect for Waist-hip Ratio at 6 months as well as 12 months. The estimated decrease in mean Waist-hip Ratio was 0.02 at the end of 6 months and 0.02 at the end of 1 year irrespective of the group. There was no significant group\*time interaction effect for waist-hip ratio (see table 13, 14 and 19).

**Table 19: ITT analysis result showing changes in Waist-hip Ratio before and after intervention (6 month and 12 months)**

Predictors	Waist-hip Ratio				
	Estimates	std. Beta	CI	standardized CI	p
(Intercept)	0.95	0.13	0.94 – 0.97	-0.10 – 0.35	<0.001
Time [6]	-0.02	-0.35	-0.04 – -0.01	-0.58 – -0.13	<b>0.002</b>
Time [12]	-0.02	-0.34	-0.04 – -0.00	-0.61 – -0.07	<b>0.013</b>
Group [YOGA]	-0.00	-0.01	-0.02 – 0.02	-0.33 – 0.31	0.952
Time [6] * Group [YOGA]	0.01	0.19	-0.01 – 0.03	-0.12 – 0.50	0.230
Time [12] * Group [YOGA]	-0.01	-0.12	-0.03 – 0.02	-0.48 – 0.25	0.532
<b>Random Effects</b>					
$\sigma^2$	0.00				
$\tau_{00}$ SN	0.00				
ICC	0.77				
N <sub>SN</sub>	160				
Observations	285				
Marginal R <sup>2</sup> / Conditional R <sup>2</sup>	0.27 0.773				

### 6.3.3 T2DM Medication Score

There was a significant group\*time interaction effect for T2DM Medication Score at 12 months favouring YBL group. The estimated decrease in mean T2DM Medication Score in YBL group was 0.87 at the end of 12 months as compared to PHE group (*see table 13, 14 and 20*).

**Table 20: ITT analysis result showing changes in T2DM Medication Score before and after intervention (6 month and 12 months)**

T2DM Medication Score					
Predictors	Estimates	std. Beta	CI	standardized CI	p
(Intercept)	2.13	0.03	1.71 – 2.56	-0.19 – 0.25	<0.001
Time [6]	-0.20	-0.11	-0.50 – 0.09	-0.26 – 0.05	0.173
Time [12]	0.19	0.10	-0.16 – 0.54	-0.08 – 0.28	0.282
Group [YOGA]	0.01	0.01	-0.59 – 0.61	-0.31 – 0.32	0.971
Time [6] * Group [YOGA]	-0.39	-0.20	-0.80 – 0.02	-0.41 – 0.01	0.062
Time [12] * Group [YOGA]	-0.86	-0.45	-1.34 – -0.39	-0.69 – -0.20	<0.001
<b>Random Effects</b>					
$\sigma^2$	0.42				
$\tau_{00}$ SN	3.36				
ICC	0.89				
N <sub>SN</sub>	160				
Observations	285				
Marginal R <sup>2</sup> / Conditional R <sup>2</sup>	0.019 / 0.892				

### 6.3.4 Blood Pressure

#### 6.3.4.1 Systolic Blood Pressure

There was a significant group\*time interaction effect for Systolic Blood Pressure at 6 months as well as at 12 months favouring YBL group. The estimated decrease in mean Systolic Blood Pressure in YBL group was 6.78 mmHg at the end of 6 months and 10.73 mmHg at the end of 12 months as compared to PHE group (*see table 13, 14 and 21*).

