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A PARALLEL-ARM CLINICAL TRIAL TO EVALUATE SAFETY AND EFFICACY OF POWER GUMMIES: HAIR AND NAIL VITAMIN; IN HAIR FALL REDUCTION, ACCELERATED HAIR GROWTH, STRENGTHENING OF HAIR WITH OVERALL HAIR AND SCALP HEALTH IMPROVEMENT IN HEALTHY FEMALE AND MALE

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ABSTRACT

Objective: Hair loss is a common problem in men and women occurring mainly due to nutritional deficiencies, and, the correct diagnosis of hair disorders is complex. Nutritional deficiency may impact both hair structure and hair growth equally in males and females. Vitamin A, E, C, B6, B12, biotin, and folic acid play a crucial role in hair health. Hair loss is often associated with poor scalp health and related complaints like greying of hair, dandruff, dry and damaged hair. Hair loss also associates with low self-esteem. There is a great need for nutritional supplements correcting the need for vitamins to maintain hair health. The aim of the study to evaluate clinical benefits of Power gummies: hair and nail vitamins contains a balanced blend of required vitamins with minerals like zinc and iodine in hair and nail health. **Material and methods:** 60 subjects were enrolled in the study after screening for compliance with inclusion criteria and were allocated into one of the arms out of 2 arms. Each arm included 2 sub-groups depending upon age and gender. Subjects were undergoing clinical examination. Vitals were recorded. They were randomized to respective study groups by computer-generated randomization. A trichogram was generated analyzing their hair and scalp. They were asked some questions related to the scalp, hair, and nail health. Their nail examination was done. **Results:** The % increase in hair intensity, no. of hair terminal, no of vellus hair, % decrease in hair loss, in females was found to be 24.4%, 20.6%, increase, 33.76 respectively. The % increase in hair intensity, no. of hair terminal, no of vellus hair, % decrease in hair loss, in males was found to be 21.1%, 24.5%, increase, 36.56% respectively. **Conclusion:** This explains that power gummies are significantly effective in improving hair density, no of hair terminal, no. of vellus hair, reduction in hair loss. Power gummies are safe and effective in the management of alopecia.

KEYWORDS: Alopecia, Power gummies, Hair intensity, Nail strength, Scalp repair.

INTRODUCTION AND BACKGROUND INFORMATION

Hair is considered to be a sign of beauty and youthfulness in society. It is normal to lose about 50-100 hair strands a day. It goes unnoticeable as there are about 100,000 hairs on the head and such a small loss is usually not considered. But there is a problem when the new hair is not replaced by the hair that has been fallen out and the balance of hair loss and hair growth is not maintained. This condition is termed as hair loss. Hair loss can develop gradually over years or can happen abruptly and can be temporary or permanent.[1,2] Depending upon the causative factor, hair loss may be non-scarring or alopecia. When the scalp appears normal with plenty of empty hair follicles is called non-scarring hair loss.[3] While, when the damage to the hair follicles is permanent it is termed as cicatricle alopecia.[4] The causal factors of hair loss are a family history of balding, physical or chemical damage, hormonal changes, significant weight loss, certain medical conditions, stress, and poor nutrition and deficiencies.[5] Vitamin A, Vitamin D, Vitamin C, Vitamin B6, Vitamin B12, Vitamin E, Biotin, Folic Acid, etc. plays a major role in developing healthy and strong hair and also promotes hair growth. The deficiencies of these nutrients often lead to hair loss, brittle nails. Various measures are available to balance the nutrition level by exogenous administration of several supplements. Various medical treatments are available to prevent hair loss like anti-androgenic medications, Minoxidil, finasteride, etc.[6,7] Long-term use of such drugs can lead to complications associated with them and short term use may produce a transient benefit. The currently available dietary supplements which are in conventional dosage forms are

found with poor consumer compliance and thus treatment adherence. This in turn can decease the outcomes and improvement in hair growth.

Thus, with an intention of developing a novel product to treat alopecia (hair loss), Aesthetic Nutrition Pvt. Ltd. has come up with Power gummies- an innovative, attractive, palatable, effective and safe solution in chewable gummies to deal with hair and nail related complications in males and females.

