Chapter 6
Results

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6.0 Results

The AY group had 30 (8 male and 22 female) subjects with an average age ± SD of 33.83 ± 6.84 years. The CT Group had an equal number of subjects matched for age and gender with an average age ± SD of 31.46 ± 7.81 years. The demographic and clinical characteristics are detailed in **Table 6**. There was one drop out in AY group on Day 90 and one each from the CT group on day 30 and 90.

Table 6: Demographic and clinical characteristics of subjects belonging to AY and CT groups

			AY	**CT**
Age	Mean		33.83	31.46
	SD		± 6.84	± 7.81
Gender	Male		8	8
	Female		22	22
Clinical characteristics	Severity of headache (intensity of pain)	Moderate	9	12
		Severe	21	18
	Average Duration of attack (in hours)		27.8	29.8
	Associated with Nausea and / or Vomiting (number of subjects)		30	30
	Number of subjects using Analgesics		30	30

6.1 Suśruta Prakṛti Inventory

The *Prakṛti* analysis showed that there were 15 subjects with *Vāta Pitta Prakṛti*, 31subjects with *Pitta Kapha Prakṛti* and 14 with *Vāta Kapha Prakṛti.* This indicated that *Pitta doṣa* was pre- dominantly seen (76.6%) in the *Prakṛti* of 46 subjects either as *pravara* (primary) or as *madhayama* (moderate) *doṣa*.

The details of the *Prakṛti* are mentioned in **Table – 6(a)**

Table 6(a): The combination of the Prakṛti seen in all 60 subjects

Prakṛti	**AY**	**CT**	**Total**	**Combined**
Vāta- Pitta	3	5	8	15
Pitta- Vāta	4	3	7	
Pitta-Kapha	9	12	21	31
Kapha-Pitta	6	4	10	
Vāta-Kapha	4	4	8	14
Kapha-Vāta	4	2	6	

6.2 Comprehensive headache related quality of life (CHQQ): The headache related quality of life included scores from physical, mental, social domains and their total score. The data of Day 1 compared to Day 90 in AY group showed significant improvement ($p<.001$, for all comparisons), while the CT group did not show any change ($p>.05$). There was a significant difference between the groups (AY and CT) when compared using a one-way ANOVA ($p<.001$). The group mean and SD of AY and CT group are mentioned in **Table - 6(b)**. Subjects with *Pitta Kapha prakṛti* had higher CHQQ scores (average score - 84.92) compared to the Vāta Pitta and Vāta- Kapha Prakṛti.

Table 6 (b): Comprehensive headache related quality of life questionnaire measuring quality of life at physical, mental and social domains recorded on Day 1 and Day 90 in Both AY as well as CT Groups. Values are Group mean ± SD.

Sl. No.	Domains	Ayurveda and Yoga group		Control group	
		Day 1	Day 90	Day 1	Day 90
1	**Physical**	50.93	86.63***	55.72	55.81
		±13.41	±10.66	± 17.77	± 16.75
2	**Mental**	50.06	80.04***	55.91	51.98
		±15.18	±9.49	± 16.88	± 13.49
3	**Social**	55.16	85.68***	59.00	59.31
		±14.35	±10.06	±20.14	±17.60
4	**Total**	51.47	83.56***$	56.52	54.91
		±13.24	±9.12	±17.05	±14.19

*** p <.001, Paired Sample t-test comparing the Mean values of the groups on Day 90 compared to Day 1 values respectively. $ p<.001, Oneway ANOVA comparing the between group differences

CHQQ-QOL score for physical domain recorded on Day 1 and Day 90 in Both AY as well as CT Groups. Values are Group mean ± SD.

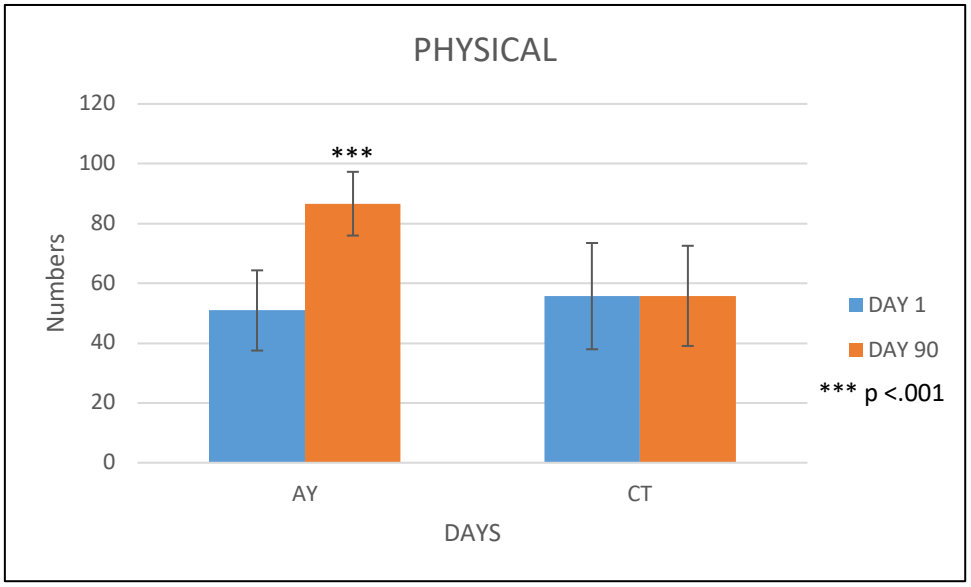


Fig 21: Graph representing Physical domain of CHQQ

CHQQ-QOL score for mental domain recorded on Day 1 and Day 90 in Both AY as well as CT Groups. Values are Group mean ± SD.

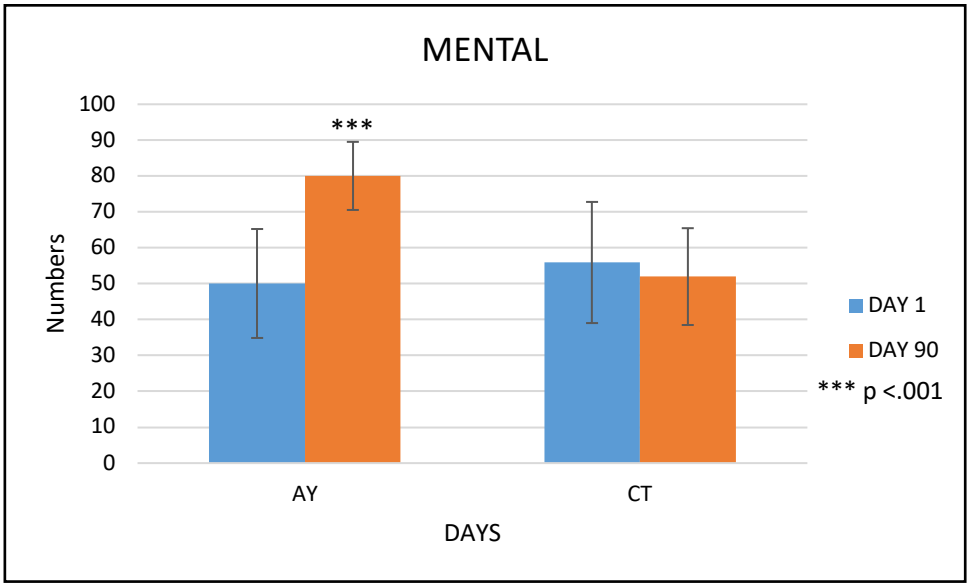


Fig.22: Graph representing mental domain of of CHQQ

CHQQ-QOL score for social domain recorded on Day 1 and Day 90 in Both AY as well as CT Groups. Values are Group mean ± SD.

