Pune District Education Association's

College of Ayurved & Research Centre

(I.D.No. P.U./P.N./AYU./081/1990)
Sector No. 25, Pradhikaran, Nigdi, Pune-411 044 (Maharashtra State), India.
Phone - 020 - 27653965 / 27659578, Fax :- 020 - 27659578, Website - www.pdeaayurvedcollege.edu.in
E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Metric-3.5.1

Average number of Collaborative activities for research, faculty exchange, student exchange/ Industry-internship etc. per year for the last five years

Detailed Program report for each extension and outreach program with specific number of students and collaborating agency participated and amount generated.

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3.5.1

1. Collaborative activity – Student exchange at Vaidya Ratnam Ayurveda Foundation

3/9/2018 to 29/9/2018

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Post event summary report

Title of Collaborative activity: Training of postgraduate students of Swasthavritta Department

Date: 3/9/2018 to 29/09/2018

Place: Kerala

Total Participants: 02

Participant details: Dr Ganesh Kathane

Dr Prasanna Gavali

Brief Activity Details: Postgraduate students of Swasthavritta Department attended training at Thaikkattussery, Ollur, Thrissur, Kerala conducted by Vaidyaratnam Ayurveda Foundation. Topic of training was Kerala speciality treatments & Panchakarma based on Ashtavaidya Tradition.

Training consist of various therapy procedures conducted through a combination of lectures, demonstration & discussions at Vaidyaratnam Ayurvdea Foundation.

3.10.2018

H. O. D.
Dept. of Swastha Vrutta
College of Ayurved & Research Centre
Nigdi

College of Ayurved & Research Centre P.D.E.A.'s AKURDI PUNE-44

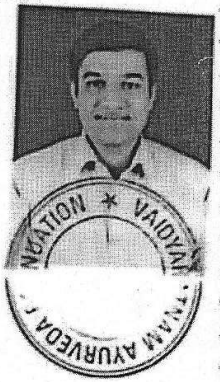
VAIDYARATNAM
AYURVEDA FOUNDATION

'CENTRE OF EXCELLENCE IN AYURVEDIC MANAGEMENT OF CHRONIC JOINT DISORDERS'

Recognized By: Ministry of AYUSH, Govt. of India

An Academy for Ayurvedic Studies

Thaikkattussery, Ollur, Thrissur - 680 306, Kerala, India



Awards this certificate to

Dr. PRASANNA MOTILAL GAVALI

in recognition of successful completion of the training

in ***'KERALA SPECIALITY TREATMENTS AND PANCHAKARMA based on ASHTAVAIDYA TRADITION'***

during the period from 3rd September 2018 to 29th September 2018

Training Consists of various therapy procedures conducted through a combination of Lectures, Demonstrations and Discussions at Vaidyaratnam Ayurveda Foundation.

TRUE COPY

Principal
College of Ayurved And Research Centre
Akurdi, Pune - 411 044

Dr. Sudeesh Kumar S.
Course Director

Ashtavaidyan E.T. Narayanan Mooss
Managing Trustee

VAIDYARATNAM
AYURVEDA FOUNDATION

'CENTRE OF EXCELLENCE IN AYURVEDIC MANAGEMENT OF CHRONIC JOINT DISORDERS'

Recognized By: Ministry of AYUSH, Govt. of India

An Academy for Ayurvedic Studies

Thaikkattussery, Ollur, Thrissur - 680 306, Kerala, India



Awards this certificate to

Dr. GANESH TUKARAM KATHANE

in recognition of successful completion of the training

in 'KERALA SPECIALITY TREATMENTS AND PANCHAKARMA based on ASHTAVAIDYA TRADITION'

during the period from 3rd September 2018 to 29th September 2018

Training Consists of various therapy procedures conducted through a combination of Lectures, Demonstrations and Discussions at Vaidyaratnam Ayurveda Foundation.

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Akurdi, Pune - 411 044

Dr. Sudeesh Kumar S.
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3.5.1

2. Collaborative activity – Teacher exchange at M.U.H.S. Nashik

15/10/2018

पु.जि.शि.मं.चे
आयुर्वेद महाविद्यालय व संशोधन केंद्र
निगडी, पुणे-४११०४४.
पावती क 3447 | 2018-19
दिनांक - 15/10/18
स्वाक्षरी
प्राचार्य

ODL report of

One day workshop on quality assurance for achieving sustainable health sciences education development

On 9.30 am reached at muhs Nasik, Dr. Meenal Lad, Dr R.G. Mane and myself attended the above workshop 9.30-10.30 registration and breakfast. The program was started at 10.30am by inauguration and Abhivadan to Late Dr APJ Kalam on the occasion of reading day. Inauguration function started with Maharashtra geet . Inauguration was done with the hands of Chief guest Dr. Vedaprakash Mishra dean of Datta Meghe Institute Nagpur. Felicitation of faculty members for above workshop was done. In that Dr Vedprakash Mishra , Dr. Raja Pechinuthu, Dr. Kushilab Bose, Dr. Sandip Mane, Dr. Vinay Golvilkar,Dr. Khamgaoankar, Dr Kalidas Chavan & Dr. Vrushali Bhosale were felicitated by Dr.Dilip Mhaisekar. Dr. Kalidas chaven had given introduction about muhs schemes & details of training workshop from 10.30-10.35. The program was hosted by Dr. Swapnil Torane. After introductory speech Dr. Mhaisekar gives vice chancellors speech from 10.35-10.40.

Sr. no.	Time	Details of lectures	Faculty
1	10.45-11.35	Academic Leadership	Dr. Vedaprakash Mishra
		Question answer session was followed after Dr. Mishra sir's lecture 1) What about Academic burden on teachers 2) How can we use art on teaching technology 3) What about average surroundings 4) What is the importance of NAAC in academics role model development 5) NAAC NABH ISO will lose teachers essences	

2	11.50-12.20	New methods of medical education Health spring family health experts	Dr. Khshilib bose - AFMC
3	12.20-13.20	Use of technology in health education	Dr. Raja Pechimuthu
4	13.20-14.20	Lunch	
5	14.20-15.30	The art of teaching communication	Dr. Sandip Mane
6	15.30-16.00	Communication skills and behavioral management	Dr. Vrushali Bhosale
7	16.00-16.35	Financial management of educational institution	Dr. Vinayak Golvilkar
8	16.35-16.45	Felicitation of iron man – Mr. Ravindar Kumar singhal	
9	16.45-17.20	Issues related to cybercrime in educational institute	
10	17.20-17.35	General crime & educational crime	Mr. Chinmay

Program was ended with Rashtra Geet

Dr Yogini Kulkarni

H. O. B.
Research Methodology
College of Ayurved And Research Centr
Akurdi, Pune - 411 044.

MAHARASHTRA UNIVERSITY OF HEALTH SCIENCES, NASHIK

MUHS

"WORKSHOP ON QUALITY ASSURANCE FOR ACHIEVING SUSTAINABLE HEALTH SCIENCES EDUCATION DEVELOPMENT"

-CERTIFICATE-

This certificate is presented to Dr./Mr./Mrs./Ms. Yogini R. Kulkarni

of College P.D.E.A's Ayu. College, Nigdi, Pune

who has participated, in "Workshop On Quality Assurance For Achieving Sustainable Health Sciences Education Development" held at MUHS, Nashik on 15/10/2018, organized by Maharashtra University of Health Sciences, Nashik.

TRUE COPY

Principal
College of Ayurved And Research Centre
Akurdi, Pune - 411 044

Dr. Kalidas D. Chavan
Registrar

Prof. Dr. Deelip G. Mhaisekar
Vice-Chancellor

SHOT ON MI A1
MI DUAL CAMERA

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3.5.1

3. Collaborative Research Project with Wellex Lab

March 2018- Jan 2019

Target Institute of Medical Education & Research

Corporate office :
A-402 A/B/C, Jaswanti Allied Business Centre,
Ramchandra Lane Extension, Kachpada,
Off Link Road, Malad West, Mumbai 400064
Phone : 022-288222252 / 022 32287239

Registered office :
205/B Blue Diamond Soc, L M Road,
Dahisar West, Mumbai 400068

To,
Dr. Shailesh Deshpande
Lecturer In Kayachikitsa
PDEA College Of Ayurveda & Research Center
Sector 25, Pradhikaran, Nigadi
Pune 28

Date : 5th Feb 2018

Subject : Budget for conducting Clinical Study on Ayuderme Capsules (Psoriasis)

Dear Dr. Shailesh Deshpande,

With regards to our discussions and further submission of documents for conducting clinical study on Ayuderme Capsules under the Title: "An Open Label, Single Arm, Multi-center, Prospective, Clinical Study to Evaluate Efficacy and Safety of WEL/PSO-01 in patients suffering from Chronic Plaque Psoriasis" we wish to submit the budget for the same below.

In this study we wish to have 10 completers. The below budget is submitted accordingly.

Sr No	Budget Head	Amount
1.	Ethics Committee Fees	15000/-
2.	Investigators Fees	10000/-
3.	Coinvestigator Fees	10000/-
4.	Research Associate/ coordinator Fees	10000/-
5.	Lab Charges*	At actual
6.	Institutional Charges	15000/-
7.	Department Development Fund	15000/-
8.	Total	75000/- Plus Lab Charges at Actual

Amount in words : Rs. Seventy Five Thousand Only Plus Lab Charges
*Lab Charges attached below.

We request you to kindly process the study at the earliest.

Target Institute of Medical Education & Research

Corporate office :
A-402 A/B/C, Jaswanti Allied Business Centre,
Ramchandra Lane Extension, Kachpada,
Off Link Road, Malad West, Mumbai 400064
Phone : 022-288222252 / 022 32287239

Registered office :
205/B Blue Diamond Soc, L M Road,
Dahisar West, Mumbai 400068

For any further details required in this regards please let us know.

Many thanks,

For,

Target Institute of Medical Education and Research,
Mumbai.

Investigation	No of times
CBC, ESR, Hb%	2
BSL-Fasting	1
Liver Function Tests (LFT): [SGOT, SGPT, Sr. Bilirubin Sr. Alkaline Phosphatase, Proteins total]	2
Renal Function Tests (RFT): [Sr. creatinine, BUN]	2
Lipid Profile: [Total sr. cholesterol, sr. triglycerides, LDL, HDL]	2
HIV I & II	1
Urine Routine & Microscopic	2
UPT	When Required

Date 15 July 2019

To,

The member Secretary,

Institutional Ethics Committee,

PDEA's college of Ayurveda & Research centre,

Nigdi, Pradhikaran, Pune 44.

Sub:- submission of clinical study report version 1.0, Dated 20th April 2019.

Ref:- clinical study report version

Respected madam,

With this reference to above subject, it is our pleasure to submit you final study report of clinical trial, **"An open label, single arm, multi center, prospective, clinical study to evaluate efficacy & safety of WEL/PSO-01 in patients suffering from Chronic Plaque Psoriasis."**

CTRI NO. – CTRI/2018/03/012615.

PROTOCOL NO. –WLX/PSO-01, Version 1.0, dated 09th Dec 2017.

Sponsored by welex Laboratories pvt ltd, & target institute Mumbai, the study was conducted in our hospital. The trial successfully completed at our site. Please note that the copy of report is for your recor, right of publication or circulation of the report partly or fully are with the sponsor.

Thanking you,

JJ phadke

Dr. Jayant Phadke

Pune District Education Association's
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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

4. Collaborative activity – Teacher exchange at Sion Ayurved college Mumbai 19/01/2019

ODL REPORT FOR 19/01/2019

Basic workshop organized at APM's Ayurveda college Sion for three days from 17-19 jan 2019. They have invited me as guest speaker for 3rd day . Fifty two 1st year post graduate students were registered from various colleges. Timings 10.30am -13.15 pm

Lectures delivered with group activity as follows-

1) **Sampling and sample size calculation**
2) **Group activity on both sampling and sample size calculation**

Dr yogini Kulkarni



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आयुर्वेद महाविद्यालय व संशोधन केंद्र
निगडी, पुणे-४११०४४.
आवक क्र 2327/2019-20
दिनांक - 19/11/2019
लेखनिक
प्राचार्य

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

5. Collaborative Research Workshop with M.U.H.S. Nashik

11/02/2019

to

13/02/2019

Report of Research Methodology workshop

11^{th} -13^{th} Feb 2019

The workshop on Research methodology was organized by our institute on 11^{th} -13^{th} Feb 2019 at P.D.E.A's College of Ayurved and Research Centre Nigdi Pune 44. As per M.U.H.S./MET guidelines the sessions were organised for three days from morning 09.30- 17.00.

The fifty delegated were registered and 49 students attended the workshop. The detailed list is attached with the report.

Sr. no	College name	Number of delegates attended
1	**P.D.E.A'S COLLEGE OF AYURVED AND RESEARCH CENTRE NIGDI PUNE 44**	40
2	**Ashwin Rural Ayurveda college Manchi Hill Sangamner**	09

Eight faculty members were invited as resource person for workshop .Dr. Shrikath Muralidharan from M.A Rangoonwala Dental college, Pune, Dr. Mohan Joshi from Tilak Ayurveda Mahavidyalaya Pune, Dr. Ramesh Bhosale & Dr. Suvarna Joshi from B.J. medical college Pune; Myself from our college; Dr. Supriya Bhalerao from IRSHA Katraj Pune; Col. S. L. Jadhav from D. Y. Patil Medical college Pimpri pune, Dr. Deepak Nagpal from D.Y. Patil Dental school; Previously the instruction was given to students that bring your synopsis titles and problems regarding synopsis so,the workshop became more interactive and fruitful to them. For group activity heterogeneous groups were performed. Pre MCQ test was taken for 30 marks. Dr. Payal Benkar from Shalyatantra department of our college was 1^{st} topper by 17 marks, Dr.Patil Supriya from Balarog department respectively of Ashwin rural Ayurveda college Manchi Hill Sangamner college was 2^{nd} toppers by 14 marks and Dr. Popuri Sireesha & Dr.Dnyaneshwar Swavant from Panchakarma & Kayachikitsa department respectively of our college were 3^{rd} toppers by 13 marks in the Pre-test.

Before starting the inaugural session Pre-test was conducted twenty minutes were given to complete. The solved papers were collected. The inauguration function started with Dhanwantari poojan and stawan. The first day session was started sharp at 09.30- 10.00 by lecture taken by me on the topic "Introduction to research methodology and formulation of RQ and Hypothesis. Next session were taken onobservational study designs descriptive and analytical by Dr. Shrikanth Muralidharan from Rangoonwala detal college . After analytical study design tea break was given, then session was continued on experimental study design upto 1 pm by Dr.Shrikanth. The post lunch session was started on 1.30 pm. with group activity taken by Dr. Shrikanth and myself. Six groups were prepared each group with 8-9 members and six problems were given. The details as follows-

Group no.	Topics given for study design group activity	Instructed to formulate as per following points
1	Find prevalence rate of anemia among women in Pune - Dr. Keshav Vishwakarma	1) Formulate the title 2) Research question & Hypothesis if necessary 3) Aims and objectives of the study 4) Independent and dependent variable 5) Short methodology how to conduct the study
2	Alcohol and Liver Cirrhosis – case control Dr. Shubhangi Avhad	
3	Caesarean and Cervical Cancer- Case control –Dr. Supriya Sanap	
4	Yoga and Obesity – Cohort study Dr.Snehal Supekar	
5	Meditation and stress- Cohort study Dr. Reshma Katakdhond	
6	Dhatrinisha tablets and Metformin in diabetes Mellitus – Dr. Pallavi Dhupe	



Next lecture was taken on qualitative research methodology after the group activity by Dr.Mohan Joshi sir from Tilak Ayurveda Mahavidyalaya completed on 4.00 First day ended at 05.00 p.m.by lecture on literature search taken by Dr Ramesh Bhosale from B. J. Medical college Pune .

The second day was started with Dhanwantari Poojan and Stawan followed by lecture on 9.00am-10 am. Data types & data presentations by me. The activity was taken on identification of data types by MCQ. After this lecture next sessions at 10 am were taken by Dr. Supriya Bhalerao madam from IRSHA Pune on " Sampling Methods and Calculation of Sample size . Before starting group activity tea was served in the auditorium. Activity was taken by few MCQ and with some sample situations to choose appropriate formula for sample calculation up to 1.pm.

After the lunch break the sessions were started on inferential statistics by Dr. S. L. Jadhav from D.Y. Patil Medical College, Pimpri. The group activity was taken on selecting the appropriate test for given problems to each table. The session was ended on 3.30 pm. For next session every delegate was requested to download EPI info 7 on their laptops and one excel data file was shared with delegates so that the "computer assistance in data analysis on Excel, epi info "with Demo was completed up to 5 pm

The third day was started with Dhanwantari Poojan and Stawan followed by lecture delivered by Dr.Suvarna Joshi madam from B. J. Medical college, Pune Lecture started at sharp 9.30 a.m on ethics in medical research, After tea break group activity was taken on pre given topics one by one the ethical issues were discussed with all six topics as follows

Group no.	Ethical issues on following topics	Presenter from the group
1	Find prevalence rate of anemia among women in Pune	Dr. Madhulika Singh
2	Alcohol and Liver Cirrhosis – case control	Dr. Darshna Gadekar
3	Caesarean and Cervical Cancer- Case control –	Dr. Dnyaneshwar Sawant
4	Yoga and Obesity – Cohort study	Dr.Snehal Ranazunzare
5	Meditation and stress- Cohort study	Dr. Shruti Deshpande
6	Dhatrinisha tablets and Metformin in diabetes Mellitus –	Dr. Pradip Hirade

The second session was started on 12.00 pm on protocol writing ended up to 13.00p.m. All points of protocol were covered in previous group activities so group activity was not conducted on protocol writing separately. After the group activity Dr Deepak Nagpal from D.Y. Patil dental school had taken session on diagnostic test completed on 13.45pm.Post lunch session started with lecture on by Dr. Deepak Nagpal completed on 3.30 pm. Sir had taken very interactive and informative lecture on questionnaire designing. Next session was started on 3.30 pm on critical journal article evaluation. Sir has distributed six different research articles for each group activity. Articles were evaluated on the basis of Title and abstract.

Post workshop evaluation MCQ test was taken. Three best improved delegates were declared and felicitated with Pen set, first topper Dr.Shubhangada Gunjal from Rognidan department improved by 09 marks, second topper Dr.Pandhare Vidya from Shalakya department improved by 08 marks and third toppers Dr.Chetlure Shivakanta from Kayachikitsa department respectively improved by 05 marks of our college. Study material given in soft copy to all delegates. After felicitation delegates were requested to comment on three days'



workshop, Dr. Pradip Hirade from Ashwin Rural Aurveda college Manchi Hill Sangamner. expressed his comments on three days' workshop. The valedictory function ended with vote of thanks by me.

The daily evaluation and whole program evaluation sheets were filled by delegates. The analysis of program evaluation is given asfollows-

Some comments given by delegates are as follows-

1) Hard copy of study material should be provided before the workshop
2) Workshop is fruitful especially group activities
3) Time management and organization of workshop is very good
4) Majority of delegates very much satisfied with group activities.
5) The group activities taken in this workshop are more beneficial.
6) The continuous lectures should not be kept, 15-20 minutes rest should be given after each session.
7) Dr. Shrikanth Muralidharan; Dr. Supriya Bhalerao; Dr. Suvarna Joshi; Dr. Mohan Joshi ;Dr. S.L.Jadhav are the best faculty members mentioned by all most all delegates.

Important suggestions by coordinator as –

1) Group activities are more effective in well-equipped digital lab of computers.

The activity started by M.U.H.S. and MET is really very much necessary and useful for up-gradation of knowledge of Research techniques to post graduate students and teachers.Thanking you,

Dr. Yogini R. Kulkarni (Coordinator)

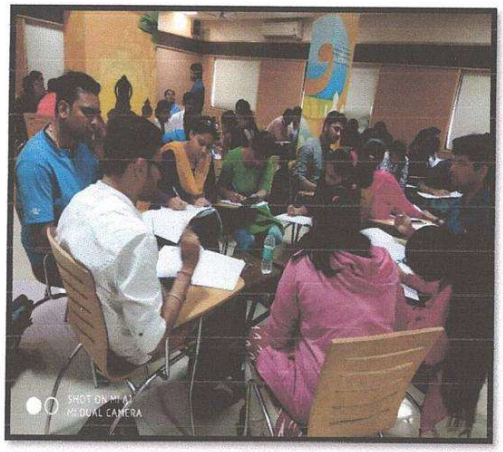
P.D.E.A.'S College Of Ayurved And Research Centre AKURDI PUNE - 44.

Principal
P.D.E.A'S
College of Ayurved And Research Centre
Nigdi, Pune - 411 044.

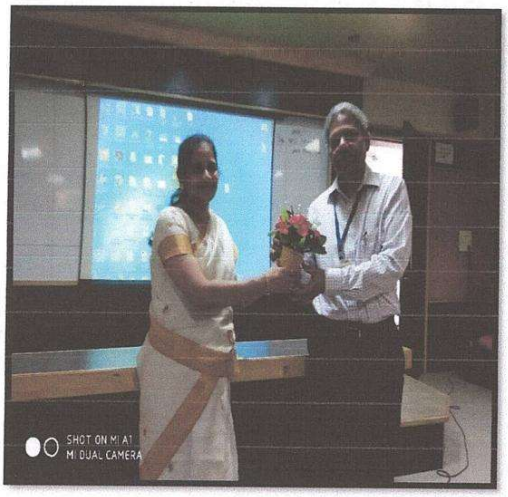
PDEA's

College of Ayurveda & Research Centre Nigdi, Pune-44

Research Methodology Workshop – 11th Feb.2019 to 13th Feb. 2019









P.D.E.A.'S College Of Ayurved And Research Centre AKURDI PUNE-44.

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

6. Collaborative activity – Teacher exchange at S.S.A.M. Hadpsar 06/03/2019-07/03/2019

Report of IRBR 06-07-march 2019

Attended meeting of Institutional review board for research (IRBR) of MAM's Sumatibhai Shah Ayurved Mahavidyalaya, Hadapsar on06-07-march 2019 from 10 am -4.30pm as external expert member od IEC. Total 08 members were present

Following research 63 MD= 1research projects were presented, discussed, different suggestions were given. After fulfilling the suggestions topics will be approved by committee.

On 6/03/2019-34 synopsis were presented

On 07/03/2019- 29 +01 synopsis +projects were presented

Prof. Dr. Yogini Kulkarni

H. O. D.
Research Methodology
College of Ayurved And Research Centre
Akurdi. Pune - 411 044

पु.जि.शि.मं.चे
आयुर्वेद महाविद्यालय व संशोधन केंद्र
निगडी, पुणे-४११०४४.
आवक क्र 3713/2019-20
दिनांक - 20/12/2019
लेखनिक
प्राचार्य

INSTITUTIONAL ETHICS COMMITTEE
Maharashtra Arogya Mandal's,
Sumatibhai Shah Ayurved Mahavidyalaya & Ayurved Hospital - Sane Guruji Arogya Kendra
Malwadi, Hadapsar, Pune - 411 028.
(An ISO 9001 :2015 Certified Mahavidyalaya)
Phone : (020) 26998937, 26999405, Fax : (020) 26999467, E-mail : ssayu@rediffmail.com

MAM/SS Ayu/975 Date :- 20/02/2019

To

Dr. Yogini Kulkarni
Member,
Institutional Ethics Committee

Sub :- Regarding IEC Meeting scheduled on 6th and 7th March 2019.

Respected Madam,

You are esteemed member of MAM's SSAM's Institutional Ethics Committee. The role of IEC has a broad scope as it examines and reviews P.G. Synopsis and Clinical Trial Projects being undertaken at hospital.

With respect to above subject I would like to invite you for 26th IEC Meeting on 6th March and 7th March 2019 at 10 a.m. to 5 p.m. Venue for the meeting will be Conference Hall, First Floor, Sane Guruji Arogya Kendra, Hadapsar, Pune.

Agenda will be as follows-

1. Welcome of all IEC members by the member secretary.
2. Review and discussion on P.G. Synopsis of all 13 Ayurved Specialties for approval.
3. Review and discussion of clinical trial proposal.
4. Any other subject with the permission of chair.

We are sending here with copies of title & synopsis of P.G. students & clinical trial proposal for your kind suggestions. Please give your valuable opinion & bring the amended copies while coming for the meeting.

Thanking you,

Sincerely yours,
#Bhosale
Dr. Mrs. Vaishali Bhosale
Member Secretary
M.A.M's
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3.5.1

7. Collaborative activity – Student exchange at Itoozhi Academy of Ayurveda Kannur

20/02/2019 to 26/02/2019

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Date-28/02/2019

Collaborative Activity Report
Department: Shalakyatantra
[Student Exchange Activity]

Title: Itoozhi Academy of Ayurveda Residentioal Gurukul Ayurveda training.

Date/Duration:21/2/2019 to 26/2/2019

Place: Itoozhi Nambothiri's Ayurveda nursing home, Kannur.

Participants details:PG Students-1. Dr. Rutuja Chandanshive, 2. Dr. Narke Sonali.

Brief activity details: Itoozhi Academy of Ayurveda Residentioal Gurukul Ayurveda training programme included different concepts of Panchakarma, practical training on panchakarma medicine preparation and Live practical procedurs,applied aspects of panchakarma therapies.

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Title; Itoozhi Academy of Ayurveda Residentioal Gurukul Ayurveda training





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3.5.1

8. Collaborative activity – Student exchange at Swasti Yoga 16/04/2019

PDEA'S COLLEGE OF AYURVED AND RESEARCH CENTRE, NIGDI, PUNE.
SWASTHAVRITTA DEPARTMENT

Title - Student exchange programme

PROGRAMME REPORT

पु.जि.शि.मं.चे
आयुर्वेद महाविद्यालय व संशोधन केंद्र
निगडी, पुणे-४४.
आवक क्र 227/2019-20
दिनांक - 16/4/2019
लेखनिक Dutt
प्राचार्य

NAME OF YOGA CENTRE - SWASTI YOGA CENTRE

No of students- 30

Report-

Under student exchange programme as per the application of swasti yoga centre on dated 16/04/2019, visit of students of swasti yoga centre was planned at PDEA's college of Ayurveda and research centre Nigdi, Pune.

Time - Visit completed successfully on 16/04/20219 in morning 10:00– 1 pm.

Students visited to total 3 departments swasthavritta department, Sharir kriya department and Sharir rachana department. Staff of three departments gave information about subject and showed them charts, models etc.



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PDEA'S COLLEGE OF AYURVED AND RESEARCH CENTRE, NIGDI, PUNE.
SWASTHAVRITTA DEPARTMENT





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3.5.1

9. Collaborative activity – Student exchange

at

Ayurved Rasashala, Karve Road,Pune for

Industrial Training

11/6/2019 to 10/7/2019

Date-15/7/2019

POST EVENT SUMMARY REPORT

Name of the collaborative activity

Industrial training at Ayurved Rasashala, Karve road , Pune.

Date/ Duration

11/6/2019 to 10/7/2019,

Place: Ayurved Rasashala, Karve road , Pune.

Participants Details: Final Year PG Students - 02

Organising department/ committee- Rasashastra evam Bhaishajya Kalpana

Brief Activity Details:

- Standardization of ASU drugs
- Standardization of Raw materials, manufacturing process and finished products for ASU drugs
- Preparation of Gokshuradi Guggulu, Kumbhjatu vati, Tribhuvankirti Rasa, Shatavari Kalpa.
- Packaging and Sealing of tablets.
- Demonstration of Bottle filling machines with various liquid formulations.
- Hands on training of Quality control measures for different formulations.

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HOD
Department of Rasashastra
Bhaishajyakalpana
College of Ayurved & Research
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Date. 10/07/2019
Out.No.- 591

CERTIFICATE

This is to certify that Vd. Minakshi Harishchandre, student of College of Ayurved & Research Centre, Akurdi has satisfactorily completed industrial training from (11.06.2019 to 10.07.2019) in Production, Raw Material, Quality Control, and R&D Department.

(Dr. Suhas Kulkarni)
General Manager
Ayurveda Rasashala, Pune 4.

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Tel. : +91 - 20 - 25440796, 25440893 Telefax : +91 - 20 - 25435711.
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Date. 10/07/2019
Out.No.– 590

CERTIFICATE

This is to certify that Vd. Rahul Phunde, student of College of Ayurved & Research Centre, Akurdi has satisfactorily completed industrial training from (11.06.2019 to 10.07.2019) in Production, Raw Material, Quality Control, and R&D Department.

(Dr. Suhas Kulkarni)
General Manager
Ayurveda Rasashala, Pune.4.

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3.5.1

10. Collaborative activity – Student exchange

at

Arya Vaidya Shala, Kottakal for

Training in Arya Vaidya Shala

01/08/2019

to

30/09/2019

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Date-03/10/2019

Collaborative Activity Report
Department: Shalakyatantra
[Student Exchange Activity]

Title: trainee physician.

Date/Duration: 01/08/2019-30/09/2019

Place: Arya vaidyashala Ayurvedic hospital and Research Centre Kottakkal,Kerala

Participants details: trainee –PG student Dr.Ashlekha Sharma.

Brief activity details: Dr.Ashlekha Sharma had taken training at Arya vaidyashala Ayurvedic hospital and Research Centre Kottakkal,Kerala for a period for 01/08/2019-30/09/2019.

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ARYA VAIDYA SALA, KOTTAKKAL
Kottakkal - 676 503, Malappuram Dist., Kerala, India. Tel: 0483 2808000, 2742216-19 Fax: 91 483 - 2742572, 2742210
E-mail: info@aryavaidyasala.com, mail@aryavaidyasala.com
Website: www.aryavaidyasala.com



PER/Trg/ 5767

July 13, 2019

PROCEEDINGS

Read: Letter dated 14.05.2019 from Dr. Ashlekha Sharma.

Dr. Ashlekha Sharma is permitted to undergo training in the Arya Vaidya Sala Ayurvedic Hospital & Research Centre, Kottakkal, as an unpaid trainee physician for the period from 01.08.2019 to 30.09.2019. The training will stand automatically terminated on the expiry of the above period. The training mentioned above may not attract any claim for future employment in Arya Vaidya Sala, Kottakkal, and no Certificate will be issued at the end of the training.

P Madhavankutty
Managing Trustee

To

Dr. Ashlekha Sharma,
Govt. Industrial Training Institute for Women,
Sector 11 C,
Chandigarh – 160 011.

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ayurveda

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3.5.1

11. Collaborative activity – Student exchange

at

Vidyarthi mitra, Vaidya M.V. Kolatkar Ayurved Pratisthan

05/08/2019- 28/08/2019

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Date :- 10/09/19

Metric No. 3.5.1

Vidyarthi Mitra, Vaidya M.V. Kolhatkar Ayurved Pratisthana – Gurukul Prathama – Certificate course.

Duration - 05/08/2019- 28/08/2019

Place - Pune

Participant details as student - 1

Activity detail

Students were trained in Samhita Adhyayan based on Ashtanga Hrudaya Sutrasthana. Students had an opportunity to learn from more than 30 practitioners from Maharashtra. They also participated in vanaspati darshan.

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This certificate was received to student at Gurukul on 05/08/2019 to 28/08/2019

विद्यार्थीमित्र-वैद्य-मा-वा-कोल्हटकर-आयुर्वेद-प्रतिष्ठानम्

श्रीमाधवाचार्य गुरुकुलम्





प्रमाणपत्रम्

श्रीमान् / श्रीमती / कु. साळवेकरकुलोत्पन्ना नरेंद्रतनया निवेदिता

अनेन/अनया प्रतिष्ठानेन संचालितस्य श्रीमाधवाचार्यगुरुकुलस्य (०५.०८.२०१९ - २८.०८.२०१९) निवासी पाठ्यक्रमोऽभ्यस्तोऽस्ति । अष्टाङ्गहृदयग्रन्थस्य सूत्रशारीरस्थाने चरकसंहितायाः निदानस्थानम् च इति एतानि स्थानानि तस्मिन् पठितानि सन्ति । सूत्रस्थानस्य केषाञ्चित् अध्यायानां कण्ठस्थीकरणम्, टीकावाचनम्, वनस्पतिदर्शनं, औषधनिर्माणं च अस्मिन् समाविष्टमासीत् । तदर्थं एतत् प्रमाणपत्रं प्रदीयते ।

वैद्यः गाडगीलकुलोत्पन्नः दिलीपः
अध्यक्षः

वैद्यः कोल्हटकरकुलोत्पन्नः वेधस्-शर्मा
सचिवः

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3.5.1

12. Collaborative activity – Teacher exchange

at

Symposium organised at MUHS regarding NAAC, MUHS, Nashik

13/11/2019

ODL REPORT OF SYMPOSIUM ORGANISED AT MUHS REGARDING NAAC ON 13-11-2019

DATE -13/11/2019 TIME -09.00-17.30

PLACE – MAHARASHTRA UNIVERSITY OF HEALTH SCIENCES NASHIK

TITLE :- SYMPOSIUM ON ASSESSMENT OF HEALTH SCIENCES COLLEGE ON THE BASIS OF NAAC PARAMETERS

For above symposium myself, Dr. Swati chobhe, and Dr. Arti firke were registered attended from our college.

Inauguration function was started on 09.40 many 3-3 delegates came from unani, ayurveda, homeopathy, nursing and medical colleges.

Dr. Swanil Torane was the anchor of the symposium Dr. Mahisekar Dr. Lahane, Dr. Kalidas Chava, Dr. Pathak, Dr. Kalaskar, Dr. Palaskar, Dr. Mrs.Naik, Dr. Shrikant Deshmukh and Dr Bagal were on the Dias

Program was started with veedyapeeth geet followed by enlightening of the lamp

Felicitation of all guest speakers of the function was done by Dr. Mhaisekar sir.

Dr Kalidas chavan registrar, muhs has given the introductory speech about symposium after introductory speech Dr. khamgaonkar sir has given guidance in few words as how to proceed for NAAC assessment

Dr. Shashank dalavi has given the guidance regarding NAAC he concluded that out of 368 colleges of MUHS only 40-50 colleges accredited by NAAC

Dr. Tatyarao lahane, eye surgeon, has given guidance regarding quality assurance and maintenance, preparation for pre accreditation. He also cherish with how to clap the hands.

Last of the inaugural function Dr. Dilip Mhaisekar has given president speech and on 10.30 the inaugural function ends followed by Lectures were delivered as follows-

On criteria 1, Curriculum aspects was taken by Dr Jairaj from 10.30-11.20, criteria 5 was taken by dr Rangaswami on student support & progression from 11.20-12.05; criteria 3 was taken by Dr shetty sir on research innovation from 12.05-12.50 after these three criteria question answer session was organized followed by criteria 4 was taken very effectively by Dr Dubhashi on Teaching learning and infrastructure from 1.15-1.45 pm

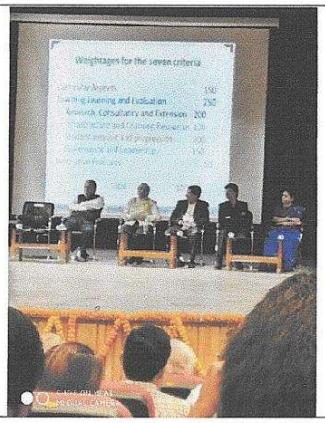
After morning session was over 1.45pm followed by lunch after that next session was started with criteria number 6, on leadership by Dr. Dubhashi very effectively followed by criteria 2 on teaching learning by Dr. Jairaj and lastly criteria 7was taken by Dr. Pichimuttu on institutional values and best practices after all criteria's the question answer session was again organized only three question were allowed to ask then two delegates has shared their thoughts related to this symposium. With vote of thanks followed by National Anthem the program was finished on 5.30pm.

Comment – This type of the symposium should be organized separately for each branch so that it will be more fruitful

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आवक क्र 4352 | 2019-20
दिनांक - 14/11/2019
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प्राचार्य

Dr. Yogini R. Kulkarni

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13. Collaborative activity – Collaborative Research of Mprex Health care

December 2019 to Oct 2020 (10 Months)

Int. J. Pharm. Investigation, 2020;10(4):581-585

Original Article

Randomized Control Trial to Assess the Efficacy and Safety of NRL/2019/5PNW with Micronutrient Fortification to Promote Health and Well-being in Woman in Fertile Age

Priya Khare[1,*], Omkar Kulkarni[1], Anuj Agrawal[1], Gayatri Ganu[2], Medha Joshi[3], Manjit Sisode[4]

[1]Netsurf Research Labs Pvt. Ltd, Baner, Pune, Maharashtra, INDIA.

[2]Clinical Research Unit, Mprex Healthcare, Nisarg Plaza, Bhumkar Nagar, Wakad, Pune, Maharashtra, INDIA.

[3]Pune District Education Association, Pune College of Ayurveda and Sterling Hospital Research Center, Pune, Maharashtra, INDIA.

[4]Janseva Multispecialty Hospital, Old Agra Rd, Deopur, Dhule, Maharashtra, INDIA.