The present study deals with the evaluation of the safety and efficacy of Power Gummies in male and female subjects with hair and nail-related complications.

MATERIALS AND METHODS

Materials

Power gummies containing multivitamins like biotin, vitamin A, vitamin D, vitamin C, etc., which helps in hair fall reduction, strengthening of hair with an overall improvement in hair and scalp condition.[8]

Methods

After getting approval from the ethics committee, the study was registered on the CTRI website, the registration number is CTRI/2020/10/028698[Registered on 28/10/2020]. Patients were enrolled in the study only after registration of study on the CTRI website.

The primary objective of the study was to evaluate the efficacy of power gummies by assessing change in the number of terminal hair and vellus hair in the target area of the scalp by Photrichograms, the reduction in the shedding range of the hair in the "60-second hair comb test", the folliscopic measurement of hair density and hair diameter, and, nail growth and satisfaction scale on nail health. All the parameters were evaluated from baseline to day 90 i.e. the end of the study on each monthly visit.

The secondary objectives of the study were to evaluate the efficacy of power gummies by assessing the improvement in the "Hair Assessment Questionnaire" (Brittleness, thinning, dryness, and damaged hair), to monitor the improvement in the "Modified hair wash test" (Brittleness and hair loss after washing), to observe the "Improvement in quality of hair" (Shininess, roughness, tangling nature, breaking force), to monitor the VAS- Visual analog scale scalp related complaints like itching, dandruff or irritation (Scalp health), to evaluate premature graying of hair by graying severity score (Premature graying), to determine the tolerability of study drug by assessing adverse events, serious adverse events during the study period, and, the global evaluation of overall improvement in scalp and hair.

Inclusion Criteria

Male/ Female subject's in generally good health and in the age group 18-40 years were included in the study. Subjects willing to give written informed consent and agree to come for a regular follow-up visit. Subjects falling under Grade I-1 to II-1 or frontal of Savin's pictorial grading of female pattern hair loss or under Grade2 to 4A of hair loss severity grade evaluated as per Norwood scale were considered to be included in trials. Subjects willing to abide by and comply with the study protocol and those who have not participated in a similar investigation in the past two weeks were considered in the trials. Subjects with hair complaints of hair fall and hair damage and the ones who were not on crash dieting were included in the study. Subjects who agree not to change the brand of currently used hair color, dye, treatment, etc., if any during the study term, and those who were willing to refrain from any type of hair treatment like head massage, oil application (on the scalp), perming, etc. during the study duration were included. Subjects with dry, damaged, brittle, thin hair, and/or with premature greying of hair by greying severity score between Score 1 (assigned to under 10% grey hair/cm2) to Score 2 (10%–30% grey hair/cm^2), and the ones with scalp related complaints like itching, dandruff or irritation.

Exclusion Criteria

Subjects who were undergoing hair growth treatment within 3 months before screening into the study were excluded. Subjects having any active scalp disease which may interfere in the study or on treatment for active acne were not considered for the study. Subjects with history or active phase of malignancy and chemotherapy, history of alcoholism, and/ or psychiatric disorder including trichotillomania were excluded. Subjects of the vulnerable population like pregnant, lactating or nursing mothers were excluded from the study. Any subjects from the investigator's viewpoint proved to be unfit for the study were excluded.

Study methodology

After the Ethics committee's approval, the clinical study was registered on the CTRI website. Subjects of age between 18 to 40 years of age were screened for eligibility criteria. A total of 60 subjects were enrolled in this study and were allocated in two arms with 2 sub-groups in each arm. On the screening visit, written informed consent was obtained from subjects as confirmation of participation. Demographic details were recorded. Clinical examination was conducted, medical history and vitals were recorded. They were screened for inclusion and exclusion criteria. During the screening visit and entire study, the subjects were advised to refrain from antioxidant agents, vitamins, anti-inflammatory drugs, hormones, Nutraceuticals, Ayurvedic, Siddha, Unani, herbal /homeopathic medicines for the maintenance of health. A screening window of 7 days was kept. For nail assessment, after subjects were assigned to groups, they were marked at lunula and observed for 30 days without treatment so effectively 30 days after lunula marking will be baseline visit. Power Gummies treatment was started at baseline day and visit 1 (Day 30 after treatment), visit 2 (Day 60 after

treatment) and visit 3 (Day 90 after treatment) was followed for nail and hair assessment.