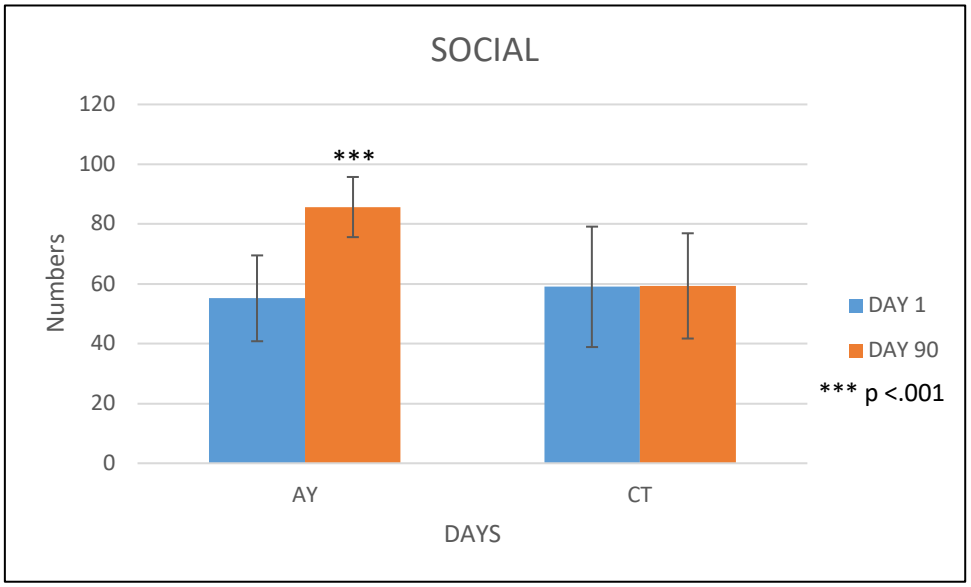


Fig 23: Graph representing social domain of CHQQ

CHQQ-QOL total scores combining physical, mental and social domains recorded on Day 1 and Day 90 in Both AY and CT Groups. Values are Group mean ± SD.

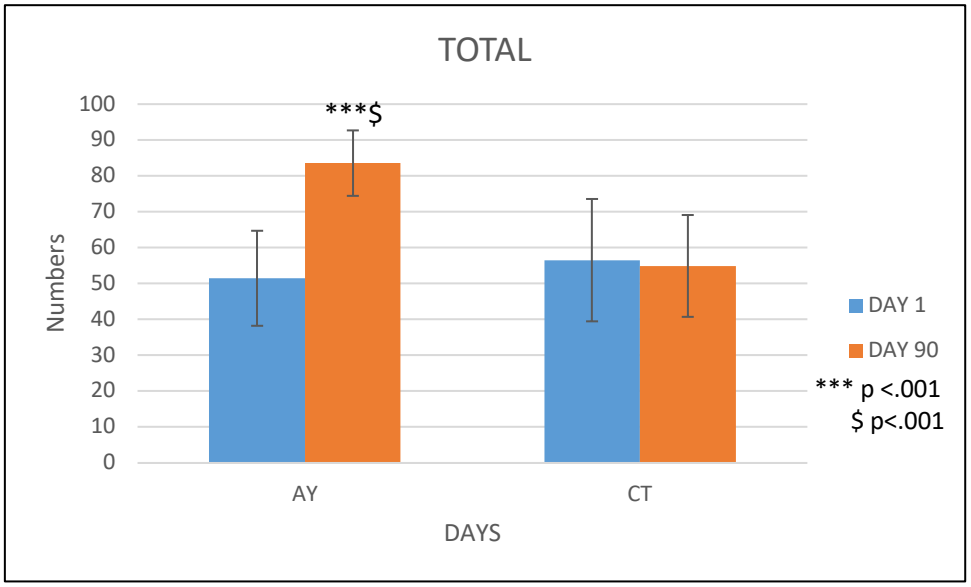


Fig.24: Graph representing total scores of physical, mental and social domains of CHQQ

6.3 The Symptom Checklist: The number of attacks and the average maximum duration of an at- tack reduced in the AY group compared to the CT group when assessed on Day 30 and Day 90 compared to Day 1 of the study. The number of subjects with severe headache, nausea and/or vomiting reduced across Day 30 and day 90 in the AY group compared to the CT group. The analgesic requirement on need basis which was noticed in all 30 participants of the AY group (100%) on day 1 reduced to 14 participants (46.6%) by day 30 and was noticed in 6 participants (20%) on day 90 compared to the CT group where the requirement reduced from 30 participants (100%) on day 1 to 27 participants (90%) on day 30 and to 26 participants (86.66%) on day 90.

Table 6(c) represents the changes in symptom checklist measuring the change in subjective symptoms recorded on Day 1 and Day 90 in both AY and CT Groups. Values are Number of subjects reporting a particular symptom for items 1, 3, 4 and 5, while values for item number 2 are group mean in hours

Sl. No	**Symptoms**	**AY**			**CT**		
		Day 1	Day 30	Day 90	Day 1	Day 30	Day 90
1.	Number of subjects with 5 or more migraine attacks in last 3 months	30 (100%)	8 (26.6%)	5 (16.7%)	30 (100%)	29 (96.6%)	26 (86.7%)
2.	Average score of maximum duration of attack in hours	27.8	8.86	5.62	43.6	29.8	45
3.	Number of subjects with severe Headache	21 (70%)	10 (33.3%)	4 (13.3%)	18 (60%)	20 (66.7%)	21 (70%)
4.	Number of subjects with nausea and/ or vomiting	30 (100%)	17 (56.6%)	4 (13.3%)	30 (100%)	27 (90%)	28 (93.3%)
5.	Number of subjects with analgesic requirement on need	30 (100%)	14 (46.7%)	6 (20%)	30 (100%)	27 (90%)	26 (86.7%)

Number of subjects with 5 or more Migraine attacks recorded on Day 1 and Day 90 in Both AY and CT Groups.

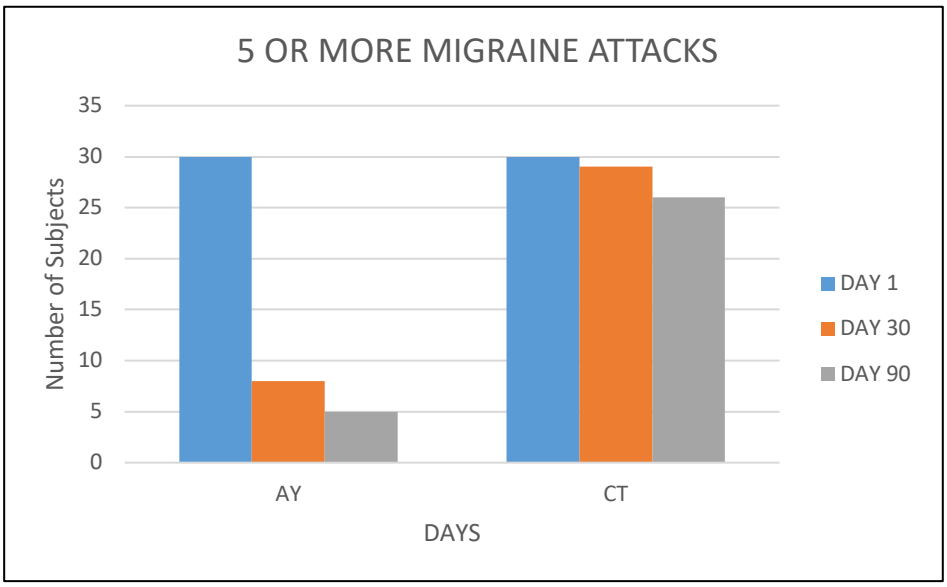


Fig 25: Graph representing 5 or more migraine attacks

Maximum duration of a migraine attack (in hours) recorded on Day 1 and Day 90 in Both AY and CT Groups.

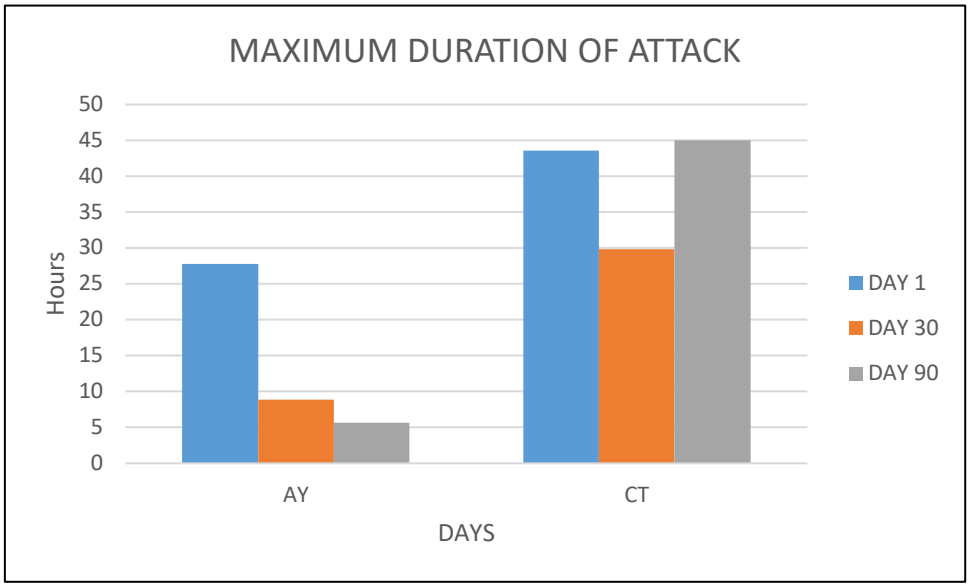


Fig 26: Graph representing maximum duration of attack

Number of subjects reporting severe headache on Day 1 and Day 90 in Both AY and CT Groups.