ABSTRACT

Background: Women appear with gender specific nutritional requirements that may affect their well-being. The nutritional requirements are there for women in rural, suburban and urban regions altogether. **Objective:** Netsurf Communications Pvt. Ltd. has developed the NRL/2019/5PNW for the women to help manage their health and wellness. The current research is designed to assess safety and efficacy of the test product. **Methods and Materials:** The trial is randomized, controlled prospective clinical trial. In the present study, 110 subjects were screened. Total 100 subjects were considered evaluable cases at the end of the study 1:1 in test and Marketed product treated group. **Results:** Test product was better in activity than marketed product in improving energy levels of the subjects throughout the day, elevating mood, improving quality of sleep and reducing stress. Improved glycemic control and reduction in total cholesterol levels were significantly reduced in test group which has preventive potential of metabolic diseases. Less events of recurrent UTI/ RTI in test treated group suggestive of improvement in immune status of females. **Conclusion:** NRL/2019/5PNW is safe and effective in promoting health and wellbeing in females in fertile age.

Key words: Curcumin, Energy level, Protein supplement, Soya, Whey.

Correspondence

Dr. Omkar Kulkarni

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DOI: 10.5330/ijpi.2020.4.101

INTRODUCTION

A woman's nutritional and fitness requirements are different than men as there are indeed some special requirements of women to lose fat, gain muscle and look lean. Protein maintain cellular structures, hair, bones and connective tissue. Proteins account for digestive enzymes, immune system and muscle strength. Immune system functionality can be improvised by proper protein supplements. Bone health and density keeps bones strong and minimize the density loss that could be anticaking. Proteins help hair and nails looking healthy and strong thus improving wellness quotient.[1]

Whey protein, soya protein together with vegetable proteins like rice, pea is a better blend in terms of presence of amino acids present and digestibility and thus assimilation. Plant-based proteins tend to be lower in calories and fat than animal proteins and higher in fiber and essential nutrients. Plant-based proteins made with peas can promote muscle thickness gains. In turn vegetable proteins help reducing hunger cravings, are easy at digestions and leads to less gastric distress than animal based source.[2]

Women have gender specific nutritional requirements that may affect wellbeing and there is great need to address the same. The requirements are there in rural, sub-urban and urban regions altogether. Anatomy and physiological stages of females and role of sex hormones throughout lifetime present nutritional challenges requiring special attention.[3] Physical demands on females during fertile age affect nutrition, appetite and health status. Cultural and social factors resulting in stressing gender-specific roles, body shape and weight put woman on risk of eating disorders and seeking unhealthy methods to lose weight. Neural and hormonal factors associate to mood swings and perception to stress in woman life.[4] Women present many nutrition-related concerns from weight maintenance to bone health. By taking in to consideration the special need of good protein for women, the Netsurf Communications Pvt. Ltd. has designed and developed the NRL/2019/5PNW for the women to help to manage health and wellness. The present study aims and clinical validation of safety and efficacy of woman protein supplement in their fertile age.[5]

MATERIALS AND METHODS

The study was initiated after Ethics Committee approval and subsequent registration of study on CTRI website (CTRI/2019/10/021717 [Registered on: 18/10/2019]). The study was conducted as per Good Clinical Practices guidelines. Patients were enrolled in the study only after registration of study on CTRI website.

The primary objectives of the study were to evaluate efficacy of NRL/2019/5PNW and marketed product in fertile women by assessing-daily energy levels, menstrual regulation, changes in biochemical parameters, immunity via number of events of recurrent UTI/RTI etc., changes in hormonal profile.

The secondary objectives of the study were to assess- quality of life (Physical, mental and social) General Health Questionnaire-28 (GHQ-28), changes in mood behavior, sleep quality questionnaire, perceived stress questionnaire, safety assessment.

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Inclusion Criteria

Fertile Women Aged 18 - 50 years with BMI in the range of 20-26 Kg/m^2 were incorporated. Subjects having good physical condition and sound mental status and in the judgment of the principal investigator, able to comply with protocol requirements were included. Subjects willing to sign written informed consent and willing to abstain from use of additional vitamin or mineral supplements, nutritional supplements and or medical foods if applicable were recruited in the trial.

Exclusion Criteria

Subjects with medical history of any major illness such as cancer, heart disease, COPD, Asthma etc. in the past were excluded. Subjects with history of any acute or chronic illness that may affect the patient's participation in the study were excluded. Subjects on prescription medications and/or nonprescription medications for weight loss were not considered in the study. Pregnant and/or breast feeding subjects, not willing to participate in study, subjects with history of hysterectomy, IUI and IVF Subjects with PCOS and or on any hormone replacement therapy were excluded. NRL/2019/5PNW powder is approved by FSSAI. It contains protein blend (whey protein concentrate, soy protein isolate, pea protein isolate, rice protein isolate), milk solids DHA (omega 3-Algal source), *curcumin*, *shatavari* extract, multivitamins and multiminerals.

As per computer generated randomization list, subject were either be randomized to test or marketed product group in 1:1 ratio. Dose of 10 gm. in the morning with 150ml of milk for 90 days were administered. Visit schedule were on baseline visit, day 30, 60 and 90.

Study procedure

Fertile female subjects of age between 18 to 50 years of age (both inclusive) attending outpatient department of study site(s) were screened for eligibility criteria. On screening visit, a written informed consent was obtained from subjects for their participation in the study. Subject's demographic details and clinical examination was recorded. Subject's medical, surgical and treatment history was taken. Subject's current medication if any was noted in the case record from (CRF). The subject was considered for further evaluation as per the inclusion and exclusion criteria. All biochemical parameters were recorded at screening visit. During screening visit and the entire study duration subjects were advised to refrain from antioxidant agents, vitamins, anti-inflammatory drugs, hormones, Nutraceutical, Ayurvedic, Siddha, Unani, herbal / homeopathic medicines. Subjects were checked for occurrence of any adverse event during screening period. Subject's daily energy levels, changes in menstrual regulation, anthropometric analysis and immunity events were assessed. Subjects were assessed for follow up visits after every month up to 3 months. On last visit the biochemical tests were repeated. All clinical and questionnaires were assessed for all visits. All the subjects were closely monitored for any adverse event.

Sample size consideration

Sample size calculation is derived taking considerations of primary and secondary outcomes by a qualified statistician. The software used for calculation of sample size is SPSS version 10.0

RESULTS

Demographic details

In the present study, 110 subjects were screened. Out of 110 subjects, 3 subjects were screen failure and 7 lost to follow up in the study. 100 subjects were considered evaluable cases at the end of the study 50 in test and 50 in Marketed product treated group.

Out of 100 completed subjects, the mean age of Test group subjects in were 35.67± 8.01 years and the mean age of Marketed product group subjects was 34.38 ± 7.36 years. If compared between the groups, the difference was statistically insignificant.

Assessment of mood disorder questionnaire (MDQ) score

There was significant (p<0.001) increase in MDQ score in Test product compared to Marketed product treated group after day 60 and 90. The results are given in Table 1.

Assessment of Pittsburgh sleep quality index (PSQI):

There was significant decrease (p<0.001) between PSQI in Test product and Marketed product treated group after day 60 and 90. The results are given in Table 2.

Assessment of perceived stress score (PSS)

There was significant decrease (p<0.001) between PSS in Test product and Marketed product treated group after day 60 and 90. The results are given in Table 3.

Assessment of general heath questionnaire-28 (GHQ-28) score

At 30, 60 and 90 days there was significant (p<0.001) increase in GHQ-28 score of Test product compared to Marketed product treated group. The results are given in Table 4.

Assessment of energy audit questionnaire

The frequency distribution of energy events depicted difference in "Very High" and "High" score is increased significantly in test treated group than marketed product treated group. The results are given in Table 5.

Assessment of anthropometric parameters

There were significant (p<0.05) reduction in fat % at day 60 and 90, in test group when compared to marketed product treated group. There

Table 1: Assessment of Mood Disorder Questionnaire (MDQ) Score between the groups.

Duration (Days)	Mean Mood Disorder Questionnaire (Mean ± SD)	
	Test (N = 50)	Marketed Product (N = 50)
Baseline	2.04±0.51	1.98±0.63
30	2.04±0.47	2.00±0.48
60	2.41±0.54**	2.02±0.40
90	2.47±0.50**	2.08±0.46

By ANOVA Test: P > 0.05 Not Significant; significant p< 0.01*, p<0.001**

Table 2: Assessment of Pittsburgh Sleep Quality Index (PSQI) between the groups.

Duration (Days)	Mean Pittsburgh Sleep Quality Index(Mean ± SD)	
	Test (N = 50)	Marketed Product (N = 50)
Baseline	5.52±2.57	5.48±2.43
30	4.28±2.40	5.43±2.37
60	2.48±1.47**	4.85±2.44
90	2.04±0.84**	4.95±3.47

By ANOVA multiple comparison Test: P > 0.05 Not Significant; significant p< 0.01*, p<0.001**

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were significant ($p<0.05$) reduction in visceral fat % at day 60 and 90, in test group when compared to marketed product treated group. There was small increase in body weight in both groups after treatment but the comparison was not significant.

Assessment of iron profile

There was significant ($p<0.05$) increase in serum iron in test group when day 90 results (73.45±22.51) were compared to baseline results (69.14±27.02) of same group. There was significant ($p<0.05$) increase in ferritin levels at day 90 between test and marketed product treated group. The mean values of ferritin were 51.34±5.98 and 45.27 in test and marketed product treated group respectively.

Assessment of hormonal profile

The hormonal ranges were normal in all subjects and there was no significant changes in serum levels of FSH, LH, PRL and testosterone after treatment with test and marketed product treated group.

Assessment of immunity events by recurrent RTI/ UTI

Total of 15 subjects of test group reported average of 15 events of RTI/ UTI prior to last month of trial commencement. Total 10 subjects (20%) reported recurrent episodes of either RTI/UTI during three months period. Total 12 subjects of marketed product treated group reported average of at least 13 events of RTI/ UTI prior to last month of trial commencement. In marketed product group, 15 (30) subjects reported 18 events of recurrent RTI/ UTI during three months period and found to be completely resolved in two to three days.

Assessment of menstrual profile

Total 5 subjects out of 50 ie 10% of test group subjects' experiences profuse blood flow at baseline of which only 2 subjects were reporting profuse blood flow after 3 months of treatment with test product. In case of marketed product, 4 out of 50 of marketed product group subject's experienced profuse blood flow at baseline and 5 subjects were reporting profuse blood flow after 3 months of treatment with test product.

Table 3: Assessment of Perceived Stress Score (PSS) between the groups.

Duration (Days)	Mean Perceived stress questionnaire(Mean ± SD)	
	Test(N = 50)	Marketed Product(N = 51)
Baseline	17.50±3.34	18.18±3.18
30	17.17±2.51	17.52±3.05
60	11.93±3.43**	17.52±3.14
90	11.63±4.53**	18.36±4.96

By ANOVA multiple comparison Test: $P > 0.05$ Not Significant; significant $p< 0.01^*$, $p<0.001^{**}$

Table 4: Assessment of General Heath Questionnaire-28 (GHQ-28) Score between the groups.

Duration (Days)	Mean General Heath Questionnaire-28(Mean ± SD)	
	Test (N = 50)	Marketed Product (N = 50)
Baseline	42.70±9.62	47.61±5.38
30	57.41±8.34**	43.43±5.98
60	71.39±6.04***	58.82±9.18
90	78.98±5.55***	61.84±9.44

By ANOVA multiple comparison Test: $P > 0.05$ Not Significant; significant $p<0.001^{**}$, $p<0.0001^{***}$

Changes in Mean parameters of complete hemogram, liver, renal, thyroid function test, serum insulin and random blood sugar levels

All the parameters in the complete hemogram, liver, renal, thyroid function test, serum insulin and random blood sugar levels were within normal range and comparable between groups at baseline. After treatment at day 90, mean value of parameters of said parameters did not show any significant change from baseline in test and marketed product treated groups. The difference was statistically insignificant.

Changes in mean parameter of lipid profile

There was significant $p<0.05$ reduction in total cholesterol of test product treated group at day 90. The results are given in Table 6.

Changes in mean HbA1C

After completion of the treatment, there was significant decrease in HbA_{1C} level in test treated group compared to marketed product treated groups. The results are given in Table 7.

Changes in vital parameters

Pulse, respiratory rate, blood pressure of subjects of both the groups was within normal limits at baseline visit. After completion of the treatment, no significant change in said parameters.

Tolerability of study drugs assessed by physician and subjects

As per physician and subjects, all the subjects (100%) from both the groups reported excellent tolerability to given intervention i e test product and marketed product.

Profile of adverse events

There were 20 (40%) and 18 (36%) subjects reported a total of 24 and 26 adverse events during the study period respectively in test and marketed product treated group. These adverse events included fever, menstrual pain, hyperacidity, injury, body ache, urinary irritation, cold, heartburn and headache. These adverse events were resolved completely after rescue medication was given. Study treatment was not stopped during these adverse events. All these adverse events were not related to the study drug.

DISCUSSION

Women of reproductive age experience many emotional disturbances, of which 20-50% percent have a broad symptomatology. These emotional distress could be a sign of premenstrual syndrome that could be not distinguished presentation so far. Mood fluctuations are very common and profound symptom in many woman which affects her quality of life. The irritable and depressed moods alters the perception to the stress triggers and develop perceived stress.[6] In the present study NRL/2019/5PNW found to be significant in improving mood status in females than in marketed product treated group from day 60. The activity of the NRL/2019/5PNW would be due to improved energy levels due to protein intake and micronutrients supplementation like vitamins and minerals.

Women show up with poorer sleep quality than men and possess risk for insomnia. Disturbed sleep could be attributed to reproductive hormones, stress, depression, aging, societal and family liabilities.[7] Reduced Pittsburgh Sleep Quality Index indicated that the NRL/2019/5PNW

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Table 5: Assessment of Energy Audit Questionnaire Mean Score between the groups.

Energy Level	Mean Energy Audit(Mean ± SD)					
	Test (N=50)			Marketed Product (N=50)		
	Day 30	Day 60	Day 90	Day 30	Day 60	Day 90
Very High	4.00±3.93	23.35±11.13	24.46±7.61	3.91±4.00	10.73±8.69	14.02±5.34
High	5.96±4.85	31.52±10.15	27.96±7.26	6.05±4.45	19.43±14.81	23.41±7.73
Moderate	35.35±13.70	27.11±9.62	23.61±7.77	34.09±14.57	37.66±10.93	32.84±9.00
Neutral	38.39±15.09	24.61±9.86	20.78±6.14	39.11±15.76	37.82±14.44	25.70±9.05
Low	15.22±10.37	7.78±4.80	2.57±2.40	15.23±10.93	8.77±5.24	2.59±2.35
Very low	19.93±21.28	4.67±3.91	0.91±1.98	20.36±21.25	5.18±4.73	0.86±1.64

By ANOVA multiple comparison Test: $P > 0.05$ Not Significant; significant $p<0.001^{**}$, $p<0.0001^{***}$

Table 6: Changes in Mean parameters of lipid profile between the groups.

Lipid Profile	Mean(Mean ± SD)			
	Test (N = 50)		Marketed Product (N = 50)	
	Baseline	Day 90	Baseline	Day 90
Total Cholesterol (mg/dl)	164.22±28.42	155.26±32.62*	166.91±30.20	169.70±25.40
Cholesterol HDL Direct (mg/dl)	54.57±11.69	52.96±13.54	56.17±11.92	55.35±12.52
Triglycerides (mg/dl)	126.84±59.50	129.53±58.75	129.70±38.91	128.80±15.05
LDL Cholesterol (mg/dl)	103.65±20.61	101.76±25.69	108.12±18.11	106.93±16.65
VLDL Cholesterol (mg/dl)	25.98±10.09	27.38±10.42	26.56±9.43	28.26±10.44

By Student's t Test: $P > 0.05$ Not Significant, $P<0.05$ Significant*

treated group experiences less disturbed sleep with less mid night awakenings and sleep latency however improved onset of sleep and duration of uninterrupted sleep etc.

One of the most widely used tool for measuring the perception of stress is the Perceived Stress Scale (PSS). This scale evaluates the degree to which situations in one's life are judged as stressful.[8] At day 60 and 90, NRL/2019/5PNW demonstrated significant reduction in PSS suggestive of lesser appraisal of stress in situations of life by subjects treated with NRL/2019/5PNW. The reduced perception to stress could be due to reduced mood fluctuations, improved sleep and energy levels.

The assessment of the GHQ-9 score depicted that there was improved score at day 30, 60 and 90 in NRL/2019/5PNW treated group than marketed product treated group.

Physical health and well-being is feeling of energy and stamina. There was assessment of energy audit questionnaire to assess subjective changes of the energy levels of the subject divided in 4 parts of day i.e. early morning till breakfast, Breakfast to lunch, Lunch to evening snack time and late evening to bedtime. The energy levels were divided into Very high, High, Moderate, Neutral, Low and Very low depending on the expression of the energy at particular time.[9] The subject reported their reading in terms of score for the day. The results are expressed as mean score and frequency of events in each score title. There was significant increase in shift of individuals experiencing Very High and High energy evidences than Low, Moderate and Neutral energy level in NRL/2019/5PNW treated group than that of marketed product. Energy levels are strongly depend on the muscular strength and vitality together with improved mood status and reduced perceived stress.

Excessive visceral fat is associated with decreased insulin sensitivity which in turn increases risk to cardiovascular disease. In case of woman the visceral fat can induce deposition of reproductive hormone and thus potentiates risk of PCOD etc.[10] The reduction in visceral fat in

Table 7: Changes in Mean HbA1C% between the groups.

Duration (Days)	Mean HbA1c %(Mean± SD)	
	Test (N = 50)	Marketed Product (N = 50)
Baseline	5.17± 0.49	5.15± 0.52
90	4.68±0.51*	5.18±0.54

Student's *t* test : $P > 0.05$ Not Significant, $P<0.05$ Significant*

NRL/2019/5PNW treated group can prove beneficial in preventing these complications.

Ferritin is a protein that stores iron. Ferritin are present in hepatocytes and reticuloendothelial cells. The ferritin binds to another substance called transferrin. It combines with ferritin to transport it to where new red blood cells are made. It's not only important to have normal iron levels, but should have enough stored iron. From the data of present study it is demonstrated that NRL/2019/5PNW improved ferritin levels significantly at day 90 than marketed product. In the data obtained in study, serum iron, total iron binding capacity and transferrin % are increased in both groups magnitude wise but non-significant in comparison. Iron helps to preserve many vital functions in the body, including general energy and focus, gastrointestinal processes, the immune system and the regulation of body temperature. It indicated the ability of NRL/2019/5PNW to improve iron profile in fertile females. This could lead in improved energy, stamina and health status.

As there are positive changes in the energy, stamina, mental state and quality, there are positive changes in immunity status as indicated by events of URI/ RTI in treatment months.

Recent research evidence that curcumin has strong anti-inflammatory and antioxidant activities and modulates inflammatory responses

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which are underlying cause to many diseases. Curcumin possess immunomodulatory effects with multilayer response such as effect on lymphoid cell populations, antigen presentation, humoral and cell-mediated immunity and cytokine production. Curcumin present in NRL/2019/5PNW can play good role in modifying immunity of subjects.[11] NRL/2019/5PNW possess extract of *Asparagus racemosus* ieshatavari. The roots of shatavari are tonic and diuretic and galactgogue and possess ulcer healing effect probably via strengthening the mucosal resistance or gastro-cytoprotection. *A. racemosus* is widely used from ancient times in keeping woman health by virtue of antihepatotoxic, immunomodulatory effects, immune adjuvant effect, uterine tonic and general tonic and rejuvenator properties.[12] Glycemic regulation is thought to be a key in maintaining healthy metabolism and preventing many metabolic diseases like diabetes, cardiovascular diseases. Protein supplements changes all paradigm of metabolism and manages to get good glycemic conditions when person is not no high fat diet.[13] Soy protein is reported to possess low glycemic index. Plant proteins like rice and pea proteins are reported to alter the glycemic and appetitive responses.[14] In the present study, though random blood sugar is not significantly reduced, but the HbA_{1c} levels are significantly reduced in NRL/2019/5PNW treated group.

It was evident that soy protein supplementation may effectively reduce serum cholesterol levels and therefore is likely to diminish the risk for cardiovascular disease.[15] In the present study there was significant ($p<0.05$) reduction in total cholesterol in NRL/2019/5PNW treated group at day 90 of treatment.

CONCLUSION

In comparison to marketed product with a protein blend with multivitamin, NRL/2019/5PNW showed marked improvement in stress score, sleep pattern, glycemic control than marketed product. NRL/2019/5PNW produced reduction in cholesterol levels and visceral fat than marketed product. There was no significant post treatment change in biochemical teats in both the groups, suggesting both the drugs were safe in human subjects. Thus NRL/2019/5PNW is safe and effective in promoting health and wellbeing in fertile females.

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CONFLICT OF INTEREST

There are no conflicts of interest.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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Assessment of the efficacy and safety of protein Supplement with micronutrient fortification (NRL/2019/5PNV) to promote health and wellbeing in healthy adults: Randomized controlled clinical trial

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Abstract

Proteins are an essential component of the diet. As a source of good protein supplement for both male and female, Netsurf communication Pvt. Ltd. has developed NRL/2019/5PNV protein supplement with micronutrient fortification to help to manage health and quality of life. The current research depicts the efficacy and safety of the NRL/2019/5PNV. It is found to be safe and effective in promoting health and wellbeing in healthy adults. It improved skeletal muscle % and reduction in body fat %. There was increased physical endurance indicated as VO_2 max. NRL/2019/5PNV was found in improving energy levels in subjects along with improved digestive behavior. There was improved glycemic control and reduction in total cholesterol levels in NRL/2019/5PNV treated group. The blend of whey, soy, rice and peas protein with vitamin, micro minerals and rejuvenating herbal extracts like *Withania sominifera* and *Aloe vera* is definitely providing better assimilation and efficacy

Keywords: protein supplement, vo2 max, energy level, whey, soya, *Withania sominifera*, *Aloe vera*

1. Introduction

Proteins are an essential component of the diet needed for the survival of animals and humans. Nutritional quality of a food depends on protein content, digestion, absorption, and utilization of proteins. Amino acids availability depends on protein sources, processing treatments, and interaction with other components of the diet [1].

Source of proteins in human diet are mainly animal proteins (e.g. egg, milk, meat and fish) and plant proteins (e.g. pulses, cereals, nuts, beans and soy products). Animal proteins have high biological value than vegetable proteins as per amino acid composition and are more biologically complete. However two plant proteins such as legumes and grains or legumes and nuts/ seeds can be combined to formulate a complete protein from two incomplete proteins. There is gaining momentum to a fact that animal proteins are possessing concerns to many vegetarians and towards digestibility difficulties as well [2].

Legumes include peas, beans, lentils, peanuts etc. can be a good source of protein. Soybeans have captured more interest of researchers because of their concentrated source of isoflavones. It is being backed up by research that isoflavones reduce the risk of cancer, heart disease, and osteoporosis [3, 4]. Soy protein is thought by many researchers as almost equivalent to animal sources in protein quality [5]. According to a study, soy protein has beneficial effects in prevention of coronary heart disease, hypolipidemic effects [6]. Being rich source of isoflavone, soya protein help in improving bone health [7], menopausal symptoms [8] and preventing breast and prostate cancers [9]. Soy protein formulas are found suitable for feeding infants who exhibit lactose intolerance or have lactase deficiency [10].

According to U.S. Food and Drug Administration, the term "dietary supplement" defines any product that supplements the diet containing any one or more of a vitamin, mineral, herb, botanical, amino acid to increase the total dietary intake of added contents [11, 12]. Plant-based supplements are rich in fiber, beta carotene, vitamin K and C, folate, magnesium, and potassium which improve dietary health index [13, 14]. There is great need of supplementing on Vitamin B12. Its deficiency leads to neurological and cognitive health weakening [15]. Vitamin B12 is suggested to be neuroprotective, particularly for memory performance [16-18].

As per many studies, supplementation with vitamin C reduces the duration and severity of common cold symptoms in adults [21, 22]. When used in combination with zinc, vitamin C supplementation can relieve symptoms such as rhinorrhea in common cold [23, 24]. According to the study, vitamin D supplements can protect against respiratory tract infections and reduce the risk of acute respiratory illness and influenza [25]. Studies has shown an excellent rationale to combine vitamins C and D with zinc to support immune functions and help minimize the risk of respiratory infection [26]. Micronutrients have proved helpful in combating the detrimental health effects of prolonged contact with environmental factors that act as vehicles for pollutants [27]. It is a proven fact that plant-based proteins are presented as lower in calories and fat than animal proteins and higher in fiber and essential nutrients. Plant-based pea proteins can help gain muscle mass, reduce hunger cravings. Its high

micronutrient profile helps reduce postmenopausal symptoms. Pea's protein is easily digested and leads to less gastric distress than animal based source.

Protein and fiber rich diet as per study was demonstrated to support successful weight-loss [28]. High-protein diets improve satiety and appetite control thereby providing an excellent way to control and reduce body weight [29]. Hunger and satiation define appetite pattern [30]. From a credible study it was hypothesized that hormones improvise hunger and satiety response such as insulin, glucagon, pancreatic polypeptide (PP) and amylin from pancreas, leptin and adiponectin from adipose tissue and ghrelin, glucagon-like peptide 1 and 2 (GLP-1, GLP-2)from intestine; and dopamine, neuropeptide Y, growth hormone releasing peptide (GHRP) from hypothalamus [31-32]. Orexigenic hormones or peptides promote appetite and anorexigenic work antagonistically, by suppressing apetite. The sensory exposure to food (e.g., sight, smell, taste) has been shown to improvise appetite [33].

High protein diets have been shown to be an effective weight-loss strategy by improving the pancreatic response to reduce hunger [34]. Proteins produce greater satiety than carbohydrates and fats. It increases energy expenditure [35]. Many researches back up the fact that protein diet gives postprandial appetite suppression and subsequent reduction in energy intake [36].

Omega-3 fatty acid, docosahexaenoic acid (DHA), is essential for normal brain function. It is a key component to support brain and eye function throughout life [37, 38]. It is also an important component of tissues of cardiovascular system. The American Heart Association and USDA Dietary Guidelines recommend Omega-3 fats as good for cardiovascular health [39].

By taking in to consideration the pressing need of good protein supplement for both male and female, Netsurf Communication has designed and developed the NRL/2019/5PNV protein supplement with micronutrient fortification for both male and female to help to manage health and quality of life.

It contains essential vitamin, minerals, herbal extracts together with a blend of whey, soy, pea, rice and milk solids. The current research depicts the efficacy and safety of the NRL/2019/5PNV with micronutrient fortification to promote health and wellbeing in healthy adults.

2. Material and Method

2.1 Investigational product details

Product Code: NRL/2019/5PNV. Key ingredients are Milk Solids, Maltodextrin, Protein blend (Whey Protein Concentrate, Soy protein isolate, Rice protein isolate, Pea protein isolate), DHA (omega 3-Algal source), *Aloe vera* extract, *Withania sominifera* extract, Minerals (Calcium phosphate tribasic, potassium citrate, sodium citrate, magnesium sulphate, ferric diphosphate, zinc sulphate, manganese sulphate, copper sulphate, sodium selenite), Vitamins (ascorbic acid, vitamin E, nicotinamide, calcium-d-pantothenate, pyridoxine hydrochloride, thiamine mononitrate, riboflavin, retinyl acetate, folic acid, d-biotin, phylloquinone ,Vitamin D2 ergocalciferol, cyanocobalamin)

2.2 Study Design

A randomized, double Blind, controlled clinical study. The subjects were distributed randomly to test NRL/2019/5PNV treated and marketed product treated group. We had used leading market brand as a protein supplement in comparator arm.

2.3 Study Objectives & Purpose

The primary objectives were assessment of daily activity questionnaire, endurance levels (steppers test), perceived stress levels, immunity via number of events of recurrent UTI/RTI etc., anthropometric analysis, HbA1c and glycemic profile ie blood sugar levels, regulation of lipid levels The secondary objectives were assessment of quality of life, changes in digestive behavior assessment, changes in mood behavior, safety profiling by LFT, RFT and thyroid profile etc., assessment of adverse events, changes in sleep quality questionnaire, palatability with dosage compliance of test product

3. Selection and Withdrawal of Subjects

3.1 Inclusion exclusion criteria

Inclusion Criteria for the study were: age group: 18 years - 65 years, BMI in the range of 20-26, subjects in good physical condition and sound mental status, in the judgment of the Principal Investigator, able to comply with protocol requirements, willing to sign written informed consent, subjects with willingness to abstain from use of vitamin or mineral supplements, nutritional supplements and or medical foods if applicable.

Exclusion Criteria for the study were: allergies to ingredients in product/ milk, Subjects with uncontrolled and uncomplicated diabetes (HbA1C NMT 7.0 % and blood pressure NMT 140/90 mm hg) may or may not be on prescription, subjects with past history of addiction abuse and rehabilitation, subjects with current medical history of any major illness such as cancer, heart disease, COPD, Asthma etc. in the past, subjects with history of any acute or chronic illness that may affect the patient's participation in the study, use of prescription medications and/or nonprescription medications for weight loss, subjects with acute illness or history of major or minor surgery in the past one year, female subjects who are currently pregnant and/or breast feeding, subjects not willing to participate in study

3.2 Recruitment Plan

We intended to complete 100 subjects (50 in each group) at the end of the study. Additional subjects were recruited to complete the required number (100) of completed subjects for analysis. Precautions have been taken not to recruit the subjects belonging to possible vulnerable groups.

3.3 Withdrawal Criteria

Subjects withdrawn from the study for the following reasons: At their own request i.e. withdrawal of consent at any time for personal reasons. If, in the investigator's opinion, continuation in the study would be detrimental to the subject's well-being. Protocol deviations that could invalidate interpretation of the results (i.e. intake of not permitted concomitant treatments etc.)

4. Treatment of Subjects

4.1 Dosage and Treatment Duration

As per computer generated randomization list, subject was either be randomized to NRL/2019/5PNV (Test) or Marketed Product Group in 1:1 ratio. Subjects were advised to take given supplement in a dose of 10 gm in the morning with 150ml of milk for 90 days.

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4.2 Visit Schedules
Subjects were asked to regularly visit at day 0, day 30, day 60 and day 90 of the treatment.

5. Measures taken to avoid bias
5.1 Randomization and study groups
All the subjects are randomly allocated (as per computer generated randomization list) to either one of the two treatment arms in 1:1 ratio. Subjects may be randomized to either NRL/2019/5PNV (Test) group or Marketed Product Group.

5.2 Blinding of the investigational products:
Identical comparator was provided as a marketed product. Primary packing of the test drug and standard was kept absolutely similar in order to keep both investigator as well as the subject blind.

6. Methodology
On screening visit, a written informed consent was obtained from the subjects for their participation in the study and their demographic details and vitals were recorded. The subject then proceeded to undergo clinical examination and their medical, surgical and treatment history was recorded. Current medication if any was noted in the case record from (CRF). The subject was considered for further evaluation as per the inclusion and exclusion criteria. Subject's blood sample were collected at the respective study centers for laboratory testing i.e. CBC, ESR, Hb%, Liver Function Tests, Lipid Profile, Renal Function test, HbA1c. During screening visit and the entire study duration subjects were advised to refrain from antioxidant agents, vitamins, anti-inflammatory drugs, hormones, Nutraceutical, Ayurvedic, Siddha, Unani, herbal /homeopathic medicines. On baseline visit, subject was recruited in the study if he or she met all the inclusion criteria. Subjects were then being to be randomized to one of the two study groups as per the computer generated randomization list. Subjects were asked for occurrence of any adverse event during screening period. Subject undergone clinical examination. Subject's Daily activity, Endurance levels (steppers test), Perceived stress levels and number of events of recurrent UTI/RTI etc. were recorded. Subject's Anthropometric analysis was performed. Following questionnaires were assessed like Quality of life (Physical, mental and social) General Health Questionnaire-28 (GHQ-28), digestive behavior assessment, mood behavior, sleep quality questionnaire. On every follow up visit the above said parameters were assessed. At baseline visit and at every follow up visit (except last follow up visit), as per computer generated randomization list, subjects were provided with investigational products. Subject were advised to consume given supplement in a dose of 10gms in the morning with 150 ml milk. Subject were advised to continue his/ her concomitant medication other than antioxidant agents, weight loss management, vitamins, anti-inflammatory drugs, hormones, Nutraceutical, Ayurvedic, Siddha, Unani, herbal /homeopathic medicines etc. The record of concomitant medication was kept in the CRF. Drug compliance was assessed by the investigator on every follow up visit. Subjects who continuously miss dosing for >3 consecutive days or total missed dose > 9 days during the study period were to be treated as drop outs.

There were no drop outs as of all were compliant. Subjects were advised to continue the diet and exercise regimen (which they are already following) during the entire study period.
On last follow up visit (i.e. Day 90) apart from all baseline assessments, subject's safety biochemical parameters along with the clinical examination were repeated. Adverse events were critically evaluated.
After completion of 3 months of study treatment, all the subjects were being asked to stop trial medications and take advice of investigator for further treatment.
All the subjects were closely monitored for any adverse event starting from baseline visit till the end of the study visit.

7. Ethical consideration and registration of study
7.1 Ethical Consideration
The study was initiated only after a written approval was from Independent/ Institutional Ethics Committee (IEC) and subsequent registration of study on CTRI website. The study was conducted as per approved protocol and as per Good Clinical Practices guidelines.

7.2 CTRI Registration
After getting approval from the ethics committee, the study was registered on CTRI website. Patients were enrolled in the study only after registration of study on CTRI website. The Registration details of study are- CTRI/2019/10/021716 [Registered on: 18/10/2019]-Trial Registered Prospectively.

8. Statistics
8.1 Sample size consideration
Sample size calculation is derived taking considerations of primary and secondary outcomes by a qualified statistician. The software used for calculation of sample size is SPSS version 10.0. There were 50 subjects recruited per group.

9. Results and observations
9.1 Demographic details
In the present study, 107 subjects were screened. Out of 107 subjects, 6 lost to follow up in the study. 101 subjects were considered evaluable cases at the end of the study 50 in test and 51 in marketed product treated group.
Out of 101 completed subjects, the mean age of Test group subjects in were 33.2± 6.83 years and the mean age of Marketed product group subjects was 33.38 ± 8.55 years. If compared between the groups, the difference was statistically insignificant.
The ratio of approximately 75:25 for male and female was decided and maintained during recruitment of the study.

9.2. Efficacy Assessments
9.2.1. Assessment of Maximum Aerobic Capacity (VO_2 Max)
There was non-significant difference between VO_2 Max calculated by 6MWT in Test product and Marketed product treated group at baseline. After day 60, there was significant increase in VO^2 Max calculated by 6MWT with test product treated group as compared to Marketed product. After day 90, there was significant increase in VO_2 Max calculated by 6MWT i.e. 24.64± 2.77with test product treated group as compared to Marketed product.

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Table 1: Assessment of Maximum Aerobic Capacity (VO_2 Max) between the groups

Duration (Days)	Mean VO_2 Max (Mean± SD)	
	Test (N = 50)	Marketed Product (N = 51)
Baseline	20.80± 3.14	20.52± 3.23
30	20.95± 3.27	20.53± 3.23
60	22.59± 2.93*	19.80± 3.27
90	24.64± 2.77**	19.87± 2.71

ANOVA multiple comparison Test: P > 0.05 Not Significant; significant p< 0.01*, p<0.001**

9.2.2. Assessment of Mood Disorder Questionnaire (MDQ) Score

After day 90, there was significant (p<0.001) increase (2.56±0.62 and 1.80±0.66 respectively) between MDQ score in Test product and Marketed product treated group. In case of intergroup analysis, test product treated group demonstrated significant increase in MDQ score at day 60 and 90 when compared to baseline value of the same group. In case of intergroup analysis, marketed product treated group demonstrated non- significant increase in MDQ score at day 30, 60 and 90 when compared to baseline value of the same group.

9.2.3. Assessment of Pittsburgh Sleep Quality Index (PSQI)

There was non-significant difference between PSQI in Test product and Marketed product treated group at baseline. After day 60, and 90 there was significant decrease (p<0.01) in PSQI with Test product treated group.

Table 2: Assessment of Pittsburgh Sleep Quality Index (PSQI) between the groups

Duration (Days)	Mean Pittsburgh Sleep Quality Index (Mean± SD)	
	Test (N = 50)	Marketed Product (N = 51)
Baseline	10.87±5.55	10.09±3.12
30	9.76±3.17	9.82±3.04
60	6.13±1.96*	9.64±2.19
90	3.22±1.43**	10.18±1.27

ANOVA multiple comparison Test: P > 0.05 Not Significant; significant p< 0.01*, p<0.001**

9.2.4. Assessment of Perceived Stress Score (PSS):

There was non-significant difference between PSS in Test product and Marketed product treated group at baseline. After 30, 60 and 90 days there was significant decrease (p<0.001) in PSS evident with Test product compared to Marketed product treated group.

Table 3: Assessment of Perceived Stress Score (PSS) between the groups

Duration (Days)	Mean Perceived stress questionnaire (Mean± SD)	
	Test (N = 50)	Marketed Product (N = 51)
Baseline	24.73± 8.70	26.09± 3.67
30	19.91± 3.55**	25.18± 3.18
60	12.71± 2.94**	22.42± 3.58
90	5.29± 1.70**	24.71± 3.27

ANOVA multiple comparison Test: P > 0.05 Not Significant; significant p< 0.01*, p<0.001**

9.2.5. Assessment of General Heath Questionnaire-28 (GHQ-28) Score

After day 60 and 90, there was significant increase (p<0.001) in GHQ-28 score of Test product treated group compared to Marketed product treated group. During intragroup analysis both groups showed significant (p<0.05) increase in GHQ-28 score from their respective baseline values.