On baseline visit, subjects were recruited based on compliance with the inclusion criteria. They were randomized to respective groups by computer-generated randomization. At baseline and every follow-up visit, they were provided with 70 gummies for use and were advised to consume a dose of 1 gummy twice a day after a meal. They were advised to continue their concomitant medication and a record of the same was kept in the CRF. All the subjects were using a mild shampoo and conditioner for personal care. Compliance of Investigational product was assessed and if consecutively 3 doses were missed or more than 6 days doses were missed during the study period, they were treated as dropouts. They were advised to continue the diet and exercise regimen during the entire study period. After the baseline visit, they were called for follow-up at respective sites after every month for up to 3 months. On every visit, clinical examination was conducted and a trichogram was generated for analysis of their head and scalp. Questions related to scalp hair and nail health were asked and nail examination was also conducted on the baseline, every follow-up visit, and also on the 3rd visit (i.e. day 90). After completion of 3 months of study treatment, an assessment of overall improvement was done. They were closely monitored for adverse effects during the entire study period.

OBSERVATIONS AND RESULTS

Study groups and allocation

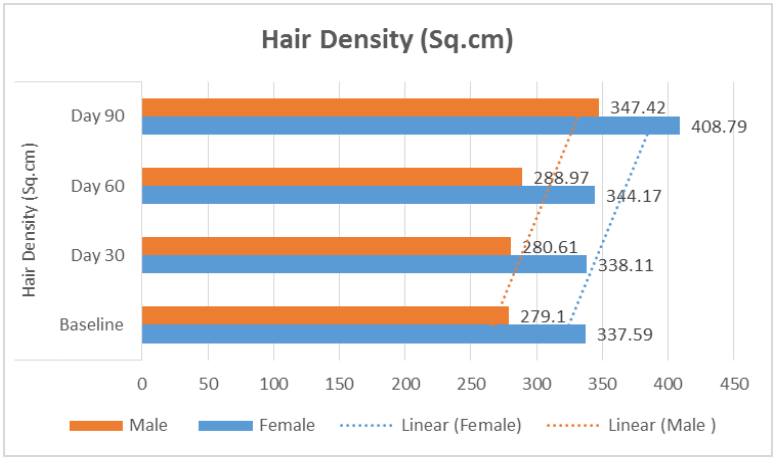
The study was divided into two groups being Group 1- Female aged between 18-40 years' sub stratified in age 18-24 and 25-40 years, Group 2- Male aged between 18-40 years' sub stratified in age 18-24 and 25-40 years. A total of 60 subjects were included in the study equally divided into groups.

Demographics and Baseline Characteristics

Female and male subjects had mean (SD) ages of 27.86 (6.79) years and 28.32 (6.47) years, respectively, which were not significantly different. There were 2 subjects (One male and one female subject) which got dropped out of the study as could not follow up. Both the groups did not demonstrate any significant differences in lifestyle attributes or baseline mental attitude qualities.

Changes in Hair Density

In the present study, the hair density was measured with a phototrichogram in a 1 sq. cm area. The hair density (sq. cm) in females at baseline, Day 30, Day 60, and Day 90 was 337.59, 338.11, 344.17, and, 408.79 respectively. The hair density (sq. cm) in males at baseline, Day 30, Day 60, and Day 90 was 279.10, 280.61, 288.97, and, 347.42 respectively. There was a significant increase in hair density in female (21%) and male (24.4%) subjects after treatment with Power Gummies for 90 days. The results are depicted in Graph 1 and the subject's image in Figure 1.

