The Potential of Revivify Gel use and evaluation of Major Post Operative Early recovery based on Fatigue

or

"**Revivify gel stimulates the immune system: potential role in health benefits including the post-surgery fatigue**"

INTRODUCTION:

Thus, REVIVIFY PRO-VITALITY ANTIOXIDANT FRUIT GEL, is a innovative, novel and unique formulation which addresses every aspect of cellular integrity of all body cells, which in turn can offer a wide ranges of health benefits. It improves metabolic disorders, pain and inflammations, neurological alertness, vascular vitality, fatigue and stresses, immunity and skin protection with luminosity, brightness, and firmness.

Just to re-cap, dietary supplement can systemically improve cellular health correcting damaged cells and various metabolic processes. The first feature of cell's survival requires energy production and respiration. That means ROS production and requirement of consequent neutralization, the first and outmost oxidant is superoxide anion which is encountered by SOD, melon source.

The formulation composed of well-balanced polyphenols from pomegranate, concord grapes, blueberries, sweet and sour cherries, goji berry, acai, aloe-vera, green tea containing quercetin [half-life 11-28 hrs], anthocyanins [half-life 2 hrs]. and flavanols [half-life 2-3 hrs] having absorption kinetics differs greatly depending on types of glycoside conjugation. Also contains ellagic acid, and punicalagins, and microbial metabolites, relate to strong antioxidant and anti-inflammatory properties, positive effects on plasma lipid levels, and modulation of glucose metabolism and endothelial system. Interestingly, formulation help immune system whereby it contains oligosaccharides/polysaccharides that provide cells with special sugars supporting healthy immunity and enable cells communicate more effectively [reduce possible auto-immune disorders, as well as destroying proteins that inhibit the pathogenic molecules invading cells].

As formulation has a concept whereby the modulation of gut microbes occurs and that is customized to host --- relates series of health benefits needed by the host. The soluble corn fiber, a patented raw material with effective concentration has added benefits to beyond expectation. ***THIS NEW CONCEPT OF HEALTHY LIVING IS THE WAY TO RENEW, REVIVE, AND REJUVANATE CELLS THAT PROMOTES HEALTHY LIVING WITH YOUNG AND VIBRANT LOOKING.***

The formulation encounters major oxidants of superoxide anion, hydroxyl radicals, singlet oxygen, peroxy-nitrite, peroxy-radicals, and hypochlorite. As a result, there is prompt actions against pain from many dysfunctions, diverse neurological improvements, instant energy and

relief of exhaustion and fatigue, improves cognitive functions, skin elegance and overall healthy young looking and well-being.

Product: The Revivify Pro-vitality Anti-oxidant Gel contains a propriatery blend of Superoxide Dismutase soluble fiber composition along with polyphenols from various food concentrates and green tea extract. The in-vitro studies showed it is very effective to attenuate the oxidant biomarkers like 8-Isoprostane, has diverse anti-inflammatory effect by attenuation of inflammatory biomarker Cox-2, and many inflammatory cytokines of IL-6, TNF-a, and T-cell activation of lymphocytes CD4 and CD8. Also modulation of probiotic such as lactobascillus, with energy resourced metabolites of Short Chain Fatty Acids [SCFAs], particularly butyrate. The antioxidant, anti-inflammatory, anti-infective, enhanced immunity all should contribute positive impact and enable to achieve less complicacy from major surgical procedures and obtain an early recovery. The fatigue evaluation is one of simple and quick method to predict the hypothesis.

Protocols: A written approved protocol is followed, addressing the administrative and job conducting team, the hospitals involved, patient selection procedures, type of operation, physical and biological parameters initially, and also followed with intervals, etc. The statistical evaluation and significance.

AIM: The purpose of this research study was to understand the health benefits of Revivify gel. Study setting and participants

MATERIALS AND METHODS:

Study Centre: The study was conducted in a tertiary care hospital in Dhaka namely "BIRDEM" hospital.