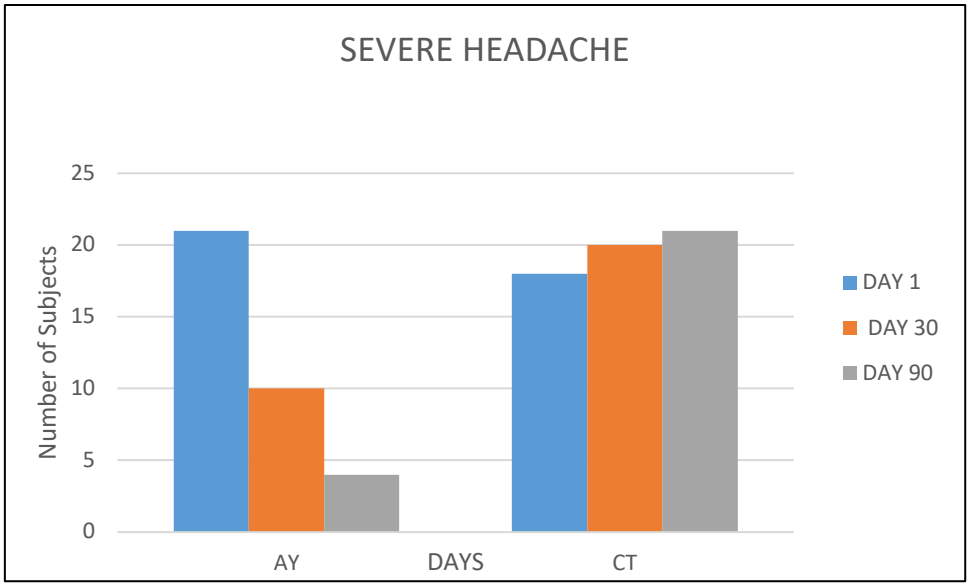


Fig.27: Graph representing severity of headache

Number of subjects reporting Nausea and/ or Vomiting on Day 1 and Day 90 in Both AY and CT Groups.

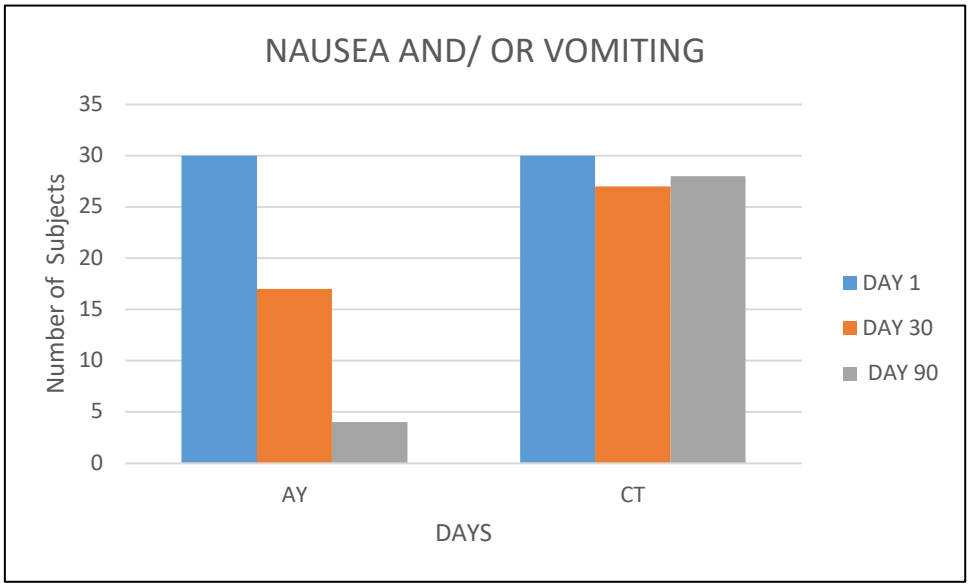


Fig.28: Graph representing episodes of nausea and/or vomiting

Number of subjects reporting analgesic requirements on Day 1 and Day 90 in Both AY and CT Groups.

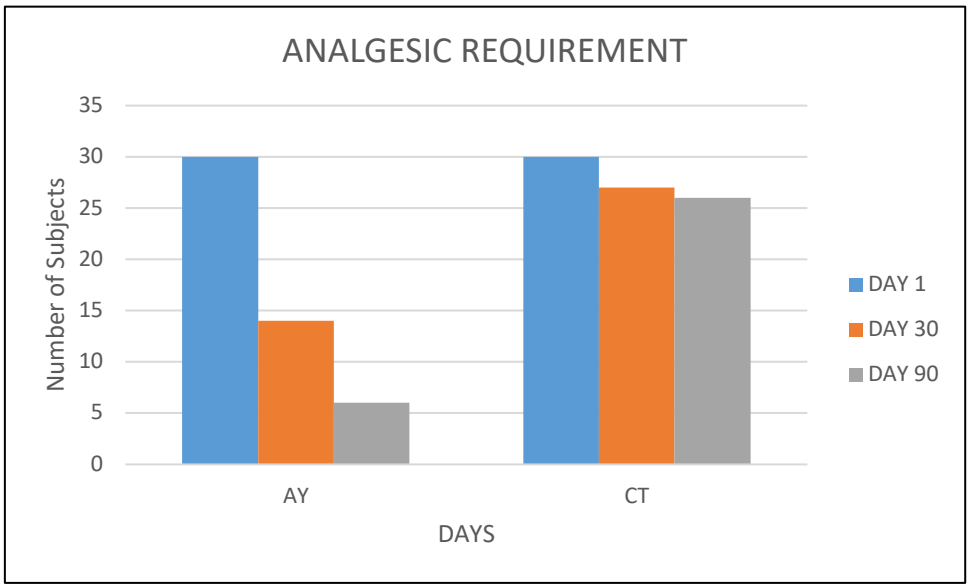


Fig.29: Graph representing analgesic requirement

6.4 Visual Analogue Scale (VAS): The pain intensity as measured by visual analogue scale has shown significant reduction in AY group (p<.001) in comparison to CT group (p>.05) which showed no change. The between group comparison also showed a significant difference between AY and CT groups (p<.001).

Details in Table 6(d) represents the changes in VAS measuring pain intensity recorded on Day 1 and Day 90 in Both AY Group as well as Control Group. Values are Group mean ± SD.

	AY		**CT**	
	Day 1	Day 90	Day 1	Day 90
VAS	7.30	2.20$^{***\$}$	7.13	7.37
	± 1.53	± 1.24	± 1.35	± 1.06

*** p <.001, Paired Sample t-test comparing the Mean values of both groups on Day 90 compared to Day 1 values respectively. $ p <.001, One-way ANOVA comparing the mean values of both groups on Day 90 compared to Day 1 values respectively.

Visual Analogue Scale (VAS) measuring pain intensity recorded on Day 1 and Day 90 in Both AY Group as well as Control Group. Values are Group mean ± SD.