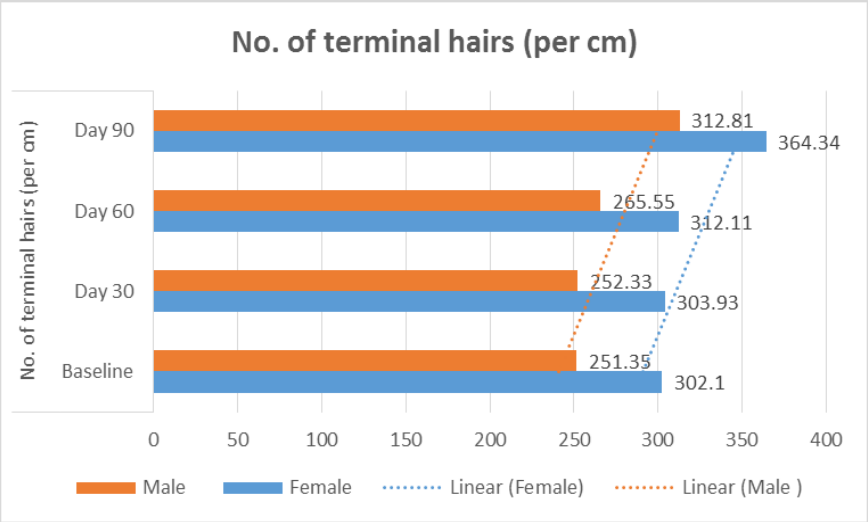


Graph 1: Changes in hair density (Sq.cm) from baseline to end of the study.

Figure 1: Illustrates the changes in hair density at the baseline and after 90 days of treatment with power gummies. Treatment with power gummies shows a significant increase in hair density.

Changes in the number of terminal hairs

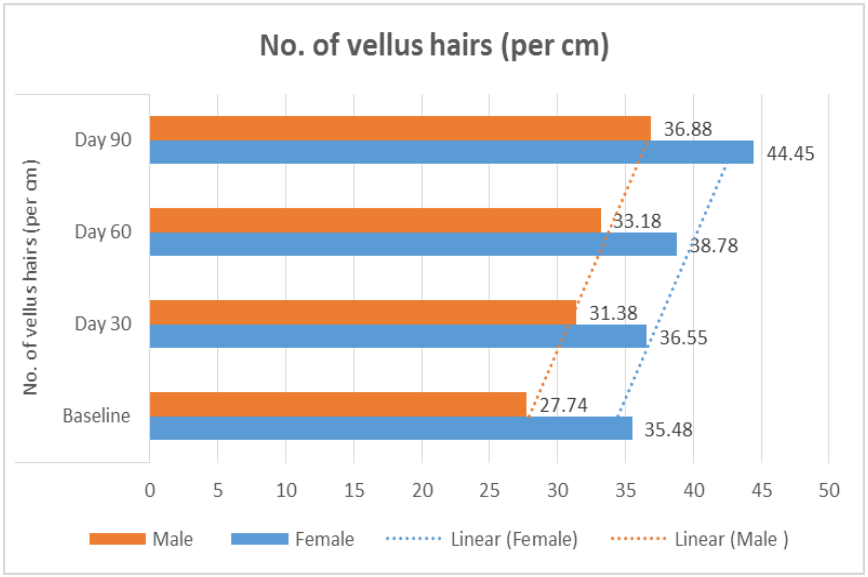
In the present study, the number of terminal hair per centimeter was measured with a phototrichogram. There was a significant increase in terminal hair count in female and male subjects after treatment with Power Gummies for 90 days. The no. of terminal hair (per cm) in females at baseline, Day 30, Day 60, and Day 90 was 302.10, 303.93, 312.11, and, 364.34 respectively. The no. of terminal hair (per cm) in males at baseline, Day 30, Day 60, and Day 90, was 251.35, 252.33, 265.55, and, 312.81, respectively. There was a 20.6 % and 24.5 % increase in terminal hair count in female and male subjects respectively after 90 days of treatment. The results are depicted in, Graph 2.



Graph 2: Changes in the number of terminal hairs (per sq. cm) from baseline to end of the study.

Changes in the number of vellus hairs

In the present study, the number of terminal hair per centimeter was measured with a phototrichogram. The no. of vellus hairs (per cm) in females at baseline, Day 30, Day 60, Day 90, was 35.48, 36.55, 38.78, and 44.45 respectively. The no. of vellus hairs (per cm) in males at baseline, Day 30, Day 60, Day 90, was 27.74, 31.38, 33.18, and 36.88, respectively. There was an increase in the number of vellus hairs in both males and females in 90 days but the difference is non-significant. The results are depicted in Graph 3.