**Table 21: ITT analysis result showing changes in Systolic Blood Pressure Score before and after intervention (6 month and 12 months)**

Systolic Blood Pressure					
Predictors	Estimates	std. Beta	CI	standardized CI	p
(Intercept)	128.01	0.08	124.29 – 131.73	-0.15 – 0.31	< <b>0.001</b>
Time [6]	1.67	0.10	-1.00 – 4.33	-0.06 – 0.27	0.220
Time [12]	2.56	0.16	-0.62 – 5.75	-0.04 – 0.35	0.115
Group [YOGA]	0.75	0.05	-4.51 – 6.01	-0.28 – 0.37	0.780
Time [6] * Group [YOGA]	-6.78	-0.42	-10.50 – -3.06	-0.65 – -0.19	< <b>0.001</b>
Time [12] * Group [YOGA]	-10.73	-0.66	-15.06 – -6.41	-0.93 – -0.39	< <b>0.001</b>
<b>Random Effects</b>					
$\sigma^2$	34.39				
$\tau_{00}$ SN	253.92				
ICC	0.88				
N <sub>SN</sub>	160				
Observations	285				
Marginal R <sup>2</sup> / Conditional R <sup>2</sup>	0.029 / 0.884				

### 6.3.4.2 Diastolic Blood Pressure

There was a significant group\*time interaction effect for Diastolic Blood Pressure at 6 months as well as at 12 months favouring YBL group. The estimated decrease in mean Diastolic Blood Pressure in YBL group was 5.10 mmHg at the end of 6 months and 7.49 mmHg at the end of 12 months as compared to PHE group (*see table 13, 14 and 22*).

**Table 22: ITT analysis result showing changes in Diastolic Blood Pressure before and after intervention (6 month and 12 months)**

<b>Diastolic Blood Pressure</b>					
<i>Predictors</i>	<i>Estimatesstd. Beta</i>		<i>CI</i>	<i>standardized CI</i>	<i>p</i>
(Intercept)	81.06	0.01	78.83 – 83.29	-0.22 – 0.25	< <b>0.001</b>
Time [6]	2.67	0.28	0.74 – 4.59	0.08 – 0.48	<b>0.007</b>
Time [12]	3.60	0.37	1.30 – 5.91	0.13 – 0.61	<b>0.002</b>
Group [YOGA]	0.57	0.06	-2.58 – 3.73	-0.27 – 0.39	0.721
Time [6] * Group [YOGA]	-5.10	-0.53	-7.79 – -2.41	-0.81 – -0.25	< <b>0.001</b>
Time [12] * Group [YOGA]	-7.49	-0.78	-10.62 – -4.36	-1.10 – -0.45	< <b>0.001</b>
<b>Random Effects</b>					
$\sigma^2$	18.26				
$\tau_{00\ SN}$	85.46				
ICC	0.82				
$N_{SN}$	160				
Observations	285				
Marginal $R^2$ / Conditional $R^2$	0.33	0.830			

### 6.3.5 Psychological Variables

#### 6.3.5.1 Depression

There was a significant group\*time interaction effect for DASS Depression Score at 12 months favouring YBL group. The estimated decrease in mean DASS Depression Score in YBL group was 1.45 at the end of 12 months as compared to PHE group (*see table 13, 14 and 23*).

**Table 23: ITT analysis result showing changes in Depression scores before and after intervention (6 month and 12 months)**

<i>Predictors</i>	<b>Depression</b>				
	<i>Estimates</i>	<i>std. Beta</i>	<i>CI</i>	<i>standardized CI</i>	<i>p</i>
(Intercept)	6.49	0.25	4.89 – 8.09	-0.01 – 0.50	<b>&lt;0.001</b>
Time [6]	-0.37	-0.06	-1.25 – 0.52	-0.20 – 0.08	0.419
Time [12]	-0.39	-0.06	-1.45 – 0.67	-0.23 – 0.11	0.468
Group [YOGA]	-0.04	-0.01	-2.30 – 2.22	-0.36 – 0.35	0.974
Time [6] * Group [YOGA]	-0.71	-0.11	-1.95 – 0.53	-0.31 – 0.08	0.261
Time [12] * Group [YOGA]	-1.45	-0.23	-2.89 – -0.01	-0.45 – -0.00	<b>0.048</b>
<b>Random Effects</b>					
$\sigma^2$	3.76				
$\tau_{00\ SN}$	49.41				
ICC	0.93				
$N_{SN}$	160				
Observations	285				
Marginal $R^2$ / Conditional $R^2$	0.007 / 0.930				

### 6.3.5.2 Anxiety

There was no significant group\*time interaction effect for the DASS Anxiety Score. Although, there was a trend towards greater reduction in the YBL group. The estimated decrease (insignificant) in mean DASS Anxiety Score in YBL group was 0.73 at the end of 12 months as compared to PHE group (*see table 13, 14 and 24*).