Study Period: March 2023 to July 2023

The administrative Personals:

The patient selections: n= 27 , M; 13 F: 14

Study design and intervals: It was a prospective cohort study with follow up. The study is designed to a specifically evaluate Revivify Pro-Vitality Anti-Oxidant Gel role that enhance immune system as well as post-surgery fatigue after the initial post-operative measure of weakness, cognitive functions, pain, and infection, or other related measure to assess the first dose of the Revivify Gel [0 days] continued to other observational measure till 30 days. The study will be carried out in the post-surgery review clinic at Dhaka, Bangladesh. Participants will be recruited from the post-surgery outpatient clinic. Patients attending the outpatient clinic will be invited to participate in the current study by a research physician.

Population: N=30, ages 30 to 60 years, with an exclusion of critical condition like cancer, pregnant women, and mentally illness patients.

Criteria/Inclusion: Participant can be taken immediate after surgery at Hospital for initial o period evaluating measure [pre] and prior to taking Revivify Gel [oral] and follow up evaluation as per protocol 0 days and 21 day.

Dose/Frequency: One pouch daily with meal.

Chalder Fatigue Scale (CFQ11) will be used, it has 11 Questionnaires, scored using 4 Point Likert Scale from 0 to 4 (better than usual = 0, No worse than usual = 1 worse than usual = 2, and much worse than usual = 3).

Physical and biological tests: Sociodemographic, anthropometric data was collected at first visit through patient guide book and physically. Blood samples was tested for routine laboratory parameters like FBS (mmol/L); ABF (mmol/L); Random Blood Sugar; Triglyceride(mg/dl); S.Cholesterol(mg/dl); Low density lipoprotein (mg/dl); High density lipoprotein (mg/dl); S. Creatinine(mg/dl); S. Calcium(mg/dl); S.phosphate(mg/dl); Cl; Co_2; Hb%(gm/dl); TC. WBC [white blood cells] counts [leukocyte, neutrophil and lymphocyte counts], CRP, and lactate dehydrogenase[LDH], IL-6 and CD25 levels to be measured in serum by ELISA R&D Systems.

Clinical covariate assessment: Routine demographic information was collected from participants. Background medical history will be assessed by obtaining a list of regular medications and list of medical commodities.

Blood sample collection: 0 and 21 days for WBC counts [leukocytes and lymphocytes], CRP and Lactate dehydrogenase [LDH], IL-6, and CD25. Blood sampling will be incorporated as part of routine phlebotomy occurring on the same day as study participation/fatigue assessment. This involved measurement of routine laboratory parameters, including white cell counts (leukocyte, neutrophil and lymphocyte counts), CRP and lactate dehydrogenase (LDH). IL-6 and sCD25 levels will be measured in serum by ELISA (R&D systems). Blood parameter will be analyzed at Orion Institute for Translational Medicine, Temple Health & Bioscience District, Room # 109; 1802 S. 1st Street, Temple, Texas 76504.

Fatigue assessment questionnaires [Chader Fatigue scale] 7 and 21 days.

Each of the 11 items are answered on a 4-point scale ranging from the asymptomatic to maximum symptomology, such as 'Better than usual', 'No worse than usual', 'Worse than usual' and 'Much worse than usual'. For all items, the least symptomatic answers are on the left of the response-set, providing an easy-to-understand checklist for respondents. Using the Likert scoring method, responses on the extreme left receive a score of 0, increasing to 1, 2 or 3 as they become more symptomatic. The respondent's global score can range from 0 to 33. The global score also spans two dimen-sions—physical fatigue (measured by items 1–7) and psychological fatigue (measured by items 8–11). The Likert scoring system allows for means and distributions to be

calculated for both the global total as well as the two sub-scales. The CFQ 11 allows the user to differentiate between fatigue 'cases' and 'non-cases'—responses in the two left-hand columns are scored with 0, while responses in the two right-hand columns receive 1. The sub-scales of physical and psychological fatigue are not used here, but rather the respondent receives a global binary fatigue score ranging from 0 to 11.