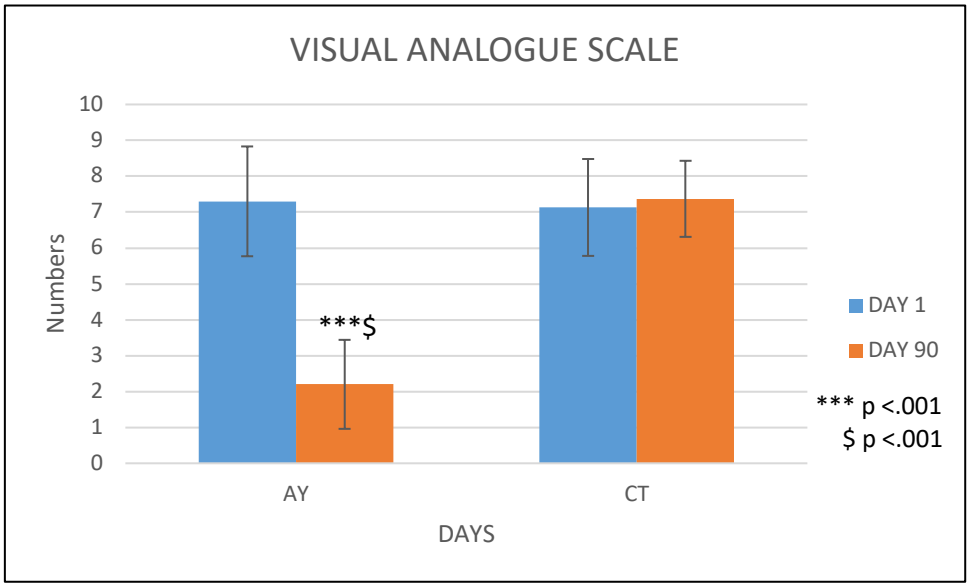


Fig.30: Graph representing values of Visual analogue scale

6.5 MIDAS: There was a significant difference in both Within-Subjects factor (Time, $p<.001$) as well as Between Subjects factor (Groups, $p<.05$). Also, the interaction between Time and Groups was significant ($p<.001$). The post-hoc analysis with Bonferroni correction suggested that there was a significant reduction in MIDAS scores for AY group on Day 30 and 90 compared to respective Day 1 values ($p<.001$, for both comparisons).

When the degree of disability was compared across Days 1, 30 and 90, the number of subjects with grade IV (severe disability) decreased from 16 (53.3%) to 4 (13.3%) to 1 (3.3%) subject whereas those belonging to grade I MIDAS (little or no disability) increased from 6 (20%) to 11 (36.6%) to 20 (66.6%) respectively. The CT group showed no change across three assessment points.

6.6 Perceived Stress Scale 10: There was a significant difference in both Within-Subjects factor (Time, $p<.001$) and Between-Subjects factor (Groups, $p<.001$). Also, the interaction between Time and Groups was significant ($p<.001$). The post-hoc analysis showed a significant reduction in PSS scores for AY group on Day 30 and 90 compared to their Day 1 values ($p<.01$, $p<.001$, respectively).

The scores of perceived stress in the AY group changed significantly across three assessments (Day1, Day 30 and Day 90). The number of subjects with low stress increased from 3 (10%) to 7 (23.3%) to 18 (60%), with moderate stress decreased from 25 (83.3%) to 22 (73.3%) to 11 (36.6%) and with high perceived stress decreased from 2 (6.6%) to 1 (3.3%) to 0 subjects. **Details in Table 6(e).**

Details in Table 6(e): Migraine Disability Assessment (MIDAS) and Perceived Stress Score (PSS) recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. Values are Group mean ± SD.

	AY			CT		
	Day 1	**Day 30**	**Day 90**	**Day 1**	**Day 30**	**Day 90**
MIDAS	25.73	10.76***	5.48***†	21.00	17.58	20.24
	±22.07	±10.39	±7.97	±15.26	±12.40	±13.48
PSS	21.20	17.03**	11.96***†††	22.30	21.34	21.51
	±4.83	±5.72	±4.85	±3.36	±2.48	±3.34

** p<.01, *** p <.001, † p<.05, ††† p<.001, Repeated measures ANOVA with Post-hoc analysis. *Comparing the Day 1 values with respective Day 30 and Day 90 values, † comparing Day 30 and Day 90 values.

MIDAS recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. Values are Group mean ± SD.

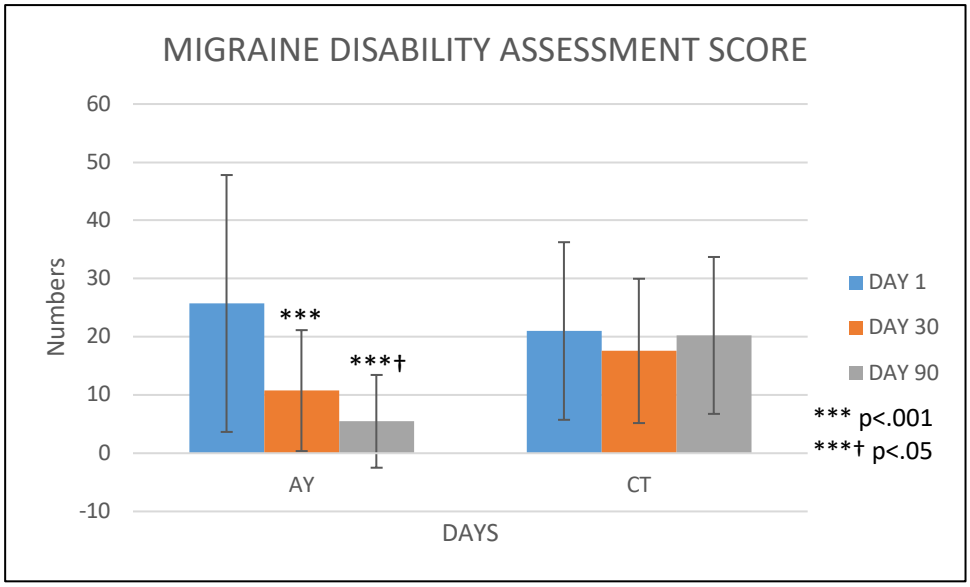


Fig.31: Graph representing MIDAS Scores.

PSS recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. Values are Group mean ± SD.

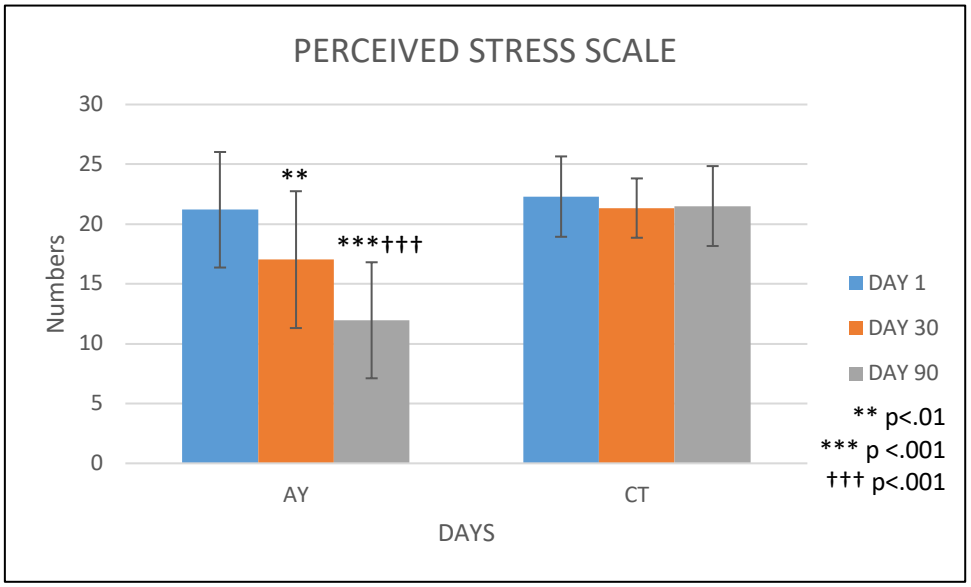


Fig.32: Graph representing perceived stress scale scores.

6.7: Autonomic variables

6.7.1: Respiratory rate

There was no significant difference in both Within-Subjects factor and Between-Subjects factor. The interaction between time and groups was significantly different ($p<.05$). The post-hoc analysis with Bonferroni correction suggested that there was a significant reduction in respiratory rate in AY group on Day 90 compared to Day 1 values ($p<.01$).

Respiratory rate as breaths per minute (BrPM) recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. The values are Group mean ± SD.