**Table 24: ITT analysis result showing changes in Anxiety scores before and after intervention (6 month and 12 months)**

<i>Predictors</i>	<b>Anxiety</b>				
	<i>Estimates std. Beta</i>		<i>CI</i>	<i>standardized CI</i>	<i>p</i>
(Intercept)	3.67	0.16	2.84 – 4.51	-0.06 – 0.38	<b>&lt;0.001</b>
Time [6]	-0.37	-0.10	-1.29 – 0.55	-0.34 – 0.14	0.429
Time [12]	-0.68	-0.18	-1.77 – 0.42	-0.47 – 0.11	0.227
Group [YOGA]	-0.02	-0.01	-1.21 – 1.16	-0.32 – 0.31	0.967
Time [6] * Group [YOGA]	-0.50	-0.13	-1.78 – 0.77	-0.47 – 0.20	0.440
Time [12] * Group [YOGA]	-0.73	-0.19	-2.22 – 0.76	-0.59 – 0.20	0.335
<b>Random Effects</b>					
$\sigma^2$	4.27				
$\tau_{00\ SN}$	10.35				
ICC	0.71				
$N_{SN}$	160				
Observations	285				
Marginal R <sup>2</sup> / Conditional R <sup>2</sup>	0.015 / 0.712				



### 6.3.5.3 Stress

There was no significant group\*time interaction effect for the DASS stress score. Although, there was a trend towards greater reduction in the YBL group compared to physical exercise group. The estimated decrease (insignificant) in mean DASS Stress in YBL group was 1.43 at the end of 12 months as compared to PHE group (*see table 13, 14 and 25*).

**Table 25: ITT analysis result showing changes in Stress scores before and after intervention (6 month and 12 months)**

Predictors	Stress				
	Estimates	std. Beta	CI	standardized CI	p
(Intercept)	6.29	0.15	5.11 – 7.47	-0.07 – 0.37	<0.001
Time [6]	-0.53	-0.10	-1.80 – 0.74	-0.34 – 0.14	0.415
Time [12]	-1.02	-0.19	-2.54 – 0.51	-0.48 – 0.10	0.191
Group [YOGA]	0.02	0.00	-1.64 – 1.69	-0.31 – 0.32	0.977
Time [6] * Group [YOGA]	-0.84	-0.16	-2.62 – 0.94	-0.49 – 0.18	0.356
Time [12] * Group [YOGA]	-1.43	-0.27	-3.50 – 0.64	-0.66 – 0.12	0.176
<b>Random Effects</b>					
$\sigma^2$	8.24				
$\tau_{00}$ SN	20.66				
ICC	0.71				
N <sub>SN</sub>	160				
Observations	285				
Marginal R <sup>2</sup> / Conditional R <sup>2</sup>	0.021 / 0.721				

### 6.3.6 Thermal Imaging Parameters

Out of 5 Thermal Imaging variables which have stronger correlation with HbA1c, Centre of Eyebrows and Right Eye showed the significant group\*time interaction effects at the end of 1 year favouring YBL group. There was also a significant group\*time interaction effect at the end of 6 months for the Right Eye and Centre of Eyebrow. *Table 26* provide the details of group\*time interaction effects in Thermal Imaging variables based on Intention to treat Analysis.