Ethical approval: Informed written consent was obtained from all participants in the current study. Approval for the study was obtained from BCSIR.

Statistical analysis: All statistical analysis was carried out using STATA v15.0 [Texas, USA] and statistical significance will be considered P<0.05. Descriptive statistics will be reported as means with standard deviations [SD] and median with interquartile ranges [IQR] as appropriate.

The between group differences in those with severe fatigue in comparison to those without severe fatigue [categorized as non-fatigued as per the case definition of CFQ-11 above] will be analyzed using t-tests, chi-square tests and Wilcoxon rank-sum tests as appropriate [data were examined for normality using Q-q plots and histograms]

Sample handling and procedures:

Data collection: Data was collected through a preset self administered questionnaire. Blood sample was collected and preserved at BCSIR Laboratory for possible above mentioned tests.

RESULT OF THE IMPERIAL STUDY:

Table 1 :Baseline Socio-demographic characteristics of the study subjects (N =27)

Variables	**Number/Mean±SD**	**Percentage (%)**
Gender		
Male	13	48.1%%
Female	14	51.9%%
Residence(present)		
Urban	10	37.0%
Semi-urban	17	63.0%%
Educational status		
Illiterate	1	3.7%
Primary	11	40.7%
Secondary	9	33.3%
Graduate	6	22.2%
Profession (chronology)		
Day Labour	3	11.1%
Official	7	25.9%

Defense	2	7.4%
Business	1	3.7%
Housewife	14	51.9%
Family Members		
<3	14	51.9%%
>3	13	48.1%%

Descriptive Frequency statistics was done

The tables 1 showed the sociodemographic characteristics of the study subjects. Male constitute 48.1% of the study subject and the rest was female. Most of them are from semi urban area with primary education background. Mainly 51% females are housewife.

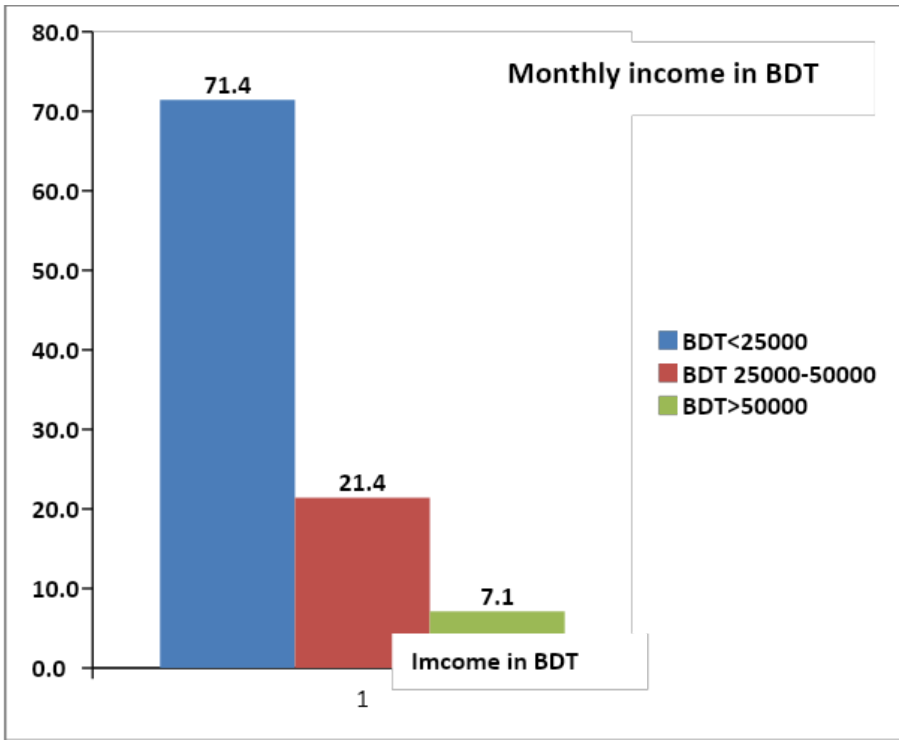

Figure 1: Monthly Income of the study subjects (N=27)

Figure 1 showed the monthly income pattern of the participants. Low income category was mostly common here.