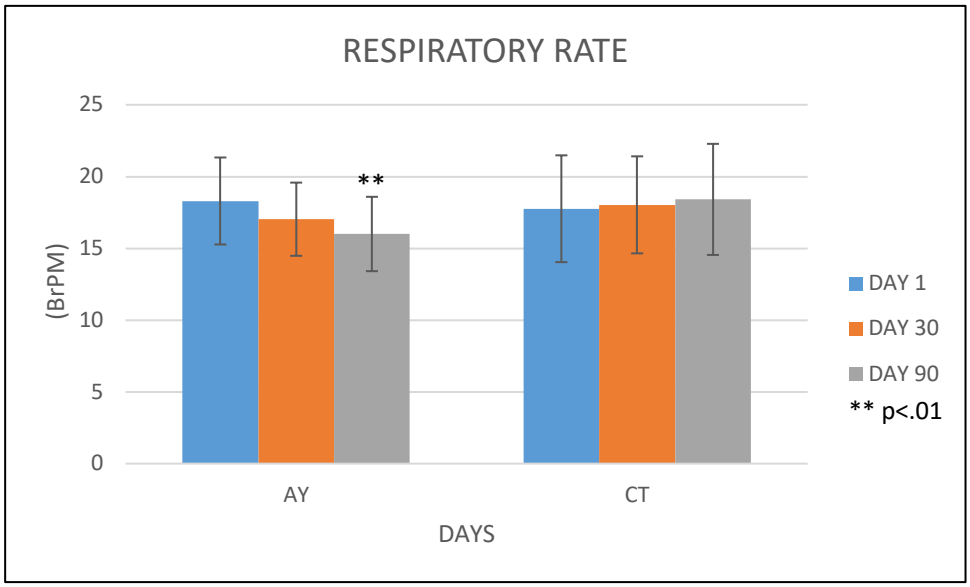


Fig.33: Graph representing respiratory rate

6.7.2: Heart Rate Variability

There was a significant interaction between time and groups for LF, HF power values in normalized units as well as LF/HF ratio ($p<.05$). The post-hoc analysis showed a significant reduction in LF power and LF/HF ratio, while HF power increased in AY group on Day 90 compared to their Day 1 and Day 30 values ($p<.01$, $p<.05$ respectively). There were no changes observed in the time domain measures of HRV.

Table 6 (f): Frequency domain and Time domain measures of Heart rate variability recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. The values are Group mean ± SD.

	AY			CT		
	Day 1	**Day 30**	**Day 90**	**Day 1**	**Day 30**	**Day 90**
LF (nu)	54.86	50.72	41.26**†	43.51	45.77	46.04
	±18.45	±17.25	±15.48	±18.33	±16.40	±16.85
HF(nu)	45.29	48.90	58.91**†	56.71	54.36	54.14
	± 18.22	±18.15	± 15.43	± 18.30	±16.37	± 16.87
LF/HF (ratio)	2.06	1.29	0.84†	1.04	1.10	1.09
	± 2.79	±0.86	± 0.59	± 0.97	±0.98	±0.89
SDNN (ms)	34.99	33.43	34.33	34.41	33.73	34.37
	±18.86	±13.65	±18.47	±13.23	±20.27	±20.20
RMSSD (ms)	25.49	23.71	28.16	30.50	30.41	33.10
	± 19.63	±14.38	± 24.60	± 20.70	±26.39	± 27.05
pNN50 (ms)	8.43	7.72	6.35	11.88	9.82	12.51
	± 14.32	±12.41	± 10.62	± 18.74	±14.78	±19.23

** p <.01, † p<.05, Repeated measures ANOVA with Post-hoc analysis. * comparing Day 1 with respective Day 30 and Day 90 values, † comparing Day 30 with Day 90 values.

LF (nu) component of HRV recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. The values are Group mean ± SD.

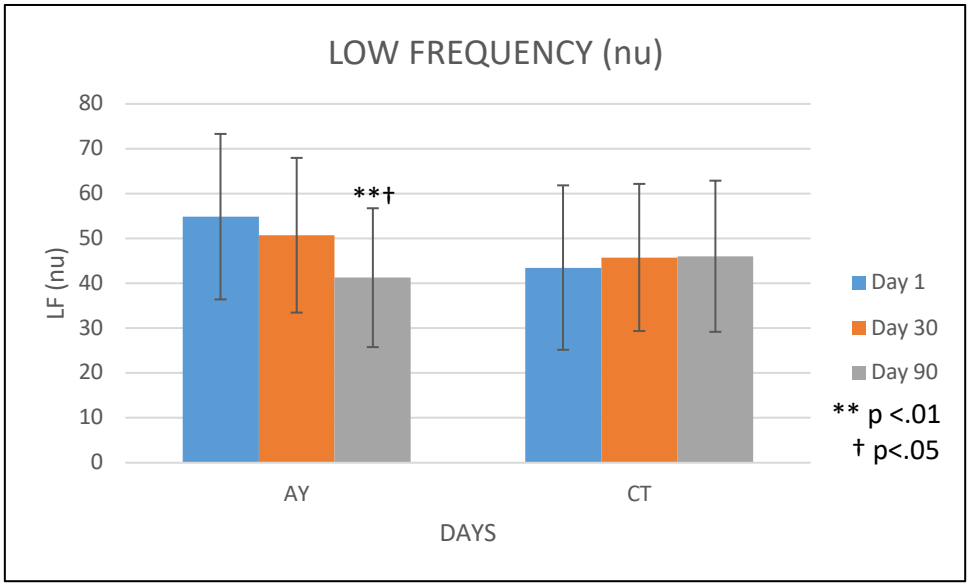


Fig.34: Graph representing low frequency component of HRV

HF (nu) component of HRV recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. The values are Group mean ± SD.

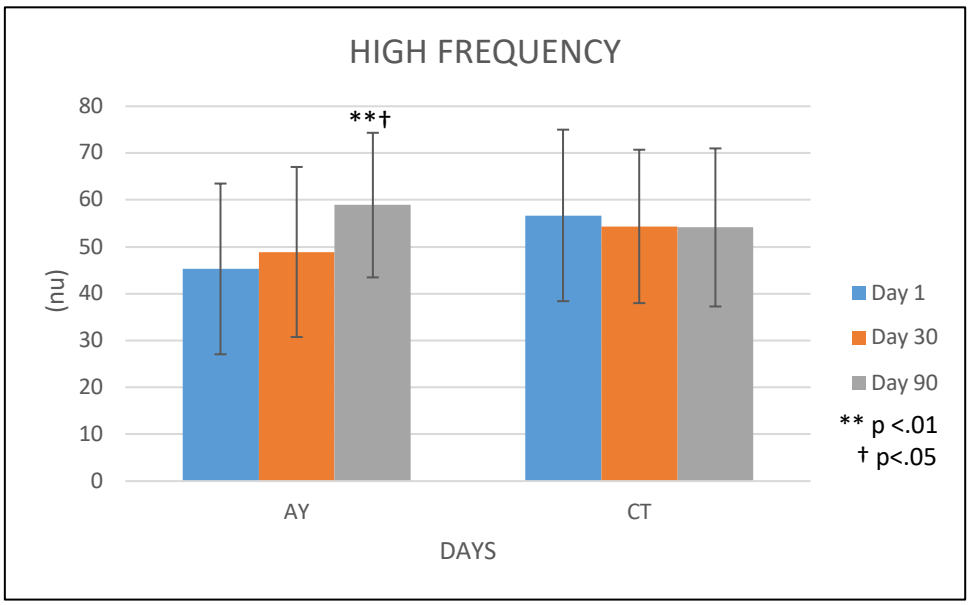


Fig.35: Graph representing high frequency component of HRV

LF/HF ratio component of HRV recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. The values are Group mean ± SD.

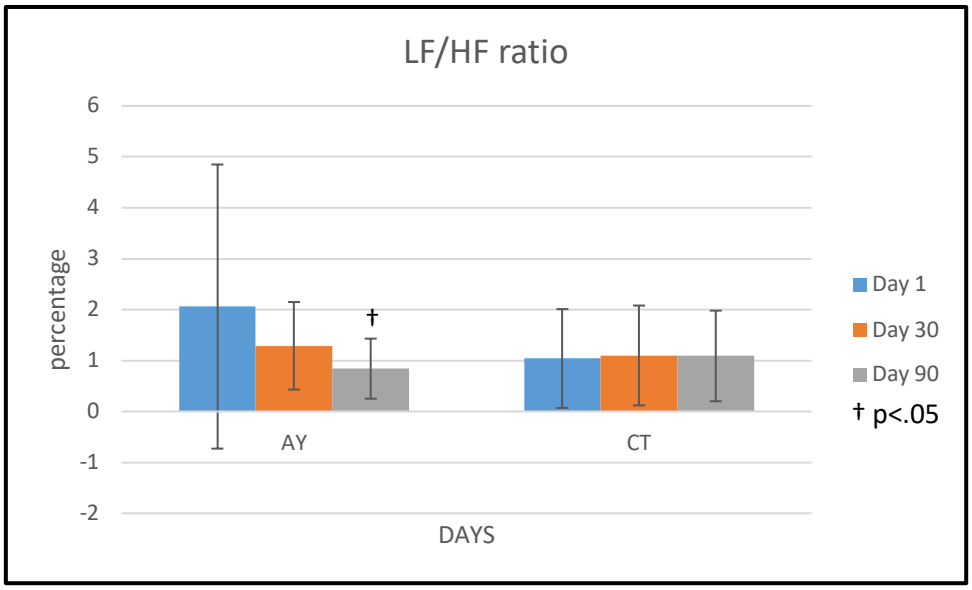


Fig.36: Graph representing LF/HF ratio of HRV

SDNN component of HRV recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. The values are Group mean ± SD.