Table 4: Assessment of General Heath Questionnaire-28 (GHQ-28) Score between the groups

Duration (Days)	Mean General Heath Questionnaire-28 (Mean± SD)	
	Test (N = 50)	Marketed Product (N = 51)
Baseline	25.60±8.35	27.60±5.32
30	44.51±5.92	43.49±5.92
60	64.42±5.78**	58.02±9.17
90	80.04±2.26***	67.64±9.42

ANOVA multiple comparison Test: P > 0.05 Not Significant; significant p<0.001**, p<0.0001***

9.2.6. Assessment of Energy Audit Questionnaire

The frequency distribution of energy events depicted difference in "Very High" score is increased significantly in test treated group than marketed product treated group. The frequency distribution of energy events depicted difference in "High" score is increased significantly in test treated group than marketed product treated group. There was shift of events from low, neutral and moderate category of energy events to High and very high score.

The frequency distribution of energy events depicted that after treatment the number of subjects representing "High" and "Very High" energy level scores were increased and "Moderate" to "Very Low" energy levels were decreased. The similar results are evident from Mean Score of Energy Audit and frequency of energy events.

9.2.7. Assessment of Digestive Behavior Score

At day 30, 60 and 90 there was significant decrease in the mean score of bloating, constipation, loss of appetite and post prandial fullness in test treated group than marketed product treated group.

9.2.8. Assessment of Anthropometric parameters

According to the results obtained regarding anthropometric parameters of Test and Marketed product treated groups, it was observed that there is no significant difference in both the groups in parameters like body weight, circumferences, BMI and arm fat index etc. There was small increase in body weight (of average 1 to 1.5 kg in 3 months) in both the groups after treatment for 90 days but the different was not significant.

There was significant reduction in fat % at day 90, in test group when compared to marketed product treated group. There was significant increase in the skeletal muscle % at day 90 in test group when compared to marketed product treated group.

9.2.9. Global assessment for overall improvement by investigator

In test group, 43 (86 %) subjects reported very much overall improvement and 07 (14 %) subjects reported much overall improvement at the end of the study.

In marketed product group, 04 (7.84%) subjects reported minimum overall improvement, 45 (88.23%) subjects reported no change and 01 (1.97 %) subject reported minimal worsening in the condition at the end of the study.

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If compared between the groups, test treated group, performed significantly better than marketed product treated group.

9.2.10. Global assessment for overall improvement by subject

In test group, 45 (90 %) subjects reported very much overall improvement and 05 (10 %) subjects reported much overall improvement at the end of the study.

In marketed product group, 04 (7.84%) subjects reported minimum overall improvement, 45 (88.23%) subjects reported no change and 01 (1.97 %) subject reported minimal worsening in the condition at the end of the study. If compared between the groups, test treated group, performed significantly better than marketed product treated group.

9.2.11. Immunity events by recurrent RTI/ UTI

In test group, at baseline, 12 subjects of test group reported average of at least 12 events of RTI/ UTI in last month to commencement of project.

In test group, 10 subjects (20%) reported recurrent episodes of either RTI/UTI during three months' period. The number frequency of events were 13 events with two to three days' duration. Resolved completely before completion of the study duration.

In marketed product group at baseline, 10 subjects of test group reported average of at least 11 events of RTI/ UTI in last month to commencement of project. In marketed product group, 9 (17.64%) subjects reported 11 events of recurrent RTI/ UTI during three months' period and found to be completely resolved in two to three days. If compared between the groups, there was no significant change in both the groups.

9.3 Safety assessment

9.3.1. Changes in Mean parameters of Complete Hemogram, liver, renal, thyroid function test and random blood sugar levels

All the parameters in the complete Hemogram, liver, renal, thyroid function test and random blood sugar levels were within normal range and comparable between groups at baseline.

After treatment at day 90, mean value of parameters of said parameters did not show any significant change from baseline in test and marketed product treated groups. The difference was statistically insignificant.

9.3.2. Changes in Mean parameter of Lipid Profile

All the parameters of lipid profile were within normal limits at baseline visit in both the groups. After completion of the treatment, no significant change in all other parameters of lipid profile was observed in both the groups i.e. test and marketed product treated group apart from total cholesterol. There was significant $p<0.05$ reduction in test product treated group at day 90.

9.3.3. Changes in Mean HbA1C

Change in Blood HbA1C levels were non-significant at baseline visit in both the groups. After completion of the treatment, there was significant decrease in HbA1C level in test treated group compared to marketed product treated groups.

Table 5: Changes in Mean HbA1C% between the groups

Duration (Days)	Mean HbA1c % (Mean± SD)	
	Test (N = 50)	Marketed Product (N = 51)
Baseline	5.34 ± 0.97	5.30±0.68
90	4.80 ± 0.46*	5.22±0.08

Student's t test P > 0.05 Not Significant, P<0.05 Significant

9.3.4. Changes in Vital parameters

Pulse, respiratory rate, blood pressure of subjects of both the groups was within normal limits at baseline visit. After completion of the treatment, no significant change in said parameters. If compared within the groups, the difference was statistically insignificant.

9.3.5. Tolerability of study drugs assessed by physician and subjects

As per physician and subjects, all the subjects (100%) from both the groups reported excellent tolerability to given intervention ie test product and marketed product.

9.3.6. Palatability and compliance

All the subjects ie 100% from both the groups reported excellent palatability and mix ability of the product. Both the groups also presented excellent compliance to both of the investigational products.

9.3.7. Profile of adverse events

In test group, 15 (30%) subjects reported a total of 17 adverse events during the study period. These adverse events included fever, menstrual pain, hyperacidity, injury, body ache, dry & irritable eyes, cold, heartburn and headache. All these adverse events were mild in severity except headache which was moderate in nature. These adverse events were resolved completely after rescue medication was given. Study treatment was not stopped during these adverse events. All these adverse events were not related to the study drug. In marketed product group, 11 (32%) subjects reported a total of 16 adverse events during the study period. These adverse events included fever, menstrual pain, headache, vomiting, lumbar pain, body ache, mouth ulcer and hyperacidity. All these adverse events were mild in severity and resolved completely after rescue medication was given. Study treatment was not stopped during these adverse events. All these adverse events were not related to the study drug. If compared between the groups, the difference was statistically insignificant.

10. Discussion

In the present study NRL/2019/5PNV was compared for its safety and clinical efficacy against Established Marketed Product. The interpretation of the study parameters obtained are expressed as follows.

VO_2 max, also known as maximal oxygen uptake which measures the maximum amount of oxygen a person can utilize during intense exercise. It is a common measurement used to establish the physical endurance of an individual before and after an oxygen requirement. Factors Affecting VO_2 max are genetics, age, lifestyle & fitness status and boy composition. Shifting body composition to lean mass improvement can improve VO_2 max to considerable level. This in turn upgrades motivation to exercise/ activeness of lifestyle and thereby improving health status. VO_2 max

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Directly measures body oxygen consumption, also get direct measurement of maximum heart rate by recording heart rate during the test. It is a measure of how well the heart and lungs work to deliver oxygen and energy to working muscles [40].

After day 60, there was significant increase in VO_2 Max calculated by 6MWT with test product treated group as compared to Marketed product. After day 90, there was significant increase in VO_2 Max calculated by 6MWT i.e. 24.64± 2.77 with test product treated group as compared to Marketed product.

Assessment of anthropometric parameters revealed following facts. There was slight increase (non-significant $p>0.05$) in body weight in both NRL/2019/5PNV and marketed product treated groups. It was evident from results that there was significant decrease in body fat % i.e. 25.13± 6.84 in NRL/2019/5PNV vs. 27.95± 7.08 % at day 90 in Marketed product treated group. Though the body weight is slightly increasing in both groups, the fat content in NRL/2019/5PNV treated group decreases that contributes to its probable anabolic effect in improving skeletal muscle mass and %. It was clearly evident in comparison of skeletal muscle % at day 90 in both groups. Skeletal muscle % was 32.30± 8.97 in NRL/2019/5PNV and 29.02± 6.05 in marketed product treated group (Significant change $p<0.05$), which indicates clinical superiority of NRL/2019/5PNV in positively modifying body composition by reducing body fat and improving skeletal muscle%. The same effect may be involved in improving VO_2 max by NRL/2019/5PNV.

The very practical and strong index of improving physical health and well-being is feeling of energy and stamina throughout the day. There was assessment of energy audit questionnaire to assess subjective changes of the energy levels of the subject divided in 4 parts of day i.e. early morning till breakfast. Breakfast to lunch, lunch to evening snack time and late evening to bedtime. There was comparable baseline energy levels in both the treatment groups before starting of treatment. The energy levels were divided into Very high, High, Moderate, Neutral, Low and Very low depending on the expression of the energy at particular time [41]. The subject reported their reading in terms of score for the day. The results are expressed as mean score and frequency of events in each score title. There was significant increase in shift of individuals experiencing Very High and High energy evidences than Low, Moderate and Neutral energy level in NRL/2019/5PNV treated group than that of marketed product. Energy levels strongly depend on the digestion behavior and muscular strength and vitality together with mental state to perceive stress. The NRL/2019/5PNV contains plant based protein and herbal extracts of *Withania somnifera* and *Aloe vera*. The plant based proteins are easy to digest and could improve digestion cycle. *Withania somnifera* by virtue of its active constituents is known for its rejuvenating, anti-stress activity [42]. *Aloe vera* is known to potentially improve digestion by reducing gastric inflammation and mild laxative action [43]. The composition of NRL/2019/5PNV must have contributed to improve wellbeing of the subjects by improving their energy levels throughout the day.

After 30 and 60 days there was again non-significant difference between MDQ score in Test product and Marketed product treated group. After day 90, there was significant ($p<0.001$) increase (ie2.56±0.62 and 1.80±0.66 respectively) between MDQ score in NRL/2019/5PNV and Marketed product treated group. The NRL/2019/5PNV proved to be more efficacious in improving mood status in subjects than the marketed product. The effect could be attributed to the improved physical stamina, energy levels and rejuvenating effects of *Withania sominifera* as a combination [42, 44].

Quality of sleep determines physical, mental well-being and work productivity. It was demonstrable from the study that NRL/2019/5PNV is more efficacious in improving sleep quality in subjects. The assessment was performed by Pittsburgh Sleep Quality Index. The NRL/2019/5PNV showed significant $p<0.001$ improvement in healthy uninterrupted sleep pattern in subjects. There is much stronger linkage in improvement of quality of sleep and energy levels. The relationship is witnessed in this research. The available scientific data support the conclusion that *Withania sominifera* is a real potent regenerative tonic (Rasayana of Ayurveda), due to its multiple pharmacological actions like anti-stress, neuroprotective, analgesic and anti-inflammatory etc. It is useful for prevention stress related sleep deprivation. The effect could be attributed to rejuvenating action of *Withania sominifera* [45].

Stress is psychological phenomenon and is greatly influenced by individual's ability to perceive the state of stress. The perception to the stress is largely dependent of lack of physical stamina, energy levels, digestion and healthy sleep pattern. NRL/2019/5PNV has demonstrated significant ($p<0.05$) reduction in perceived stress score from 30 days of treatment up to 90 days when compared to marketed product. Protection to the human physiological system against diverse stressor, recent studies shows that the *Withania sominifera* having adaptogens which could induce a state of non-specific increase of resistance to affect internal homeostasis. The adaptogens improve the response to stress and help the body to adapt by normal physiological processes in times of increased stress. The anti-stress activity of *Withania sominifera* must have contributed through its adaptogenic action to combat stress situation. Antistress and adaptogenic properties of *Withania sominifera* have been investigated in all these studies using adult rats were carried out by swimming endurance stress test [42].

The right combination of essential vitamins and minerals are very important to keep the health and wellbeing to its maximum. NRL/2019/5PNV has blend of multivitamin and multimineral to improve and restore the normal physiology of body and exert immunomodulatory and antioxidant potential. Omega 3 fatty acid present in NRL/2019/5PNV is known to restore cellular functioning, integrity and energy balance. Omega 3 fatty acids are cardio protective, neuroprotective nature.

It is well researched fact that protein's nutritional value also depends on its rate of digestion in the gastrointestinal tract. Whey proteins were digested more rapidly than casein. Whey proteins, which are highly soluble in acidic conditions, pass through the stomach and are rapidly hydrolyzed in the duodenum, causing rapid absorption. Soy proteins are digested faster than casein and are slower than whey proteins. Thus, the postprandial muscle protein synthesis rate is more in whey and soy proteins than milk proteins. Plant proteins like rice and pea proteins are not as good as improving anabolic effect but are easy to digest and

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improve short term goals in body composition and help in skin, hair and nails health. It can adjust the overall digestibility of the protein blend [46].

After assessment of Digestive Behavior Score following were the observations. At day 30, 60 and 90 of treatment, there was significant decrease in the mean score of bloating, post prandial fullness and constipation ($p<0.001$ respectively for 30, 60 and 90 days) in NRL/2019/5PNV treated group than marketed product treated group. At day 30, 60 and 90 there was significant decrease in the mean score of loss of appetite ($p<0.001$ respectively for 30, 60 and 90 days) in test treated group than marketed product treated group. There is significant decrease in occasional abdominal pain and heartburn in NRL/2019/5PNV treated group as compared to marketed product, at day 90 ($p<0.001$). The results suggest not only the ease in digestion of the NRL/2019/5PNV but also improvement in overall digestive behaviour. The attribution might go to the balanced blend of Whey, soya and plant based proteins like rice and peas together with goodness of *Aloe vera* as a digestive promoter.

Earlier epidemiological studies demonstrate that poor glycaemic control is an independent risk factor for CVD. Whey protein administration has been demonstrated to reduce postprandial glycaemia, mediated through various mechanisms including an enhancement of insulin secretion. Whey protein ingestion has also been shown to elicit an incretin effect, enhancing the secretion of glucose-dependent insulinotropic peptide and glucagon-like peptide-1, which may also influence appetite regulation and glycemic control [47]. Soy protein is reported to possess low glycemic index, suggesting that soy protein tend to improve control of blood glucose and insulin levels. Plant proteins like rice and pea proteins are reported to alter the glycemic and appetitive responses as per a clinical trial conducted which help promoting glycemic control [48]. The research evidence suggests a possible effect of *Aloe vera* on glycemic control in prediabetes and type 2 diabetes.

In the present study, though random blood sugar is not significantly reduced, but the HbA1C levels are significantly reduced in NRL/2019/5PNV treated group than that of the marketed produce treated group. This can suggest possible potential of NRL/2019/5PNV in improving glycemic control by virtue of the protein blend and herbal blend present in product.

Pre-diabetics are at risk of developing type-two diabetes. Many of the Indians are at risk of development of diabetes in near future as a result of borderline or higher levels of blood sugar and cholesterol levels. A randomized controlled trial with pre-diabetes reported reduction in the cholesterol levels after treatment of *Aloe vera* extracts [50].

The lipid-lowering effect of a soy-based protein supplement was evaluated by researchers in patients with hypercholesterolemia. It was evident that soy protein supplementation may effectively reduce serum cholesterol levels and therefore is likely to diminish the risk for cardiovascular disease. Previous studies have suggested that whey supplementation may have beneficial effects on lipid profile. Whey protein proved to be modest in lowering total cholesterol and triglycerides.

In the present study there was significant ($p<0.05$) reduction in total cholesterol but no change in TG, HDL, LDL and VLDL in NRL/2019/5PNV treated group at day 90 of treatment.

GHQ-9 is a standard questionnaire to assess Quality of Life. The assessment of the GHQ-9 score depicted that there was improved score at day 60 and 90 in NRL/2019/5PNV treated group than marketed product treated group.

11. Conclusion

NRL/2019/5PNV is safe and effective in promoting health and wellbeing in healthy adults. There was increased physical endurance by NRL/2019/5PNV treatment indicated as VO2 max compared to marketed product. This can be linked to exercise motivation, work efficiency and improved quality of life. The NRL/2019/5PNV was equally tolerated and compliant as that of marketed product. NRL/2019/5PNV was better in improving energy levels of the subjects throughout the day, elevating mood, improving quality of sleep. Together these parameters are true measures of wellbeing. NRL/2019/5PNV is promoting wellbeing and thus its consumption can elevate health status. NRL/2019/5PNV was found better in reducing the perception to the stress and thus improving quality of life. NRL/2019/5PNV improved digestive behavior of the subjects like reducing constipation, bloating, and loss of appetite and post prandial fullness. These are essentially complaints with sedentary lifestyle. NRL/2019/5PNV consumption is suitable for people with sedentary lifestyle experiencing digestive disturbances. There was improved glycemic control indicated as significant reduction in HbA1C in NRL/2019/5PNV. A balanced blend of proteins like whey, soy, rice and peas along with proportionate vitamin and micro mineral fortification and addition of rejuvenating herbal extracts like *Withania sominifera* and *Aloe vera* is definitely providing better assimilation of the product and efficacy.

12. References

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3.5.1

15. Collaborative activity – Collaborative Research of Mprex Health care

Dec.2019 to April 2021 (1year 4 months)

Original Article

A randomized controlled trial to assess the efficacy and safety of children's health supplement with micronutrient fortification to promote growth, health, and wellbeing in children

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Abstract

Background: Proteins are one of the strong pillars of sound physical health and cognitive abilities. Protein and micronutrient deficiency can hamper the health and growth of many children globally, delaying their physical and mental improvement and increase proneness to infections. The current research depicts the efficacy and safety of the children's health supplement with micronutrient fortification to promote growth, health, and wellbeing in children. A multicenter randomized controlled trial. **Material and Methods:** Two centers one being a teaching institute with a hospital and the second one private hospital. Total 105 subjects visiting the out patient department (OPD) section participated of which 100 completed the trial with five being dropped out as lost to follow-up. Children's health supplement (NRL/2019/5PNK) contains essential vitamins, minerals, herbal extracts together with a blend of whey, soy, pea, rice proteins, and milk solids. It was consumed as 90 days' treatment in a dose of 10 g daily with 150 mL milk. Children's health supplements improved anthropometric parameters and growth of children indicated by height-to-age and weight-to-age z-scores defined by world health organization (WHO). **Results:** There was a 45.70% increased physical endurance by children's health supplement. Enhanced immunity status indicated by reduced illness episodes and missed school days. Children's health supplements improved child's eating behavior and cognitive performance better than the marketed product. It was found better in improving digestive behavior in children. **Conclusion:** Children's health supplement found safe and effective in promoting growth, health, and wellbeing in healthy children.

Keywords: Nutrition, physical endurance, wellbeing, z-score

CTRI/2019/11/021993-Registered Prospectively.

INTRODUCTION

Scientific background and rationale

Protein and micronutrient deficiency can impede the health and growth of many children globally. It can delay their physical and mental improvement and increase proneness to infections. Protein deficiency could result in a negative nitrogen balance. Essential amino acids contribute the most to the mental and physical health of the child. There are several symptoms of protein deficiency that often are overlooked such as fatigue, lack of concentration, slowed growth, and lowered immunity. As per a study conducted by Abbott Laboratories, one in seven school-aged children in the US is not consuming enough protein; the numbers are almost double in developing countries like India.[1] Protein nutrition is one of the strong pillars of sound physical health and

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cognitive abilities.[2] Undernutrition with proteins and infection is a vicious cycle, along with deteriorating illness and declining nutritional status. Protein undernutrition could be the main cause of the immunocompromised state, such children are more prone to gastrointestinal (GI) and respiratory infections, and it is important to consider opportunistic infections such as viruses, gram-negative bacteria, fungal, and parasitic infestations. Undernutrition, low growth rate, overweight, micronutrient deficiencies, and osteopenia are nutritional confounders that affect the impairment neurologically.[3]

The stage of growth in children is defined by the attributes of height and weight. For attaining the same, all nutrients must be ingested, absorbed, metabolized, and excreted properly since better assimilation translates to nutritional sufficiency. In the case of children, their metabolism is a constantly evolving mechanism and not a fixed combination that could work, but easy digestibility will make difference in better assimilation.[4] Families with a low socioeconomic status often have little access to micronutrient-rich foods like fruits, vegetables, meat, fish, and dairy. In affluent profile families, protein malnourishment can result from excessive ingestion of fatty, carbohydrate, and sugar-rich food.[5] A wide range of traditional as well as contemporary health products is available for children and the pressure is on the homemaker to keep the health of the children up to the mark. There is a great need for a researched product with proven safety and effectiveness to completely rely on the product for child consumption.

Netsurf Communications Pvt. Ltd. has developed children's nutraceutical supplement (NRL/2019/5PNK, henceforth will be termed as test product) containing protein with micronutrients fortification, with a natural product designed to promote general health and wellbeing of children, to support the optimum natural growth and development of children, enhanced immunity, and to the maintenance of adequate natural cognitive function. It contains essential vitamins, minerals, herbal extracts together with a blend of whey, soy, pea, rice, and milk solids. It is in powder form, 10 g of it is mixed in water or milk for consumption. The current research depicts the efficacy and safety of the test product with micronutrient fortification to promote growth, health, and wellbeing in children.

Study hypotheses

The hypothesis of the research was "Was test product as effective as the marketed comparator in safety and efficacy and were there any additional benefits of test product against the marketed product to promote growth, health, and wellbeing in children?"

MATERIAL AND METHODS

Trial design

The study was a randomized, double-blind, parallel-arm, controlled clinical trial. The subjects were randomized to test the product or marketed product (market comparator) group (comparator is the leading brand of protein supplement for children) in a 1:1 ratio.

Ethical consideration

The study was initiated only after written approval is obtained from the Independent Ethics Committee (IEC) and subsequent registration of the study on the clinical trial registry of India (CTRI) website. The study was conducted as per approved protocol and as per Good Clinical Practices guidelines.

Data availability and CTRI registration

After getting approval from the ethics committee, the study was registered on the CTRI website. Patients were enrolled in the study only after registration of study on the CTRI website. The Registration details of the study are: CTRI/2019/11/021993 [registered on November 13, 2019] – Trial Registered Prospectively.

Selection criteria of subjects

The subjects along with their guardians/parents visiting out patient department (OPD) of the two trial sites were screened for the inclusion and exclusion criteria for the said trial. The subjects who fulfilled inclusion criteria and did not meet any exclusion criteria had been selected to participate in the trial.

Inclusion criteria for the study were: children aged 6 to 11 years inclusive (both gender), providing consent by an understanding of the study and willingness to participate as evidenced by subject's parents and/or legal guardian's voluntary written informed consent; ready for compliance; and is willing, able, and likely to comply with all study procedures and restrictions.

Exclusion criteria for the study

Following were the exclusion criteria: the subject with a known allergy or intolerance to the study product or ingredients, on a special diet and cannot consume the study product, subject with a current illness requiring hospitalization, subject with a GI infection and/or acute diarrhea at the time of inclusion in the study, and the subject on medication that could affect absorption/metabolism of study product. The subject is diagnosed with recurrent respiratory infections due to cystic fibrosis, active tuberculosis, acute hepatitis B or C or HIV, malignancy (as per history in the medical records) were excluded, as per discretion of investigation; subject with a history of diabetes (as per history and documentation in the medical records), subject been on antibiotic therapy within the last 1 month before the start of the study (before study day 1), subject with dysphasia, aspiration risk, and difficulty in swallowing due to acquired/congenital abnormalities that would hamper oral intake of the study product were excluded (as per history and documentation in the medical records); subject with a clinically significant nutritional deficiency requiring specific treatment with any other nutritional supplement (not study product) as diagnosed by the investigator were excluded for the safety concern.

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Intervention details

Test product and a market comparator product were administered to subjects 10 g in the morning daily with 150 mL milk for 90 days' treatment period. The subjects along with their guardian/parent were asked to visit over a schedule of day 30, 60, and 90 as follow-up visits.

Outcome measures

The primary objectives of the study were to evaluate the efficacy of children's health supplement with micronutrient fortification by assessing growth – change in weight [world health organization (WHO) *z*-score], anthropometry tests, questionnaire for evaluation of development and behavior, physical endurance by VO_2 max in comparison with the market comparator.

The secondary objectives were assessment of immunity profile via a number of recurrent acute upper respiratory tract infection (URTI), number of sick days per month assessed by the presence of any acute URTI, number of days required to recover from an episode of infection, appetite score questionnaire, emotional quotient questionnaire, safety biochemical tests, serum brain-derived neurotrophic factor (BDNF) levels, adverse events profiling, etc., in comparison with the market comparator.

There were no changes in objectives after the commencement and completion of the trial. All the outcomes were assessed at each time point of the study, that is, on days 0, 30, 60, and 90.

Sample size consideration

Sample size calculation is derived taking considerations of primary and secondary outcomes by a qualified statistician. The software used for analysis is SPSS version 10.0.

Statistical methods

The safety biochemical parameters were analyzed from baseline to end of the study using student paired and unpaired *t* test. Primary outcomes at baseline and every visit till the end of the study were analyzed by analysis of variance (ANOVA) followed by multiple comparison tests. Other variables like a global assessment for overall improvement, tolerability of study drugs, and adverse events were analyzed by the chi-square test.

Randomization sequence generation

It was a randomized study wherein all the subjects were randomly allocated (as per computer-generated randomization list) to either one of the two treatment arms in a 1:1 ratio. Subjects were randomized to either the test group or marketed product group.

Visit schedules

Screening visit, baseline visit (day 0), visit 1 (day 30), visit 2 (day 60), visit 3 (day 90).

Allocation concealment mechanism

Sequentially numbered containers as per enrollment number were used to conceal the randomization in identical primary packaging.

Blinding

The identical packaging and flavor of both the interventions were kept similar to keep both investigators as well as the subject blind of which drug he/she was receiving.

Procedure

Principle investigator obtained informed consent from subjects' guardians or parents visiting at OPD of research sites and randomized the subjects as per the computer-generated list allots subject to the respective group after fulfillment of their inclusion and exclusion criteria. The subject's demographic details were recorded. The subject underwent clinical examination (general and systemic examination). The subject's medical, surgical, and treatment history was recorded. The current medications of the subject if any were noted in the case record form. The subject was considered for further evaluation as per the inclusion and exclusion criteria. Blood samples for biochemical tests were collected. During the screening visit and the entire study duration subject's guardians were advised to refrain subject from consuming antioxidant agents, vitamins, health supplements, nutraceuticals, Ayurvedic, Siddha, Unani, or herbal/homeopathic medicines. On baseline visit, the subject was recruited in the study if he/she fulfilled all the inclusion criteria. Subjects were then randomized to one of the two study groups as per the computer-generated randomization list. The subject's parent/guardian was asked for the occurrence of any adverse event during the screening period. The subject underwent clinical examination (general and systemic examination). Subject's growth – weight change (WHO *z*-score), anthropometric parameters, and questionnaire, were assessed along with VO_2 max.

At baseline visit and every follow-up visit (except last follow-up visit), as per the computer-generated randomization list, the subject's guardians were provided with an investigational product with instructions for its use. Product compliance was assessed by the investigator on every follow-up visit. Subjects who continuously missed dosing for >3 consecutive days or total missed dose >9 days during the study period were treated as dropouts. The records of the compliance were kept as a telephonic log (calls to the subject's parents).

Subjects were called to respective study sites for follow-up visits after every month up to 3 months after the baseline visit. On every follow-up visit, all the parameters performed on the baseline visit are assessed.

On the third follow-up visit (i.e., day 90) all the assessments of the subject were repeated along with the biochemical tests from blood samples. Global improvement and palatability

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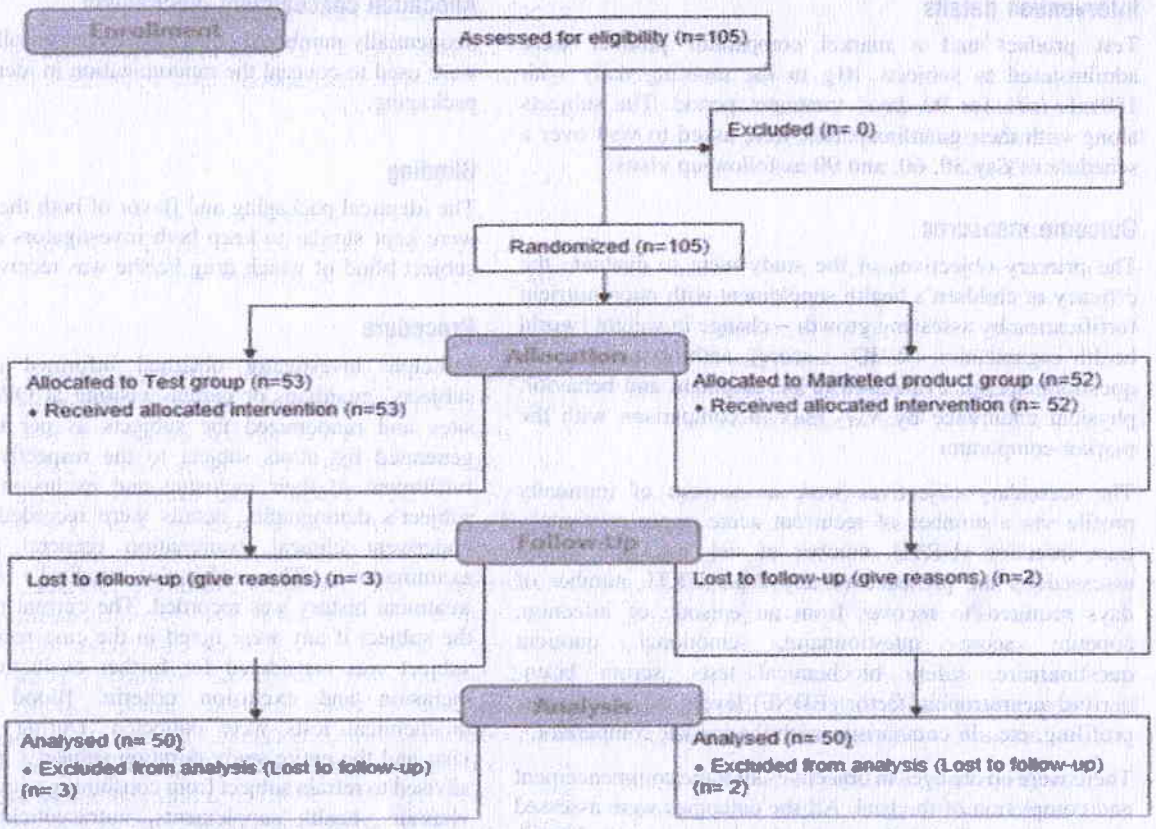


Figure 1: Participants' flow diagram

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assessment were carried out by the subject guardian as well as the investigator. After completion of 3 months of study treatment, all the subjects were asked to stop trial medications and take the advice of the investigator for further treatment. The participant's details are explained in Figure 1.

RESULTS

In the present study, 105 subjects were screened. Out of 105 subjects, five lost to follow-up in the study. Total 100 subjects were considered evaluable cases at the end of the study: 50 in test and 50 in the marketed product treated group.

Out of 100 completed subjects, the mean age of test group subjects was 8.5 ± 2.44 years and the mean age of marketed product group subjects was 8.89 ± 3.01 years; the difference was statistically insignificant. The ratio of 50:50 for males and females was maintained during recruitment of the study.

Assessment of physical endurance (VO2 max)

There was a nonsignificant difference between VO_2 max calculated by PREFIT test in test product and marketed product treated group at baseline and till day 60. After day 90, there was a significant increase ($P < 0.05$) in VO_2 max calculated by PREFIT test with the test product treated group as compared to marketed product. Within-group analysis, test product treated group demonstrated 45.7% and marketed product treated group showed 21.25% increase in VO_2 max at day 90 when compared to the baseline value of the respective group as shown in Table 1.

Assessment of WHO z-score

There was a nonsignificant difference in height-to-age and weight-to-age z-score in the test product and marketed product treated group at baseline till day 90. In the case of within-group analysis, the test and marketed product treated group demonstrated significant improvement in height-to-age and weight-to-age z-score at day 30, 60, and 90 when compared to the baseline value of the same group as shown in Table 2.

Assessment of Child Eating Behavior Questionnaire

The Child Eating Behavior Questionnaire was assessed based on the response from the subject's parent/guardian. After day 60, there was significant ($P < 0.001$) improvement in certain domains in eating behavior like food responsiveness, enjoyment of food, eating speed (reduced sluggishness) in the test product treated group than marketed product treated group. After day 90, there was significant ($P < 0.001$) improvement in certain domains in eating behavior like food responsiveness, emotional overeating (got reduced after treatment), enjoyment of food, desire to drink, satiety

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responsiveness, eating speed (reduced sluggishness after treatment), emotional undereating (got reduced after treatment) in test product treated group than marketed product treated group as shown in Table 3.

Table 1: Assessment of maximum aerobic capacity (VO2 max) between the groups

Duration	Mean VO_2 max	
	Test	Marketed product
Baseline	40.18±3.96	41.20±4.96
Day 30	42.59±3.60	42.90±4.62
Day 60	48.87±3.96	47.32± 4.70
Day 90	58.50±4.69*	52.32±2.33

By one-way ANOVA followed by Bonferroni selective multiple comparison test: $P > 0.05$, not significant. ANOVA, analysis of variance.

Assessment of Emotional Intelligence Questionnaire

The Emotional Intelligence Questionnaire was assessed based on the response from the subject's parent/guardian. After day 90, there was significant ($P < 0.0001$) improvement in scores of the following domain of the questionnaire, such as social skills, motivation, self-regulation, self-awareness, and empathy in test product treated group than marketed product treated group as shown in Table 4.

Assessment of Evaluation of Development and Behavior Questionnaire

The Development and Behavior Questionnaire was assessed based on the response from the subject's parent/guardian. After day 90, there was a significant improvement

Table 2: Assessment of WHO *z*-score

WHO z-score	Mean WHO z-score(Mean ± SD)							
	Test				Marketed product			
	Baseline	Day 30	Day 60	Day 90	Baseline	Day 30	Day 60	Day 90
Height-to-age(z-score)	−0.89± 1.40	−0.66± 1.34	−0.60± 1.29	−0.51± 1.29	−1.10± 1.37	−0.79± 1.41	−1.68± 1.51	−1.58± 1.29
Weight-to-age (z-score)	−1.33± 1.48	−1.29± 1.45	−1.06± 1.47	−0.89± 1.10	−1.46± 1.58	−1.35± 1.58	−1.28± 1.92	−0.95± 1.41

By one-way ANOVA followed by Bonferroni selective multiple comparison test: $P > 0.05$, not significant. *Symbol represents that results are significant i.e. P value < 0.05. ANOVA, analysis of variance; WHO, world health organization; SD, standard deviation.

Table 3: Assessment of Child Eating Behavior Questionnaire between the groups

Questionnaire	Mean Child Eating Behavior Questionnaire score(Mean ± SD)			
	Test		Marketed product	
	Baseline	Day 90	Baseline	Day 90
Food responsiveness	11.16±2.41	6.27±1.05†	10.53±2.83	11.59±3.76
Emotional overeating	10.55±2.11	6.38±1.68†	10.32±1.88	10.29±1.82
Enjoyment of food	7.27±1.63	16.47±1.10†	7.19±1.52	9.53±3.34
Desire to drink	8.30±1.32	11.07±0.75†	8.48±1.34	9.39±1.40
Satiety responsiveness	19.55±1.45	12.56±1.78†	19.59±1.81	19.45±14.68
Slowness in eating	15.60±1.34	10.77±1.24†	15.36±2.24	14.29±2.39
Emotional undereating	15.26±2.47	7.67±1.93†	14.86±2.82	13.52±3.17
Food fussiness	16.55±2.23	18.33±1.22	15.48±3.86	18.42±2.79

By one-way ANOVA followed by Bonferroni selective multiple comparison test: $P > 0.05$, not significant. †$P < 0.001$. *Symbol represents that results are significant i.e. P value < 0.05. ANOVA, analysis of variance; SD, standard deviation.

Table 4: Assessment of Emotional Intelligence Questionnaire (EIQ) between the groups

Questionnaire	Mean Emotional Intelligence Questionnaire score(Mean ± SD)			
	Test		Marketed product	
	Baseline	Day 90	Baseline	Day 90
Social Skills	6.02±1.04	8.07±0.75†	5.91±0.95	6.00±0.99
Motivation	5.17±1.81	8.27±0.84†	5.44±1.18	5.74±1.16
Self-regulation	4.67±1.51	7.93±0.94†	4.81±1.38	5.26±1.26
Self-awareness	4.39±0.86	7.89±0.91†	4.18±1.24	6.31±1.04
Empathy	3.98±1.44	8.07±0.72†	4.07±1.35	7.60±11.18

By one-way ANOVA followed by Bonferroni selective multiple comparison test: $P > 0.05$, not significant. †$P < 0.001$. *Symbol represents that results are significant i.e. P value < 0.05. ANOVA, analysis of variance; SD, standard deviation.

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($P < 0.0001$) in all domains of Development and Behavior score in test product than marketed product treated group as shown in Table 5.

Assessment of anthropometric parameters

According to the results obtained regarding anthropometric parameters of test and marketed product treated groups, it was observed that there is no significant difference in both the groups in parameters like body weight, circumferences, body mass index (BMI), arm fat index, etc. In the within-group analysis, test product and marketed product treated group showed significant improvement ($P < 0.05$) in anthropometric parameters at day 90 compared to baseline reading with height, weight, and BMI as shown in Table 6.