*Table 26: Intention to treat analysis results showing group\*time interaction in thermal imaging variables*

SN	Variables	Time*Group 6 months (YBL minus PHE)			p <sup>a</sup> Value	Time*Group 12 months (YBL minus PHE)			p <sup>a</sup> Value
		Std. Beta	Standardized CI			Std. Beta	Standardized CI		
1	Left Eye	0.57	0.32	-0.07 – 0.72	0.11	0.75	0.43	-0.03 – 0.89	0.06
2	Right Eye	0.73	0.42	0.04 – 0.80	0.03*	0.79	0.45	0.01 – 0.90	0.04*
3	Left Ear	-0.04	-0.02	-0.48 – 0.44	0.9	0.48	0.30	-0.23 – 0.84	0.26
4	Right Ear	0.01	0.01	-0.41 – 0.43	0.96	0.45	0.29	-0.21 – 0.78	0.25
5	Centre of Eyebrows	1.09	0.59	0.20 – 0.97	0.003*	1.27	0.68	0.23 – 1.13	0.003*

*Abbreviations:* CI: Confidence Interval; Std.: standardized; YBL: Yoga Based Lifestyle; PHE: Physical Education and Health Education Programme

<sup>a</sup> Intention to treat with mixed model approach: Linear mixed-effects (LME) model with Restricted Maximum Likelihood (REML) estimation

\*p < 0.05

We found significant time effects at six months for Left Eye, Right Eye, Right Ear and Centre of Eyebrows irrespective of the group. Whereas at the end of 1 year, there was significant time effect for only Centre of Eyebrow. All the Thermal Imaging variables analysed by intention to treat analysis showed the trend of increase in temperature after the intervention, which is in line with per protocol analysis results. *Table 27* provide the details of time effects in Thermal Imaging variables based on Intention to treat Analysis.

**Table 27: Intention to treat analysis results showing time interaction in thermal imaging variables**

SN	Variables	Time effect	Std. Beta	Standardized CI	p <sup>a</sup> Value	Time effect	Std. Beta	Standardized CI	p <sup>a</sup> Value
		<i>6 months</i>				<i>12 months</i>			
1	Left Eye	0.64	0.36	0.08 – 0.64	0.01*	0.48	0.28	-0.06 – 0.61	0.11
2	Right Eye	0.58	0.33	0.06 – 0.61	0.02*	0.52	0.30	-0.03 – 0.63	0.07
3	Left Ear	0.44	0.28	-0.05 – 0.61	0.09	0.08	0.05	-0.34 – 0.44	0.81
4	Right Ear	0.55	0.35	0.05 – 0.65	0.03*	0.22	0.14	-0.22 – 0.50	0.45
5	Centre of Eyebrows	0.62	0.34	0.06 – 0.61	0.02*	0.64	0.35	0.01 – 0.68	0.04*

*Abbreviations:* CI: Confidence Interval; Std.: standardized

<sup>a</sup> Intention to treat with mixed model approach: Linear mixed-effects (LME) model with Restricted Maximum Likelihood (REML) estimation

\*p < 0.05

### 6.3.7 Electro-photonic Imaging Parameters

Intention to treat analysis revealed that there was significant group\*time interaction effects at the end of 1 year for EPI Stress, Balance, Organs Balance, Cerebral Zone Cortex Balance, Digestive System Balance and Adrenals Balance favouring YBL group which is in line with the results demonstrated by the per protocol analysis. EPI Stress, Balance, Cerebral Zone Cortex Balance, Digestive System Balance and Adrenals Balance showed significant group\*time interaction effects at the end of 6 months too favouring YBL group. The results of the ITT analysis is in line with the results demonstrated by the per protocol analysis. *Table 28* provides the details of the group\*time interaction effects for EPI variables.