Graph 3: Changes in the number of vellus hairs (per sq. cm) from baseline to end of the study.

Changes in the number of hair strands lost in 60 Second Comb Test

In the present study, the number of hair strands lost in the "60 Second Comb Test" was counted after combing hair for 60 seconds. There was a significant decrease in the number of hair strands lost in the 60 Second Comb Test in female and male subjects after treatment with Power Gummies for 90 days. There was 33.76% and 36.56% decreased hair loss in female and male subjects respectively after 90 days of treatment. The results are depicted in Table 1.

Table 1: Changes in the number of hair strands lost in the 60 Second Comb Test from baseline to end of the study.

Group	Number of hair strands lost (N)				P-Value	% decrease in Hair loss
	Baseline	Day 30	Day 60	Day 90		
Female	215.93 (68.91)	188.13 (52.59)	153.03 (44.10)	143.03 (52.59)	0.00007	33.76
Male	62.03 (43.28)	58.87 (36.23)	47.48 (34.13)	39.35 (26.91)	0.04335	36.56

Analyzed by One-Way ANOVA, significant at p<0.05

Change in nail growth

The basal nail growth rate of the female participants was on average 2.41 (0.42) mm/month. After 12 weeks of treatment with Power Gummies, the growth rate improved significantly (P < .05) to 2.68 (0.47) mm/month. These results showed an improvement in nail growth of 10% after 12 weeks of Power Gummies intake in the females.

The basal nail growth rate of the male participants was on average 2.08 (0.38) mm/month. After 12 weeks of treatment with Power Gummies, the growth rate improved non-significantly (P > .05) to 2.18 (0.44) mm/month. These results showed an improvement in nail growth of around 5% after 12 weeks of Power Gummies intake in males.

Change in satisfaction score on nail health

A satisfaction questionnaire assessed patient satisfaction with the treatment on a 5-point scale (very satisfied, satisfied, neither satisfied nor unsatisfied, unsatisfied, and very unsatisfied). Patients were also asked to rate the overall improvement of their nails from 0 to 10, and to answer the following questions: (i) Do you think your nails are stronger? (ii) Do you think your nails are growing faster?

The majority of female participants (90%) agreed that the use of Power Gummies had improved their nails' appearance and was satisfied or satisfied with the performance of the treatment. In contrast, only 10% were indifferent about or unsatisfied with the treatment. The overall improvement was on average 7.8 (2.3) scale points on the 0-10 scale as assessed by the participants. Around 90% of subjects provided scores between 8 to 10 for nails appearing stronger and growing faster.

Of the 30 male participants, 10 rated the overall improvement with 8 to 10 scale points (30% of all study participants). Moreover, the rest 70% of patients perceived their nails as stronger but not growing much faster than baseline.

Changes in subject's complaints related to hair and nails

In the present study, the frequency of the subjects from different age groups reported certain complaints regarding hair aspects. After 90 days of treatment, there was around 50-60% reduction in hair fall as reported by subjects and around 40-50% reduction in other hair, scalp, and nail-related complaints. Power Gummies treatment for 90 days was found to be effective both in males and females.

Changes in nail growth & satisfaction questionnaire score

In the present study, the subject reported nail growth and satisfaction score was measured by 0-10 VAS scale there was an improvement in satisfaction from baseline to day 90 gradually. The change was statistically significant. The results are depicted as a mean score in Table 2.

Table 2: Changes in nail growth & satisfaction questionnaire score.

	Mean Score (SD) in Female (0-10 VAS)									
	18-24 years				P value	25-40 years				P value
	Baseline	Day 30	Day 60	Day 90		Baseline	Day 30	Day 60	Day 90	
Q1	2.85(0.75)	4(0.76)	5.78(0.87)	8(0.76)	<0.05	4.20(0.75)	5.13(0.96)	6.27(0.77)	7.73(0.85)	<0.05
Q2	3.14(0.75)	4.21(0.78)	5.92(0.81)	8.21(0.78)		4.87(0.72)	5.53(0.50)	6.93(0.77)	8.47(0.62)	
	Mean Score (SD) in Male (0-10 VAS)									
	18-24 years				P value	25-40 years				P value
	Baseline	Day 30	Day 60	Day 90		Baseline	Day 30	Day 60	Day 90	
Q1	3.46(1.12)	4.53(0.99)	6.06(0.88)	8.06(0.79)	<0.05	3.87(0.80)	5(0.81)	6.12(0.80)	7.62(0.95)	<0.05
Q2	3.93(0.70)	4.66(0.72)	6.33(0.81)	8.13(0.74)		5.06(0.77)	5.87(0.71)	7.06(77)	8.12(0.71)	