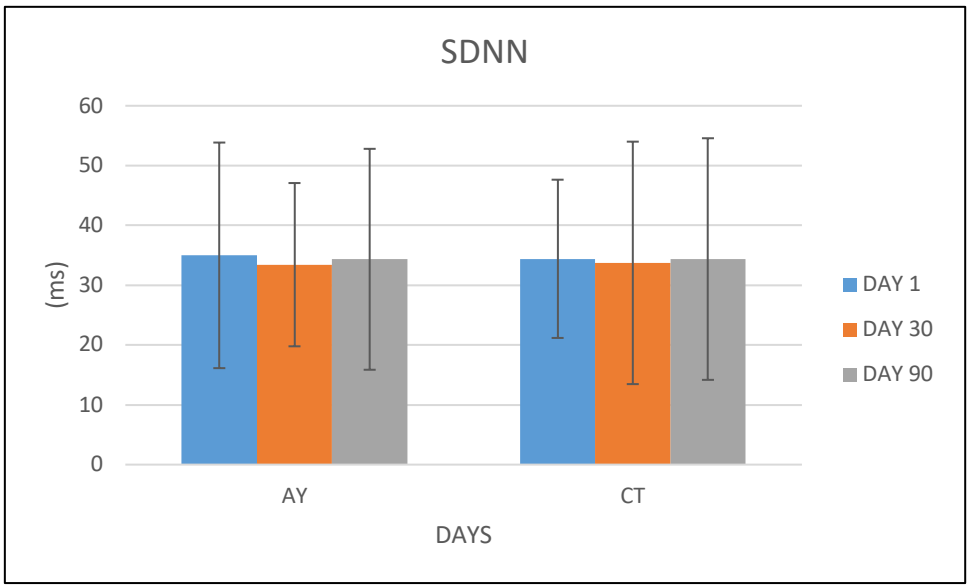


Fig.37: Graph representing SDNN component of HRV

RMSSD component of HRV recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. The values are Group mean ± SD.

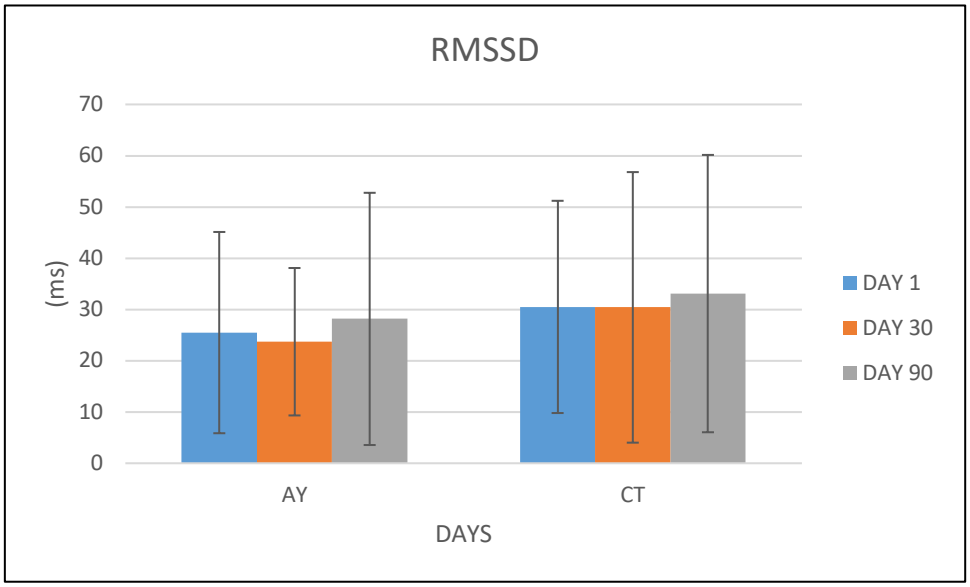


Fig.38: Graph representing RMSSD component of HRV

pNN50 (ms) component of HRV recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. The values are Group mean ± SD.

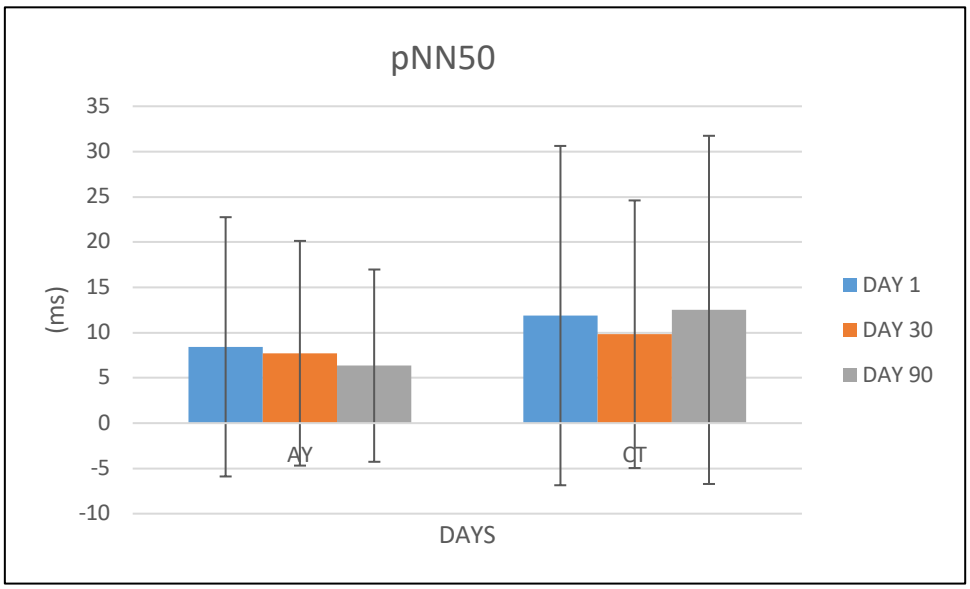
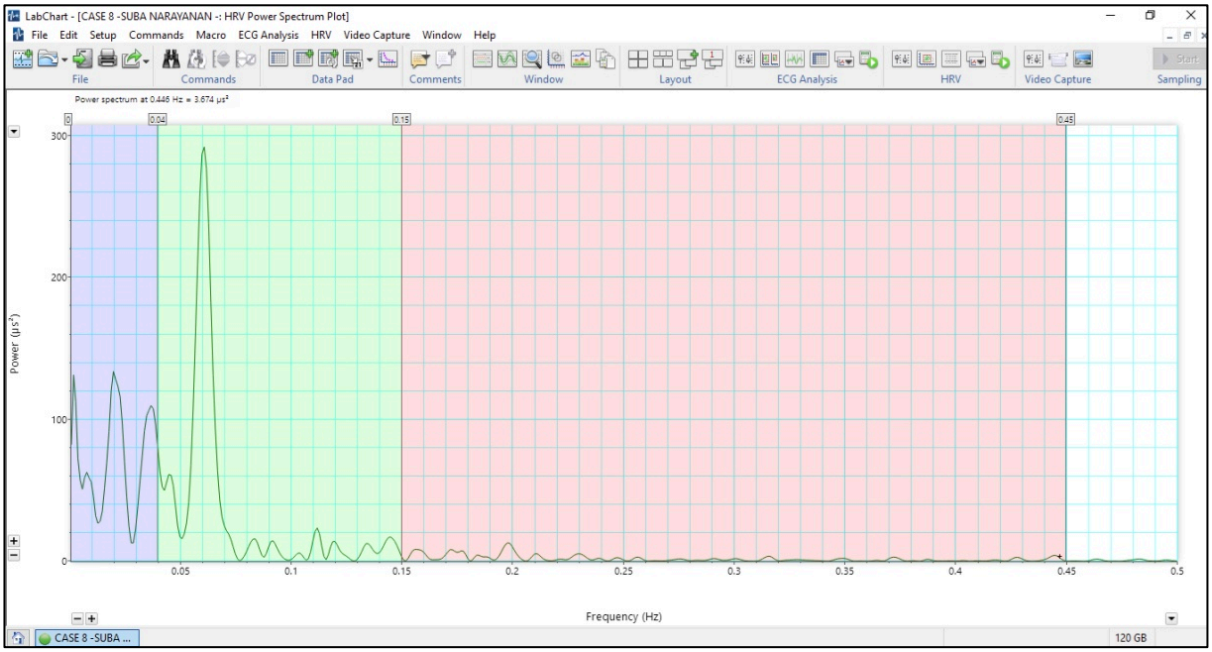