Table 2 :Anthropometric Parameters of the study subjects (N =27)

Variables	Mean ±SD		
	Male (N=13)	Female (N=13)	P Value
Age(yrs)	55.15±11.10	56.57±11.38	.565
BMI (kg/m^2)	22.85±1.99	23.98±3.48	.017*
Monthly Income BDT)	26727±25651	23333±15275	.703
Duration of DM (Yrs)	12.50±5.80	14.36±5.06	.839
Systolic Blood Pressure (mmHg)	135.38±12.65	137.31±8.80	.503
Diastolic Blood Pressure (mmHg)	79.23±5.71	81.92±5.60	.023*

*Independent sample t test was performed. * marked as significant*

Table 2 showed that BMI, and DBP were highly significant among female than their counterpart.

Table 3 :Biochemiocal Parameters of the study subjects in first visit (N =27)

Investigation	Study Population (n=27)		P value
	Male (n=13)	Female (n=14)	
FBS (mmol/L)	7.38±1.58	7.59±.78	.051
ABF (mmol/L)	10.83±2.28	10.76±2.56	.859
Random Blood Sugar	10.75±.94	12.80±2.54	.041*
Triglyceride(mg/dl)	197.50±50.63	182.00±78.74	.047*
S.Cholesterol(mg/dl)	177.12±18.98	170.27±35.47	.050*
Low density lipoprotein (mg/dl)	111.62±29.37	99.30±22.97	.268
High density lipoprotein (mg/dl)	37.50±3.96	37.73±5.72	.091
S. Creatinine(mg/dl)	1.21±.48	1.31±1.07	.012*
S. Calcium(mg/dl)	138.66±5.13	139.33±4.03	.747
S.phosphate(mg/dl)	3.63±.30	3.95±.44	.273
Cl	103.50±3.53	104.50±6.45	.312
Co_2	18.80±7.86	25.00±2.82	.299
Hb%(gm/dl)	9.92±1.28	10.30±1.20	.632
TC	11729.44±2849.60	8827.00±4238.61	.094

*Independent sample t test was performed. * marked as significant*

Table 2 showed that in first visit random blood sugar, TG and S creatinine, were highly significant among female than their counterpart.

Table 4 :Biochemiocal Parameters of the study subjects in second visit(N =27)

Investigation	**Study Population (n=16)**		**P value**
	Male (n=8)	**Female (n=8)**	
FBS (mmol/L)	6.52±.89	6.32±.88	.0001
ABF (mmol/L)	9.15±1.00	8.88±2.12	.012*
Triglyceride(mg/dl)	165.00±32.07	152.25±35.38	.971
S.Cholesterol(mg/dl)	148.75±13.56	145.62±28.71	.041*
Low density lipoprotein (mg/dl)	91.12±24.32	81.50±11.23	.080
High density lipoprotein (mg/dl)	41.37±5.44	37.25±6.64	.349
S. Creatinine(mg/dl)	.90±.11	.90±.20	.201*
SGPT	57.00±42.42	23.00±13.02	.003*
Hb%(gm/dl)	11.67±1.45	10.50±1.02	.231
TC	9300.00±1620.69	8900.00±1312.23	.002*

*Independent sample t test was performed. * marked as significant*

Table 4 showed that in second visit ABF, S.Cholesterol(mg/dl), S. Creatinine(mg/dl) and SGPT were highly significant among female than their counterpart.