**Table 28: Intention to treat analysis results showing group\*time interaction in EPI variables**

SN	Variables	Time*Group 6 months (YBL minus PHE)			p <sup>a</sup> Value	Time*Group 12 months (YBL minus PHE)			p <sup>a</sup> Value
		Std. Beta	Standardized CI			Std. Beta	Standardized CI		
1	Stress	-0.35	-0.70	-1.12 – -0.28	0.001*	-0.58	-1.16	-1.65 – -0.67	<0.001*
2	Balance	4.20	0.56	0.09 – 1.02	0.02*	6.06	0.80	0.27 – 1.33	0.003*
3	Organs Balance	3.57	0.37	-0.08 – 0.82	0.11	8.69	0.90	0.37 – 1.42	0.001*
4	Kidneys Balance	-1.36	-0.13	-0.66 – 0.40	0.64	-3.24	-0.30	-0.91 – 0.31	0.33
5	Cerebral Zone Cortex Balance	8.10	0.83	0.33 – 1.32	0.001*	10.31	1.05	0.48 – 1.62	<0.001*
6	Cerebral Zone Vessels Balance	1.76	0.19	-0.34 – 0.72	0.49	0.03	0.00	-0.60 – 0.61	0.99
7	Digestive System Balance	7.75	0.78	0.27 – 1.28	0.002*	11.79	1.18	0.60 – 1.76	<0.001*
8	Adrenals Balance	7.71	0.58	0.05 – 1.11	0.03*	8.21	0.62	0.01 – 1.23	0.04*
9	Liver Balance	4.44	0.33	-0.20 – 0.86	0.22	1.04	0.08	-0.53 – 0.69	0.80
10	Lumbar Spine Balance	1.26	0.12	-0.41 – 0.64	0.66	-0.38	-0.04	-0.64 – 0.57	0.91

*Abbreviations:* CI: Confidence Interval; Std.: standardized; YBL: Yoga Based Lifestyle; PHE: Physical Education and Health Education Programme

<sup>a</sup> Intention to treat with mixed model approach: Linear mixed-effects (LME) model with Restricted Maximum Likelihood (REML) estimation

\*p < 0.05

Intention to treat analysis revealed that there was significant time effects for Balance, Organs Balance, Kidneys Balance, Cerebral Zone Vessels Balance and Lumbar Spine Balance at the end of 1 year irrespective of the group. There was significant time effects for Balance, Organs Balance and Lumbar Spine Balance at the end of 6 months. *Table 29* provides the details of the time effects for EPI variables.

**Table 29: Intention to treat analysis results showing time interaction in EPI variables**

SN	Variables	Time effect	Std. Beta	Standardized CI	p <sup>a</sup> Value	Time effect	Std. Beta	Standardized CI	p <sup>a</sup> Value
		<i>6 months</i>				<i>12 months</i>			
1	Stress	-0.12	-0.24	-0.54 – 0.06	0.12	-0.17	-0.34	-0.70 – 0.02	0.06
2	Balance	4.71	0.62	0.29 – 0.95	<0.001*	5.63	0.74	0.35 – 1.13	<0.001*
3	Organs Balance Left	4.54	0.47	0.14 – 0.79	0.005*	3.99	0.41	0.02 – 0.80	0.03*
4	Kidneys Balance	4.43	0.42	0.04 – 0.79	0.03	8.96	0.84	0.39 – 1.29	<0.001*
5	Cerebral Zone Cortex Balance	0.74	0.08	-0.28 – 0.43	0.67	1.31	0.13	-0.28 – 0.55	0.53
6	Cerebral Zone Vessels Balance	3.50	0.37	-0.00 – 0.75	0.05	6.90	0.74	0.29 – 1.18	0.001*
7	Digestive System Balance	0.18	0.02	-0.34 – 0.38	0.92	0.09	0.001	-0.41 – 0.43	0.97
8	Adrenals Balance	2.03	0.15	-0.22 – 0.53	0.43	1.84	0.14	-0.31 – 0.58	0.54
9	Liver Balance	4.57	0.34	-0.03 – 0.72	0.07	2.02	0.15	-0.30 – 0.60	0.51
10	Lumbar Spine Balance	5.50	0.51	0.14 – 0.89	0.01*	7.64	0.71	0.27 – 1.15	0.002*

