Edits required in the protocol published on 18-2-2020.

1. Results were reanalysed by a biostatistician and the results section has been edited as per the results copied below.

COMPDIAM PARTICIPANT FLOW



**Demographic characteristics and distribution at baseline**

**No of participants enrolled in Control & Intervention groups**

Table :1

| N=30 | Count | Column N % |
| --- | --- | --- |
| group | Control(SOC) | 15 | 50.0% |
| Intervention(Pranichealing+SOC) | 15 | 50.0% |

Table 2: Gender distribution of patients studied

|  |  |  |  |
| --- | --- | --- | --- |
| **Gender** | **Group I** | **Group II** | **Total** |
| Female | 3(20%) | 2(13.3%) | 5(16.7%) |
| Male | 12(80%) | 13(86.7%) | 25(83.3%) |
| Total | 15(100%) | 15(100%) | 30(100%) |
|  |  |  |  |

 P=1.000, Fisher Exact test

Table 2: Age distribution of patients studied

|  |  |  |  |
| --- | --- | --- | --- |
| **Age in years** | **Group I** | **Group II** | **Total** |
| 41-50 | 6(40%) | 1(6.7%) | 7(23.3%) |
| 51-60 | 5(33.3%) | 5(33.3%) | 10(33.3%) |
| 61-70 | 4(26.7%) | 7(46.7%) | 11(36.7%) |
| >70 | 0(0%) | 2(13.3%) | 2(6.7%) |
| Total | 15(100%) | 15(100%) | 30(100%) |
| Mean ± SD | 53.03±10.39 | 62.00±8.48 | 57.53±10.37 |
|  |  |  |  |

 P=0.015, student t test

Table 3 : Grade of Wagner Scale Diabetic Foot Ulcer on recruitment

| Wagner grade  on recruitment | group |
| --- | --- |
| Control(SOC) | Intervention (Pranic healing+SOC) |
| Count | Column N % | Count | Column N % |
|  | Grade 1 |  9 | 60 | 5 | 33.33 |
| Grade 2 | 6 | 40 | 7 | 46.66 |
| Grade 3 | 0 | 0% |  3 | 20.00 |

**Table 2 : Results**

**Summary of Primary Outcome Measures at the end of the trial**

**A. Statistical Interpretation**

**Table:** Intra group Comparison (Between D1 and D35) of wound size among test group and control group –Paired T test

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | N | Mean | SD | Mean Difference | t | P Value | 95% Confidence Interval of the Difference |
| Lower | Upper |
| Test Group | D1 | 12 | 4.25 | 5.01 | 2.15 | 2.916 | 0.014 | 0.52 | 3.76 |
| D35 | 12 | 2.10 | 2.7 |
| Control Group | D1 | 9 | 10.16 | 25.07 | -1.84 | -0.807 | 0.443 | -7.09 | 3.41 |
| D35 | 9 | 12.0 | 31.78 |

\*Statistical significance set at 0.05; N: Number of samples; SD: Standard Deviation

**Interpretation:**

Paired sample t test displays a statistically significant reduction in wound size**(t=2.91; P=0.014; CI: 0.52 to 3.76)** after intervention with Pranic Healing (Test Group) for 35 days (D35) when compared to D1. The control group did not exhibit a statistically significant difference in wound size between D1 and D35. **(t=-0.807; P=0.443; CI: -7.09 to 3.41).**

**Table:** Intra group Comparison (Between D1 and D35) of HBA1c among test group and control group –Paired T test

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | N | Mean | SD | Mean Difference | t | P Value | 95% Confidence Interval of the Difference |
| Lower | Upper |
| Test Group | D1 | 11 | 9.86 | 2.31 | 1.45 | 2.811 | **0.018\*** | 0.301 | 2.607 |
| D35 | 11 | 8.40 | 2.08 |
| Control Group | D1 | 8 | 8.78 | 1.48 | 0.33 | 1.093 | 0.311 | -0.392 | 1.067 |
| D35 | 8 | 8.45 | 1.67 |

**Interpretation:**

Paired sample t test displays a statistically significant reduction in HBA1c level **(t=2.81; P=0.018; CI: 0.301 to 2.607)** after intervention with Pranic Healing (Test Group)for 35 days (D35) when compared to D1. The control group did not exhibit a statistically significant difference in HBA1c levels between D1 and D35. **(t=0.33; P=0.311; CI: -0.392 to 1.067).**

**B. Outcomes represented by change in percentages**

**Average change across groups in primary outcome during the trial**

|  |  |  |
| --- | --- | --- |
| S No | **Parameter** | **Group average** |
| **Trial**(N=12) | **Control**(N=9) |
| 1. | Reduction in wound size (cm2)(Mean; ± SD) (D35-D1) | 2.15 ±2.7(CI: 0.52 to 3.76)**P=0.014\*** | -1.84±31.78(CI: -7.09 to 3.41)**P=0.443** |
| 2 | Percentage change in wound size  (D1-D-35) | 69.07 % | 23.22% |
| 3**.** | Improvement in wound bed (approx) (qualitative) | 52.50% | 29.4% |
| 4. | Reduction in Wagner Grade (moved to lower grade) (number) | 66.67%8/12 | 44.44%4/9 |
| 5. | Improvement in Monofilament test(number) | 18%2/11 | 0% |
| 6. | Improvement in Vibratory Perception Test (number) | 45%5/11 | 22.3%2/9 |
| 7. | Reduction in stress/anxiety(number) | 75%9/12 | 11%1/9 |
| 8. | Lowering of Hba1c level (Mean; ± SD) (D35-D1) | 1.45 ± 2.08CI: 0.301 to 2.607**P=0.018\*** | 0.33 ±1.67CI: -0.392to 1.067**P=0.311** |
| 9. | Percentage lowering of Hba1c level (D35-D1) | 13.47% | 3.43% |

**Average change across groups in secondary outcome during the trial**

|  |  |  |
| --- | --- | --- |
| **S No** | **Parameter** | **Group average** |
| **Trial** | **Control** |
| 1. | Lowering of average glycemic level (hba1c/RBS) | 14.24% | 4.8% |
|  |  |

**Adverse Events**: There were no adverse events associated with this trial.