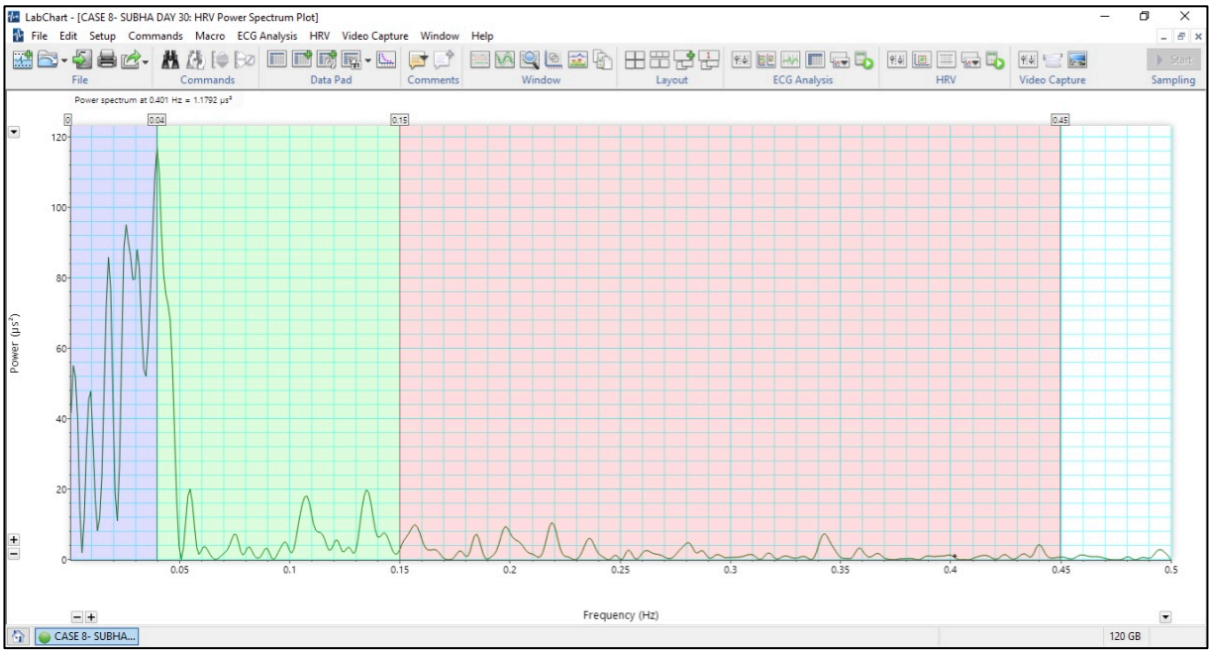
Fig.39: Graph representing pNN50 component of HRV

Changes in Power spectrum plot of HRV between Day 1, 30 and 90.

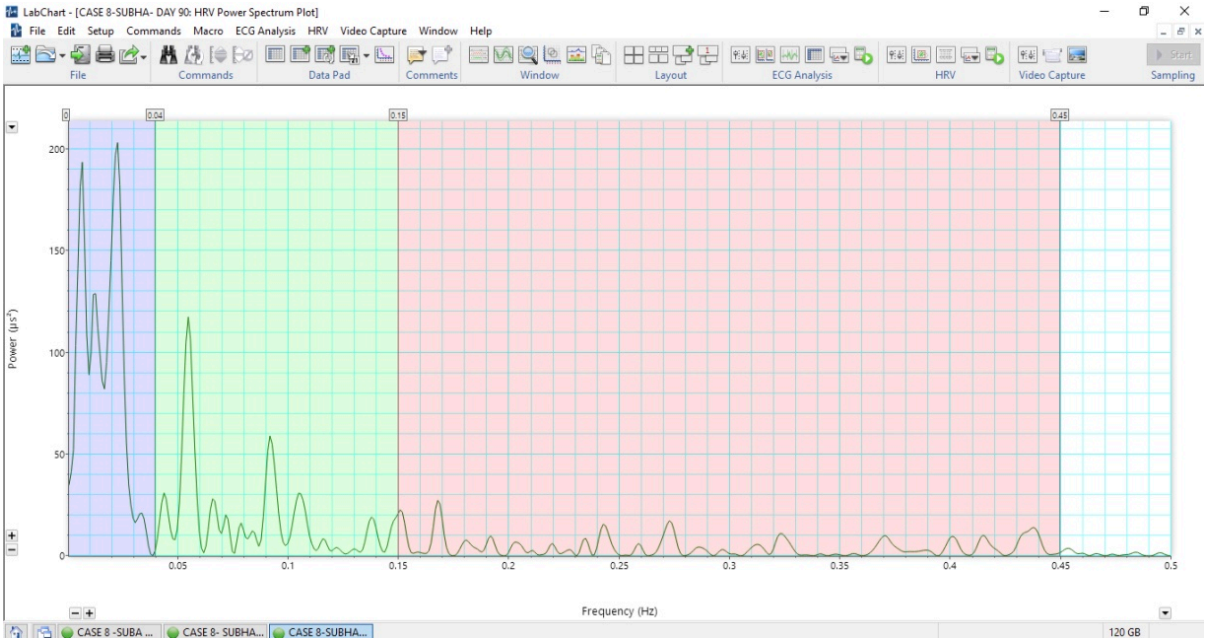
Day 1



Day 30



Day 90



6.7.4 Heart Rate- There was a significant difference in Within-Subjects factor (Time, $p<.05$). The post-hoc analysis with Bonferroni correction showed no significant difference across multiple comparisons for both groups.

Details in Table 6 (g): The Heart rate (HR) and Respiratory rate (RR) recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. The values are Group mean ± SD.

	AY			**CT**		
	Day 1	**Day30**	**Day 90**	**Day 1**	**Day 30**	**Day 90**
HR (BPM)	82.95	84.72	78.53	86.58	87.05	84.09
	±11.53	±12.63	±11.12	±9.74	±11.93	±14.24
RR (BrPM)	18.30	17.03	16 **	17.76	18.03	18.41
	± 3.03	±2.55	± 2.59	± 3.72	±3.38	± 3.87

**p<.01, Repeated measures ANOVA with Post-hoc analysis comparing the Day 1 values with respective Day 30 and Day 90 values. BPM – Beats Per Minute, BrPM – Breaths Per Minute.

Heart rate as beats per minute (BPM) recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. The values are Group mean ± SD.

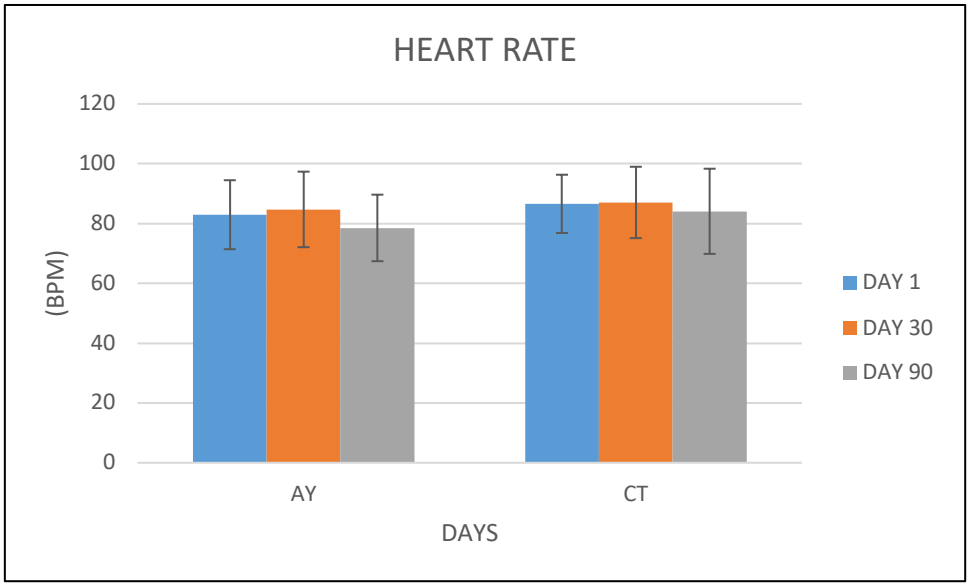


Fig.40: Graph representing Heart rate

6.8 Surface Electromyography (sEMG): The Mean RMS EMG showed a significant difference in Within-Subjects factor (time, $p<.05$), Between Subjects factor (groups, $p<.05$) and the interaction between time and groups ($p<.01$). The post-hoc analysis showed a significant reduction on Day 90 compared to respective Day 1 and Day 30 values ($p<.001$and $p<.05$, respectively).