Changes in mean serum BDNF level

Mean serum BDNF levels were within normal limits at baseline visit in both the groups. After completion of the treatment, no significant change in serum BDNF level was observed in both the groups, that is, test and marketed product treated groups. If compared within the groups, there was a nonsignificant improvement in serum BDNF when 90 days readings were compared to baseline values of the respective groups as shown in Table 7.

Table 5: Assessment of Evaluation of Development and Behavior score between the groups

Development and behavior	Mean Emotional Intelligence Questionnaire score(Mean ± SD)			
	Test		Marketed product	
	Baseline	Day 90	Baseline	Day 90
Motor skills – gross motor skills	8.91 ± 1.77	18.20 ± 1.42†	9.05 ± 1.33	14.31 ± 1.87
Attention and concentration	11.79 ± 1.32	20.67 ± 2.01†	11.62 ± 1.45	13.62 ± 2.21
Overactivity and impulsivity	14.05 ± 2.06	22.31 ± 2.07†	13.70 ± 2.45	14.78 ± 1.82
Passivity/inactivity	6.48 ± 0.92	12.20 ± 1.36†	6.64 ± 1.06	8.44 ± 1.20
Planning/organizing	5.49 ± 0.86	10.73 ± 1.03†	5.58 ± 0.85	7.73 ± 1.30
Perception of space and directions	6.52 ± 0.99	12.58 ± 1.14†	6.66 ± 0.86	7.91 ± 1.28
Perception of visual forms and figures	5.66 ± 1.08	11.00 ± 0.88†	5.62 ± 0.94	7.82 ± 1.25
Memory	13.45 ± 4.41	24.04 ± 2.74†	13.23 ± 1.75	15.98 ± 1.84
Comprehension of spoken language	6.79 ± 0.86	12.16 ± 1.04†	7.16 ± 2.06	9.07 ± 2.02
Verbal communication	4.64 ± 1.83	8.24 ± 0.86†	4.77 ± 2.92	6.00 ± 1.24
Acquisition of academic skills	12.66 ± 1.38	25.53 ± 1.83†	12.20 ± 1.93	15.30 ± 2.70
Social skills	13.93 ± 1.53	27.53 ± 2.30†	14.02 ± 1.47	15.82 ± 2.04
Emotional issues handling	17.79 ± 1.73	36.98 ± 2.71†	17.80 ± 2.51	19.20 ± 2.47
Obsessive actions or thoughts	8.57 ± 2.47	5.27 ± 1.81†	8.70 ± 2.50	9.62 ± 1.81

By one-way ANOVA followed by Bonferroni selective multiple comparison test: $P > 0.05$, not significant. †$P < 0.001$. *Symbol represents that results are significant i.e. P value < 0.05. ANOVA, analysis of variance; SD, standard deviation.

Table 6: Assessment of anthropometric parameters between the groups

Parameters	Mean(Mean ± SD)			
	Test		Marketed product	
	Baseline	Day 90	Baseline	Day 90
Height (cm)	126.19 ± 10.65	131.76 ± 10.77	124.34 ± 10.22	128.29 ± 11.10
Weight (kg)	24.13 ± 6.14	26.75 ± 4.59	23.87 ± 6.71	26.82 ± 12.22
Waist circumference (cm)	22.94 ± 2.45	23.48 ± 2.11	22.86 ± 2.42	23.45 ± 1.09
Hip circumference (cm)	26.17 ± 2.18	26.42 ± 2.30	26.01 ± 3.05	26.40 ± 1.88
Upper arm circumference (cm)	7.34 ± 0.96	7.82 ± 1.34	7.56 ± 8.68	7.98 ± 3. 77
Triceps skinfold thickness (cm)	14.57 ± 5.77	17.71 ± 18.10	14.53 ± 5.58	16.39 ± 4.66
Head circumference (cm)	19.93 ± 1.12	20.80 ± 1.08	20.01 ± 1.45	20.44 ± 1.19
Chest circumference (cm)	23.48 ± 2.32	23.76 ± 2.26	23.32 ± 2.27	23.97 ± 2.32
Foot length (cm)	26.82 ± 3.41	27.20 ± 3.10	26.04 ± 3.60	26.88 ± 3.20
Arm length (cm)	15.78 ± 1.98	16.23 ± 2.88	15.58 ± 2.71	15.90 ± 1.50
Body mass index	14.65 ± 2.07	15.22 ± 2.93	15.26 ± 2.79	15.91 ± 2.10
Body fat %	7.52 ± 6.05	8.06 ± 4.09	8.69 ± 6.51	9.08 ± 7.10

By one-way ANOVA followed by Bonferroni selective multiple comparison test: $P > 0.05$, not significant. ANOVA, analysis of variance; SD, standard deviation.

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Table 7: Changes in mean serum iron level between the groups

Duration(days)	Mean serum BDNF (pg/mL)(Mean ± SD)	
	Test	Marketed product
Baseline	583.92± ± 96.93	594.82 ± 89.92
90	597. 63± 92.38	608.39 ± 98.38

Student *t* test; $P > 0.05$, not significant. BDNF, brain-derived neurotrophic factor. SD, standard deviation.

DISCUSSION

Physical fitness is an indicative sign of health in children and adolescents. For instance, low fitness levels are associated with a higher risk of developing obesity, cognitive disorders, and musculoskeletal weakness later in life. In this study, to assess the physical endurance, a modified 20 m PREFIT project framework was utilized. There were correlations and equations based on heart rate, distance covered, and velocity of running in the stipulated distance. It will give us a fair idea about the cardiovascular fitness of children.[6] In the present study, after day 90, there was a significant increase ($P < 0.05$) in VO_2 max calculated by PREFIT test with test product treated group as compared to marketed product. There was 45.70% VO_2 max improvement in the test product treated group compared to 21.25% improvement in the marketed product treated group. The results are indicative of muscle strength improvement and thus physical stamina.

WHO recognizes a system by which a child or a group of children can be compared for the rate of growth, to the reference population: *z*-scores (standard deviation scores), percentiles, and percent of median.[7,8] For population-based assessment including surveys and nutritional surveillance, the *z*-score is widely recognized as the best system for analysis and presentation of anthropometric data because of its advantages compared to the other.[9] Mainly height-to-age and weight-to-age are interpreted by using the *z*-score classification system as a great indicator of growth rate and its adequacy. The *z*-score system expresses the anthropometric value as several standard deviations or *z*-scores below or above the reference mean or median value.

The current WHO recommendation is to use the *z*-score for grading undernutrition. Children who are with 1 standard deviation (SD) below the reference median, that is, around −1 are borderline undernourished, more than 2 SD below the reference median (i.e., a *z*-score of less than −2) are considered to be undernourished, that is, to be stunted, wasted, or to be underweight. Children with measurements below 3 SD (a *z*-score of less than −3) are considered to be severely undernourished.[10]

In the present study, children who represented marginal undernourishment though were not having severe symptoms and were randomly sampled. There was a nonsignificant difference in height-to-age and weight-to-age *z*-score in the test product and marketed product treated group at baseline. After 30, 60, and 90 days there was a nonsignificant difference in height-to-age and weight-to-age *z*-score between the test product and marketed product treated group. The *z*-score as height and weight indicator with age were improving in magnitude but the comparison was nonsignificant. In the case of intragroup analysis, the test product treated group and marketed product treated group demonstrated significant improvement in height-to-age and weight-to-age *z*-score at day 30, 60, and 90 when compared to a baseline value of the respective group. It indicated that the test product was equally good in promoting the growth rate of the child.

Dietary habits are shaped at a young age and maintained during later life with tracking over time. Eating behaviors established in childhood persist, with implications such as fussiness, undernourishment, or obesity. It is very important thus to check if the dietary supplement in terms of the blend of macro- and micronutrients are offering some sort of positive impact in child's eating behavior.[8] In the present study, the behavior is assessed through a well-researched and validated Child Eating Questionnaire. There are a set of questions to be assessed from the parent/guardian of the child in the following domain: food responsiveness, emotional overeating, enjoyment of food, desire to drink, satiety responsiveness, sluggish eating, emotional undereating, etc. The response can measure the eating habit and role of nutritional supplement in improving this domain to get positive and nourishment contained eating habits.

In the present study, after day 90, there was a significant ($P < 0.001$) improvement in scores of all domains in the test product treated group compared to the marketed product treated group. There is an important consideration of better absorption and assimilation of nutrients from nutritional supplements to bring about changes in the eating habits in the child as a result of nutritional sufficiency. It can be concluded that the test product proved better to alter the eating habits and behavior in children than the marketed product.

The appetite score was assessed and found to be improved in both test and marketed product treated groups. Almost 70% of parents of subjects from both the groups complained of less appetite on the baseline for their children. But there was a significant difference in appetite score after day 60 and day 90 in the test and marketed product treated group. It shows test product better performing to improve appetite which will inculcate good eating habits thus optimal food response to avoid under- and overeating in children.

It is a well-researched fact that there is a correlation between emotional intelligence and eating misbehavior in school-going children. The emotional quotient and intelligence is the major key component in the development of child to grow as a socially responsible person. Emotional intelligence is related to the following domains: social skills, motivation, self-regulation, self-awareness, and empathy.[11] The questionnaire assessing the emotional intelligence domain was implemented in the present study to be answered by

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the parent or guardian of the subject to come to the score representing the emotional intelligence orchestra of the child. It was found that after day 90, there was significant ($P < 0.0001$) improvement in scores of the following domain of the questionnaire: such as social skills, motivation, self-regulation, self-awareness, and empathy in the test product treated group than marketed product treated group. This is indicative of the potential of the test product to find a link between physical nutrition and psychological soundness. The result could be due to the improved eating pattern, appetite, nutritional sufficiency by the supplement, and joint effort of *Brahmi* (*Bacopa* extract) from the test product as it is reported to possess effectiveness in improving the psychosomatic functionalities at an early age.[12]

The overall development of the child is quite incomplete without cognitive and behavioral development in the right way. These aspects are studied in this research through a standard questionnaire involving a set of questions to be answered by the parent or guardian of the child. There are strong links between macro- and micronutritional sufficiency and behavior and cognitive development. In turn, better cognition and behavior uplift a child's self-image and thus train the self-esteem to take newer challenges and develop.

Gross motor skills are helping the child to be active, competitive, and alert in group or isolation and require physical and mental stamina which can be built by a correct nutritional supplement. Attention and concentration not only help the child to improve in academics but also can cultivate nature to work in a team. Children with attention deficit could face a lot many psychosocial challenges in the later stages of their lives. On the contrary to this overactivity through less attention, the extreme polar condition is passivity and child's tendency of being passive and not taking interest in the academics as well as interactive opportunities. It could be reversed by counseling and therapies but the nutritional balance and omega supplements can play a key role in improving this condition. Planning, perception to space, and visual forms and figures are the part of the neurological development of a child to perform more complex processes in the later stage of life along with verbal and spoken language communications. Cognitive development performs a pivotal role in child development and always is a major concern from the parent's perspective.

With the current results of scores of the questionnaire in the present study, it could be concluded that all the set of developmental parameters are better improved (significance: $P < 0.001$) at day 90 by test product when compared to the marketed product. Academic and social skill scores were also improved in the test-treated product than the marketed product.

Bacopa monnieri, popularly known as *Brahmi*, has been traditionally used in Ayurveda for ages for its memory-enhancing properties. The reported study which planned to evaluate the effect of *B. monnieri* on the memory of students for 6 weeks revealed improved memory, both visual as well as verbal.[13] *B. monnieri* is reported to improve working memory and short-term verbal memory in children.[14]

According to the results obtained regarding anthropometric parameters of test and marketed product treated groups, it was observed that there is an increase in height, weight, BMI, circumferences of chest, waist, and head, etc., as the children are under growing phase but no significant difference in both the groups in parameters like body weight, circumferences, BMI, and arm fat index, etc.

As a clinical measure of the immune status of the children, we had considered episodes of recurrent respiratory tract infection (RTI) and illness episodes as a scale. Following are the results of the current study: in the test group, at baseline, 20 subjects of the test group reported an average of at least 20 events of RTI in the previous month. On the contrary, 10 subjects (20%) reported recurrent episodes of RTI during 3 months period. The number frequency of events was 10 events with 2 to 3 days duration and was resolved completely before completion of the study duration. In the test group, the total missed days of the subjects were 13 days.

In the marketed product group, at baseline, 15 subjects of the test group reported an average of at least 18 events of RTI in the previous month whereas nine (17.64%) subjects reported 12 events of recurrent RTI during the 3 month test period and was found to be completely resolved in 2 to 3 days and total missed days of the subjects were 15 days. If compared between the groups, there was no significant change in both the groups. Test product improved immune status of the child by reducing illness episodes and thus the missed school days as a result of protein sufficiency and development of strength to combat the infections. *Ashwagandha* extract used in the test product is thought to be an excellent immunomodulator in action. It is reported to possess anti-inflammatory, antioxidant values. Many clinical trials have witnessed the usefulness of *Ashwagandha* to promote both innate and acquired immunity.[15] The micronutrient supplementation like vitamin C and D in the test product has immunity-building potential. Colostrum used as an ingredient in test products possesses immunity modifying properties that could contribute to the ability to cope up with.[16,17]BDNF is a protein of the neurotrophin family. It is expressed in human brains. It is associated with synaptic plasticity, connectivity, and neuroprotection. It also serves an important role during neurological development through the regulation of neural circuit development. BDNF plays an important role in learning and memory at an early age. It is found in most concentrations in the hippocampus region of the brain. BDNF is an important factor in neurodevelopment. It is reported in a research that serum BDNF may present an inverse correlation with the intelligence, attention, and cognition of preschool children with neurodevelopmental disorders such as intellectual disability, and attention-deficit/hyperactivity disorder (ADHD) can very well be correlated to abnormal free peripheral BDNF.[18] In the present study, the serum BDNF levels in both the group

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were within the normal range at baseline and did not produce any significant change after treatment with test and marketed product treatment for 90 days.

As an assessment of adverse event profile, there was no significant difference in both groups. Both groups represented mild adverse event episodes like fever, injury, dry and irritable eyes, cold, muscle pain, etc. All these adverse events were mild in severity. These adverse events were resolved completely after 1 to 3 days with rescue medication. Study treatment was not stopped during these adverse events. All these adverse events were not related to the study drug. Global assessment for overall improvement by subject parent/guardian and investigator revealed that children's health supplement demonstrated much-very much overall improvement in both treatment groups. Excellent tolerability of both the drugs was reported by subjects and physicians at the end of the study. No significant post-treatment change in any of the laboratory investigations was observed in both the groups like complete hemogram, liver, kidney, lipid, and thyroid profile tests. In the present study, there were nonsignificant changes in random blood sugar and hemoglobin A1c (HbA1c) in children's health supplement treated and marketed product treated group. There is no significant change in serum calcium levels in both groups. In the present study, there was a significant ($P < 0.05$) reduction in total cholesterol but no change in triglycerides (TG), high density lipoprotein (HDL), low density lipoprotein (LDL), and very low density lipoprotein (VLDL) in the children's health supplement treated group at day 90 of treatment. There was no significant posttreatment change in vitals such as pulse rate, blood pressure, body temperature, and respiratory rate was observed in both the groups, suggesting both the drugs were safe in human subjects. Thus children's health supplement with micronutrient fortification is safe and effective in children. Children's health supplements and marketed products both presented excellent palatability and mixability with milk. There was 100% compliance for both children's health supplements and marketed products by subjects during the study. The trial complies external validity, also called generalizability as these results can be generalized in population as the broader inclusive criteria yet potentially excluding the subjects may prove inappropriate for the study had made the generalization feasible.

CONCLUSION

The children's health supplement is safe and effective in promoting growth, health, and wellbeing in healthy children. It improved the growth of children indicated by height-to-age and weight-to-age *z*-scores defined by WHO was comparable with the marketed product. Height, weight, BMI, and circumferences of chest, waist, and head were increased as an indicator of child's physical growth in children's health supplement as well as marketed product treated groups. There was 45.70% increased physical endurance by children's health supplement treatment indicated as VO_2 max compared to baseline. This can be linked to physical stamina. Enhanced immunity status was indicated by reduced illness episodes and missed school days in children's health supplement and marketed product treated groups. Children's health supplement improved child's eating behavior better than the marketed product. It reduced fussy eating; also food responsiveness and satiety of food score as per the questionnaire was improved after children's health supplement treatment as compared to marketed product. Emotional intelligence score was better in children's health supplement treatment than the marketed product. Improved cognitive performance was seen in children's health supplement treatment than the marketed product. The children's health supplement was found better in activity than the marketed product counterpart in improving digestive behavior in children.

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Conflicts of interest

There are no conflicts of interest.

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3.5.1

16. Collaborative Research Workshop

With MUHS Nashik

27 /01/2020 to 29/01/2020

Report of Research Methodology workshop

6th -8th Jan 2020

The workshop on Research methodology was organized by our institute on 6th -8th Jan 2020 at P.D.E.A's College of Ayurved and Research Centre Nigdi Pune 44. As per M.U.H.S./MET guidelines the sessions were organised for three days from morning 09.30- 17.00.

The fifty delegated were registered & attended the workshop. The detailed list is attached with the report.

Sr. no	College name	Number of delegates attended
1	**P.D.E.A'S COLLEGE OF AYURVED AND RESEARCH CENTRE NIGDI PUNE 44**	50

Seven faculty members were invited as resource person for workshop. Col. S. L. Jadhav from D. Y. Patil Medical college Pimpri pune, Myself from our college Pune, Dr. Mohan Joshi from Tilak Ayurveda Mahavidyalaya Pune; Dr. Supriya Bhalerao from IRSHA Katraj Pune; Dr. Shrikath Muralidharan faculty , Dr. Gaurang Baxi from D.Y. Patil college of Physiotherapy pimpri ; Dr. Deepak Nagpal from D.Y. Patil Dental school; Previously the instruction was given to students that bring your synopsis titles and problems regarding synopsis so,the workshop became more interactive and fruitful to them. For group activity heterogeneous groups were performed. Pre MCQ test was taken for 30 marks. Dr. Gulhane vedanti & Dr. Chavan umesh from Rasashastra & Shalakya department respectively of our college was 1st topper by 14 marks, Dr. Limaye from Kayachikitsa department was 2nd toppers by 13 marks and Dr. Rajesh Deshmukh from Agadtantra department of our college was 3rd toppers by 12 marks in the Pre-test.

Before starting the inaugural session Pre-test was conducted twenty minutes were given to complete. The solved papers were collected. The workshop was started with Dhanwantari poojan and stawan. The first day session was started sharp at 09.30- 10.00 by lecture taken by Col. S. L. Jadhav from D.Y. Patil college,Pimpari on the topic "Introduction to research methodology and formulation of RQ and Hypothesis. Next session were taken on observational study designs descriptive and analytical. After analytical study design tea break was given, then session was continued on experimental study design up to 1 pm by Dr.Mohan Joshi from Tilak Ayurveda Mahavidyalaya. The post lunch session was started on 1.30 pm. with group activity taken by Dr. Mohan Joshi and myself. Six groups were prepared each group with 8-9 members and six problems were given. The details as follows-

Group no.	Topics given for study design group activity	Instructed to formulate as per following points
1	Cross sectional study to evaluate divaswap as causative factor in Pama - Dr. Shilpa Gawande	1) Formulate the title 2) Research question & Hypothesis if necessary 3) Aims and objectives of the study 4) Independent and dependent variable 5) Short methodology how to conduct the study
2	A case control study to evaluate obesity is the causative factor of type 2 diabetes – case control study Dr. Ganesh Palhade	
3	Daily Alcohol consumption causes liver cirrhosis - Cohort study –Dr. Rajesh Deshmukh	
4	A case control study to evaluate Mudbhakshan is the causative factor of	

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	Pandu – case control study Dr. Priti Harkal	
5	Jatamansi shirodhara &tablet in anxiety a Dr.Indrayani nakshane	
6	Jatamansi taila shirodhara and Coconut hair oil shirodhara in insomnia – Dr.Ashwini Morankar	

Next lecture was taken on qualitative research methodology after the group activity by Dr.Mohan Joshi sir from Tilak Ayurveda Mahavidyalaya completed on 4.00 First day ended at 05.00 p.m.by lecture on literature search taken by Dr Mohan Joshi in the beginning of lecture he shared one google form to know what knowledge delegates have about literature search so the in unknown areas sir has taken detailed study so that it was fruitful to all delegates.

The second day was started with Dhanwantari Poojan and Stawan followed by lecture on 9.30am-10.30 am. Sampling by Dr.Supriya Bhalerao from IRSHA Pune After this lecture next sessions at 10.30 a.m. was taken by Dr. Supriya Bhalerao madam on " Types of data and presentation of data" The activity was taken on identification of data types by MCQ. The session ends at 11.30 am. Morning session ends with Calculation of Sample size by Dr Bhalerao madam. Before starting group activity tea break was given. Activity was taken by few with some sample situations to choose appropriate formula for sample calculation up to 1.pm.

After the lunch break the sessions were started on inferential statistics by Dr. Shrikanth Muralidharan faculty of RMW workshop. The group activity was taken on selecting the appropriate test for given problems to each table. The session was ended on 3.30 pm. For next session every delegate was requested to download EPI info 7 on their laptops and one excel data file was shared with delegates so that the "computer assistance in data analysis on Excel, epi info"with Demo was completed up to 5 pm

The third day was started with Dhanwantari Poojan and Stawan followed by lecture delivered by Dr.Gaurang Baxi from D. Y. Patil Physiotherapy college, Pune Lecture started at sharp 9.30 a.m on ethics in medical research with group activity.one link was shared for group activity to enlist ethical issues in given problem. After that lecture was taken on protocol writing by Dr. Gaurang Baxi and group activity was taken by myself on pre given topics on protocol writing and one-one group member presented their protocols on given topics as follows

Group no.	Protocol and Ethical issues on following topics	Presenter from the group
1	Cross sectional study to evaluate divaswap as causative factor in Pama -	Dr. Shilpa Gawande
2	A case control study to evaluate obesity is the causative factor of type 2 diabetes – case control study	Dr. Ganesh Palhade
3	Daily Alcohol consumption causes liver cirrhosis - Cohort study	Dr. Yamini Patil
4	A case control study to evaluate Mudbhakshan is the causative factor of Pandu – case control study	Dr. Priti Harkal
5	Study the efficacy of Jatamansi taila shirodhara & clanzepam in anxiety - RCT	Dr. Indrayani Nakshane
6	Study the effect of Jatamansi taila	Dr. Neha Sharma



	shirodhara and Coconut oil shirodhara in insomnia – RCT	

The session ends at 13.00pm. After lunch Dr. Deepak Nagpal from D.Y. Patil dental school had taken session on diagnostic test completed on 13.45pm. Dr. Deepak Nagpal completed on 3.30 pm. Sir had taken very interactive and informative lecture on questionnaire designing. Next session was started on 3.30 pm on critical journal article evaluation ended on 5 pm by group activity.

Post workshop evaluation MCQ test was taken. Three best improved delegates were declared and felicitated with Pen set, first topper Dr. Khaire Sayali from Agadtantra department improved by 11 marks, second topper Dr. Chaitali deore from Agadtantra department improved by 10 marks and third toppers Dr. Wadkar Somnath from Shalyatantra department improved by 09 marks of our college. Study material given in soft copy to all delegates. After felicitation delegates. The valedictory function ended with vote of thanks & Pasaydan by me.

The daily evaluation and whole program evaluation sheets were filled by delegates. The analysis of program evaluation is given asfollows-

Some comments given by delegates are as follows-

1) Workshop duration should be increased.
2) Hard copy of study material should be provided before the workshop
3) Workshop is fruitful especially with group activities
4) Time management and organization of workshop is very good
5) Majority of delegates very much satisfied with group activities.
6) After every session MCQ test should be conducted for better understanding of subject.
7) The continuous lectures should not be kept, 15-20 minutes rest should be given after each session.
8) Dr. Mohan Joshi; Dr. Shrikanth Muralidharan & Dr. Supriya Bhalerao are the best faculty members mentioned by all most all delegates.

Important suggestions by coordinator as –

1) Group activities are more effective in well-equipped digital lab of computers.
2) Online attendance of delegates is more time taking so should be continued with previous method

The activity started by M.U.H.S. and MET is really very much necessary and useful for up-gradation of knowledge of Research techniques to post graduate students and teachers.Thanking you,

Dr. Yogini R. Kulkarni (Coordinator)

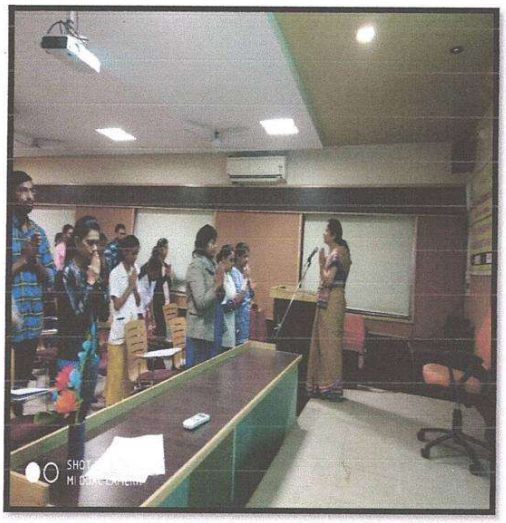
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Nigdi, Pune - 411 044.

H. O. D.
Research Methodology
College of Ayurved And Research Centre
Akurdi. Pune - 411 044

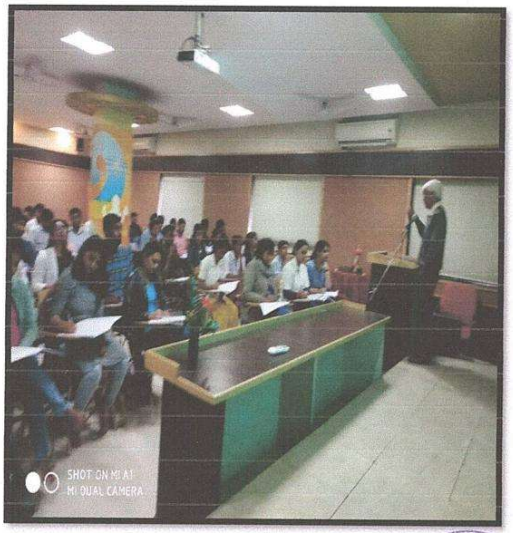
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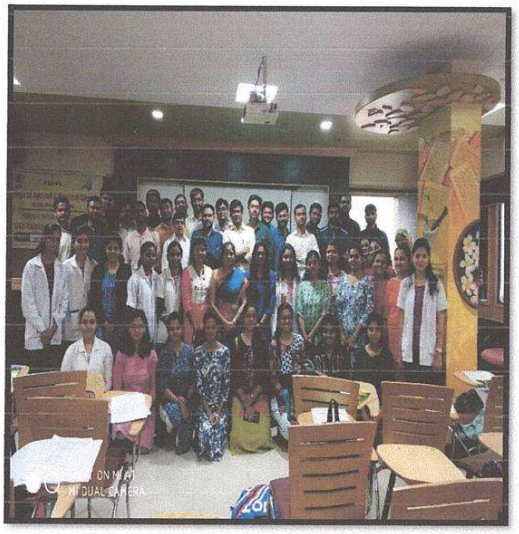
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College of Ayurveda & Research Centre Nigdi, Pune-44

Research Methodology Workshop – 6 Jan. to 8th Jan 2020









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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

17. Collaborative activity – Faculty Exchange

at

SDM, Hassan

21-22/01/2020

REPORT FOR 21-22/01/2020

Scientific writing and synopsis writing workshops were organized on 21/01/2020-22/01/2020 at SDM Hassan for 1st& 2nd year PG students and teachers.Total 120 students were registered for synopsis writing (90 students and 30 faculties) and 150 delegates (1st year+2nd year +teachers) were registered for scientific writing. Ten groups were defined for group activity in scientific writing workshop

Lectures delivered on 21/01/2020 as follows-

1) Scientific writing overview with group activity
2) Guidelines for reporting clinical and observational studies with group activity
3) Assignments given for group activity -10 different clinical , observational studies articles were given and asked for structured and not structured abstract after completing this task one-one team member was presented the abstract .CONSORT and STROBE checklists for abstract writing were circulated to check the complete and correctness of the abstract.
4) After this group activity same article asked to read in groups. CONSORT and STROBE checklists for articles were circulated. Asked to check the articles as per check list and mention the page number where the point is discussed, allot the marks for that point.All assignments were collected for assessment to convey some suggestions for improvement
5) On 22/01/2020 the session was taken on research areas in Ayurveda
6) Pre and post assessment scientific writing goggle form was circulated to judge the knowledge regarding scientific writing before and after the workshop
7) Panel discussions were taken after all sessions completed on 21st and 22nd Jan 2020

पु.जि.शि.मं.चे
आयुर्वेद महाविद्यालय व संशोधन केंद्र
निगडी, पुणे-४११०४४.
आवक क्र 47111202021
दिनांक - 23/1/2020
लेखनिक
प्राचार्य

Dr Yogini Kulkarni
H. O. D.
Research Methodology
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Akurdi. Pune - 411 044.



COLLEGE OF AYURVEDIC RESEARCH * P.D.E.A.S. AKURDI PUNE - 44

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llege of Ayurved And Research Centre
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28 Years Quality Ayurveda Education & Health Service 1992-2019 SDM HASSAN 2018-19

Sri Dharmasthala Manjunatheshwara College of Ayurveda & Hospital, Hassan, India

Managed by: SDM Educational Society®, Ujire, Karnataka, India
Affiliated to: Rajiv Gandhi University of Health Sciences, Karnataka, Bengaluru
Recognized by: CCIM, Ministry of AYUSH, Govt. of India, New Delhi

CERTIFICATE

This is to certify that Dr Yogini Kulkarni, from PDEAs College of Ayurved Research Centre, Nigdi, Pune has participated as resource person in Workshop on Scientific writing and Synopsis Writing held on 21st and 22nd January 2020, organized by Research & Development.

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Principal
College of Ayurved And Research Cente
Akurdi, Pune - 411 044

Coordinator

Dean, Research

Principal



SHOT ON MI A1
MI DUAL CAMERA

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

18. Collaborative Research Workshop with MUHS Nashik

27 /01/2020 to 29/01/2020

पुणे जिल्हा शिक्षण मंडळाचे,

आयुर्वेद महाविद्यालय व संशोधन केंद्र

सेक्टर नं. २५, प्राधिकरण, निगडी, पुणे-४११०४४ (महाराष्ट्र) भारत
आय.डी.नं. पी.यु./पी.एन./आयु./०८१/१९९०
फोन : (०२०)२७६५९५७८, २७६५३९६५ फॅक्स : (०२०)२७६५९५७८
ईमेल : carc2006@rediffmail.com, carcakurdi@gmail.com वेबसाईट : www.pdeacarcayu.com

॥ सर्वे सन्तु निरामयः ॥

संस्था पदाधिकारी

अध्यक्ष
अजित पवार

मानद सचिव
संदिप कदम

अध्यक्ष प्रतिनिधी
राजेंद्र घाडगे

खजिनदार
ॲड. मोहनराव देशमुख

उपसचिव
पी. ई. कुलकर्णी

प्राचार्या
डॉ. आर.आर.पाटील

जावक क्रमांक : 220619-20

दिनांक :
25 JAN 2020

To,

Dr. Deepanjali Lomate

MET cell in-charge

MUHS Nashik

Subject: - Report of Research Methodology workshop- - 27th-29th Jan 2020

Respected madam,

Sending herewith the detailed program report of Research Methodology workshop held in our institute for PG students on –27th -29th Jan 2020

Following documents are attached with this letter-

1) Daily Attendance sheet of students and faculty (scanned copy)
2) Program report (soft copy)
3) Data base of students, faculty members (soft copy)
4) Timetable of workshop
5) Workshop payment receipt

The workshop is successful because of your appropriate guidance, thanking you

Yours faithfully

Dr. Yogini R. Kulkarni
(Co-ordinator)
Director
Post Graduate Studies
College of Ayurved & Research Centre
Pradhikaran, Nigdi, Pune- 411 044.

Dr. Ragini R. Patil
(Principal)
Principal
College of Ayurved & Research Centre
Akurdi, Pune - 411044.

Report of Research Methodology workshop

27th -29th Jan 2020

The workshop on Research methodology was organized by our institute on 27th -29th Jan 2020 at P.D.E.A's College of Ayurved and Research Centre Nigdi Pune 44. As per M.U.H.S./MET guidelines the sessions were organised for three days from morning 09.30- 17.00.

The fifty delegated were registered & attended the workshop. The detailed list is attached with the report.

Sr. no	College name	Number of delegates attended
1	P.D.E.A'S College Of Ayurved And Research Centre Nigdi Pune 44	13 students + 8 teachers
2	Keshav Ayurveda medical college And hospital Aklera Jhalawar Rajsthan	1 teacher
3	SVNHT's Ayurved College, Rahuri Factory, Rahuri, Maharashtra	1 student
4	Seth Govindaji Raoji Ayurved Mahavidyalaya, Solapur	8 students
5	R.A.podar medical college ayurved, worli	6 students
6	S.N.D. college of Nursing Babhulgaon yeola	1 student
7	D. S. Homoeopathic medical College pune	3 students
8	R.T. Ayurveda Mahavidyalaya Akola	2 students
9	Vamanrao Ithape Homoeopathic medical College, sangamner	7 students

Six faculty members were invited as resource person for workshop. Dr. Madhav mutalik from Dr. D. Y. Patil Dental school, Charoli, Lohgaon; Myself from our college Pune; Dr. Shrikath Muralidharan faculty of RMW , Col. S. L. Jadhav from D. Y. Patil Medical college Pimpri pune; Dr. Swati Raje from MIMER medical college talegaon ; Dr. Suvarna Joshi from B.J. Medical college Pune ; Previously the instruction was given to students that bring your synopsis titles and problems regarding synopsis so,the workshop became more interactive and fruitful to them. For group activity heterogeneous groups were performed. Pre MCQ test was taken for 30 marks. Dr.Talokar Sanket from Panchakarma department of R A Podar college by 13 marks was 1st topper, Dr. More Shweta from kriya department teacher from CARC Akurdi & Dr Mogane Mahesh from organon of medicine from Ithape hpmeopathic college sangamner were 2nd toppers by 12 marks marks in the Pre-test.

Before starting the inaugural session Pre-test was conducted twenty minutes were given to complete. The solved papers were collected. The workshop was started with Dhanwantari poojan and stawan. The first day session was started sharp at 09.30- 10.00 by lecture taken Dr. Madhav Mutalik from D.Y. Patil dental school Charoli Lohagaon ,on the topic "Introduction to research methodology and formulation of RQ and Hypothesis. Next session were taken on observational study designs descriptive and analytical. After analytical study design tea break was given, then session was continued on experimental study design up to 1 pm by Dr.Shrikanth Muralidharan Faculty of RMW. The post lunch session was started on 1.30 pm. with group activity taken by Dr. Shrikanth Muralidharan and myself. Six groups were prepared each group with 8-9 members and six problems were given. The details as follows-

Group no.	Topics given for study design group activity	Instructed to formulate as per following points
1	A Cross sectional study to evaluate the	

P.D.E.A's College Of Ayurved And Research Centre AKURDI PUNE - 44.

	prevalence of amlapitta in the persons who are doing night shift duties from last year Dr. Rajat Bansal	1) Formulate the title 2) Research question & Hypothesis if necessary 3) Aims and objectives of the study 4) Independent and dependent variable 5) Short methodology how to conduct the study
2	Cross sectional study to assess the prevalence of dry eye syndrome in IT professionals working on computers more than 8 hours in Hinjewadi - Not asked to present	
3	A case control study of hetu ratrojagaran on urdhwag amlapitta in age group in 20-40 years in UK based call center located in Pune since the period of more than 6 months - Dr. Pravin Tate	
4	Case control study of consumption of junk food on obesity in the group of 25 to 40 years –not asked to present	
5	Clinical concurrent parallel study to evaluate the effectiveness of constitutional form of medicine in type II diabetes in who are taking allopathic medicine and who are not taking in the age group of 40-60 years in 6 months Comparative concurrent parallel study to evaluate the effect of yograj guggul and triphala guggul in the management of sandhigatvata in adult age group of 30-60 years from R A poddar hospital. Not asked to present	
6	Clinical study of calcium supplement in case of 40-60 years and adults not taking calcium supplement by randomized concurrent cross over study in period of 3 month with on 1 month wash out period – Dr. Devyani Shinde	

Next lecture was taken on qualitative research methodology after the group activity by Dr. Shrikanth Muralidharan completed on 4.00 First day ended at 05.00 p.m.by lecture on literature search taken by Shrikanth Muralidharan that it was fruitful to all delegates.

The second day was started with Dhanwantari Poojan and Stawan followed by lecture on descriptive statistics- types of data and presentation of the data from 9.30am-10.30 am.by Col. S. L. Jadhav from D. Y. Patil Medical college Pimpri, Pune. Sir had taken activity as preparation of some tables on the given data to all groups. After this lecture the next lecture was taken on Sampling by Dr. S. L. Jadhv Sir. The session ends at 11.30 am. Morning session ends with Calculation of Sample size by Col. S. L. Jadhav sir on Win Pepi software. The group activity was taken as pre previous allotted groups with specific topics as per study designs one member from each group calculating sample size on WIN PEPI software – the hands on training was given by dr S L Jadhav up to 1.pm.