Analyzed by One-Way ANOVA, significant at p<0.05
Question 1 (Q1): Do you think your nails are stronger?
Question 2 (Q2): Do you think your nails are growing faster?

Changes in scalp improvement score

In the present study, the subject reported scalp condition improvement score was measured by 0-10 VAS scale there was an improvement in satisfaction from baseline to day 90 gradually. The change was statistically significant. The results are depicted as a mean score in Table 3.

Table 3: Changes in the number of vellus hairs (per cm) from baseline to end of the study.

	Mean Score (SD) in Female (0-10 VAS)							
	18-24 years			P- Value	25-40 years			P- Value
	Day 30	Day 60	Day 90		Day 30	Day 60	Day 90	
Itching	3.35(0.84)	4.85(0.77)	7.5(0.65)	0.00001	2.33(0.81)	4.8(0.77)	7.66(0.72)	0.00001
Dandruff	2.57(0.85)	4.85(0.77)	7.64(0.63)		2.26(0.79)	4.66(0.61)	7.73(0.70)	
Irritation	2.57(0.85)	4.92(0.73)	7.57(0.64)		2.4(0.91)	4.8(0.67)	7.76(0.61)	
	Mean Score (SD) in Male (0-10 VAS)							
Itching	2.46(0.74)	4.73(0.70)	7.86(0.74)	0.00001	2.18(0.83)	5(0.73)	7.62(0.61)	0.00001
Dandruff	2.6(0.91)	4.8(0.67)	7.73(0.70)		2.37(0.88)	4.68(0.60)	7.43(0.51)	
Irritation	2.4(0.91)	4.8(0.67)	7.86(0.74)		2.31(0.79)	5(0.81)	7.87(0.71)	

Analyzed by One-Way ANOVA, significant at $p<0.05$

Changes in hair assessment questionnaire

In the present study, hair quality improvement was analyzed by rating brittleness, thinning, dry, damaged, rough, dull hair, and tangling parameters on a 1-5 ordinal scale of 1 (Very much improved and 5 as worse change). It was observed in the study that there was a gradual shift of subjects both male and female to very much (1) or much (2) improvement. It is suggestive of the overall clinical improvement of hair health.

Assessment of Global evaluation of overall improvement in scalp and hair by the investigator

It was observed in the present study that there was an excellent improvement in the scalp and hair-related complaints in 88% of subjects and good improvement in 12% of subjects assessed by the investigator.

Assessment of tolerability of investigational product by the investigator

It was observed that 100% of subjects excellently tolerated investigational product Power Gummies with 100% compliance. There were no adverse events related or possibly related to the Power Gummies. There were a total of 11 adverse events of menstrual pain, headache, cramps, and hyperacidity. The adverse events were mild and required no rescue medication nor requirement to stop investigational product.

DISCUSSION

The results of this study showed that the administration of Power Gummies: hair and nail vitamin was safe and effective in hair fall reduction, accelerated hair growth, strengthening of hair with overall hair and scalp health improvement in healthy female and male in 90 days.