Integral EMG ($p<.001$) showed a significant difference in the interaction between time and groups ($p<.001$). The post-hoc analysis showed a significant reduction in integral EMG values in AY group on Day 90 compared to respective Day 1 values ($p<.01$).

The control group showed no significant changes across assessments (Days 30 and 90, compared to Day 1) for different variables ($p>.05$).

Details in Table 6 (h): The Integral EMG **(µv)** and RMS EMG **(µv)** recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. The values are Group mean ± SD.

	AY			CT		
	Day 1	**Day 30**	**Day 90**	**Day 1**	**Day 30**	**Day 90**
Integral EMG	11.80	8.74	6.52**††	9.31	10.96	12.04
	±8.49	±4.85	±2.77	±3.90	±5.42	±6.31
RMS EMG	133.43	113.99	75.44***†	128.50	159.41	128.31
	± 58.25	±68.61	± 35.19	± 69.53	±129.39	± 65.87

** p <.01, *** p <.001, † p<.05, †† p<.01, Repeated measures ANOVA with Post-hoc analysis.

* Comparing Day 1 with respective Day 30 and Day 90 values, † comparing Day 30 with Day 90 values.

The Integral EMG **(µv)** recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. The values are Group mean ± SD.

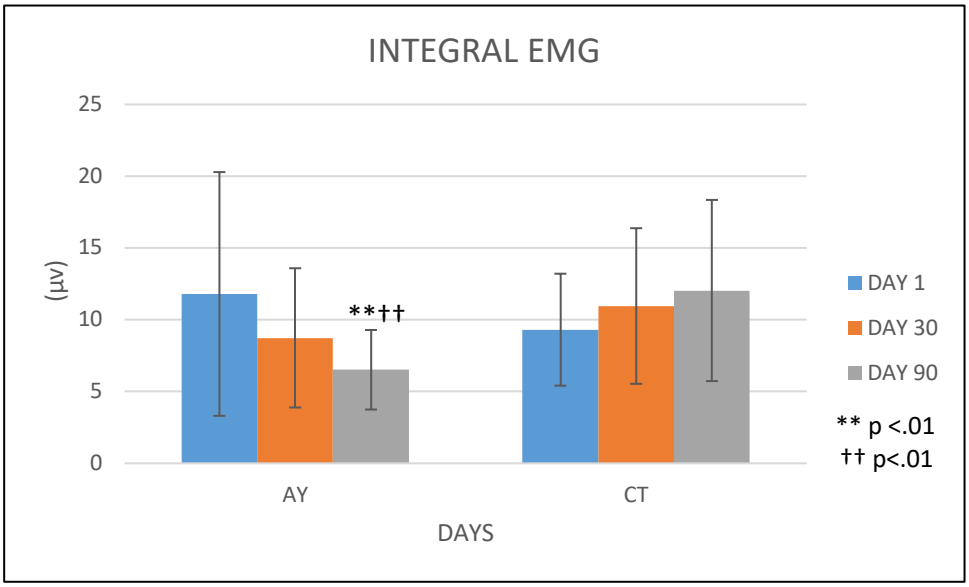


Fig.41: Graph representing Integral EMG

The RMS EMG **(µv)** recorded on Day 1, Day 30 and Day 90 in both AY and CT groups. The values are Group mean ± SD.

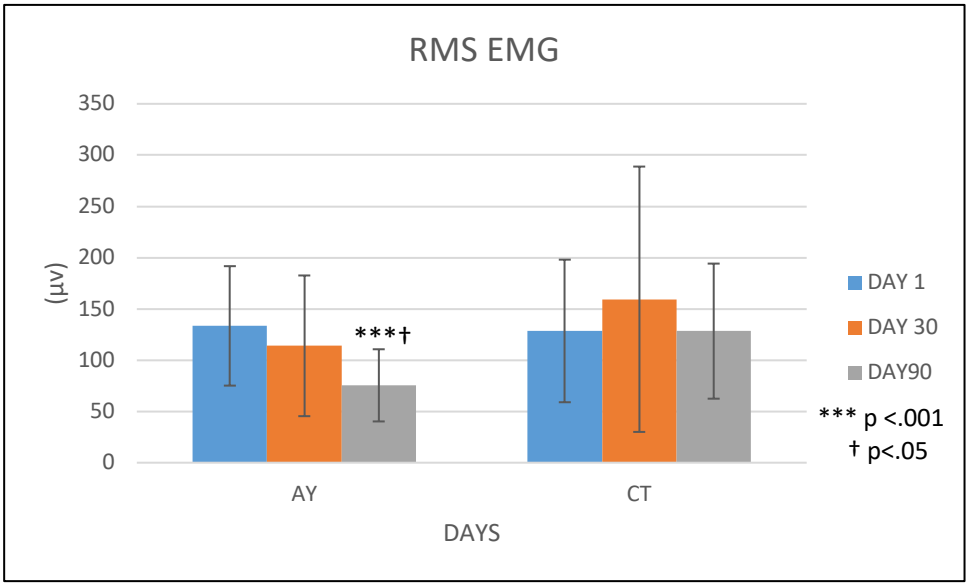
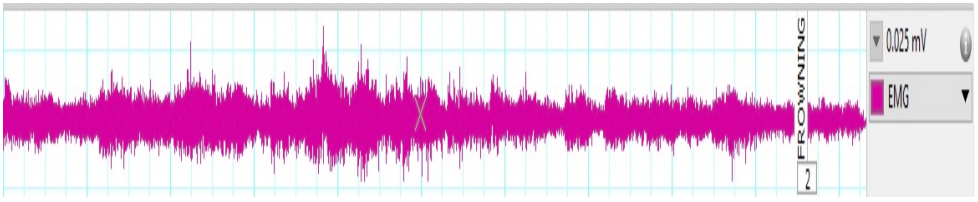
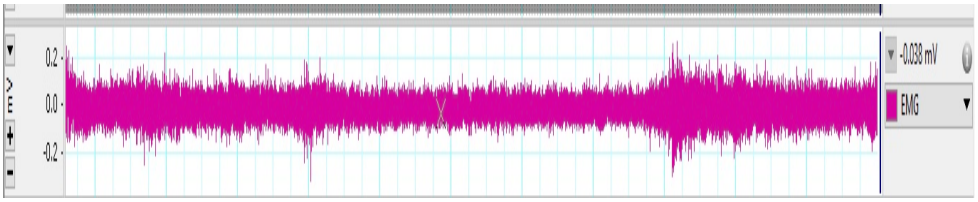


Fig.42: Graph representing RMS EMG

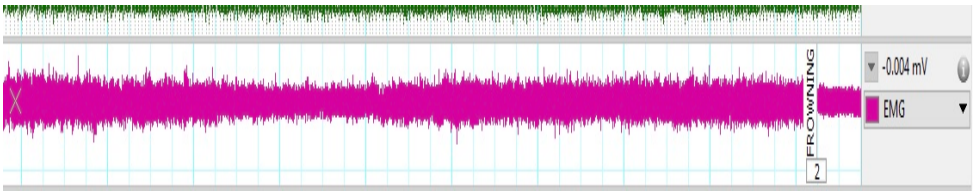
Comparing the sEMG wave pattern between Day1, Day 30 and Day 90



sEMG Day 1



sEMG Day 30



sEMG Day 90