5	Clinical concurrent parallel study to evaluate the effectiveness of constitutional form of medicine in type II diabetes in who are taking allopathic medicine and who are not taking in the age group of 40-60 years in 6 months Comparative concurrent parallel study to evaluate the effect of yograj guggul and triphala guggul in the management of sandhigatvata in adult age group of 30-60 years from R A poddar hospital.	Dr. Tanvi Joshi
6	Clinical study of calcium supplement in case of 40-60 years and adults not taking calcium supplement by randomized concurrent cross over study in period of 3 month with on 1 month wash out period –	Dr. Mahesh Mogane

The session ends at 13.00pm. After lunch Dr. Suvarna Joshi from B.J. Medical college had taken session on diagnostic test completed on 14.00 pm. Dr. Suvarna Joshi madam had taken very interactive and informative lecture on questionnaire designing. Next session was started on 3.30 pm on critical journal article evaluation ended on 5 pm by group activity.

Post workshop evaluation MCQ test was taken. Three best improved delegates were declared and felicitated with Pen set, first topper Dr. Prajisha from Dhondumama Sathe Homeopathic college pune Medicine department improved by 10 marks, second topper Dr. Mamata Maharwade from Panchkarma department of R A Podar college Worali improved by 07 marks and third toppers Dr. Prajkta Barkade From Swasthvrutta department of our college improved by marks of our college. Study material given in soft copy to all delegates. After felicitation delegates. The valedictory function ended with vote of thanks by me.

The daily evaluation and whole program evaluation sheets were filled by delegates. The analysis of program evaluation is given asfollows-Some comments given by delegates are as follows-

1) Workshop duration should be increased.
2) study material should be provided before the workshop
3) Workshop is fruitful especially with group activities
4) Time management and organization of workshop is very good
5) Groups should be performed by lottery method for group activity
6) Goggle forms should be given for feedback and for pre and post test
7) Majority of delegates very much satisfied with group activities.
8) Dr. Madhav Mutalik ,Dr. Shrikanth Muralidharan, Dr SL Jadhav, Dr Suvarna Joshi & Myself are the best faculty members mentioned by all most all delegates.

Important suggestions by coordinator as –

1) Group activities are more effective in well-equipped digital lab of computers.
2) Online attendance of delegates is more time taking so should be continued with previous method

The activity started by M.U.H.S. and MET is really very much necessary and useful for up-gradation of knowledge of Research techniques to post graduate students and teachers.Thanking you,

Dr. Yogini R. Kulkarni (Coordinator)

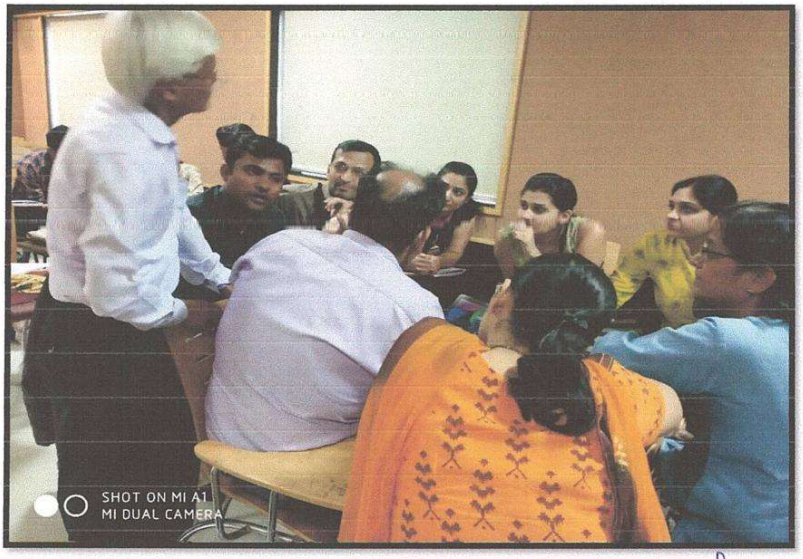
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Research Methodology Workshop – 27th Jan.2020 to 29th Jan 2020





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3.5.1

19. Collaborative activity - Student Exchange with Garbhasanskar Antenatal Services Pvt.Ltd.

05/02/2020

To

03/03/2020

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Date: 6/3/2020

Post event summary report

Title of Collaborative activity: Training of postgraduate students of Swasthavritta Department

Date: 5/2/2020 to 03/03/2020

Place: Pune Maharashtra

Total Participants: 01

Participant details: Dr Madhulika Singh

Brief Activity Details: Postgraduate students of Swasthavritta Department attended training at Pune, Maharashtra conducted by Garbha Sanskar Antenatal Services PVT. Ltd. Topic of training was Garbha Sanskar Antenatal programme.

Training consist of various protocols for the process of Garbha Sanskar Antenatal programme conducted through a combination of lectures, demonstration of unique Yogic technique based on Yoga, Pranayam, Dharana & Dhyan. This training is helpful to understand standard process of Supraja Nirmitee & Garbhasanskar.

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Dept. of Swastha Vrutta
College of Ayurved & Research Centre
Nigdi

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P.D.E.A.'S

GARABHA SANSKAR ANTENATAL SERVICES PVT. LTD.

Certificate

This is to certify that

Dr. Madhulika Ranabahadur Singh

has successfully completed the Post Graduate training program on **Garbhasanskar Antenatal Program** conducted between **5th Feb. 2020 - 3rd March 2020.**

This certificate is presented for attending the workshop for skill development & upgradation of knowledge.

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For
Garbhasanskar Antenatal
Services Pvt. Ltd.



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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

20. Collaborative activity - Student Exchange

Educational Visit to CARC by students of Swasti Yoga Centre

22/2/2020

Title - Student exchange programme

PROGRAMME REPORT

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आयुर्वेद महाविद्यालय व संशोधन केंद्र
निगडी, पुणे-४११०४४.
आवक क्र. 342/2020
दिनांक - 22/2/2020
लेखनिक
प्राचार्य

NAME OF YOGA CENTRE - SWASTI YOGA CENTRE

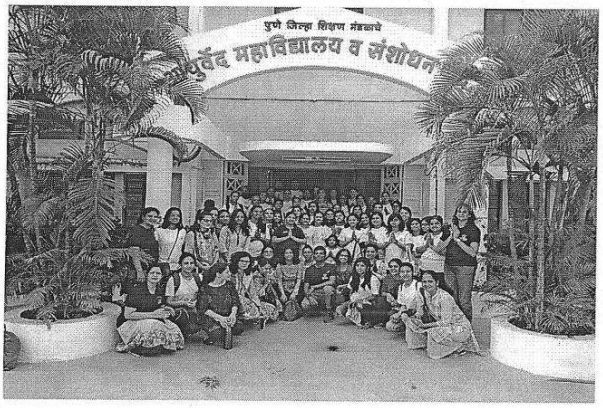
No of students- 123

Report-

Under student exchange programme as per the application of swasti yoga centre on dated 20/2/2020, visit of students of swasti yoga centre was planned at PDEA's college of Ayurveda and research centre Nigdi, Pune.

Time - Visit completed successfully on 22/2/2020 in morning 10:30 – 1 pm.

Students visited to total 3 departments swasthavritta department, Sharir kriya department and Sharir rachana department. Staff of three departments gave information about subject and showed them charts, models etc.



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Dept. of Swastha Vrutta
College of Ayurved & Research Centre
Nigdi











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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

21. Collaborative activity - Teacher Exchange

Bharti Vidyapeeth College Of Ayurveda

18/08/2020

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Matrix no- 3.5.1

POST EVENT SUMMARY REPORT

Title of collaborative activity-Chairperson for National webinar 'Kumarbharati 2020'paper presentation session.

Date/duration-18/08/2020 to 19/08/2020

Place-Bharati Vidyapeeth College of Ayurveda, Pune

Participant details (student/teachers with numbers)-Teacher -01,
Dr. Madhavi S. Deodas –as chairperson

Brief activity details-

Dr. Madhavi S. Deodas invited as chairperson in paper presentation session in a national webinar "Kumarbharati-2020" organized by department of Kaumarbhritya, Bharati Vidyapeeth College of Ayurveda, Pune. The topic of webinar was "common urinary system disorders in children". It was two days webinar and Dr. Deodas was chairperson on 18/08/2020.Around 18 presenters were evaluated, by the evaluation sheet parameter provided form the college.

Deodas

Signature

Designation-HOD & Professor

Name- Dr.Madhavi S.Deodas

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Dept. of Kaumarbhrutya Tantra
College of Ayurved & Research Centre
Nigdi

Bharati Vidyapeeth
(Deemed to be University)
Pune, India.
Founder Chancellor : Dr. Patangrao Kadam

COLLEGE OF AYURVED, PUNE

4 Accredited with 'A' Grade (2014) by NAAC 4
4 Category-I University Status by UGC 4
4 NIRF Ranking - 64 4

"Social Transformation Through Dynamic Education"

Prof. Dr. Shivajirao Kadam
Chancellor

Prof. Dr. M. M. Salunkhe
Vice Chancellor

Dr. Vishwajeet Kadam
Pro Vice Chancellor

Dr. Abhijit B. Patil
Principal

Ref. No. : BVDU/COA/2021/Webinar/01 Date : 13/8/20

To,
Dr. M. Devdas,
Professor and HOD
PDEA's College of Ayurved,
Akurdi, Pune

Subject: Invitation as a Chair Person for 'KUMARABHARATI 2020' Paper Presentation 2 day National Webinar regarding

Respected Sir/Madam,

We feel honored to inform you that department of 'Kaumarabhritya/Balaroga' (Ayurvedic Pediatrics), Bharati Vidyapeeth (Deemed to be University) College of Ayurved, Pune is going to organize a 2 day national webinar on **'Common Urinary System Disorders In Children'** on 18th and 19th August 2020. You are invited to be a Chair Person at this Paper Presentation Session of the webinar on **18.08.2020.** The Schedule of programme and the list of presenters and an evaluation sheet will be sent to you by mail shortly.

Thanking you,

Regards

Prof. Abhijeet B. Patil
Principal
Bharati Vidyapeeth (Deemed to be University)
College of Ayurved
Pune 411043

Prof. Rahul H. Gujarathi
H.O.D., Dept. of Kaumarabhritya-Balaroga
Bharati Vidyapeeth (Deemed to be University)
College of Ayurved
Pune 411043

Pune-Satara Road, Pune - 411 043 (INDIA)
Tel. : 020-24373954 (O) 020-40555600 (H) | Fax : 020-24365289. | E-mail : bvcoa@gmail.com | Web : www.coayurved.bharatividyapeeth.edu

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CERTIFICATE

OF APPRECIATION

We are thankful to

DR MADHAVI DEODAS

participated as Chair-Person in Scientific Session

"KUMAR-BHARATI 2020"

2 Day National Webinar on Common Urinary System Disorders in Children

organized by the **Department of Kaumarabhritya**

Bharati Vidyapeeth (Deemed to be University)

College of Ayurved & Hospital, Pune

Dr.Preetham Pai
Organizing President

Dr.Rahul Gujarathi
Organizing Secretory

Dr.A.B.Patil
Organizing Chairman

Pune District Education Association's
College of Ayurved & Research Centre
(I.D.No. P.U./P.N./AYU./081/1990)
Sector No. 25, Pradhikaran, Nigdi, Pune-411 044 (Maharashtra State), India.
Phone - 020 - 27653965 / 27659578, Fax :- 020 - 27659578, Website - www.pdeaayurvedcollege.edu.in
E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

22. Collaborative activity - Student Exchange Industrial training at Punarvasu Aushadhshala PVT.LTD. 10/2/2021 to 10/3/2021

Pune District Education Association's
College of Ayurved & Research Centre
(I.D.No. P.U./P.N./AYU./081/1990)
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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Date-15/3/2021

POST EVENT SUMMARY REPORT

Name of the collaborative activity

Industrial training at Punarvasu Aushdhashala Pvt. Ltd, Shivane,Pune.

Date/ Duration

10/2/2021 to 10/3/2021

Place: Punarvasu Aushdhashala Pvt. Ltd, Shivane,Pune.

Participants Details: Final Year PG Students - 02

Organising department/ committee- Rasashastra evam Bhaishajya Kalpana

Brief Activity Details:

- Standardization of ASU drugs
- Standardization of Raw materials, manufacturing process and finished products for ASU drugs
- Preparation of Gokshuradi Guggulu, Trayodashang Guggulu, Shatavari Kalpa.
- Shodhan of different Rasadravyas like Tankan,Tamra and Roupya.
- Preparation of various Kupipakwas like Suvarna raj vangeshwar and Makardhwaj
- Hands on training of Quality control measures for different formulations.

P.D.E.A.'S College Of Ayurved And Research Centre NIGDI PUNE - 44

HOD
Department of Rasashastra
Bhaishajyakalpana
College of Ayurved & Research
Centre, Akurdi Pune 44

Punarvasu Aushadhshala Pvt. Ltd.

Works : S. No. 78/1/1, Shiv Kamal Industrial Area, Shed No. 11, Shivane, Pune - 411023.
Regd. Address : 2D+E, Shail-neel Co-op. Society, 13 Rambag Colony, Paud Rd., Pune - 411 038.
Ph.: 020 2529 0116.Email : punarvasuaushadhshala@gmail.com

Date : / / 20

Date: 15/03/2021

CERTIFICATE OF ATTENDANCE / VISIT

This is to certify that

Dr. PRIYANKA KALE
Dr. SUSMITA PATIL

Who are students of last year M.D. Rasashastra and Bhaishjya kalpana, Pune District Education Assiciation's College of Ayurved and Research centre,Akurdi, Pune , have taken training in our Aushadhshala from 10 th February 2021 to 10 th March 2021.

Both students have observed and worked on various topics related with Rasa aushadhi and Bhaishjya kalpana with Quality control management.

I wish them all the best in future.

For

Vd. Vivek D. Sane,

Director,

Punrvasu Aushadhshala Pvt. Ltd. Pune

PUNARVASU AUSHADHSHALA PVT. LTD.
S.No. 78/1, Shiv-Kamal Industrial Estate,
Shed No. 11, Shivane, Pune - 411 023.

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

23. Collaborative activity - Student Exchange Industrial training at Punarvasu Aushadhshala PVT.LTD. 10/3/2021 to 22/4/2021

Pune District Education Association's
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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Date-26/4/2021

POST EVENT SUMMARY REPORT

Name of the collaborative activity

Industrial training at Punarvasu Aushdhashala Pvt. Ltd, Shivane,Pune.

Date/ Duration

10/3/2021 to 22/4/2021

Place: Punarvasu Aushdhashala Pvt. Ltd, Shivane,Pune.

Participants Details: Final Year PG Students - 02

Organising department/ committee- Rasashastra evam Bhaishajya Kalpana

Brief Activity Details:

- Standardization of ASU drugs
- Standardization of Raw materials, manufacturing process and finished products for ASU drugs
- Preparation of Kaishor Guggulu, Triphala Guggulu, Shatavari Kalpa.
- Shodhan of different Rasadravyas like Hartala,Gandhak and Parada.
- Preparation of various Kupipakwas like Rasasindura and Rasmanika
- Hands on training of Quality control measures for different formulations.

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HOD
Department of Rasashastra
Bhaishajya Kalpana
College of Ayurved & Research
Centre, Akurdi Pune 44

Punarvasu Aushadhshala Pvt. Ltd.

Works : S. No. 78/1/1, Shiv Kamal Industrial Area, Shed No. 11, Shivane, Pune - 411023.
Regd. Address : 2D+E, Shail-neel Co-op. Society, 13 Rambag Colony, Paud Rd., Pune - 411 038.
Ph.: 020 2529 0116.Email : punarvasuaushadhshala@gmail.com

Date : / / 20

Date: 23/04/2021

CERTIFICATE OF ATTENDANCE / VISIT

This is to certify that

Dr. VRUSHALI BHUTADA
Dr. APURVA KONDE

Who are students of last year M.D. Rasashastra and Bhaishjya kalpana, Pune District Education Assiciation's College of Ayurved and Research centre,Akurdi, Pune , have taken training in our Aushadhshala from 10 th March 2021 to 22 nd April 2021.

Both students have observed and worked on various topics related with Rasa aushadhi and Bhaishjya kalpana with Quality control management.

I wish them all the best in future.

Vd. Vivek D. Sane,

Director,

Punrvasu Aushadhshala Pvt. Ltd. Pune

PUNARVASU AUSHADHSHALA PVT. LTD.
S.No. 78/1, Shiv-Kamal Industrial Estate,
Shed No. 11, Shivane, Pune - 411 023.

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Principal
College of Ayurved And Research Center

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

24. Collaborative activity - Student Exchange Industrial training at Punarvasu Aushadhshala PVT.LTD.

10/3/2021 to 22/5/2021

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Date-25/5/2021

POST EVENT SUMMARY REPORT

Name of the collaborative activity

Industrial training at Punarvasu Aushdhashala Pvt. Ltd, Shivane,Pune.

Date/ Duration

10/3/2021 to 21/5/2021

Place: Punarvasu Aushdhashala Pvt. Ltd, Shivane,Pune.

Participants Details: Final Year PG Students - 01

Organising department/ committee- Rasashastra evam Bhaishajya Kalpana

Brief Activity Details:

- Standardization of ASU drugs
- Standardization of Raw materials, manufacturing process and finished products for ASU drugs
- Preparation of Kaishor Guggulu, Triphala Guggulu, Shatavari Kalpa.
- Shodhan of different Rasadravyas like Hartala,Gandhak and Parada.
- Preparation of various Kupipakwas like Rasasindura and Rasmanikya
- Hands on training of Quality control measures for different formulations.

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HOD
Department of Rasashastra & Bhaishajyakalpana
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Regd. Address : 2D+E, Shail-neel Co-op. Society, 13 Rambag Colony, Paud Rd., Pune - 411 038.
Ph.: 020 2529 0116.Email : punarvasuaushadhshala@gmail.com

Date : / / 20

Date: 21/05/2021

CERTIFICATE OF ATTENDANCE / VISIT

This is to certify that

Dr. PRATIKSHA SANGHAVI

Who is students of last year M.D. Rasashastra and Bhaishjya kalpana, Pune District Education Assiciation's College of Ayurved and Research centre, Akurdi, Pune , has taken training in our Aushadhshala from 10 th March 2021 to 21 st MAY 2021.

She has observed and worked on various topics related with Rasa aushadhi and Bhaishjya kalpana with Quality control management.

I wish her all the best in the future.

Vd. Vivek D. Sane,

Director,

Punrvasu Aushadhshala Pvt. Ltd. Pune

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

25. Collaborative Research Workshop – With MUHS Nashik

31/05/2021 to 02/06/2021

Report of Research Methodology workshop

31st May – 2ndJune 2021

The workshop on Research methodology was organized by our institute on 31st May – 2nd June 2021 organized by our college P.D.E.A's College of Ayurved and Research CentreNigdi Pune 44. As per M.U.H.S./MET guidelines the sessions were organised for three days online workshop on zoom from morning 09.30- 17.00.

The fifty delegated were registered&attended the workshop. The detailed list is attached with the report.

Sr. no	College name	Number of delegates attended
1	**P.D.E.A'S COLLEGE OF AYURVED AND RESEARCH CENTRE NIGDI PUNE 44**	50

Seven faculty members were invited as resource person for workshop.Dr. Prasad Pore from BVDU Katraj Pune ; Dr. Deepak Nagpal from D. Y. Patil dental College Col. S. L. Jadhav from D. Y. Patil Medical college Pimpripune, Myself from our college Pune,Dr.ShrikanthMuralidharanPune;Dr.Suvarna Joshi fromB. J. Medical college Pune;Dr.MadhavMutalik from D. Y. Patil Dental college.Previously the instruction was given to students as with synopsis topics so, the workshop became more interactive and fruitful to them. For group activity five heterogeneous groups were performed. Pre MCQ test was taken for 30 marks. Dr.ApoorvaMundargi fromswasthvruttadepartment was 1st topper , she received 19 marks Dr.PradnyaLondhe from kayachikitsa, Dr.SurabhiPatil and Dr NehaGhadge from Balaroga department were 2nd topper they were received 18 marks out of 30. On first day two goggle links were shared for 1st day feedback and pre-test MCQ.

Before starting online workshop Pre-test was conducted with Google form. The quiz link was shared sharp at 9 am and closed on 9.25 , twenty minutes were given to complete. The responses were saved .The workshop was started withDhanwantaristawan chanted by me. The first day session was started sharp at 09.30- 10.00 bylecturetaken by me on the topic "Introduction to research methodology and formulation of RQ and Hypothesis. Next session was taken onobservational study designs descriptive by me only.the session was completed at 10.45 am After the descriptive study designs analytical study design , experimental study designs were taken by Dr. Prasad Pore from BVDU's medical college katraj Pune.The post lunch session was startedon 1.30 pm. with group activity taken by me. Five groups were prepared each group with 10 members and five types of designs were given. Twenty minutes were given for preparation one delegate from each group presented the assignment and suggestions were given by me for improvement of design The details as follows-

Group no.	Topics given for study design group activity	Instructed to formulate as per following points
1	Cross sectional study to evaluate correlation between prakrutee and hypothyroidism - Dr. SachinBhor	1) Formulate the title 2) Research question & Hypothesis if necessary 3) Aims and objectives of the study 4) Independent and dependent variable 5) Short methodology how to conduct the study
2	A longitudinal study to evaluate occurrence of DM those have paternal history of diabetes Dr. MrunalDorage	
3	case control study on Aamlapiita to evaluate vidahiaahar as causative factor by	

P.D.E.A'S College Of Ayurved And Research Centre AKURDI PUNE - 44.

	supriyaPatwardhan	
4	compare the incidence of covid 19 those are vaccinated and not vaccinated Dr. nehaghadage	
5	Compare the efficacy of dashamulataila(control group) and bilvataila(experimental group) karnapurana in karnabadhirya. Dr madhavtalhar	

Next lecture was takenon qualitative research methodology after the group activity by Dr.DeepakNagpal from D Y Patil dental college completed on 4.00 First day ended at 05.00 p.m.by lecture on literature search taken byDr.DeepakNagpal from D Y Patil dental college. The responses of 1st days feedback was saved.

The second day was started by lecture on 9.30am-10.30 am.Sampling and sample size by Dr.SudhirJadhav from D Y Patil college After this lecture the activity of sampling and sample size given to groups and 15 minutes was given to prepare the evey group presenter presented the title objectives sampling frame and requirements for calculation of sample size.

Group no.	Topics given for sampling and sample size group activity	Instructed to formulate as per following points
1	Cross sectional study to evaluate correlation between prakrutee and hypothyroidism - Dr. SachinBhor	1) title 2) objectives of study 3) sampling frame and method 4) requirements for sample size
2	A longitudinal study to evaluate occurrence of DM those have paternal history of diabetes Dr. MrunalDorage	
3	case control study on Aamlapiita to evaluate vidahiaahar as causative factor by supriyaPatwardhan	
4	compare the incidence of covid 19 those are vaccinated and not vaccinated Dr. nehaghadage	
5	Compare the efficacy of dashamulataila(control group) and bilvataila(experimental group) karnapurana in karnabadhirya. Dr madhavtalhar	

The groups as mentioned in the above table. Next sessions was started at 11.30 a.m.was taken bymeon "Types of data and presentation of data" The activity was taken on identification of data types bydisplaying MCQ. The session ends at 1.pm.

After the lunch break the sessions were started on inferential statistics byDr.ShrikanthMuralidharanfaculty of RMW workshop. The group activity was taken on selecting the appropriate test for given problems to each group. They had given 15 minutes for preparation and one by one group one delegate presented the title, type of data and appropriate selection of statistical tests. The session was ended on 3.30 pm.



Group no.	Topics given for appropriate selection of statistical tests group activity	Instructed to formulate as per following points
1	Cross sectional study to evaluate correlation betweenKaphaprakrutee and hypothyroidism - Dr. SachinBhor	1) title 2) type of data 3) choosing appropriate statistical test as per data
2	A longitudinal study to evaluate occurrence of DM those have paternal history of diabetes Dr. MrunalDorage	
3	case control study on Aamlapiita to evaluate vidahiaahar as causative factor by supriyaPatwardhan	
4	compare the incidence of covid 19 those are vaccinated and not vaccinated Dr. nehaghadage	
5	Compare the efficacy of dashamulataila(control group) and bilvataila(experimental group) karnapurana in karnabadhirya. Dr madhavtalhar	

For next session every delegate was requested to download EPI info 7in their laptops and one excel data file was shared with delegates so that the "computer assistance in data analysis on Excel,epiinfo with Demo was completed up to 5 pm

The third day was started with lecturesdelivered byDr.Suvarna Joshi from B.J. Medical College, Pune Lecture started at sharp 9.30 a.m on ethics in medical research with group activity. Ethical issues from it one-one group member presented their ethical issues from it and drSuvarna Joshi madam guided well to correct ethical issues on given topics as follows

Group no.	Ethical issues on following topics	Presenter from the group
1	Cross sectional study to evaluate correlation between kaphaprakrutee and hypothyroidism	Dr. SachinBhor
2	A longitudinal study to evaluate occurrence of DM those have paternal history of diabetes	Dr. ShubhankarKulkarni
3	case control study on Aamlapiita to evaluate vidahiaahar as causative factor	Dr. TejalSuryavanshi
4	compare the incidence of covid 19 those are vaccinated and not vaccinated Dr. nehaghadage	Dr.NehaGhadge
5	Compare the efficacy of dashamulataila(control group) and bilvataila(experimental group) karnapurana in karnabadhirya.	Dr.RakhiManiyar



Next session was taken on protocol writing by Dr.Suvarna Joshi from B.J. Medical college, Pune from 11 am and group activities weretaken on pre given topics onprotocol writing as they have to formulate title, project summery, Background and rationale, specific objectives, methodology, forms and data handling plan for statistical analysis, deviation and amendments of protocol and references from it one-one group member presented their protocols from iton given topics as follows

Group no.	protocol writing on following topics	Presenter from the group
1	Cross sectional study to evaluate correlation between kaphaprakrutee and hypothyroidism	Dr. SachinBhor
2	A longitudinal study to evaluate occurrence of DM those have paternal history of diabetes	Dr. UmeshMallewar
3	case control study on Aamlapiita to evaluate vidahiaahar as causative factor	Dr. KalpanaNaramwar
4	compare the incidence of covid 19 those are vaccinated and not vaccinated Dr. nehaghadage	Dr.NehaGhadge
5	Compare the efficacy of dashamulataila(control group) and bilvataila(experimental group) karnapurana in karnabadhirya.	Dr.RakhiManiyar

The session ends at 13.15pm. After lunchDr.MadhavMutalikfrom D.Y. Patil dental school had taken session on diagnostic test. Sir had taken very interactive and informative lecture on questionnaire designing.Next session was started on 3.30 pm oncritical journal article evaluation ended on 5 pm by group activity one article and evaluation form shared with delegates previously for reading and presented one -one group their findings regarding shared article.Dr.MadhavMutaliksir's sessions were very informative & interactive.

Post workshop evaluation by postMCQ test was taken by quiz .In that quiz following are the toppers.

26.00 / 30	DrKirtiHanumantJadhav 1st topper
25.00 / 30	DR APURVA NAGRAJ MUNDARGI 2nd topper

DrKirtijadhav shared her views regarding three days' workshop, with concluding remarks by me workshop ended at 5.10 pm. All Power point presentations were shared to all delegates on their personal email address.

The daily evaluation and whole program evaluation sheets were filled by delegates. The analysis of program evaluation is given asfollows-

Some comments given by delegates are as follows-

1) Workshop duration should be increased.
2) Workshop should take offline
3) Workshop is fruitful especially with group activities
4) Time management and organization of workshop is very good



5) Majority of delegates very much satisfied with group activities.
6) More group activitiesshould be conducted for better understanding of subject.
7) Cisco webex software should be used for online workshop
8) Dr. Prasad Pore;Dr. ShrikanthMuralidharan& Dr. S L Jadhav Dr. SuvarnaJoshi , Dr. MadhavMutalik all are the best faculty members mentioned by all most all delegates.

The activity started by M.U.H.S. and MET is really very much necessary and useful for up-gradation of knowledge of Research techniques to post graduate students and teachers.Thanking you,

Dr. Yogini R. Kulkarni (Coordinator)

Principal
P.D.E.A'S
College of Ayurved And Research Centre
Nigdi, Pune - 411 044.

H. O. D.
Research Methodolo
College of Ayurved And Research Centre
Akurdi. Pune - 411 044.

P.D.E.A'S College Of Ayurved And Research Centre
AKURDI
PUNE - 44.

Pune District Education Association's

College of Ayurved & Research Centre

Research Methodology Workshop – 31 May to 2nd June 2021





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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

26. Collaborative Research Project with

EMR Ayush

01Aug 2020

to

15 Dec 2020 (4 months)

Pune District Education Association's

Ayurved Rugnalaya
and Sterling Multispeciality Hospital

Sector No. 27, Pradhikaran, Nigadi, Pune - 411044 (Maharashtra) India I.D.No. PU/PN/AYU/081/1990
Ph. (020) 27659460, 27658734 Fax. (020)27659578 E-mail : carchospital@gmail.com Website : www.pdeacarcayu.com
Recognized by : Ministry of AYUSH, Govt. of India & CCIM, New Delhi Affiliated by : Maharashtra University of Health Sciences (M.S.)

Managing Trustee

President
Ajit Pawar

Vice President
Rajendra Ghadge

Hon. Secretary
Adv. Sandeep Kadam

Treasurer
Adv. Mohanrao Deshmukh

Dy. Secretary
L. M. Pawar

Supreteadant
Dr. Ragini Patil

Ref. No. 1216/2022-23

Date : 03 SEP 2022

To,

Under-secretary (EMR)

Ministry of AYUSH

Govt. of India

Ayurgyan Scheme

NBCC Building 2nd Floor, Tower no 03 East Kidwai Nagar New Delhi 110023

Subject: - Sending reply on comments and suggestions dated 30/08/2022 received through mail under S-14011/06/2020 scheme

Respected madam,

Dr.Renu – Research officer

Title of the Project: Clinical trial to evaluate prophylactic action of Twakadi Herbal Tea in Police professionals working in COVID 19 pandemic.

PI & Institute: Prof. Dr. Yogini R. Kulkarni, PG Director & HOD of department of Research, P.D. E.A.'s College of Ayurveda & Research Centre Nigdi Pune.

Sending herewith the reply/ clarification on your comments and suggestions

Following documents are attached with this letter-

1) Scanned copy of reply/ clarification dated 25/07/2022 & 30/08/2022
2) Scanned revised reportof project

Yours faithfully

Dr. Yogini R. Kulkarni

(Principal Investigator)

Dr.Ragini R. Patil

(Superintendent)

Principal
P.D.E.A's
College of Ayurved And Research Centre
Nigdi, Pune - 411 044.

P.D.E.A's COLLEGE OF AYURVEDIC RESEARCH AKURDI PUNE - 44

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Principal
College of Ayurved And Research Centre
Akurdi, Pune - 411 044

CCRAS

Title of the Project: Clinical trial to evaluate prophylactic action of Twakadi Herbal Tea in Police professionals working in COVID 19 pandemic.

PI & Institute: Prof. Dr. Yogini R. Kulkarni, PG Director & HOD of department of Research, P.D. E.A.'s College of Ayurveda & Research Centre Nigdi Pune.

Justification on comments /suggestions received by CCRAS (30/08/22)

i. Sample size calculation-some reference may be mentioned as the basis for justification.

Answer- –

It is recommended that when the researcher has no idea as to what the level of P is in the population, choosing 0.5 for P in the formula sample size will always provide through observations, irrespective of actual value of the true proportion. In Such circumstances, the following formula should be used in order to estimate the population proportion to within d percentage points of the true P

Reference-Adequacy of sample size in health studies by Author Stanley Lemeshow, David W. Hosmer Jr., Janelle Klar& Stephen K. Lwanga Page no 2

ii. Data described in the entire table are not in proper format. Percentage (%) format must be used in such type of variable.

Answer – All tables' values are expressed in percentage. Only on page no 10, table number 6 is corrected as in percentage recommended by the honorable dignitaries.

iii. Between the groups comparison is not reported.

Answer-

Between the groups comparison is given in table number 9 on page no. 13-14 of the revised report

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iv. Randomization & blinding procedure are not clearly defined.

Answer-

Randomization and Sequence generation – Alphanumeric codes were given to each packet of the tea bags for both the groups by the manufacturer.

Allocation concealment mechanism – Packets were given to the eligible and consented volunteers, and corresponding alphanumeric code was noted down. Investigators were blinded to the allocation of the participants. The alphanumeric codes were given by the manufacture and later-on un-blinded only at the stage of data analysis.

Blinding – Double blinding (participants and investigator blinding) was done. Those packets looked alike from outside so that volunteers and investigators did not know as to which packet containedTwakadi tea and which packet contained plain tea.Efforts were taken to maintain the similarity of both the packets of control and test drug. Look and feel of both all the packets was same. Participants had no access to the packets; hence they had nothing to compare with. Besides, double coating of plastic bags was done to minimize the essence, and was successfully achieved.

Implementation – Alphanumeric codes were given by the manufacturer to test and control groups packets and packets were given to participants randomly. In the CRF, code number was noted for each participant. Packets looked alike from outside with same weight and dimensions.

v. As said in the table No. 6. Of the report, Friedman test was applied, but no p-value has been reported.

Answer –

On page number 11 of revised report, in table no. 6A and 6B all p values are mentioned.

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vi. The table presented reply to point no. 11 of previous comments, doesn't include total sample size. The table may be revised and incorporated in the revised report.

Answer- This comparison was done on the basis of those patients (10 subjects from control group and 8 subjects from trial group) who were having the ILI like symptoms during the duration of treatment. So the whole sample size not reflecting

Group	Present ILI like symptoms at the end of the treatment	Absent ILI like symptoms at the end of the treatment	Chi square test Statistic	P value
Control	6	4	0.003	0.958
Test	4	4		

vii. The revised report must include the reply to previous and current (incorporated under appropriate heading) and may be submitted for final remarks.

Dr. Yogini R. Kulkarni
(Principal Investigator)

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CCRAS

Title of the Project: Clinical trial to evaluate prophylactic action of Twakadi Herbal Tea in Police professionals working in COVID 19 pandemic.

PI & Institute: Prof. Dr. Yogini R. Kulkarni, PG Director & HOD of department of Research,P.D. E.A.'s College of Ayurveda & Research Centre Nigdi Pune.

Justification on comments /suggestions received by CCRAS (14/07/22)

1) In the report the control arm is differently described at various places it is written normal tea plain tea and normal green tea at certain places uniformity in the drug used in the control arm may be mentioned.

Answer – Uniformity of the drug used in the control armas plain tea is maintained.

2) Description of efforts taken for maintaining the essence flavour similarity in the control arm tea bags with the interventional product for the sake of blinding may be provided.

Answer – Efforts were taken to maintain the similarity of both the packets of control and test drug. Look and feel of both was same. Participants had no access to both the type of packets; hence they had nothing to compare with. Besides, double coating of plastic bags was done to minimize the essence, and was successfully achieved.

3) Mean age (along with statistical significance of the difference if any) of the enrolled participants in both groups is not mentioned.

Answer – As *P* value > 0.05, there is no significant difference in Mean Age of both the groups

GROUP	Mean Age	Std. dev.	P value
Control	41.68	9.5	0.315
Test	39	9.2	

4) Justification/ Reason for unequal gender wise inclusion of study participants may be given.

Reason –

Inclusion criteria:

1. Police professional working in COVID 19 pandemic having age 25-and above irrespective of gender

As per inclusion criteria was (irrespective of gender)and availability of police professionals working in Covid 19.

Female police were very less in number compared to their male counterpart. However, there is no statistically significant (As p value > 0.05) differencebetween the groups as far as genderdistribution is concerned as per the following table:

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(1)

Group	Gender		Chi square test statistic	p value
	Male	Female		
Control	16	9	0.157	0.692
Test	19	7		

5) Content in the Table No. 4 describes the data at baseline or some other assessment point during the study period is unclear.

Answer –

Table no.4 describes only information about group wise distribution of participants on the basis of close contact history and travel history in containment zone. So it's only baseline information, and not follow-up wise assessment.

6) How many participants had history of diagnosed Covid-19 or ILI during at least one month prior to the day of screening may be mentioned.

Answer- Not a single participant had the history of diagnosed Covid-19 .ILIduring at least one month prior to the day of screening this information was not taken.

7) The last two columns of Table No. 6 have same headings. Kindly revise -

Answer – Revised on page no 10 Table no 6. Observations of test& control group for flu like symptoms

8) Sample size justification is unsuitable for this study design

Answer –

Sample size – on the basis of pilot study

- Proportion effect of treatment (p)= 0.5
- q= 1-p=0.5
- Allowable error (d) = 0.18
- Level of significance = ($\bar{\alpha}$)= 0.05
- So $Z_{\bar{\alpha}/2} = 1.96$
- Sample size = $Z_{\bar{\alpha}/2}^2 pq / d^2 = 29.64 \approx 30$
- By considering 10 % drop out rate sample size was 34 in each group
  Total 69 participants were enrolled in the study. Test group had 34 participants and 35 participants were enrolled in the control group. But because of missed follow up 8 participants from test group and 10 participants from control group were dropped out. so sample size of control group was 25 and of test group was 26.