Abbreviations: CI: Confidence Interval; Std.: standardized; YBL: Yoga Based Lifestyle; PHE: Physical Education and Health Education Programme

<sup>a</sup> Intention to treat with mixed model approach: Linear mixed-effects (LME) model with Restricted Maximum Likelihood (REML) estimation

\*p < 0.05

## 6.4 RECAPITULATION

Both per-protocol and ITT analysis demonstrated a significant group\*time interaction effect for HbA1c at 6 months ( $p=0.001$ ) as well as at 1 year ( $p<0.001$ ) favouring the YBL group. The estimated decrease in mean HbA1c in the YBL group was 0.80 at 6 months and 1.25 at 1 year as compared to the PHE group. There was also significant group\*time interaction effects for PPBS ( $p=0.04$ ) and DASS depression score ( $p=0.04$ ) at 1 year favouring the YBL group. The estimated decrease in mean PPBS in the YBL group was 37.75 as compared to the PHE group. The estimated decrease in mean DASS depression score in the YBL group was 1.45 at 1 year as compared to the PHE group.

ITT analysis showed the significant group\*time interaction effects for BMI, T2DM medication score and blood pressure levels favouring the YBL group. The estimated decrease in mean BMI in the YBL group was 1.01 at the end of 1 year as compared to the PHE group ( $p=0.001$ ). The estimated decrease in mean Medication Score in the YBL group was 0.87 at the end of 1 year as compared to the PHE exercise group ( $p<0.001$ ). The estimated decrease in mean Systolic Blood Pressure in the YBL group was 6.78 mmHg at the end of 6 months ( $p<0.001$ ) and 10.73 mmHg at the end of 1 year ( $p<0.001$ ) as compared to the PHE group. The estimated decrease in Mean Diastolic Blood Pressure in the YBL group was 5.10 mmHg at the end of 6 months ( $p<0.001$ ) and 7.49 mmHg at the end of 1 year ( $p<0.001$ ) as compared to the PHE exercise group. The per-protocol analysis demonstrated the significant group\*time interaction effects for FBS and DSSS stress score favouring the YBL group. The FBS reduced significantly at 6 months ( $p=0.03$ ) as well as at 1 year ( $p=0.005$ ) as compared to the PHE group. The DASS stress score reduced significantly only at 6 months as compared to the PHE group ( $p=0.01$ ).

Out of 59 thermal imaging variables selected for the study, 29 variables showed significant negative correlations with the HbA1c level ( $r = -0.16$  to  $-0.32$ ,  $p<0.05$ ). Seven thermal imaging variables which have stronger correlation with HbA1c (Right Knee, Left Knee, Right Ankle,

Left Ankle, Right Shin Average, Left Shin Average, Centre of Eyebrows, Right Eye) showed a significant increase in temperature in the YBL group compared to PHE group ( $p < 0.05$ ) at 1 year. A total of 11 EPI variables showed significant correlations with HbA1c. EPI Balance, Organs balance right, Organs balance left, Kidneys balance, Digestive system balance, Adrenals balance, Cerebral zone vessels balance, Cerebral zone cortex balance, Liver balance and Lumber spine balance showed significant negative correlation ( $r = -0.26$  to  $-0.50$ ,  $p < 0.001$ ), and EPI Stress variable showed a significant positive correlation ( $r = 0.42$ ,  $p < 0.001$ ) with HbA1c. Out of 11 EPI variables showing correlation with HbA1c, 7 variables (EPI Stress, Balance, Organs Balance Right, Organs Balance Left, Digestive System Balance, Adrenals Balance, and Cerebral Zone Cortex) improved significantly at 1 year in the YBL group compared to PHE ( $p < 0.05$ ).