The results showed a significant increase in the hair density, the number of terminals, vellus hair counts at 90 days gradually. There was an increase in terminal hair count from baseline to day 90. There was an increase in vellus hair count, vellus hair may get converted in terminal hair to improve the hair density. The beneficial effects of Power Gummies were observed in both males and females hence it's an efficacious product for both genders. Power Gummies presented excellent compliance and tolerability with no adverse events related to its long-term consumption. It also showed significant visible improvement in grow of hair and quality of hair in the treatment group, as observed by investigator. These outcomes demonstrated a steady improvement from baseline to day 90, suggesting that improvement may progress with continued treatment. There was also a strong trend in reducing hair breakage and improving hair density as well as hair diameter hence making hairs stronger and may improve hair length as well. The hair with the consumption of Power Gummies was less brittle and strong from roots that there was decreased hair fall in the hair comb and wash test. It is suggestive of the improved strength of the hair. As hair density is very important component for long and voluminous hair, from this present study it can be observed that there was an improvement in the follicular density which can, in turn, accelerate hair growth. Hair loss is often associated with scalp-related complaints like irritation, itching, dandruff, etc. With the consumption of Power Gummies, the scalp-related complaints showed a reduction in 30 days gradually following the trend toil day 90. On day 90 there was much significant reduction in scalp-related complaints on the visual analog scale. There was satisfactory around 10% in females and 5% in the male enhanced growth rate of nails. It was observed from the study that there was improved satisfaction through augmented stronger and longer nails in subjects. The perception of hair loss for an individual can be distinct from clinical observations hence in the present study we had combined the subjective as well as objective assessment of hair and nail health. On both of the grounds, Power Gummies proved to be efficacious i.e. improving hair quality in phototrichogram and improving subject assessed satisfaction score. The stress of hair loss gets compounded by a lack of available treatment options. In this study, the overwhelming majority of subjects consuming Power Gummies found it to be more convenient to incorporate into their daily routine. Carefully selected composition in the Power

Gummies can provide a unique therapeutic value because of multi-modal clinical biological activity against multiple molecular and environmental causative factors of hair loss. Power gummies contain multivitamins like biotin, vitamin A, vitamin D, vitamin C, etc., which is reported to help in hair fall reduction, strengthening of hair with an overall improvement in hair and scalp condition.[9] Hair, skin and nails are mainly composed of a basic protein called keratin. It's evident fact from earlier researches that biotin improves the body's keratin infrastructure. There is evidence from the clinical studies with biotin supplementation improving brittle nail syndrome and other underlying hair pathologies, such as uncombable hair syndrome.[10] Vitamin C has antioxidant properties that provides protection against oxidative stress due to the free radicals. Vitamin C is the key factor to create a protein known as collagen -an important part of the hair structure. It is well-researched fact that Vitamin C also helps the body absorb iron, a mineral necessary for hair growth. Deficiency of vitamins may lead to alopecia which is a medical term for hair loss. Vitamin D may help create new follicles thus improving follicular density and new hair growth. Low levels of vitamin A can cause various issues, like hair loss. Vitamin A also helps skin glands make a substance called sebum. Sebum moisturizes the scalp and helps keep hair healthy.[11] These results support the hypothesis of the clinical trial and thus Power Gummies: hair and nail vitamin; can prove beneficial in hair fall reduction, accelerated hair growth, strengthening of hair with overall hair and scalp health improvement in healthy female and male.

CONCLUSION

Hair loss is a common problem in men and women occurring mainly due to nutritional deficiencies, and, the correct diagnosis of hair disorders is complex. Nutritional deficiency may impact both hair structure and hair growth equally in males and females. Vitamin A, E, C, B6, B12, biotin, and folic acid play a crucial role in hair health. Hair loss is often associated with poor scalp health and related complaints like greying of hair, dandruff, dry and damaged hair. Hair loss also associates with low self-esteem. There is a great need for nutritional supplements correcting the need for vitamins to maintain hair health. Power gummies: hair and nail vitamins contains a balanced blend of required vitamins with minerals like zinc and iodine which help accelerate hair growth and reduce hair fall.

It was concluded from the present study that Power Gummies: hair and nail vitamin helped to correct the nutritional deficiency in both males and females and led to decreased hair loss and improved growth of hair after 90 days of treatment. There was a reduction in hair and scalp-related complaints. The assessment of hair quality revealed that the quality of hair got improved in 90 days' treatment. Nail appearance, strength, and growth were improved in 90 days. There were no adverse events and 100% tolerance for Power Gummies: hair and nail vitamin. Subject compliance was also 100% as a result of the tasty gummy dosage form. Overall Power Gummies: hair and nail vitamin are safe and effective formula in hair fall reduction, accelerated hair growth, strengthening of hair with overall hair, and scalp health improvement in healthy females and males.

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