9) Previous comments are not appropriately incorporated in the current report
Answer: All previous comments are clarified in the attached file of revised report

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10) As per primary outcome there is no effect of Twakadi Herbal tea is prophylactic of Covid 19.

Answer: It may be due to less duration (14 days) of the treatment or inadequate dose for prophylactic action. And after duration of the treatment period, follow-up was not taken.

11) If any participant has suffered and recovered from ILI like symptoms during the fourteen days duration , then whether this information was retrospectively collected and recording in CRF or not may be specified. If such data was collected then analysis of this data should also be done to strengthen the results of study

Answer - This information was collected and recorded in the CRF during the study, and NOT retrospectively. The analysis was also done,however it doesn't show significant difference (as p value>0.05)between the groups as per following table.

Comparison between Control and Test group for ILI like symptoms observed during 14 days duration

Group	Present	Absent	Chi square test Statistic	P value
Control	6	4	0.003	0.958
Test	4	4		

Interpretation: As p value > 0.05, there is no significant difference between both groups

12) Overall both the objectives of the study do not seem to be achieved. May provide appropriate justification for this

Answer: There could be various reasons: 1. Sample size (25 in the control group and 26 in test group). If few hundreds volunteers were considered for enrollment, effect might have been visible; however it would have budget implications 2. Short duration (14 days) of the treatment period: More number of days of treatment could have made the difference visible, and objective could have been achieved. 3.Inadequate dose:In the study, dip -dip tea bags were used for both the groups. This might have caused the inadequate dosing. Considering the cumulative effect of these three reasons, objectives might not have achieved.

(2)
Dr. Yogini Rikulkarni
(P.I)



1. **Title of the Project**: Clinical trial to evaluate prophylactic action of Twakadi Herbal Tea in Police professionals working in COVID 19 pandemic

2. **PI (name and address)**- Prof. Dr. Yogini R. Kulkarni M.D. (Dravyaguna) Ph.D. ; M.A, (Sanskrit and Sangeet); Diploma in Yoga and Ayurveda ; F.I.I.M) .Survey no 119/2, SaritaVaibhav Building no. B-4 Flat no 17 opposite P.L. Garden Sinhagad Road Pune 411030

3. **Co-I (name and address)-**

1) Co-Investigator(s): Prof. Dr. Mrs. RaginiRajanPatil M.D. Ph.D (Scholar) (Ayurveda- Rognidan) ConiferGaikwad Nagar flat no 3 Aundh Pune 411007

2) Co- Investigator:-Dr. Bharat Oza M.S. (Ayurveda- Shalyatantra) Rhythm society A1 Building, Flat no 302 KalewadiphataChowkKalewadi Pune 411057

3) Co- Investigator:-Dr. Pravin Tate M.D. (Ayurveda- Rasashastra) 56, VatanngarTalegaonDabhade Tal. Maval District-410507

4. Other Scientific Staff engaged in the study-

1) Dr. RanavirEdake M.S. 1st year

Address:-Ekbote house Near CARC sector no 27 Pradhikaran , Nigdi Pune 411044

2) Dr. RajashreeAmilkanthwar M.S. 1st year

Address :-NigdiPradhikaran Pune 411044

5. Non-Scientific Staff engaged in the study-

1) Mrs. Vandana Ram Pawar – Accountant

2) Mr. Pravin More – Accountant

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6. Implementing Institution and other collaborating Institutions- Nil

7. **Date of commencement-** 30/10/2020

8. **Duration-** three months

9. **Date of completion- 15/12/2020**

10. Objectives as approved-

Primary objective:-

To compare the incidence of COVID19 between the control and test group of Police professionals working in COVID 19 pandemic

Secondary Objectives:-

To compare the severity of the symptoms after the incidence of disease in control and test group of Police professionals working in COVID 19 pandemic

11. **Deviation made from original objectives if any, while implementing the project and reasons thereof-** nil

12. Experimental work giving full details of experimental set up, methods adopted, data collected supported by necessary tables, charts, diagrams and photographs.

Trial design –This was adouble-blind, Randomized Controlled study, with 1:1 randomization, with a study period 14 days from the date of enrollment

Methods -

Participants – Participants attending the P.D.E.A's Ayurveda Rugnalaya and Sterling Multispecialty Hospital, NigdiPradhikaran Pune 44, who were police professionals, were screened for RT-PCR and known COVID 19 negative eligible and willing were enrolled in the study. Total 73 participants were screened with RTPCR and 69

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eligible and willing participants were enrolled after written consenting.

Twakadi herbal tea bags preparation – Raw material was procured from the market and was authenticated from Agharkar Research institute (Certificates of Authentication are attached in Annexure no 6). After authentication, tea bags were prepared with *bhavitchoorna* of below mentioned drugs (2.250 gms / bag) from a GMP certified pharmacy with finished product standardization (Certificate of standardization is attached in Annexure no 7) .

Intervention and control –

The intervention in the trial has background in Ayurveda. Twakadi herbal tea bag 2.250 gm containing Tulasi –Leaves (*Ocimumtenuiflorum* L.); Pippali *Fruits (Piper longum* L.); Yashtimadhu Stolon (*Glycyrrhizaglabra* L.) ; Ginger Rhizome (*Zingiberofficinale* L.);Draksha fruits (*Vitisvinifera* L.) AndDalchinibark*Cinnamomumzeylanicum*Blume.

The control group: plain tea bags of a standard company

Outcomes -

Primary outcome -

Number of participants with laboratory confirmed COVID-19 positivity in 14 days

Secondary outcome

1. Inflammatory markers (CRP) at the baseline and end of treatment.
2. Adverse Drug Reaction / Adverse Events recorded
3. Number of participants who suffered with any type of infective disease during the trial period

Sample Size – On the basis of pilot study

proportion effect of treatment (p)= 0.5

q= 1-p=0.5

Allowable error (d) = 0.18

Level of significance = ($\bar{\alpha}$)= 0.05

So $Z_{\bar{\alpha}/2}$ = 1.96

Sample size = $Z_{\bar{\alpha}/2}^2 pq / d^2 = 29.64 \approx 30$



By considering 10 % drop out rate sample size will be 34 in each group

Randomization and Sequence generation – Alphanumeric codes were given to each packet of tea bags for both the groups by the manufacturer.

Allocation concealment mechanism – Investigators were blinded to the allocation of the participants to both the groups. The alphanumeric codes were given by the manufacture & later-on un-blinded only at the stage of data analysis.

Blinding – Double blinding (participants and assessor blinding) was done. Those packets look alike from outside so that patients and investigators did not know as to which packet contains twakadi tea and which packet contains plain tea.Efforts were taken to maintain the similarity of both the packets of control and test drug. Look and feel of both was same. Participants had no access to both the type of packets; hence they had nothing to compare with. Besides, double coating of plastic bags was done to minimize the essence, and was successfully achieved.

Implementation – Alphanumeric codes were given by the manufacturer to test and control groups packets and packets were given to participants randomly. In the CRF, code number was noted for each participant. Packets looked alike from outside with same weight and dimensions.

Screening of the participants - Police professionals, were screened by RT-PCR and known COVID 19 negative eligible and willing were enrolled in the study. Total 73 participants were screened with RTPCR and 69 eligible participants were enrolled.

Inclusion criteria for test and control group-
Inclusion criteria:



1. Police professional working in COVID 19 pandemic having age 25-and above irrespective of gender
2. Negative for COVID 19
3. Who are willing to provide signed informed consent are included in the study

Exclusion criteria – Pregnant ladies

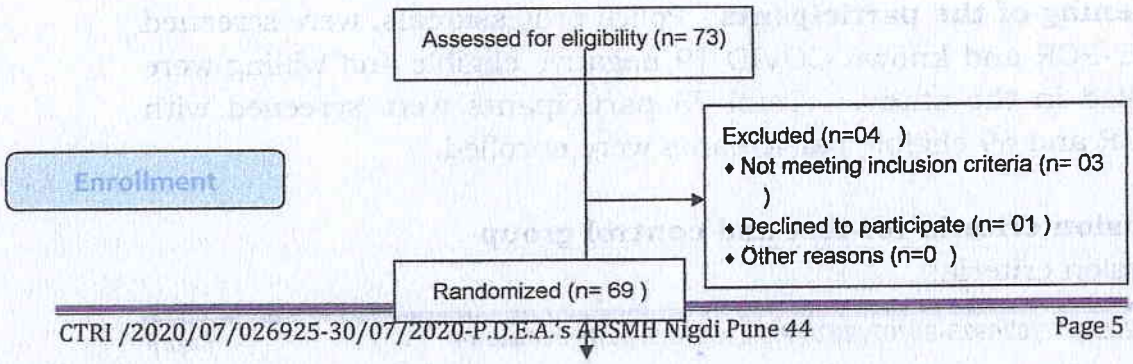
Withdrawal criteria –

1) Those who missed to take medicines and follow up were withdrawn from the study.
2) Those who were not willing to continue, were withdrawn from the study

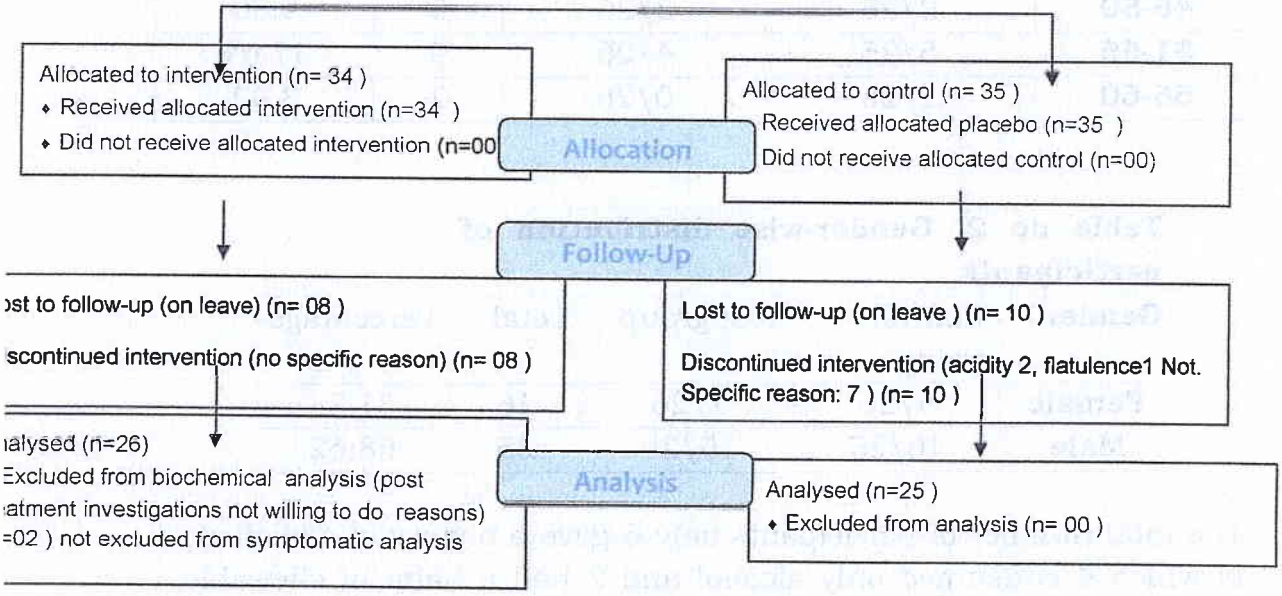
Statistical methods –

The data was collected, coded and entered in Microsoft excel 2013. It was checked for duplicates and incomplete entries. The data was then checked for normality of distribution using the Shapiro Wilk test. It was found to be normally distributed. Mean and Standard deviation was calculated for the quantitative data related to the change in the parameters under observations. The paired t- test was used for comparison (inter and intra group comparison). All p-values less than 0.05 was considered to be statistically significant. Statistical Package for Social Software (SPSS) 22.0 (IBM Analytics, New York, U.S.A) was used to carry out the analysis.

All data in quantitative and before and after from both the groups so for before and after treatment analysis paired t test is applied and for in between groups unpaired t test is applied.



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Recruitment- Date of 1st participant enrollment was 2nd Nov 2020 and last enrollment was on8th Nov 2020. Follow-ups were completed on 26th Nov 2020

RESULTS:

Baseline demographic and clinical data –

Total 69 participants were enrolled in the study. Test group had 34 participants and 35 participants were enrolled in the control group

Demographic data details –

Table no 1. Age-wise distribution of police professionals in test and control groups

Age group	Control group	Test group	Total	Percentage
26-30	4/25	5/26	9	17.64
31-35	6/25	6/26	12	23.52
36-40	2/25	4/26	6	11.76

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41-45	4/25	4/26	8	15.69
46-50	2/25	3/26	5	9.80
51-55	5/25	4/26	9	17.64
56-60	2/25	0/26	2	3.92

Table no 2. Gender-wise distribution of participants

Gender	Control group	Test group	Total	Percentage
Female	9/25	7/26	16	31.38
Male	16/25	19/26	35	68.62

The total number of participants only 6 gave a history of addiction; of which 4 consumed only alcohol and 2 had a habit of chewable tobacco.

Table no 2. Group-wise distribution of participants regarding addictions

Addiction	Control group	Test group	Total	Percentage
Alcohol	1/25	3/26	4/51	7.84
Tobacco	1/25	1/26	2/51	3.92

Comorbidities details –

Table no 3. Co morbidities

Disease	Control group	Test group	Total number	Percentage
Diabetes Mellitus	4/25	5/26	9/51	17.64
Hypertension	3/25	3/26	6/51	11.76

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Asthma	0/25	1/26	1/51	1.96

Medical history was noted. At the time of enrollment, 9 individuals had given the history of diabetes but after investigation of pretreatment, 4 individuals were observed to have raised random sugar levels. Also, in case of hypertension, 6 individuals had given the history of hypertension; however, 3 more cases of high blood pressure were identified when the initial checkup of the participants was carried out

Close contact history & Travel history in containment zone –

Table no 4. Group-wise distribution of participants on the basis of close contact history and travel history in containment zone

History	Control group	Test group	Total	Percentage
Close contact history	**19/25**	**20/26**	**39/51**	**76.47**
Travel history in containment zone	**25/25**	**26/26**	**51/51**	**100**

All participants were at high risk due to travel history in containment zone. Out of them19 participants from control group and 20 participants from test group were in close contact history with covid cases.

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Drug Administration details as per groups- For test group Twakadi herbal tea was given as 2.250 gm. tea bag dipped for 5 minutes in one cup (150 ml) of boiling water, squashed and taken for two twice a day before breakfast; and in the afternoon at tea time; for a duration of two weeks (14 days).

For control group plain tea bags are given. They are following the same procedure as test group.

Investigational product packaging: Packaging was done in plastic sealed bag, 7 tea bags in one pouch and the instruction stickers in Marathi and English was stacked on the plastic bag regarding preparation of the tea and drug administration details. Four bags were packed in one plastic bag, which was sealed later. This packaging strategy was done for both, Twakadi herbal tea bags and plain tea bags. A total of 35 packets were prepared each for both the groups and alpha numeric coding was given by manufacturer. After completion of follow ups the coding was decoded for statistical analysis.

Assessments -

Below mentioned investigations were done and flu like symptoms recording were done as Rhinitis, Muscle Pain, Fever, Sneezing, cough, Sour throat, headache, debility in breathing and abdominal discomfort . If the symptoms observed it was recorded as 1 and if absent; recorded as 0.

Table No 5Investigation schedule

Sr. No	Investigation details	0 day	7th day	14th day
1	Nasopharyngeal /Throat Swab for RT-PCR for SARS-CoV-2	√	-	√
2	Haemogram	√	-	√
3	RFT- routine urine	√	-	√

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	S. urea S. creatinine			
4	BSL random	√	-	√
5	CRP	√	-	√
6	Serum Ferritin	√	-	If positive √

Table no 6. Observations of test& control group for flue like symptoms

Flue like symptoms	Present in Control group out of 25 participants before treatment	Present in Control group out of 25 participants after treatment	Present in Test groupout of 26 participants before treatment	Present in Test group out of 26 participants After treatment
Rhinitis	0 (0%)	1(4%)	2(7.69%)	1(3.84%)
Muscle Pain	2(8%)	1(4%)	1(3.84%)	1(3.84%)
Fever	0(0%)	0(0%)	0(0%)	0(0%)
Sneezing	0(0%)	1(4%)	1(0%)	1(3.84%)
Cough	1(4%)	1(4%)	0(0%)	2(7.69%)
Sore throat	0(0%)	0(0%)	3(11.53%)	3(11.53%)
Headache	1(4%)	0(0%)	0(0%)	0(0%)
Abdominal discomfort	1(4%)	0(0%)	0(0%)	0(0%)
Difficulty in breathing	0(0%)	0(0%)	0(0%)	0(0%)

The statistical test Friedman was applied; but no significant difference was observed. As per following table number 6 A & 6 B



Table No. 6 A

Friedman test result		
Test group	p value	S/NS
Rhinitis	0.368	Not significant
Muscle pain	1	Not significant
Fever	0.368	Not significant
Sneezing	1	Not significant
cough	0.097	Not significant
Sour throat	0.223	Not significant
headache	0.368	Not significant

Table No. 6 B

Friedman test result		
Control group	p value	S/NS
Rhinitis	0.368	Not significant
Muscle pain	0.097	Not significant
Fever	0.368	Not significant
Sneezing	0.607	Not significant
cough	1	Not significant
headache	0.368	Not significant
Abdominal discomfort	0.368	Not significant

13. Detailed analysis of results indicating contributions made towards increasing the state of knowledge in the subject.

Observations of control group for flue like symptoms on 0 day 7th day and 14th day. The statistical test Friedman was applied; but no significant difference was observed.

Statistical analysis was done using paired t test for analyzing the difference between before and after treatment, the results are as follows and the unpaired t test was applied to assess the difference between two treatments. But no significant difference was seen in the groups.

Table number 7. Laboratory parameters of control group before and after treatment statistical analysis findings by paired t test

Control group	**Mean with standard deviation**				
	Before	**After**	**St. dev.**	**p value**	**Reference range**
HB	13.86	13.868	0.72	0.957	13.0-17.0g/dL
TLC	7452.8	7407.2	1673.70	0.893	4000-10000/cmm



Lymphocytes	36.93	35.06	7.87	0.249	20-40%
Monocytes	4.91	4.96	1.19	0.843	2-10%
Neutrophils	54.7	56.48	9.17	0.343	40-80%
Eosinophil	3.16	3.43	2.01	0.506	1.6%
Basophils	0.14	0.29	0.55	0.187	0.1-2%
Platelet	2.6288	2.5964	0.33	0.631	150000-400000/cmm
BSL	127.87	152.39	48.82	0.019	<200 mg/dl
Serum urea	21.58	21.464	4.40	0.896	12.8-42.8 mg/dl
Serum creatinine	0.8716	0.884	0.23	0.793	0.67-1.17 mg/dl
CRP	3.306	2.846	2.22	0.101	1-5 mg/l
pH	5.568	5.82	1.33	0.389	4.5 - 8.0
Specific gravity	1.012	1.013	0.007	0.894	1.001-1.030
Glucose	0.85	0.96	1.019	0.68	Absent
Protein	0	0	0	-	Absent
Pus cells	2.14	3	3.46	0.256	0-5/hpf
Bacteria	5.59	8.14	6.20	0.068	Less than 20/hpf
NLR Ratio	1.62	1.72	0.05	0.38	less than 3

Table number 8. Laboratory parameters of test group before and after treatment statistical analysis findings by paired t test

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Test Group	Mean with Standard deviation		Standard deviation	p value	Reference range
	Before	After			
HB	14.12	14.30	1.48	0.570	13.0-17.0g/dL
TLC	6921.67	6811.25	1343.95	0.691	4000-10000/cmm
Lymphocytes	36.025	33.75	10.00	0.277	20-40%
Monocytes	4.55	5.14	1.12	0.019	2-10%
Neutrophils	55.87	57.28	10.40	0.516	40-80%
Eosinophil	3.32	3.53	1.64	0.523	1.6%
Basophils	0.25	0.29	0.633	0.726	0.1-2%
Platelet	2.4433	2.3721	0.495	0.488	150000-400000/cmm
BSL	109.75	114.12	33.58	0.53	<200 mg/dl
Serum urea	20.05	21.737	7.33	0.271	12.8-42.8 mg/dl
Serum creatinine	0.9183	0.8625	0.095	0.009	0.67-1.17 mg/dl
CRP	1.64	3.49	8.66	0.306	1-5 mg/l
pH	5.67	5.98	1.388	0.304	4.5 - 8.0
Specific gravity	1.0123	1.0128	0.008	0.803	1.001-1.030
Glucose	0.52	0.61	0.288	0.162	Absent
Protein	0	0	0	-	Absent
Pus cells	2.09	2.35	0.964	0.208	0-5/hpf



Bacteria	5.83	7.52	6.56	0.229	Less than 20/hpf
NLR Ratio	1.845	1.805	0.07	0.785	less than 3

Table no. 9. Between the groups comparison for quantitative data-

	Result of unpaired t test					
Biochemical parameters	Group	N	Mean	Std. Deviation	p value	S / NS
Hb	Control	25	13.87	1.89	0.286	not significant
	Test	26	20.23	29.42		
TLC	Control	25	7407.20	1427.72	0.143	not significant
	Test	26	6811.25	1368.28		
lympho	Control	25	35.07	6.94	0.510	not significant
	Test	26	33.75	6.95		
mono	Control	25	4.96	1.26	0.570	not significant
	Test	26	5.14	0.80		
neutro	Control	25	56.48	7.35	0.711	not significant
	Test	26	57.28	7.66		
eosino	Control	25	3.43	2.62	0.889	not significant
	Test	26	3.53	2.43		
baso	Control	25	0.30	0.42	0.972	not significant
	Test	26	0.29	0.45		
platelate	Control	25	2.60	0.60	0.245	not significant
	Test	26	2.37	0.73		
BSL	Control	25	152.40	76.52	0.052	not significant
	Test	26	114.13	55.71		
surea	Control	25	21.46	6.04	0.883	not significant
	Test	26	21.74	6.91		
screat	Control	25	0.88	0.27	0.737	not significant
	Test	26	0.86	0.15		
CRP	Control	25	2.85	2.53	0.751	not significant
	Test	26	3.49	9.76		
pH	Control	25	5.78	0.94	0.514	not significant
	Test	26	5.98	1.07		
sgravity	Control	25	1.01	0.01	0.904	not significant
	Test	26	1.01	0.01		
protine	Control	25	0.00	0.00	–	not significant
	Test	26	0.00	0.00		

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glucose	Control	25	0.91	1.68	0.508	not significant
	Test	26	0.61	1.41		
pus cells	Control	25	2.96	3.30	0.393	not significant
	Test	26	2.35	0.71		
bacteria	Control	25	8.22	5.34	0.646	not significant
	Test	26	7.52	4.84		
NRL ratio	Control	25	1.72	0.63	0.637	not significant
	Test	26	1.81	0.57		

As p value> 0.05for all above parameters, there is no significant difference in control and test group

Table no. 10. Between the groups comparison for qualitative data-

Comparison between Control and Test group for ILI like symptoms observed during 14 days duration

This comparison was done on the basis of those patients (10 subjects from control group and 8 subjects from trial group)who were having the ILI like symptoms during the duration of treatment.

Group	Present ILI like symptoms at the end of the treatment	AbsentILI like symptoms at the end of the treatment	Chi square test Statistic	P value
Control	6	4	0.003	0.958
Test	4	4		

Interpretation: As p value > 0.05, there is no significant difference between both groups

Overall observations:

- Although as this was the exploratory study, there were two interesting findings:
  - Sr. Creatinine was reduced statistically significantly in Test Group. On day 0 the mean Sr. Creatinine was 0.91, which became 0.86 after 14 days,*P* value: 0.009 with SD 0.095.



- Random Blood Sugar Level (BSL) in the control group increased statistically significantly. On day 0, the mean BSL was 127.8 mg/dl which became 152.3 mg/dl, with *P* value 0.019 with SD 48.82

- Those frontline vulnerable cases who come in contact with COVID cases directly or indirectly can take this study drug as a pre- prophylactic medication.
- Since the study population was free of any underlying immune compromised condition or infection, the overall effect of the drug as compared to the baseline was not significant.
- Further detailed studies under controlled environment can help understand the role of the drug in active infection as well as prevention of re-infection among the high risk cases.

Discussion:

The present study was an interventional study among the frontline police personnel who are at a greater risk for COVID infection due to their regular contacts with common people as well as cases during their hospital duties. Since COVID affects the immunity of the individual, we decided to test if the Ayurveda product can be of used to maintain the immune levels among such cases that are vulnerable to infection on a daily basis.

Hence the present study was carried out with the intention to provide a natural remedy to maintain the immunity of these cases. The IP was thoughtfully selected in such a way that there is no need to pop a pill or capsule to gain the protection, but drinking tea, which is a routine ritual might help the user to gain the protection against the disease.

Primary objective of the study was to compare the incidence of COVID19 between the control and test group of Police professionals working in COVID 19 pandemic

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As per observations in both the groups incidence of covid 19 was not observed.

Secondary Objective was to compare the severity of the symptoms after the incidence of disease in control and test group of Police professionals working in COVID 19 pandemic but in the present study the incidence of Covid 19 was not observed in both the groups ultimately severity of symptoms not possible to assess.

Probable mode of action of Twakadi herbal tea all ingredients are effective onKaphadisorders, Kasahara, Swasahara, Kanthashodhaneeya,swarya, jeevaneeya, jwarahara. A

As per Ayurveda the ingredients of Twakadi herbal tea have specific actions which are as follows -

तुलसी तुवरा तिक्ता तीक्ष्णोष्णा कटुपाकिनी ||१५५४||
रूक्षा हृद्या लघुः कट्वी दाहपित्ताग्निवर्धनी |
जयेद् वातकफश्वासकासहिध्मावमिकृमीन् ||१५५५||
दौर्गन्ध्यपार्श्वरुक्कुष्ठविषकृच्छ्राश्मदृग्गदान् |१५५६|
(कै.नि - ओषधिवर्ग)

पिप्पली दीपनी वृष्या स्वादुपाका रसायनी |
अनुष्णा कटुका स्निग्धा वातश्लेष्महरी लघुः ||५०||
पिप्पली रेचनी हन्ति श्वासकासोदरज्वरान् |
कुष्ठप्रमेहगुल्मार्शः प्लीहशूलाममारुतान् ||५१||
आर्द्रा कफप्रदा स्निग्धा शीतला मधुरा गुरुः |
पित्तप्रशमनी सा तु शुष्का पित्तप्रकोपिणी ||५२||
पिप्पली मधुसंयुक्ता मेदःकफविनाशिनी |
श्वासकासज्वरहरा वृष्या मेध्याऽग्निवर्धिनी ||५३||
जीर्णज्वरोऽग्निमान्द्ये च शस्यते गुडपिप्पली |
कासाजीर्णारुचिश्वासहृत्पाण्डुकृमिरोगनुत् |
द्विगुणः पिप्पलीचूर्णाद् गुडोऽत्र भिषजां मतः ||५४|| (भा.प्र)



यष्टी हिमा गुरुः स्वाद्वी चक्षुष्या बलवर्णकृत् ।
सुस्निग्धा शुक्रला केश्या स्वर्या पित्तानिलास्रजित् ।
व्रणशोथविषच्छर्दितृष्णाग्लानिक्षयापहा ॥१४६॥

Shloka No: 146 Bhav Prakash Nighantu Haritakyadi Varga)

कटूष्णामार्द्रकं हृद्यं विपाके शीतलं लघु ।
दीपनं रुचिदं शोफकफकण्ठामयापहम् ॥९१॥
कफानिलहरं स्वर्यं विबन्धानाहशूलजित् ।
कटूष्णं रोचनं वृष्यं हृद्यं चैवाऽऽर्द्रकं स्मृतम् ॥९२॥ध. नि.
आर्द्रिका भेदिनी गुर्वी तीक्ष्णोष्णा दीपनी मता
कटुका मधुरा पाके रूक्षा वातकफापहा
ये गुणाः कथिताः शुण्ठ्यास्तेऽपि सन्त्यार्द्रकेऽखिलाः ।४६।
भोजनाग्रे सदा पथ्यं लवणार्द्रकभक्षणम्
अग्निसन्दीपनं रुच्यं जिह्वाकण्ठविशोधनम् ।४७।
कुष्ठपाण्ड्वामये कृच्छ्रे रक्तपित्ते व्रणे ज्वरे
दाहे निदाघशरदोर्नैव पूजितमार्द्रकम् ।४८। भा.प्र
कटूष्णं दीपनं वृष्यं रुच्यमार्द्रकनागरम् ॥११५४॥
श्वासकासवमिहिक्काबातश्लेष्मविबन्धनुत् ।११५५। कै. नि.

मधुरा मधुराम्ला च द्राक्षेति द्विविधा मता ।
मधुरा वातपित्तघ्नी साम्ला तु कफपित्तकृत् ॥३००॥
आमा साम्लगुणा गुर्वी सैवाम्ला रक्तपित्तकृत् ।
द्राक्षाम्लोष्णा सरा गुर्वी वातघ्नी कफपित्तदा ॥३०१॥
पक्वा स्निग्धा सरा स्वर्या स्वादुपाकरसा हिमा ।
हृद्या सा तुवरा वृष्या चक्षुष्या सृष्टमूत्रविट् ॥३०२॥
कोष्ठमारुतकृद् गुर्वी कफपुष्टिरुचिप्रदा ।
निहन्ति वातपित्तास्र तिक्तास्यत्वक्षतक्षयान् ॥३०३॥
रक्तपित्तज्वरश्वासतृष्णादाहमदात्ययान् ।
तद्वद् गोस्तनिका द्राक्षा स्वाद्वी वृष्यतमा मता ॥३०४॥

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त्वचं लघूष्णं कटुकं स्वादु तिक्तञ्च रूक्षकम् ।
पित्तलं कफवातघ्नं कण्ड्वामारुचिनाशनम् ।
हृद्वस्तिरोगवातार्शःकृमिपीनसशुक्रहृत् ।।५६।।
(भा.प्र)

There is literature published on almost all of these about efficacy as an immune-booster or modulator. Computational studies have shown efficacy of Piperine as an ACE-2 receptor blocker. Draksha and Yashtimadhu are potent anti-oxidants. Tulsi, Pippali, Aardrak and Yashtimadhu possess properties of having affinity towards *Pranavahsrotas*(respiratory system). Also, antiviral activities of Tulsi, Pippali, Aardrak are well-known, and Ayurved physicians regularly prescribe these herbs in flu-like symptoms and similar diseases. Per Ayurved view-point, ingredients like Tulsi, Pippali, Twak and Aardrak are *Ushna* in *Veerya*, while Draksha and Yashtimadhu are *Sheetaveerya*herbs. There is a balance of hot-cold potency within the drug. Ayurved believes in 'early intervention' (*chayevajayetdosham*). Majority of the herbs in the tea possess *deepak-pachak*properties, thus attempting to stop the disease at the very early stage / not letting it to prosper at all. We may say that this formulation might be effective as prophylactic for Covid19 and similar infections, however,due to relatively small sample size and less duration,this could not be confidently established.This is the limitation of the study. We recommend the study in larger populations and for longer duration, and also in high serum creatinine patients. Strength of the study is, it provided insight that such unique study, especially with regards to formulation and unique way of preparation is feasible to be conducted in high-risk population.

We observed that there was no change in the immune markers like TLC, or lymphocytes. Though mean values post intervention of TLC dropped a bit as compared to baseline, the difference was not



statistically significant. A raised TLC could mean persistent infection or stress values. So a normal level post intervention, could suggest that the drug acts to prevent the onset of infection.

Further studies are required to explore this parameter. In general, cells like monocytes, basophils/ eosinophil etc. are activated during infection or malnourishment or any underlying disease like cancer or post-surgery etc. So a rise or fall in these numbers in cases with prophylaxis to the present study medication could be due to overlapping reasons. So a direct cause or causes cannot be pointed out in the present small study population.

Monocytes are increased either in sub-acute infection or during recovery from bacterial infection. We cannot surely state that all these people in the trial group had a rise in monocyte count only due to COVID. It could be due to other infections as well. At times some may develop allergic reactions that also may be the cause of the raised monocyte count.

Except for the lymphocytes and the platelets, the present study population showed a rise in the count as compared to the baseline.

The influence of the study drug to the cell counts need to be further analyzed in-depth under stricter controlled environments and especially in cases with an active infection. No significant rise in hemoglobin was seen in the study population. Since the drug is not a hematinic agent, no significant post intervention rise was expected. Also for any rise to be seen in the hemoglobin levels, the time of intervention has to be long. This was not possible in the present study design.

ADR /AE – Three participants from the control group complained ofhyperacidity and flatulence. As they were from control group, they had received plain tea. They withdrewtheir consents from the study and hence were considered as drop-outs.

Some of the participants recorded their feedback as 'increased appetite' and of feeling 'light and fresh' and they were from the test group.

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14. Conclusions summarizing the achievements and indication of scope for future work.

Within the given time framework of the study design, we would like to conclude that-

No statistically significant results were found in any of the parameters. The control group which received normal green tea also didn't witness any conversion to Covid positive status. All the cases, who received the Twakadi herbal tea (IP) remained Covid negative at the end of the study duration of 14 days. Twakadi herbal tea's efficacy in declining Sr. Creatinine can be explored in further studies.

Apart from smaller duration of the study period, one reason of such a result could be that the study was conducted when there was already a down-wave in place, and number of new infections was overall low as compared to the peak of the wave.

Limitations of the study:

1. Smaller sample size
2. Time span was only 15 days
3. Respondent's bias, since they didn't take the drug under direct observations

15. Procurement/usage of Equipment- Nil

16. Science and Technology benefits accrued:

I. List of research publications with complete details:

Study team is planning to publish the manuscript in a peer reviewed journal.



Authors, Title of paper, Name of Journal, Vol., page, year

II. Manpower trained in the project:

a. Research Scientists or Research Fellows: Study team including co-investigators, SRF and volunteers such as Dr. RaginiPatil, Dr. Bharat Oza, Dr. Pravin Tate, Dr. HrishikeshRangnekar, Dr. RanveerEdake, Dr. RajashreeAmilkanthawar

b. No. of Ph.Ds produced: Nil

c. Other Technical Personnel trained: Nil

Patents taken, if any: Nil
IV. Products developed, if any: Nil. However, there is a scope to develop and market the IP

17. A summary sheet of not more than two pages under following heads (Title, Introduction, Rationale, Objectives, Methodology, Results, and Translational Potential).

Title :- Clinical trial to evaluate prophylactic action of Twakadi Herbal Tea in Police Professionals working in COVID 19 pandemic

Introduction - Ayurveda has unique aspect prevention of diseases. Here in this project, efforts have been made to evaluate prophylactic treatment against COVID 19.

Study Rationale - Prevention is better than cure. In this pandemic, any intervention that might keep the infection at bay would be need of the hour.
Contents of Twakadi combination (Investigational Product) have distinctive properties as antioxidants and they also act as immune-modulators.

Primary objective:-

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To compare the incidence of COVID19 between the control and test group of Police professionals working in COVID 19 pandemic

Secondary Objectives:-

To compare the severity of the symptoms after the incidence of disease in control and test group of Police professionals working in COVID 19 pandemic

Trial design –This was a double-blind, Randomized Controlled study, with 1:1 randomization, with a study period 14 days from the date of enrollment

Methodology -

Participants – Participants attending the P.D.E.A's Ayurveda Rugnalaya and Sterling Multispecialty Hospital, NigdiPradhikaran Pune 44, who were police professionals, were screened for RT-PCR and known COVID 19 negative eligible and willing were enrolled in the study. Total 73 participants were screened with RTPCR and 69 eligible and willing participants were enrolled after written consenting.

Intervention and control –

The intervention in the trial has background in Ayurveda. Twakadi herbal tea bag 2.250 gm containing Tulasi –Leaves (*Ocimumtenuiflorum* L.); Pippali Fruits (*Piper longum* L.); Yashtimadhu Stolon (*Glycyrrhizaglabra* L.) ; Ginger Rhizome (*Zingiberofficinale* L.) ;Draksha fruits (*Vitisvinifera* L.) andDalchini bark *Cinnamomumzeylanicum*Blume .

The Control group: plain tea bags of a standard company

Outcomes -

Primary outcome -

Number of participants with laboratory confirmed COVID-19 positivity in 14 days



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3.5.1

27. Collaborative Research Project with EMR Ayush

Sep 2020-March 2021

(6 months)

PDEA's

Ayurved Rugnalaya and Sterling Multispecialty Hospital, Nigdi, Pune

AYUSII ,EMR Project

Title of Project
Randomized comparative clinical trial to assess the efficacy of Pippali Rasayana and Nagaradi Kashaya Ghana Vati combination as an adjuvant treatment with ICMR directed therapy in Covid -19 positive mildly symptomatic cases.

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TRUE COPY
Principal
College of Ayurved and Research Centre
Akurdi, Pune - 411 044

FINAL REPORT

(2020-2021)

1. **Title of the Project:**
   Randomized comparative clinical trial to assess the efficacy of Pippali Rasayana and Nagaradi Kashaya Ghana Vati combination as an adjuvant treatment with ICMR directed therapy in Covid -19 positive mildly symptomatic cases.