Table 5 : Clinical comparison of study subjects in between two visit (21 days after 1st visit)

Investigation	**Study Population (n=27)**		**P value**
	1st Visit (n=27)	**2nd Visit (n=16)**	
FBS (mmol/L)	7.49±1.21	5.42±.86	.022*
ABF (mmol/L)	10.80±2.37	9.01±1.61	.531
Triglyceride(mg/dl)	188.52±67.11	138.62±33.28	.041*
S.Cholesterol(mg/dl)	173.15±29.17	117.18±21.75	.003*
Low density lipoprotein (mg/dl)	104.77±25.97	56.31±18.96	<.001*
High density lipoprotein (mg/dl)	37.62±4.88	46.31±6.24	.031*
S. Creatinine(mg/dl)	1.26±.80	.70±.16	.004*
Hb%(gm/dl)	10.13±1.22	12.44±1.36	.509
TC	9220.00±1414.92	10201.841±3848.22	.044*
SGPT	45.66±35.85	29.33±13.12	.004*

*Independent sample t test was performed. * marked as significant*

Table 5 showed that when we compared the two visits the we found that FBS, TG, Cholesterol, LDL, HDL S. Creatinine, TC and SGPT has been decreased in 2nd visit.

Table 6: Chalder Fatigue Scale Score

		1st Visit		2nd Visit	
		Male	**Female**	**Male**	**Female**
CFS-PF: Chalder Fatigue Scale-Physical Fatigue,	Mean±sd	6.3± 3.4	8.6 ±3.9	6.3± 3.4	8.6±3.8
	Median (Range)	7 (4–8)	8 (6–12)	7 (4–8)	8 (6–11.5)
CFS-MF: Chalder Fatigue Scale-Mental Fatigue,	Mean±sd	3.1± 1.9	3.8± 7.7	3.1± 1.8	3.7± 1.8
	Median (Range)	3 (2–5)	4 (2–5)	3 (1–4)	4 (2–5)
CFS: Chalder Fatigue Scale as a whole	Mean±sd	11± 4.8	12.3±4.9	9.4±4.6	12.2± 4.8
	Median (Range)	11 (8–15)	12 (9–16)	10 (6–12)	12 (9–16)

Table 6 showed the mean (SD) CFS score was 12.2 (4.8) and 9.4 (4.6) for female and male participants, respectively. Female participants had higher scores than male participants obviously. Tere were no marked changes in values with visit. Slightly changes has been observed.

Table 7: Test–retest reliability and internal consistency of the Chalder Fatigue Scale

	κ	**ICC**	**94% CI**		**r**
			Lower	**Upper**	
1. Do you have problems with tiredness?	0.22		0.20	0.33	0.50
2. Do you need to rest more?	0.21		0.10	0.22	0.37
2. Do you feel sleepy or drowsy?	0.22		0.20	0.34	0.52
3. Do you have problems starting things?	0.22		0.14	0.22	0.51
4. Do you lack energy?	0.30		0.29	0.41	0.70

	κ	ICC	94% CI		r
			Lower	Upper	
5. Do you have less strength in your muscles?	0.34		0.22	0.45	0.51
7. Do you feel weak?	0.21		0.10	0.22	0.57
CFS-PF			0.57		
7. Do you have difficulty concentrating?	0.22		0.10	0.23	0.50
9. Do you make slips of the tongue when speaking?	0.32		0.29	0.44	0.29
10. Do you find it more difficult to find the correct word?	0.22		0.20	0.35	0.35
11. How is your memory?	0.23		0.20	0.39	0.27
CFS-MF		0.57	0.44	0.75	
CFS			0.57	0.72	

κ: Weighted kappa coefficient, ICC: intraclass correlation coefficient, CI: Confidence interval, r: Pearson correlation coefficient for item-total correlation, CFS-PF: Chalder Fatigue Scale-Physical Fatigue, CFS-MF: Chalder Fatigue Scale-Mental Fatigue, CFS: Chalder Fatigue Scale

Table 6 showed the lower the value lower the fatigue.

Recording and verified:

Statistical evaluation and significance:

Remarks