2. **Principal Investigator:**
Dr. Medha M. Joshi
Professor& Head,
Department of Kayachikitsa,
P.D.E.A.'s Ayurveda Rugnalaya & Sterling Multispeciality Hospital, Pune - 411044.
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3. **Co- Investigator:**
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Co- Investigator:
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Co- Investigator:
Dr. Vinayak Shinde
Nodal Officer (Covid-19 @ARSMH), Associate Professor Dept. of Streerog Prasuti
P.D.E.A.'s Ayurveda Rugnalaya & Sterling Multispeciality Hospital, Pune - 411044.
Email id: drvkshinde@yahoo.com

4. **Other Scientific Staff engaged in the study:**
Dr.Abhishek Taksale
Asst.Professor
Department of Kayachikitsa,
P.D.E.A.'s Ayurveda Rugnalaya & Sterling Multispeciality Hospital, Pune - 411044.
Dr.Dnyaneshvar Sawant,Dr.Sandip Bhorje- Registrar- Kayachikitsa
Dr.Gargi Limaye,Dr.Manali Ambre,Dr.Ganesh Palhade-Houseman- Kayachikitsa
Dr.Rohit Shukla-P.G. scholar,Roganidan Vikruti Vidnyana.
Sister Snehal Limaye
Sister Vanaja Nair

5. **Non-Scientific Staff engaged in the study:**
Smt.Vandana Pawar-Accounts
Mrs.Sarita Pandit-Clerk
Mr.Avinash Patil-Store Keeper

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Mr.Khandagale-Lab. attendant
Mr.Sudhakar Sable-Ward Attendant

6. **Implementing Institution and other collaborating Institutions:**
Implementing Institution: P.D.E.A.'s Ayurveda Rugnalaya & Sterling Multispeciality Hospital, Nigdi Pradhikaran, Pune- 411044

Collaborating Institution: NA

7. **Date of commencement:**
Ethics approval- 29/6/2020
Project Sanction Letter-17/8/2020
Raw material authentication from Agharkar Research Institute, Pune -5/10/2020
Pushkarmool authentication from CSIR-IIIM, Jammu-19/10/2020
Revised IEC Approval-7/11/2020
Start of screening -9/11/2020
Standardisation of Formulation - 13/11/2020
First patient recruitment -17/11/2020
Final follow up of last patient-20/01/2021

8. **Duration:** 6 months

9. **Date of completion:**20/01/2021

10. **Objectives as approved:**

- **Primary Objective**

1. To assess the efficacy of Pippali Rasayana +Nagaradi Kashaya Ghana Vati combination given as an adjuvant treatment in Covid-19 positive mildly symptomatic cases.

- **Secondary Objective**

1. To compare the efficacy of PippaliRasayana +Nagaradi Kashaya Ghana Vati combination with ICMR directed treatment in Covid-19 positive mildly symptomatic cases.
2. To compare time taken for symptomatic relief in both the groups.
3. To observe adverse effect if any

11. **Deviation made from original objectives if any, while implementing the project and reasons there of**
Some patients failed to undergo X-ray and ECG either in 1st or 2nd round because they have preferred HRCT thorax and refused for repeated X-ray exposure. Hence, these patients were recruited without X-ray report. Although we have planned to conduct 6 minutes' walk test pre and post treatment, most of the patients refused to undergo this test, probably due to weakness and fear associated with the disease.

12. **Experimental work giving full details of experimental set up, methods adopted, data collected supported by necessary tables, charts, diagrams and photographs.**
It was a clinical trial, conducted to assess the efficacy of Pippali Rasayana and Nagaradi Kashaya Ghana Vati combination as an adjuvant treatment with ICMR directed therapy in Covid -19 positive mildly symptomatic cases compared to ICMR directed therapy. The data collected is presented below in results.

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Experimental set up and methodology followed in detail:
Study setting-P.D.E. A' S Ayurved Rugnalaya and Sterling Multispecialty Hospital, Nigdi, Pune-411044
The patients recruited in the study were either admitted at the hospital or home quarantined. The reasons for admission were patient specific; absence of separate space at home for isolation, need of observation for patients in elderly age group, presence of comorbidities etc.

Prior preparation: Raw herbs pertaining to the study drug Pippali Rasayan and Nagaradi Kashaya Ghana Vati were procured from authentic sources. All the raw drugs except Pushkarmool were authenticated at Agharkar Research Institute, Pune while Pushkarmool was procured from Jammu and authenticated from CSIR-IIIM, Jammu. The formulation was prepared as per procedure mentioned in Sharangdhara Madhyama Khanda. Lastly, the finished product was standardized. (Appendix 1)

Ethics approval & CTRI Registration:
The Institutional Ethics Committee Approval was obtained on 29/6/2020 (IEC/03/2020-21). The trial was registered with Clinical Trial Registry of India in October 2020 (CTRI/2020/10/028230).

Study design:
An open label randomized add on prospective clinical study.

Eligibility criteria:
Inclusion Criteria

- Patients with mild symptoms of Covid 19, confirmed using RT-PCR throat/ nasopharyngeal swab test
- Patients of either sex in the age group of > 20- < 70 years
- Patients willing to participate in the study.

Clinical severity	Clinical presentation	Clinical parameters	Remarks
Mild	Patients with uncomplicated upper respiratory tract infection, may have mild symptoms such as fever, cough, sore throat, nasal congestion, malaise, headache.	Without evidence of breathlessness or hypoxia (Normal saturation)	Managed at home or at Covid care Centre

Exclusion Criteria:

- Patients requiring immediate intensive care.
- Patients having complications of major illnesses such as Liver/Kidney failure Encephalopathy, Epileptic attacks, Coagulopathies, Neuromuscular diseases, Cancer
- Patients with uncontrolled DM(HbA1c> 7.5) and its complications
- Patients with uncontrolled HTN and its complications
- Patients with active infection of Tuberculosis, Pleural Effusion, collapse of any lobe of Lung, Ca Lung, COPD patients with dyspnoea SPO2<90, Respiratory rate > 20, requiring Nebulization frequently

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- Immunocompromised patients
- Patients with anaemia having Hb<7g/dl
- Patients with BMI >40 kg/m^2
- Pregnant and Lactating females

Sample size determination:
The calculation was done using Primer of Biostatistics software. The difference assumed in average days required for symptomatic relief between the groups was 4 and the standard deviation of the population was 5 at α 5% level of significance. The power of the study was assumed at 80%. The sample size was thus calculated to be 26 per group and considering a drop- out rate of 5%, it was decided as 28 per group.

Interventions and dosage:
The COVID- 19 positive patients were randomised to two groups based on administration of treatment –

1. Group 1- Conventional treatment given based on ICMR Guideline (which included Covid specific Antiviral drugs, Azithromycin/other Antibiotics, Antipyretic and other Vitamin supplements) + combination of Pippali Rasayana (2g once a day at morning empty stomach with 3g honey and 5g ghee) and Nagaradi Kashaya Ghana Vati (500mg twice a day post lunch and dinner with lukewarm water) for 14 days
2. Group 2- Conventional treatment given based on ICMR Guideline for 14 days (as mentioned above)

Methodology:
The patients approaching the study site with mild symptoms of respiratory illness were screened through nasopharyngeal/ throat swab RT- PCR test for COVID- 19. Already confirmed covid positive patients were also included in the study as per the inclusion criteria. A written informed consent form was obtained from the patients prior to screening. In addition, the following tests were done at baseline-

- Complete blood count (CBC)
- Blood sugar levels (Fasting and Post prandial)
- C- Reactive Protein (CRP)
- Renal Function tests (RFT)
- Glycosylated haemoglobin (HbA1C)
- ECG
- X ray Chest (PA view)

Ayurvedic parameters viz. Prakriti, Agni, Koshtha of the patients from both the groups were documented at baseline.

The patients admitted at Covid centre were followed up daily, while the patients quarantined at home were contacted telephonically every day and physically every 7 days. In either case, the vitals such as pulse, blood pressure, body temperature, respiratory rate and oxygen saturation were recorded at baseline every day. All the tests mentioned above (except HbA1C) were repeated on Day 14.

Outcome measures:
The outcome of the study was based on negative Covid-19 report finding at the end of treatment (day 14) in ICMR Trial group along with early symptomatic relief in the same group based on symptom gradation scale.

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Safety:
Renal function tests and ECG were done to assess safety of the interventions.

Adverse events:
There were 3 patients who suffered from adverse events: 1 from ICMR group and 2 from trial group. The patient in ICMR group suffered from Adhmaan while those in trial group suffered from Bhrama. No rescue medication was administered for the patient with Adhmaan while symptomatic medications were administered for Bhrama. Though Bhrama was relieved at third day, medicines were continued for the duration of 5- 15 days

The details of Adverse Events (AE) are provided below.

Sr no.	Nature of AE	Group	Start day	Resolving day	Treatment provided
1	Adhmana	ICMR	5th	7th	No Medicine
2	Bhrama	Trial	7th	9th	1)Tab Rabeprazol 20mg + Tab Domperidone(30 mg)- 12 hourly * 5days 2)Tab Ecosprine (75mg)- OD * 15 days
3	Bhrama	Trial	1st	2nd	No Medicine

- The conventional methods to explore association of AE with study drug like de-challenge and re-challenge were not used considering the clinical condition i.e. COVID-19.

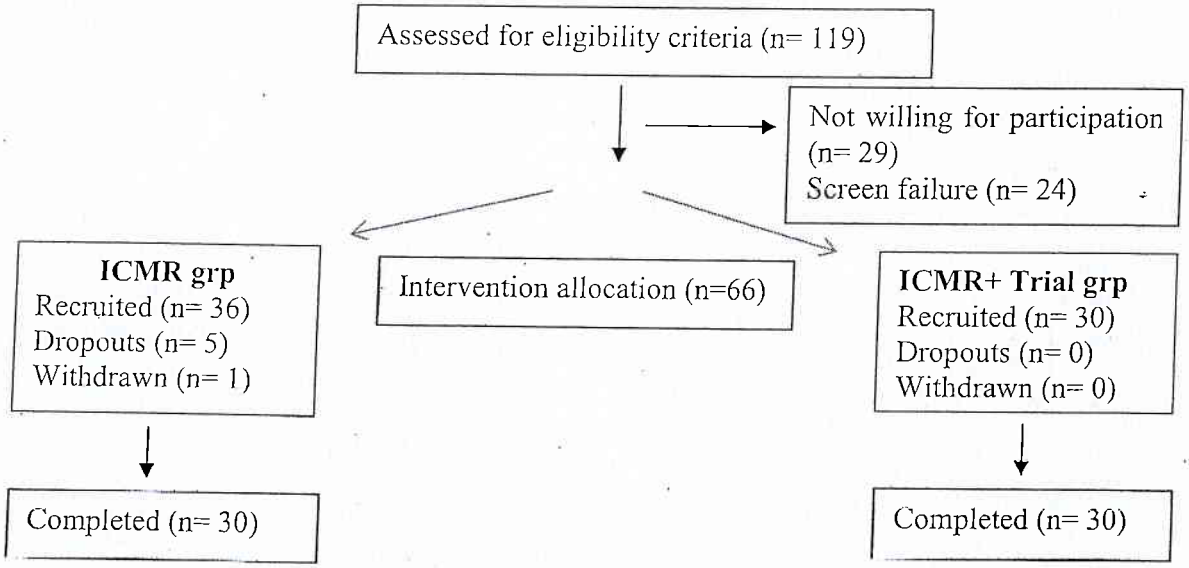
- A total of 13 patients from trial group and 11 patients from ICMR group were hospitalized from day 1 of the treatment due to lack of personal space at home for isolation or to prevent disease progression due to accompanied comorbidities. Hence, the hospitalisation/prolongation of hospital stay was not considered as an AE.

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Statistical analysis:
The parametric data is presented as Mean ± SD and analysed using Unpaired t test while the non-parametric data is presented as Median (Range) and analysed using Mann Whitney test. The categorical data was analysed using Chi square test.

Results:

Participant flow:



Description of losses and exclusions after randomisation

Dropouts:
There was total 5 dropouts in the ICMR group. These patients refused to opt for the post treatment throat swab test (RT-PCR). No drop out was seen in the ICMR + Trial group.

Withdrawal:
There was one withdrawal in the study- in the Group 2 (ICMR group). The individual reportedly had a Rapid antigen positive test report, instead of the mandatory RT- PCR report and so was not eligible to be recruited in the study as per the inclusion criteria.

Recruitment:
The screening of patients began in the month of November2020, and the first recruitment was done thereafter. The last participant was recruited in the month of January 2021.

End of study:
All the recruited patients completed the follow up visits in month of January2021.

Demographic characteristics of the recruited patients:
There was no significant difference in any of the demographic characteristics indicating that both the groups were similar at baseline (Table 1).

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Table 1: Baseline demographic data group wise

Characteristics	ICMR + trial	ICMR
Sex	Males – 17	Males – 19
	Females – 13	Females – 11
Age (years)	44 ± 13	41.83 ± 13.40
BMI (kg/m^2)	25.8 ± 3.74	23.7 ± 2.92
Prakriti	VP- 14 PV – 3 PK - 1 KP - 8 VK - 3 KV – 1	VP- 20 PV – 5 PK - 1 KP - 2 VK – 2
Agni	Manda – 22 Visham – 2 Tikshna – 3 Sama – 3	Manda – 20 Visham – 7 Tikshna – 2 Sama – 1
Koshtha	Mrudu - 8 Madhyam - 18 Krura- 4	Mrudu – 10 Madhyam - 17 Krura – 3
Co-morbid conditions	Hypertension – 2 Diabetes – 1 Hypothyroidism – 2 HTN, DM – 1 HTN, DM, Hypothyroidism - 1	Hypertension 3 Diabetes – 3

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Effect of intervention on vital parameters

There was a gradual decrease in temperature and pulse rate noted in both the groups. The difference between the groups was not significant statistically. There was increase in the oxygen saturation seen in both groups, again the difference was not significant statistically. No difference was seen in any other parameter.

Table 2: Effect of Interventions on vital parameters

Groups	*Vital parameters		
	Day1	**Day7**	**Day14**
	T1	**T7**	**T14**
ICMR+ Trial	99 (97.4-101.30)	98.25 (96.5-99.2)	98.05 (96.4-98.8)
ICMR	99.05 (97.5-100.7)	98.2 (97.3-98.8)	98.1 (96.9-99.8)
	RR1	**RR7**	**RR14**
ICMR+ Trial	19±2	18±1	19±1.3
ICMR	19±1	19±2	19±1.3
	Sp1	**Sp7**	**Sp14**
ICMR+ Trial	96 ± 1.2	97 ± 1	98 ± 0.81
ICMR	96 ± 1.3	97 ± 1	98 ± 1
	P1	**P7**	**P14**
ICMR+ Trial	89 ± 8.7	82 ± 5.6	81 ± 7.8
ICMR	87 ± 6	82 ± 5	80 ± 5.3
	BPs1	**BPs7**	**BPs14**
ICMR+ Trial	123 ± 9.52	122 ± 9.53	121.6 ± 8.27
ICMR	123 ± 10.9	120 ± 8.91	121.1 ± 7.13
	BPd1	**BPd7**	**BPd14**
ICMR+ Trial	81.5 ± 6.82	80.7 ± 7.4	81.07 ± 7.58
ICMR	80 ± 7.43	80.3 ± 8.09	78.07 ± 7.17

*Abbreviations: T- temperature, RR- respiratory rate, Sp- oxygen saturation, P- pulse, BPs- blood pressure systolic, BPd- blood pressure diastolic



Effect of interventions on number of patients with symptoms:

The number of patients suffering from symptoms reduced on day 14 in both the groups compared to day 0. The effect of trial drug was seen more on symptoms of cough and muscle pain compared to ICMR group. (Table 3)

Table3: Effect of interventions on number of patients with symptoms

Groups	*Symptoms		
	Day1	**Day7**	**Day14**
	C1	**C7**	**C14**
ICMR+ Trial	25	19	1
ICMR	24	21	4
	R1	**R7**	**R14**
ICMR+ Trial	14	8	1
ICMR	9	6	0
	ST1	**ST7**	**ST14**
ICMR+ Trial	15	8	1
ICMR	21	12	0
	H1	**H7**	**H14**
ICMR+ Trial	9	3	0
ICMR	13	8	0
	MP1	**MP7**	**MP14**
ICMR+ Trial	24	19	1
ICMR	24	22	4
	B1	**B7**	**B14**
ICMR+ Trial	7	5	0
ICMR	4	4	2
	LT1	**LT7**	**LT14**
ICMR+ Trial	6	5	1
ICMR	7	2	1
	A1	**A7**	**A14**
ICMR+ Trial	7	6	0
ICMR	7	5	0
	D1	**D7**	**D14**
ICMR+ Trial	1	0	0
ICMR	0	0	0

*Abbreviations: C- cough, R- rhinitis, ST – sore throat, H- headache, MP- muscle pain, B- breathlessness, LT- loss of taste, A- anosmia, D- diarrhoea

- As mentioned in the protocol, the severity of symptoms was documented daily. Since there was no much difference in day-to-day severity pattern of the symptoms, the composite symptom score has been calculated on day 1, day 7 and day 14. The same has been mentioned in the Table 5. In addition, the incidence of the symptoms on specific days was also analysed, which has been presented in Table 3.
- The mean and Median time taken for symptomatic relief in the trial group was 12 days in both the groups. It is evident that it was comparable in both groups. At the end of the study, 2 patients from trial group and 5 patients from ICMR group did not show complete symptomatic relief.

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Effect of interventions on biochemical and haematological parameters

Total lymphocyte count was found to be increased in both the groups, which was in normal range. There was no significant difference between the groups. The NL ratio also increased in both groups with no significant difference. The RBC count and corresponding Hb count was seen to be increased in ICMR + Trial group. The platelet count improved in both groups with more increase in ICMR + Trial group. While the ESR increased in ICMR + Trial group, it showed reduction in ICMR group. There was a decrease seen in both fasting and post-prandial sugar levels in both the groups, it was more in ICMR group. In case of PPS, the difference between the groups was statistically significant on day 14. Safety parameters viz. blood urea and creatinine decreased marginally in both groups. CRP levels were found to be increased significantly in ICMR + Trial group as compared to ICMR group.

Table 4: Effect of interventions on biochemical and haematological parameters

Groups	*Biochemical parameters		Reference ranges
	Day1	Day14	
	TL1	TL14	
ICMR+ Trial	6850±3321	7735±1930	4000-10000/cmm
ICMR	6004±1679	7098.3±1735.4	
	NLR1	NLR14	
ICMR+ Trial	1.71 (0.66-19.8)	2.24 (1.03-6.48)	1-3
ICMR	1.89 (0.67-9.96)	2.07 (1.02-8.26)	
	RBC1	RBC14	
ICMR+ Trial	4.73±0.6	4.76±0.52	3.4-4.8 mil/cmm
ICMR	4.7±0.4	4.6±0.41	
	Hb1	Hb14	
ICMR+ Trial	13.6±1.88	13.7±1.93	12.0-15.0 g/dl
ICMR	14±1.8	13±1.7	
	Pl1	Pl14	
ICMR+ Trial	260167±76867	302933±100327	150000-400000/cmm
ICMR	274277±85759.7	298800±86518.2	
	ESR1	ESR14	
ICMR+ Trial	10.5(0-94)	12(4-71)	2-20 mm/hr
ICMR	17 (3-94)	12 (3-45)	
	BSf1	BSf14	
ICMR+ Trial	101.3±29.77	97.4±33.69	<100 mg/dl
ICMR	98±30	92.7±26.2	
	BSpp1	BSpp14	
ICMR+ Trial	116 (80.4-388.7)	112.1 (79.7-319.2)##	<140 mg/dl
ICMR	125.7 (76.4-363.5)	95.8 (55.7-241)	
	BU1	BU14	
ICMR+ Trial	23.6±11.2	19.6±8.27	12.8-42.8 mg/dl
ICMR	23±9	21±6.4	
	C1	C14	
ICMR+ Trial	0.9±0.2	0.84±0.16	0.51-0.95 mg/dl
ICMR	1±0	0.8±0.2	

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	CRP1	CRP14	
ICMR+ Trial	3.5 (1-55.1)	4.3 (1-16.9)#	1-5 mg/l
ICMR	5.2 (1-44)	2.25 (1-40)	

# p<0.05, ### p<0.001 as compared to ICMR group
*Abbreviations: Tl- total leucocytes, NLR- neutrophil lymphocyte ratio, RBC- red blood cells, Hb- haemoglobin, Pl- platelets, ESR- erythrocyte sedimentation rate, BSf- blood sugar fasting, BSpp- blood sugar post prandial, BU- blood urea, C- creatinine, CRP- C- reactive protein.

Effect of interventions on radiological findings &ECG:
Since the patients with mild severity/symptoms were recruited in the study, there were no/minimal changes seen in the X-ray chest at baseline and hence no changes can be observed after treatment.
There were no significant changes observed in the ECG at baseline and at the end of the study.

Effect of interventions on key parameters:
Interestingly, of the 30 patients who completed the study in both groups, 4 patients remained RT-PCR positive in the ICMR group while only 1 patient was positive in the ICMR + Trial group on day 14. Lung fibrosis, a severe complication of COVID 19 was reported in 1 patient from ICMR group while none of the patients from trial group reported any such complications. The composite symptom score decreased gradually in both the groups, with no significant difference between the groups. While 8 patients worsened in ICMR group, only 4 patients worsened in ICMR + Trial group. The requirement of IV medication was more in ICMR + Trial group. However, 1 patient in ICMR group needed plasma therapy. The number of patients requiring O_2 therapy was equal in both the groups. The number of patients without any symptom was more (28) in ICMR + Trial group as compared to ICMR group (25). Lastly, the number of dropouts was more in ICMR group as these patients were afraid to undergo RT PCR test post-treatment. None of the patient in ICMR+ Trial group dropped out for this reason. This may be due to reduction in psychological stress by Ayurvedic medicines given to Trial group.

Table 5: Effect of interventions on key parameters (number of patients)

Parameter	ICMR + Trial	ICMR
RT-PCR positive at day 14	1	4
Complication	0	1
Composite score: Median (Range)		
Day 1	7 (5-10)	7 (4-12)
Day 7	3 (1-7)	3 (1-7)
Day 14	0 (0-3)	0 (0-6)
Worsening from mild to moderate/severe condition	4	8
Requirement of IV medicines	11	7
Requirement of plasma therapy	0	1
Requirement of O2	3	3
No symptoms on day 14	28	25
Dropouts	0	5

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- As mentioned in Table 5, four patients in Trial group and eight patients in ICMR group worsened during the study duration, which means the disease severity was found worsening in these patients. Apart from these patients, there was 1 patient from ICMR group who received plasma therapy on 11th and 13th day. There were 3 patients each from ICMR and trial group who received intermittent O_2 therapy by nasal cannula and mask on 2nd/3rd/ /4th day for 1-3 days, but not a single patient received high flow O_2 therapy. No one shifted to NIV, or no one was critically ill. All these episodes happened during the study
- 11 patients in ICMR group and 7 patients in Trial group were given IV medications. All these medications were given as per discretion of the treating physician. Some of these treatments were given as prophylactic measures to arrest worsening of the disease and hence cannot be considered as indicators of the disease worsening.

- All the recruited patients were mild cases as per the Inclusion criteria. Of these, 11 patients in ICMR group and 7 patients in Trial group were given IV medications. The IV medications were administered as per the treating physician's discretion required for management of comorbidities or prevention of disease progression. Majority of the patients were given antibiotics and steroids at the time of admission.

- The cases in which disease progressed from mild to moderate/severe were also considered for final statistical analysis. Although the withdrawal criteria mentions the point of condition/symptoms worsening, the operational definition for 'worsening' for statistical analysis was considered as 'critically ill patients requiring NIV or further ICU management'.

Effect of interventions on number of patients with other symptoms:

Daurbalya and Kshudhamandya were the 2 major other symptoms observed in both groups. The effect of trial drug was seen more on these symptoms as compared to ICMR group. Details are as follows (Table 6)

Table 6: Effect of interventions on number of patients with other symptoms

Groups	***Other Symptoms**		
	Day1	**Day7**	**Day14**
	D1	**D7**	**D14**
ICMR+ Trial	14	09	02
ICMR	14	09	05
	K1	**K7**	**K14**
ICMR+ Trial	06	02	00
ICMR	09	04	03

*Abbreviations: D- Daurbalya , K- Kshudhamandya

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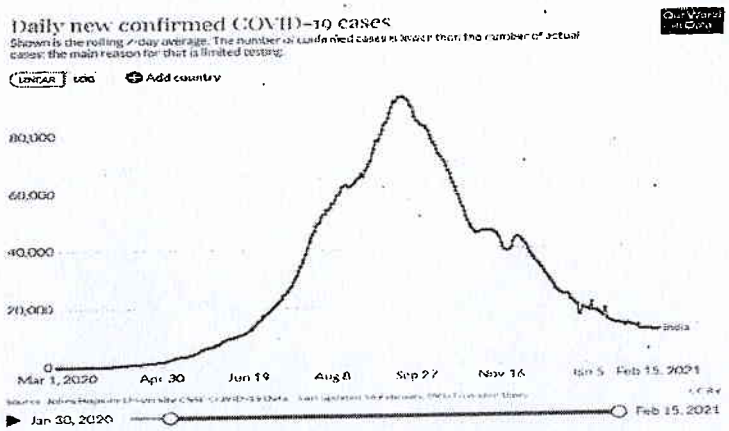
- Number of patients relieved from symptom Daurbalya was found more in Trial group .This may be due to Rasayana effect of Pippali Rasayana [1]and Guduchi .[2]
- Number of patients relieved from symptom Kshudhamandya was also found more in Trial group as compared to ICMR group. This may be due to addition of Deepan ,Pachan,Tikta Katu Ushna dravya like Pippali[3], Shunthi[4], Pushkarmool[5] Guduchi [6],Kantakari[7] as an add on therapy in Trial group.

13. Detailed analysis of results indicating contributions made towards increasing the state of knowledge in the subject.

The present study did not show any major difference between ICMR and ICMR + Trial group in terms of vital parameters as well as haematological and biochemical parameters, ICMR + Trial group performed better in terms of overall disease outcomes (as reflected in key parameters). These findings need to be considered in view of the following facts:

- The first case of COVID- 19 in India was reported on 30th January 2020 following which there was a steady rise in the number of COVID cases. A major lockdown throughout the country was imposed since the third week of March. There was fear in the community due to which people from all walks of the society abided by the norms set up by the Health Ministry. The fear prevalent in the community in March- April was overtaken by the fear of survival due to the dwindling financial situation leading to a change in the psychological mind set.
- The dynamics of the disease has been evolving and changing continually. The management strategies (including ICMR directive) are also changing accordingly.
- The number of COVID 19 cases in India, post the month of September began to drop remarkably (Figure 1).[8]

Figure 1: Monthly record of COVID 19 case distribution between Jan 2020-21



- The ICMR conventional drug regimen is being offered to the patients as per the physician's discretion based on clinical judgement and local guidelines. Hence, the rationale behind the ICMR regimen cannot be explained objectively. This portrays as a challenge in the analysis of the two treatments.

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These facts have affected the study and thereby the results in many ways as mentioned below:

- Difficulty in recruitment of the patients (of 119 screened, 29 patients not willing to participate).
- Change in situation (individual, community and management level) from project application to project completion
- Inclusion of mild cases which get fairly managed by ICMR recommended treatment leaving less scope for Ayurvedic medicines to demonstrate their additional efficacy.

14. Conclusions summarizing the achievements and indication of scope for future work.

- The trial drugs (Pippali Rasayana and Nagaradi Kashaya Ghana Vati) can prove useful as an adjuvant treatment with ICMR directed therapy in Covid -19 positive mildly symptomatic cases specially on crucial indicators of the disease. A standalone study (Ayurvedic treatment vs. ICMR directed therapy) in mild patients or add-on study in moderate patients can be considered in future
- We tried to follow up the all the participants one month after the study period to know post-COVID complications. One patient from ICMR group reported lung fibrosis along with severe tingling and numbness in both the lower limbs. In all 10 patients complained about occasional fatigue. Available data is not enough to analyse the outcomes.

15. Procurement/usage of Equipment: Not applicable

16. Manuscript for Publication (300 words for possible publication in Council's Bulletin).

Not yet started.

17. A summary sheet:

Attached separately



References:

1. P G Nanal (Translator) ,Sarth Bhavaprakash Poorvkhand ,Haritakyadi Varga ,Verse 53,Pune Raghuvanshi Prakashan ,1929:97
2. P G Nanal(Translator) ,Sarth Bhavaprakash Poorvkhand ,Guduchyadi Varga ,Verse 9,Pune Raghuvanshi Prakashan ,1929:125
3. P G Nanal (Translator) ,Sarth Bhavaprakash Poorvkhand ,Haritakyadi Varga ,Verse 53,Pune Raghuvanshi Prakashan ,1929:97
4. P G Nanal(Translator) ,Sarth Bhavaprakash Poorvkhand ,Haritakyadi Varga ,Verse 43-44,Pune Raghuvanshi Prakashan ,1929:97
5. P G Nanal(Translator) ,Sarth Bhavaprakash Poorvkhand ,Haritakyadi Varga ,Verse 163,Pune Raghuvanshi Prakashan ,1929:107
6. P G Nanal(Translator) ,Sarth Bhavaprakash Poorvkhand ,Guduchyadi Varga ,Verse 9,Pune Raghuvanshi Prakashan ,1929:125
7. P G Nanal(Translator) ,Sarth Bhavaprakash Poorvkhand ,Guduchyadi Varga ,Verse 39-40,Pune Raghuvanshi Prakashan ,1929:128
8. The Mystery Behind India's Success in Flattening the Curve available at https://covexit.com/the-mystery-behind-india-success-in-flattening-the-curve/) Last accessed on March 4, 2021.

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Dr. Medha Joshi (Principal Investigator)

Dr.Ragini Patil (Co-.Investigator)-

Vd.Yogita Jamdade(Co-.Investigator)-

Dr.Vinayak Shinde(Co-.Investigator)-

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3.5.1

28. Collaborative activity – Student Exchange

Symbiosis Institute Of Foreign And Indian Languages

Aug 2021 to oct 2021

(100 hours)

Pune District Education Association's
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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Date-26/10/2021

Collaborative Activity Report
Department: Shalakyatantra
[Student Exchange Activity]

Title: Spanish A1 online course.

Date/Duration: Aug 2021 to Oct 2021

Place: online course at symbiosis institute of foreign and indian languages, Pune.

Participants details:PG student- Dr. Shubhangi Avhad.

Brief activity details: Dr. Shubhangi Avhad (PG student) had completed Spanish A1 (with grade- O') online course at symbiosis institute of foreign and Indian languages, Pune on 21/10/2021.

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Nigdi

॥वसुधैव कुटुम्बकम्॥

SIFIL

SYMBIOSIS INSTITUTE OF FOREIGN & INDIAN LANGUAGES

Certificate

This is to certify that Mr./ Ms. Shubhangi Avhad

was a student of the Spanish A1 Online Course.

He / She has passed it with "O" Grade.

Symbiosis Institute of Foreign & Indian Languages wishes the student a bright future.

Place: Pune

Date: 21 October 2021

Institute of Foreign & Indian Languages * Symbiosis * Pune

Seal of the Institute

Prof. Anupam Siddhartha
Director

SIFIL: Gokhale Cross Road, Model Colony, Pune - 411 016
Ph. 020-25662822/2567/431/32. Email - info@sifil.edu.in

Score Sheet

Duration: August, 2021-October, 2021 Clock Hours: 100 Attendance Percentage: 94%

Percentage of Marks: **91%** Grade Secured: **"O"**

Final Exam Written (out of 40)	Final Exam Oral (out of 40)	Internal Tests Average (out of 20)	Marks deducted due to less attendance	Total (out of 100)
37	36	18	0	**91**

Marks	Grade
85 & above	O
81 to 84	A+
76 to 80	A
71 to 75	B+
66 to 70	B
60 to 65	C
Below 60	Fail

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3.5.1

29. Collaborative activity – Student Exchange with Dvjei Netralaya Jotapur Jabalpur

13/09/2021 to 03/10/2021

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Date-06/10/2021

Collaborative Activity Report
Department: Shalakyatantra
[student Exchange Activity]

Title: Training fellowship in SICS

Date/Duration: 13/09/2021 to 03/10/2021

Place: Dvjei Netralaya Jotpur,Jabalpur

Participants details: PG student- Dr Chandanshive Rujuta

Brief activity details: Dr Chandanshive Rujuta had completed Training fellowship in SICS at Dvjei Netralaya Jotpur,Jabalpur from 13/09/2021 to 03/10/2021.

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Dept of Shalakya Tantra
College of Ayurved & Research Centre
Nigdi

Medical Director of

Ref. No. 2021-21

DADA VIRENDRAPURI JI EYE INSTITUTE

DVJEI NETRALAYA, JOTPUR, JABALPUR

Congratulates

DR. RUJUTA CHANDANSHIVE.

For successfully completing Training Fellowship in

SMALL INCISION CATARACT SURGERY (SICS)

From 13/09/2021 *to* 03/10/2021

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Principal
College of Ayurved And Research Centre
Akurdi, Pune - 411 044

Dr. Pawan Sthapak
Founder & Chairman

Dr. Ayush Tandon
Director Academic

Dr. Arpita Sthapak
Medical Superintendent & Course Coordinator

Pune District Education Association's
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3.5.1

30. Collaborative activity – Student Exchange with Dvjei Netralaya Jotapur Jabalpur

05/10/2021 to 21/10/2021

Pune District Education Association's
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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Date-26/102021

Collaborative Activity Report
Department: Shalakyatantra
[Student Exchange Activity]

Title: Training fellowship in Phaco Emulsification.

Date/Duration: 05/10/2021 to 21/10/2021

Place: Dvjei Netralaya Jotpur,Jabalpur.

Participants details:PG student- Dr Chandanshive Rujuta.

Brief activity details: Dr Chandanshive Rujuta had completed Training fellowship in Phaco Emulsification at Dvjei Netralaya Jotpur,Jabalpur from 05/10/2021 to 21/10/2021.

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Dept of Shalakya Tantra
College of Ayurved & Research Centre
Nigdi

Ref. No. 2021-22

Medical Director of

DADA VIRENDRAPURI JI EYE INSTITUTE



DVJEI NETRALAYA, JOTPUR, JABALPUR

Congratulates

DR. RUJUTA CHANDANSHIVE

For successfully completing Training Fellowship in

PHACO EMULSIFICATION SURGERY

From 05/10/2021 *to* 21/10/2021

TRUE COPY

Principal
College of Ayurved And Research Centre
Akurdi, Pune - 411 044

Dr. Pawan Sthapak
Founder & Chairman

Dr. Ayush Tandon
Director Academic

Dr. Arpita Sthapak
Medical Superintendent & Course Coordinator

Pune District Education Association's
College of Ayurved & Research Centre
(I.D.No. P.U./P.N./AYU./081/1990)
Sector No. 25, Pradhikaran, Nigdi, Pune-411 044 (Maharashtra State), India.
Phone - 020 - 27653965 / 27659578, Fax :- 020 - 27659578, Website - www.pdeaayurvedcollege.edu.in
E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

31. Collaborative activity – Teacher Exchange RAV Dept of Ayush 14/12/2021

Dat16/12/2021

Report of **Resource Person for CME at Nashik.**

Activity: Resource Person for CME For Teachers in Rachana Sharir Sponsered by Ministry of AYUSH Govt. of India at ASS's Ayurved Mahavidyalaya, Nashik.

Place: Auditorium of ASS Ayurved Mahavidyalaya, Nashik.

Participants: Teachers of Rachana Sharir From all over India, Total -30

Speaker: Dr. Prashant B. Tople

Professor & HOD Rachana Sharir

College of Ayurved & Research Center, Nigdi,Pune.

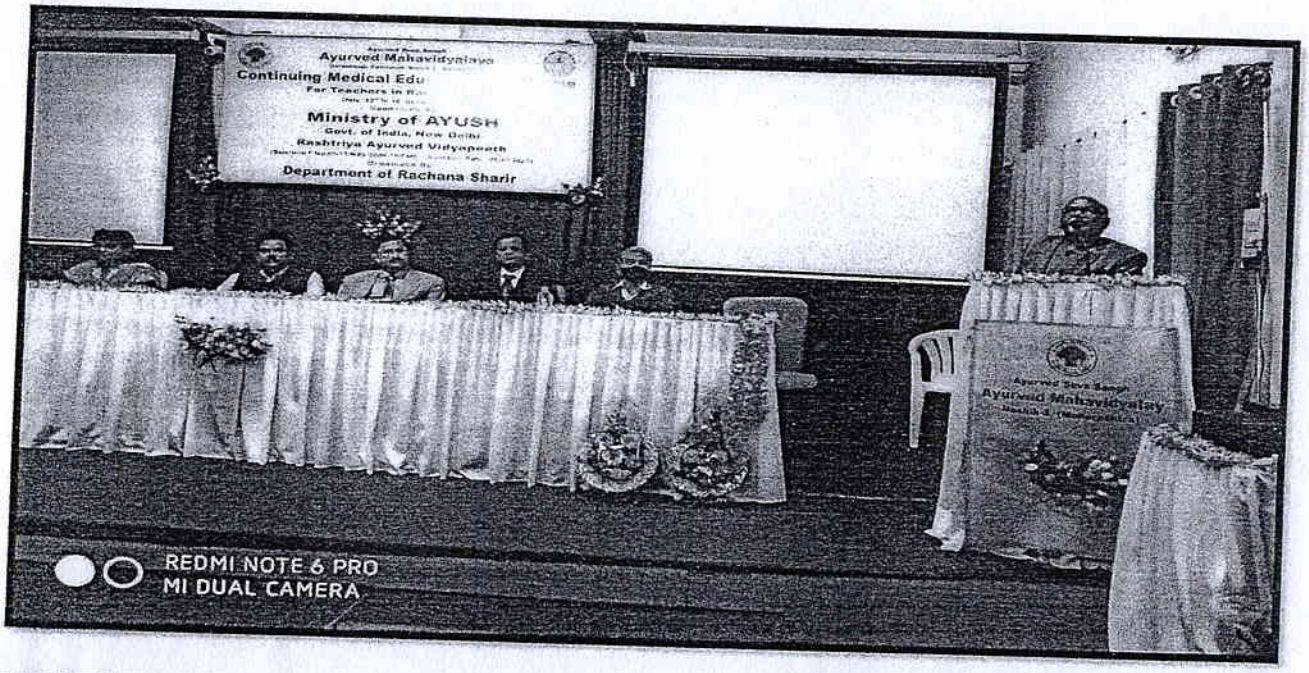
Date: 14/12/2021 Time: 2 pm.to 5 pm.

Organized by: ASS's Ayurved Mahavidyalaya, Nashik.CME For Teachers in Rachana Sharir Sponsered by Ministry of AYUSH Govt. Of India

Topic: 1) Concept of Sankhya Sharir 2) Sandigdha Sharir Paribhasha

पु.जि.शि.मं.चे
आयुर्वेद महाविद्यालय व संशोधन केंद्र
निगडी, पुणे-४११०४४.
आवक क्र 2577/2021-22
दिनांक - 6/12/2021
लेखनिक
प्राचार्य

Photos of **Resource Person for CME at Nashik.**





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Principal
College of Ayurved And Research Centre
Akurdi, Pune - 411 044

Principal
P.D.E.A'S
College of Ayurved And Research Centre
Nigdi, Pune - 411 044.

Name of the Department Rachana Sharir. NAAC Metric No.3.5.1

Ayurved Seva Sangh

AYURVED MAHAVIDYALAY

Ganeshwadi, Panchvati, Nashik 422003 (Maharashtra)

Continuing Medical Education Programme For Teachers in Rachana Sharir

Sponsored by

Ministry of AYUSH, Govt. of India

Rashtriya Ayurved Vidyapeeth

(Sanction F.No. 65-13/RAV/2009-10/CME Sanction Date - 05/07/2021)

Organized By

Department of Rachana Sharir

Certificate of Participation

This is to certify that Dr. Tople . Prashant . Bhaskar. has participated as a Resource Person in Continuing Medical Education Programme for Teachers in Rachana Sharir held at Ayurved Seva Sangh's Ayurved Mahavidyalaya, Nashik **From 13th to 18th December 2021.**

Organising Secretary

P.D.E.A.S. COLLEGE OF AYURVED AKURDI PUNE - 44

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Principal

College of Ayurved and Research Center

Akurdi, Pune - 411 044

Principal
Ayurved Mahavidyalaya
Nashik

B.S.1

Pune District Education Association's
College of Ayurved & Research Centre
(I.D.No. P.U./P.N./AYU./081/1990)
Sector No. 25, Pradhikaran, Nigdi, Pune-411 044 (Maharashtra State), India.
Phone - 020 - 27653965 / 27659578, Fax :- 020 - 27659578, Website - www.pdeaayurvedcollege.edu.in
E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

32. Collaborative activity – Student Exchange

Punarvasu Aushadhshala PVT.LTD.

03/01/2022 to 02/02/2022

Pune District Education Association's
College of Ayurved & Research Centre
(I.D.No. P.U./P.N./AYU./081/1990)
Sector No. 25, Pradhikaran, Nigdi, Pune-411 044 (Maharashtra State), India.
Phone - 020 - 27653965 / 27659578, Fax :- 020 - 27659578, Website - www.pdeaayurvedcollege.edu.in
E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Date-7/2/2022

POST EVENT SUMMARY REPORT

Name of the collaborative activity

Industrial training at Punarvasu Aushdhashala Pvt. Ltd, Shivane,Pune.

Date/ Duration

3/1/2022 to 2/2/2022

Place: Punarvasu Aushdhashala Pvt. Ltd, Shivane,Pune.

Participants Details: Final Year PG Students - 03

Organising department/ committee- Rasashastra evam Bhaishajya Kalpana

Brief Activity Details:

- Standardization of ASU drugs
- Standardization of Raw materials, manufacturing process and finished products for ASU drugs
- Preparation of Kaishor Guggulu, Triphala Guggulu, Arogyawardhini vati,Chandraprabhavati and Laghusutshekhar.
- Shodhan of different Rasadravyas like Hartala,Gandhak and Vanga.
- Preparation of various Kupipakwas like Suvarnaraj vangeshwar and Rasmanikya
- Hands on training of Quality control measures for different formulations.

P.D.E.A.'S College Of Ayurved And Research Centre NIGDI PUNE - 44

HOD
Department of Rasashastra
Bhaishajya Kalpana
College of Ayurved & Research
Centre, Akurdi Pune 44

Punarvasu Aushadhshala Pvt. Ltd.

Works : S. No. 78/1/1, Shiv Kamal Industrial Area, Shed No. 11, Shivane, Pune - 411023.
Regd. Address : 2D+E, Shail-neel Co-op. Society, 13 Rambag Colony, Paud Rd., Pune - 411 038.
Ph.: 020 2529 0116.Email : punarvasuaushadhshala@gmail.com

Date : / / 20

Date: 02/02/2022

CERTIFICATE OF ATTENDANCE / VISIT

This is to certify that

Dr.Miss SHEETAL DHOBALE

Who is student of AYURVED MAHAVIDYALAYA AND SANSHODHAN KENDRA, AKURDI

have attended our Aushadhshala

Fom 03/01/2022 TO 02/02/2022

We had a thorough discussion on various topics related with Rasa aushadhi preparations.

She also seen various preparations and its management

I wish her all the best in future.

Vd. Vivek D. Sane,

PUNARVASU AUSHADHSHALA PVT. LTD.
S.No. 78/1, Shiv-Kamal Industrial Estate,
Shed No. 11, Shivane, Pune - 411 023.

Director,

Punrvasu Aushadhshala Pvt. Ltd. Pune

P.D.E.A.S. COLLEGE OF AYURVEDIC RESEARCH AKURDI PUNE - 44

TRUE COPY

Principal
College of Ayurved And Research Centre
Akurdi

Punarvasu Aushadhshala Pvt. Ltd.

Works : S. No. 78/1/1, Shiv Kamal Industrial Area, Shed No. 11, Shivane, Pune - 411023.
Regd. Address : 2D+E, Shail-neel Co-op. Society, 13 Rambag Colony, Paud Rd., Pune - 411 038.
Ph.: 020 2529 0116.Email : punarvasuaushadhshala@gmail.com

Date : / / 20

Date: 02/02/2022

CERTIFICATE OF ATTENDANCE / VISIT

This is to certify that

Dr.Miss VEDANTI GULHANE

Who is student of AYURVED MAHAVIDYALAYA AND SANSHODHAN KENDRA, AKURDI

have attended our Aushadhshala

Fom 03/01/2022 TO 02/02/2022

We had a thorough discussion on various topics related with Rasa aushadhi preparations.

She also seen various preparations and its management

I wish her all the best in future.

Vd. Vivek D. Sane,

PUNARVASU AUSHADHSHALA PVT. LTD.
S.No. 78/1, Shiv-Kamal Industrial Estate,
Shed No. 11, Shivane, Pune - 411 023.

Director,

Punrvasu Aushadhshala Pvt. Ltd. Pune

P.E.S.'S COLLEGE OF AYURVEDIC RESEARCH AKURDI PUNE - 44

TRUE COPY

Principal
College of Ayurved And Research Center
Akurdi, Pune - 411 044

Pune District Education Association's
College of Ayurved & Research Centre
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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

33. Collaborative activity – Faculty Exchange SSAM, Hadapsar 24/03/2022

Pune District Education Association's

College of Ayurved & Research Centre

Report of IRBR 24/03/2022

Institutional review board for research (IRBR) of MAM's Sumatibhai Shah Ayurved Mahavidyalaya, Hadapsar on 24/03/2022 from 10 am -5.20 pm as research expert was attended. Total 10 members were present

Total research twenty Ph.D projects were discussed & different suggestions were given. After fulfilling the suggestions topics will be approved by committee.

One pharma trial protocol hard copy circulated in all members

Prof. Dr. Yogini Kulkarni



P.D.E.A.'S College of Ayurved And Research Centre Akurdi Pune-44

INSTITUTIONAL ETHICS COMMITTEE
Maharashtra Arogya Mandal's,
Sumatibhai Shah Ayurved Mahavidyalaya & Ayurved Hospital - Sane Guruji Arogya Kendra
Malwadi, Hadapsar, Pune - 411 028.
(An ISO 9001 :2015 Certified Mahavidyalaya)
Phone : (020) 29522505 / 29522506, E-mail : ssayu@rediffmail.com

MAM/SS Ayu/778 Date :- 10/03/2022

To

Dr. Yogini Kulkarni,
Member,
Institutional Ethics Committee

Sub :- **Regarding IEC Meeting scheduled on 24th March 2022.**

Respected Madam,

You are esteemed member of MAM'S Sumatibhai Shah Ayurved Mahavidyalaya Institutional Ethics Committee. The role of IEC has a broad scope as it examines and reviews P.G., Ph.D Synopsis and Clinical Trial Projects being undertaken at hospital.

With respect to above Subject I would like to invite you for 33rd IEC Meeting on 24th March 2022 at 10 a.m. to 4 p.m. Venue for the meeting will be Conference Hall no 7, First Floor, Sumatibhai Shah Ayurved Mahavidyalaya, Hadapsar,Pune.

Agenda will be as follows :-

1. **Welcome of all IEC members by Member Secretary.**
2. **Review and discussion on Ph.D Synopsis of all 04 Ayurved Specialties for approval.**
3. **Any other Subject with the permission of chair.**

We are sending here with 20 copies of title & synopsis of 17 Ph.D students & 03 faculties. Please give your valuable suggestions & bring the copies while coming for the meeting.

Thanking you,

Sincerely Yours,

(Dr. Vandana A. Avhad)
Member Secretary
Institutional Ethics Committee
MAM'S SSAM Hadapsar, Pune

Maharashtra Arogya Mandal's
SUMATIBHAI SHAH AYURVEDMAHAVIDYALAYA,
Malwadi, Hadapsar, Pune - 411 028.
Phone : (020)-29522505,29522506
Web : www.ssayurved.org, E-mail : ssayu@rediffmail.com, ssayucollege@mam.org.in

MAM/SS Ayu/818 Date : 24/03/2022

To,

Dr. Yogini Kulkarni,
Member,
Institutional Ethics Committee

Respected Madam,

We are very thankful to you for review of title & synopsis of our Ph.D students. We look forward for your valuable guidance for the betterment & excellence of Ph.D research programme as well as many other research activities of staffs and students.

Thanking you,

Yours faithfully,

(Dr. Nilesh Phule)
Principal

Principal
M. A. M's. Sumatibhai Shah
Ayurved Mahavidyalaya,
Hadapsar, Pune- 411 028.

Pune District Education Association's
College of Ayurved & Research Centre
(I.D.No. P.U./P.N./AYU./081/1990)
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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

34. Collaborative activity – Faculty Exchange

BVDU's Ayurveda College, Katraj, Pune

20/05/2022

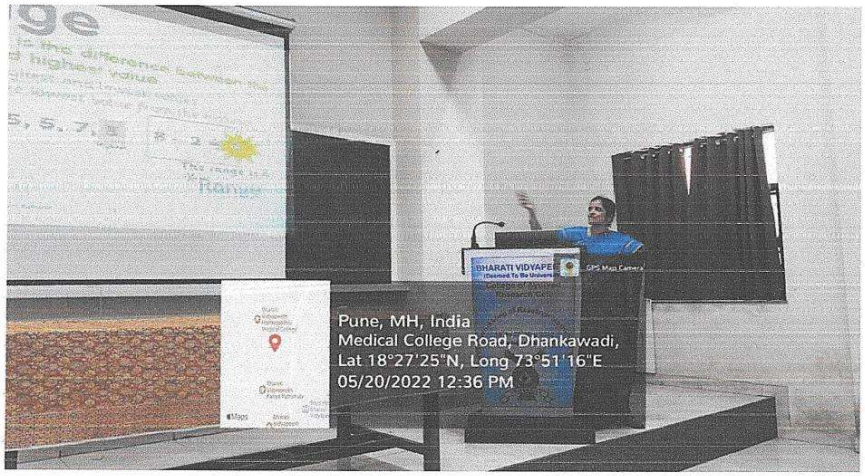
Pune District Education Association's

College of Ayurved& Research Centre

ODL REPORT FOR 20/05/2022

Basic workshop organized at BVDU Ayurveda College Katraj, Pune from 18May 2022-20May 2022. They have invited me as guest speaker for 3rd day for teachers. 28 delegates were registered from BVDU Ayurveda college, Katraj, Pune Total 35 delegates present for my sessions Timings11.15 am -12.30pm
Lecture delivered with group activity on Descriptive Statistics

Dr Yogini Kulkarni



COLLEGE OF AYURVEDIC RESEARCH AKURDI PUNE-44

Name of the Department - Research	NAAC Metric No. 3.5.1

Pune District Education Association's

College of Ayurved& Research Centre

Bharati Vidyapeeth
(Deemed to be University)
Pune, India.
Founder Chancellor : Dr. Patangrao Kadam
COLLEGE OF AYURVED, PUNE
★ Accredited with 'A+' Grade (2017) by NAAC ★
★ Category-I University Status by UGC ★
★ NIRF Ranking - 68 ★
"Social Transformation Through Dynamic Education"

Prof. Dr. Shivajirao Kadam
M.Sc., Ph.D
Chancellor
Prof. Dr. M. M. Salunkhe
M.Sc., Ph.D., F.R.S.C.
Vice Chancellor

Celebrating and Beyond
Dr. Vishwajeet Kadam
B.Tech., M.B.A., Ph.D.
Pro Vice Chancellor
Dr. Abhijit B. Patil
B.A.M.S., D.T.F.M., Ph.D.
Principal

Ref. No. : BVDU / COA / /

Date : 12/05/2022

To,
Dr. Yogini Kulkarni
PG Director & HOD, Research
PDEA'S College of Ayurved & Research Centre,
Akurdi, Nigdi.

Subject:-Invitation as a Resource person for **Basic Workshop of Research Methodology** 18th May -20th May 2022.

Dear Madam,

With reference to the telephonic discussion with you, we invite you for the **Basic Workshop of Research Methodology** at Bharati Vidyapeeth (Deemed to be University) College of Ayurved, Pune-411043. We request you to kindly accept our invitation as resource person and share your knowledge.

The details are as follows:-

Date – 20/05/2022

Lecture-1

Time-11:30am – 12-15pm

Topic- Descriptive Statistics

We would be happy to take care of local hospitality.

With kind regards,

PRINCIPAL

[See UGC gMTF]

COLLEGE OF AYURVEDIC RESEARCH AKURDI PUNE - 44

Name of the Department - Research	NAAC Metric No. 3.5.1

Pune District Education Association's

College of Ayurved& Research Centre

Bharati Vidyapeeth

(Deemed to be University)

Pune, India.

Founder Chancellor : Dr. Patangrao Kadam

COLLEGE OF AYURVED, PUNE

★ Accredited with 'A+' Grade (2017) by NAAC ★

★ Category-I University Status by UGC ★

★ NIRF Ranking - 68 ★

"Social Transformation Through Dynamic Education"

Celebrating and Beyond

Prof. Dr. Shivajirao Kadam
M.Sc., Ph.D.
Chancellor

Prof. Dr. M. M. Salunkhe
M.Sc., Ph.D., F.R.S.C.
Vice Chancellor

Dr. Vishwajeet Kadam
B.Tech., M.B.A., Ph.D.
Pro Vice Chancellor

Dr. Abhijit B. Patil
B.A.M.S., D.T.F.M., Ph.D.
Principal

Ref. No. : BVDU / COA / 288 / 22-23

Date : 13/05/2022

ATTENDENCE CERTIFICATE

This is to certify that **Dr. Yogini Kulkarni** has attended **Basic Workshop of Research Methodology** on **Friday, 20.05.2022** to deliver the designated lectures.

Centre of Workshop: Bharati Vidyapeeth (Deemed to be University)
College of Ayurved,
Pune-Satara Road
Pune – 411 043.

Principal

COLLEGE OF AYURVED RESEARCH AKURDI PUNE-44

Name of the Department - Research	NAAC Metric No. 3.5.1

Pune District Education Association's
College of Ayurved & Research Centre
(I.D.No. P.U./P.N./AYU./081/1990)
Sector No. 25, Pradhikaran, Nigdi, Pune-411 044 (Maharashtra State), India.
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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

35. Collaborative Research Workshop –with MUHS Nashik

13/06/2022 to 15/06/2022

Report of Research Methodology workshop

13th -15th Jun 2022

The workshop on Research methodology was organized by our institute on 13th -15th Jun 2022at P.D.E.A's College of Ayurved and Research Centre Nigdi Pune 44. As per M.U.H.S./MET guidelines the sessions were organised for three days from morning 09.30- 17.00.

The thirty delegated were registered&attended the workshop. The detailed list is attached with the report.

Sr. no	College name	Number of delegates attended
1	**P.D.E.A'S COLLEGE OF AYURVED AND RESEARCH CENTRE NIGDI PUNE 44**	30

Eight faculty members were invited as resource person for workshop. Dr.Suvarna Joshi madam from B. J. Medical college Pune, Myself from our college Pune; Dr.Pranita Joshi from SSAM HadapsarPune;Col. S. L. Jadhav from D. Y. Patil Medical college Pimpri Pune; Dr.Namrata Jain Statistician from our college nigdi; Dr.Shrikath Muralidharan from National institute of Naturopathy pune;Adv.Dr.DhananjayMhasade from Pune; Dr.MadhavMutalik from D.Y. Patil Dental school Charoli ; Previously the instruction was given to students that bring your synopsis titles and problems regarding synopsis so,the workshop became more interactive and fruitful to them. For group activity heterogeneous groups were performed. Pre MCQ test was taken for 30 marks. Dr.Rujuta Korday from swasthvrutta department by 21 marks rank 1st in pre-test & Dr.Krushna Jamadar from Rasashastra department by 19 marks rank 2nd in pre-test &Dr.Supriya Pundage from Agadatantra department by 18 marks rank 3rd in pre-test.

Before starting the inaugural sessiononline Pre-test was conducted twenty minutes were given to complete. The responses were collected through goggle form. The workshop was started with Dhanwantari poojan and stawan. The first day session was started sharp at 09.30- 10.00 bylecturetaken by Dr.SuvarnaJoshi madam from B. J. Medical college Pune on the topic "Introduction to research methodology and formulation of RQ and Hypothesis. Next session were taken onobservational study designs descriptive and analytical. After analytical study design tea break was given, then session was continued on experimental study design up to 1 pm by myself .The post lunch session was startedon 1.30 pm. with group activity taken by Dr.Suvarna Joshi and myself. Five groups were prepared each group with 6 members and five problems were given. The details as follows-

Group no.	Topics given for study design group activity	Instructed to formulate as per following points
1	Cross sectional study to evaluate Aaharaj Abhiruchi in Pitta pradan prakruti- Dr. Shrinath Agnihotri	1) Formulate the title 2) Research question with FINER& Hypothesis if necessary 3) Aims and objectives of the study 4) Independent and dependent variable 5) objectives
2	A case control study to evaluate preserved food exposure in healthy and not healthy persons as the causative factor Dr. RujutaKorday	
3	Experimental study to evaluate the efficacy of Tila navaneeta lepa in Bhallataka induced toxicity on albino rats Dr.Supriya Pundge	
4	Randomized controlled clinical Study to evaluate adjuvant effect of Varunadi kwath	



	compared with thyroxin in Hypothyrodism – DrAnkushPatle	
5	Randomized controlled clinical study to compare the efficacy of dadim swarasa with conventional treatment in Raktarsha by Dr Rimaa Anklekar	

Next lecture was takenon literature search with online demo by Dr.Pranita Joshi sir from SSAM college Hadapsar completed on 5.00 First day ended at 06.00 p.m.by lecture on qualitative research by Dr Pranita Joshi.1st days feedback link was shared on their personal mails and Collected the responses on goggle form.

The second day was started with Dhanwantari Poojan and Stawan followed by lecture on 9.30am-11.30 am.Sampling & sample size with group activity on software Win Pepi software byDr.S. L. Jadhav from D. Y. Patil medical college Pune. Next session taken by Mrs.Namrata Jain on"Types of data and presentation of data" The activity was taken on identification of data types by MCQ. The session ends at 12.45 am. Then lunch break was given

After the lunch break the sessions were started on inferential statistics by Dr.Shrikanth Muralidharan faculty of RMW workshop. The group activity was taken on selecting the appropriate test for given problems to each table. The session was ended on 3.30 pm. For next session every delegate was requested to download EPI info 7on their laptops and one excel data file was shared with delegates so that the "computer assistance in data analysis on Excel, epiinfo"with Demo was completed up to 5 pm . 2nd days feedback link was shared on their personal mails and collected the responses on goggle form.

The third day was started with DhanwantariPoojan and Stawan followed by lecturedelivered myself onprotocol writing with group activity ended at 12 noon. The group activity wastaken for each and every content of protocol starting from title to references.After that lecture was taken on ethics in medical research byDr.DhananjayMhasade and group activity wastaken by on given topics as follows

Group no.	Protocol and Ethical issues on following topics	Presenter from the group
1	Cross sectional study to evaluate Aaharaj Abhiruchi in Pitta pradan prakruti -	Dr. Shrinath Agnihotri
2	A case control study to evaluate preserved food exposure in healthy and not healthy persons as the causative factor	Dr. RujutaKorday
3	Experimental study to evaluate the efficacy of Tila navaneeta lepa in Bhallataka induced toxicity on albino rats	Dr.supriyapundge
4	Randomized controlled clinical Study to evaluate adjuvant effect of Varunadi kwath compared with thyroxin in Hypothyrdism –	Dr. Ankush Patle
5	Randomized controlled clinical study to compare the efficacy of dadim swarasa with conventional treatment in Raktarsha	Dr Rimaa Anklekar



The session ends at 13.00pm. After lunch Dr. Madhav Mutalik from D.Y. Patil dental school had taken session on diagnostic test completed on 13.45pm.Next session was taken by Dr.Madhav Mutalik on questionnaire designing completed session 3.30 pm. Sir had taken very interactive and informative lecture. Next session was started on 3.30 pm oncritical journal article evaluation ended on 5 pm by group activity. Article was shared to every delegate and also checklist also shared for evaluation before one day of session so that everyone can read the article for critical evaluation.

Post workshop evaluation MCQ test was taken. Three best improved delegateswere declaredand felicitated with Pen set, first topper Dr. Supriya Pundage from Agadtantra department I by 26marks, second topperfromDr. Krushna Jamadar from Rasashastra department by 24marks and third toppers Dr. Rasika Kulkarni fromSharir kriya department by22marks of our college. Study material given in soft copy to all delegates. After felicitation delegates. The valedictory function ended with vote of thanks& Pasaydan by me.

The daily evaluation and whole program evaluation sheets were filled by delegates. The analysis of program evaluation is given asfollows-

Some comments given by delegates are as follows-

1) Workshop duration should be increased.
2) Workshop is fruitful especially with group activities
3) Time management and organization of workshop is very good
4) Majority of delegates very much satisfied with group activities.
5) The continuous lectures should not be kept, 5 minutes rest should be given after each session.
6) Dr. S. L. Jadhav, Mrs. NamrataJain ;Dr. ShrikanthMuralidharan; Dr. MadhavMutalik& Dr. Yogini Kulkarni are the best faculty members mentioned by all most all delegates.

1st days feedback analysis -

DrSuvarnajoshi A	107
B	107
C	107
Dr. Yogini Kulkarni D	107
Dr. Yogini &Dr. Suvarna GA E	108
Dr. Pranita Joshi F	105
G	104

2nd days feedback analysis –

Dr. S L. Jadhav A	112
B	110
Mrs Namrata jain C	111
Dr. Shrikanth Muralidharan D	111
E	112
F	108



3rd days feedback analysis –

Dr dhananjay mhasade A	107
B	107
Dr. Yogini Kulkarni C	109
D	108
Dr. Madhav Mutalik E	108
F	109
G	108

Important suggestions by coordinator as –

1) Group activities are more effective in well-equipped digital lab of computers.
2) Online attendance of delegates is more time taking so should be continued with previous method
3) If the organized college delegates only allowed by MUHS MET cell then such instructions should circulated to all medical colleges because more phone calls to coordinator form other college students

The activity started by M.U.H.S. and MET is really very much necessary and useful for up-gradation of knowledge of Research techniques to post graduate students and teachers.Thanking you,

Dr. Yogini R. Kulkarni (Coordinator)

Principal
P.D.E.A'S
College of Ayurved And Research Centre
Nigdi, Pune - 411 044

H. O. D.
Research Methodology
College of Ayurved And Research Centre
Akurdi, Pune - 411 044

P.D.E.A.'S College Of Ayurved And Research Centre
AKURDI
PUNE - 44.

Pune District Education Association's

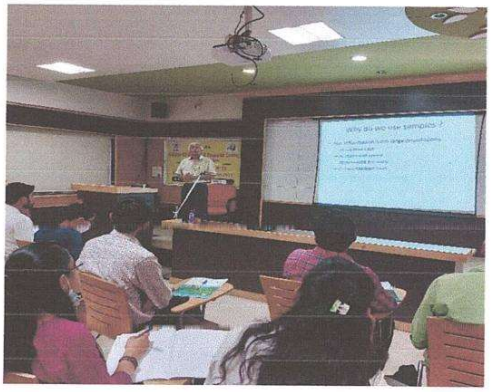
College of Ayurved & Research Centre

Research Methodology Workshop – 13th June to 15th June 2022













P.D.E.A's College Of Ayurved And Research Centre AKURDI PUNE - 44.

Principal
P.D.E.A'S
College of Ayurved And Research Centre
Nigdi, Pune - 411 044.

Pune District Education Association's
College of Ayurved & Research Centre
(I.D.No. P.U./P.N./AYU./081/1990)
Sector No. 25, Pradhikaran, Nigdi, Pune-411 044 (Maharashtra State), India.
Phone - 020 - 27653965 / 27659578, Fax :- 020 - 27659578, Website - www.pdeaayurvedcollege.edu.in
E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

36. Collaborative Workshop – with MUHS Nashik

27/06/2022 to 29/06/2022

Report of Research Methodology workshop

27th -29th June 2022

The workshop on Research methodology was organized online by our institute on 27th -29th June 2022at P.D.E.A's College of Ayurved and Research CentreNigdi Pune 44. As per M.U.H.S./MET guidelines the sessions were organised for three days from morning 09.30- 17.00.

The Forty three delegated were registered&attended the workshop.Thirty seven PG students of 1st year and 6 teachers of our college were participated in this workshop. The detailed list is attached with the report.

Sr. no	College name	Number of delegates attended
1	**P.D.E.A'S COLLEGE OF AYURVED AND RESEARCH CENTRE NIGDI PUNE 44- 1ST YEAR PG STUDENTS**	37
2	**P.D.E.A'S COLLEGE OF AYURVED AND RESEARCH CENTRE NIGDI PUNE 44- TEACHERS**	06
	Total	43

Seven faculty members were invited as resource person foronline workshop. Dr.Suvarna Joshi madam from B. J. Medical college Pune, Myself from our college Pune; Dr.Pranita Joshi from SSAM HadapsarPune;Col. S. L. Jadhav from D. Y. Patil Medical college Pimpri pune; Dr.Namrata Jain Statistician from our college nigdi; Dr.Hrishikesh Rangnekar from QUEST clinical solutions Pune; Dr.Madhav Mutalik from D.Y. Patil Dental school Charoli; Previously the instructions were mailed to each and every participantsso,the workshop became more interactive and fruitful to them. For group activity heterogeneous 7 groups were performed. Pre MCQ test was taken for 30marks.on goggle form. Dr.Jitendra Tapswi from teacher from Dravyaguna department by21 marks rank 1st in pre-test &Dr.Jayant Shinde PG student From Balaroga department by 18marks rank 2nd in pre-test & Dr.Nikita Kurai PG student from Rasashastra department by 16 marks rank 3rd in pre-test.

Before starting the inaugural sessiononline Pre-test was conductedtwenty minutes were given to complete. The responses were collected through goggle form. The workshop was started with Dhanwantari stawan. The first day zoom link was shared with delegates for online session was started sharp at 09.30- 10.00 bylecturetaken by me on the topic "Introduction to research methodology and formulation of RQ and Hypothesis. Next session were taken onobservational study designs descriptive and analytical. After analytical study design tea break was given, then session was continued on experimental study design up to 1 pm by Dr. Hrishikesh Rangnekar from QUEST clinical solutions.

The post lunch session was startedon 1.30 pm. Lecture was taken on literature search with online demo by Dr.Pranita Joshi sir from SSAM college Hadapsar. Next session on qualitative research was completed by Dr Pranita Joshi at 3.30 pm.

After the sessionsfirst group activity was rescheduled and taken by me. Seven groups were prepared each group with 6 members and seven problems were given. After discussion one of the members from each group presented the activity, the suggestions were given to improve the activity allotted. The details as follows-

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Group no.	Topics given for study design group activity	Instructed to formulate as per following points
1	Cross sectional study to assess Bala in Medovruddhi individuals having age 17-30 years by using fatigue index - Dr. SanketChatar	1) Formulate the title 2) Research question with FINER& Hypothesis if necessary 3) Aims and objectives of the study 4) Independent and dependent variable 5) objectives
2	An Observational study to find the relation between chinta &Rasavaha sortas dushti in Health care professionals Dr. MinakshiNagpure	
3	Pharmaceutico-Analytical study of NimbadiGhrita – Dr. Nikita Kurai	
4	Comparative clinical Study to compare the effect of DrakshaKwath and Badar Kwath as Virechanopaga yoga – Dr.Shubhangi Maske	
5	Randomized controlled open labelled clinical study to evaluate the efficacy of Vatari Guggulu with Agnikarma in Grudhrasi (Sciatica) Dr. Harsh Naikawdi	
6	A Randomised standard controlled clinical study to assess the efficacy of AgaruKarnaDhoopan in PutikarnaDr.PrajaktaMetkari	
7	Case control study to evaluate cause and effect relationship between Mrudbhakshan (Soil eating) and Pandu in school going children between age group 8-12 years	

1st days feedback link was shared on their personal mails andcollected the responses on goggle form.

The second day was started with Dhanwantari Stawan followed by lecture on 9.30am-10.30 am on "Types of data and presentation of data" by me. The activity was taken on identification of data types by MCQ.Sampling & sample size with group activity on software Win Pepi software by Mrs.Namrata Jain from our college. The session ends at 1 pm. Then lunch break was given

After the lunch break the sessions were started on inferential statistics byCol. S. L. Jadhav from D. Y. Patil Medical College Pimpripune. The group activity was taken on selecting the appropriate test for given problems to each table. The session was ended on 3.30 pm. For next session every delegate was requested to download EPI info 7on their laptops and one excel data file was shared with delegates so that the "computer assistance in data analysis on Excel,epiinfo"with Demo was completed up to 5 pm. 2nd days feedback link was shared on their personal mails and collected the responses on goggle form.

The third day was started with Dhanwantari Stawan followed by lecture delivered Dr.Suvarna Joshi from B. J. Medical College Puneonprotocol writing& Ethics in medical research. After that lecture group activity was taken on ethical issues in medical research by Dr.Suvarna Joshi madam and group activity waspresented on given topics as follows,group activity ended at 1 pm

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Nigdi, Pune - 411 044.

Group no.	Protocol and Ethical issues on following topics	Presenter from the group
1	Cross sectional study to assess Bala in Medovruddhi individuals having age 17-30 years by using fatigue index -	Dr. SanketChatar
2	An Observational study to find the relation between chinta & Rasavaha sortas dushti in Health care professionals Dr. Minakshi Nagpure	Dr. MohiniKulkarni
3	Pharmaceutico-Analytical study of NimbadiGhrita – Dr. Nikita Kurai	Dr.Nikita Kurai
4	Comparative clinical Study to compare the effect of DrakshaKwath and BadarKwath as Virechanopaga yoga – Dr.ShubhangiMaske	DrShubhangiMaske
5	Randomized controlled open labelled clinical study to evaluate the efficacy of Vatari Guggulu with Agnikarma in Grudhrasi (Sciatica) Dr. Harsh Naikawdi	Dr . Harsh Naikwadi
6	A Randomised standard controlled clinical study to assess the efficacy of AgaruKarna Dhoopan in Putikarna Dr.PrajaktaMetkari	Dr.Dhanashri navale
7	Case control study to evaluate cause and effect relationship between Mrudbhakshan (Soil eating) and Pandu in school going children between age group 8-12 years	Dr.Mayura Jadhav

After lunchDr.MadhavMutalik from D.Y. Patil dental school had taken session on diagnostic test completed on 2 pm.Next session was taken by Dr.MadhavMutalikon questionnaire designing completed session 3.30 pm. Sir had taken very interactive and informative lecture. Next session was started on 3.30 pm oncritical journal article evaluation ended on 5 pm by group activity. Article was shared to every delegate and also checklist also shared for evaluation before one day of session so that everyone can read the article for critical evaluation.

Post workshop evaluation MCQ test was taken. Three best improved delegateswere declaredand felicitated with Pen set, first topper Dr.Divyashree& Dr. Vrinda from samhita and Kayachikitasa department teachers by 23 marks, second topper from Dr. Jitendra and Dr. Chinmay from Dravyaguna and Samhita department teachers by 21marks and third toppers Dr. Nikita & Dr. Nidhi from Rasashastra and Nidan department P.G. students by18marks of our college. Study material given in soft copy to all delegates. The valedictory function ended with vote of thanks &Pasaydan by me.

The daily evaluation and whole program evaluation sheets were filled by delegates. The analysis of program evaluation is given asfollows-

Some comments given by delegates are as follows-

1) Workshop duration should be increased.
2) Workshop is fruitful especially with group activities
3) Time management and organization of workshop is very good

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4) Majority of delegates very much satisfied with group activities.
5) The continuous lectures should not be kept, 5 minutes rest should be given after each session.
6) Dr. Pranita Joshi, Dr. Rangnekar Dr. Yogini Kulkarni, Dr. Madhav Mutalik are the best faculty members mentioned by all most all delegates.

1st days feedback analysis -

1st days Sessions	Faculty	Grades obtained
A	Dr. Yogini	148
B	Dr. Yogini	148
C	Dr. Yogini	146
D	Dr. Rangnekar	144
E	Dr. Yogini	148
F	Dr. Pranita Joshi	149
G	Dr. Pranita Joshi	148

2nd days feedback analysis –

2nd days Session	faculty	grades obtained
A	Mrs Jain	145
B	Mrs Jain	144
C	Dr. Yogini	148
D	Dr. S. L. Jadhav	147
E	Dr. S. L. Jadhav	147
F	Dr. S. L. Jadhav	146

3rd days feedback analysis –

Session	faculty	grades obtained
A	Dr. Suvarna Joshi	137
B	Dr .Suvarna Joshi	136
C	Dr. Suvarna Joshi	136
D	Dr. Suvarna Joshi	136
E	Dr. MadhavMutalik	138
F	Dr. MadhavMutalik	139
G	Dr. MadhavMutalik	136

Important suggestions by coordinator as –

1) Offline workshop will be more helpful many delegates posted this feedback
2) Online attendance of delegates is more time taking so should be continued with previous method
3) If the organized college delegates only allowed by MUHS MET cell then such instructions should circulated to all medical colleges because more phone calls to coordinator form other college students

The activity started by M.U.H.S. and MET is really very much necessary and useful for up-gradation of knowledge of Research techniques to post graduate students and teachers.Thanking you,

Dr. Yogini R. Kulkarni (Coordinator)

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H. O. D.
Research Methodology
College of Ayurved And Research Centre
Nigdi, Pune - 411 044

Pune District Education Association's

College of Ayurved & Research Centre

Research Methodology Workshop 27 June 2022 to 29 June 2022





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College of Ayurved And Research Centre
Nigdi, Pune - 411 04

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College of Ayurved & Research Centre
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Phone - 020 - 27653965 / 27659578, Fax :- 020 - 27659578, Website - www.pdeaayurvedcollege.edu.in
E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

37. Collaborative activity – Student Exchange

Swasti Yoga Centre Pune

14/09/2022

Pune District Education Association's

College of Ayurved & Research Centre

Post event summary report **Date- 26/09/2022**

Name of the event- Visit to College of Ayurved & Research Centre, Nigdi, Pune by students of Swasti Yoga Centre, Chinchwad Pune under student exchange programme

Date of the event-14/09/2022

Organising department- Swasthavritta & Rachana sharir

Location of the event- College of Ayurved & Research Centre, Nigdi, Pune

पु.जि.शि.म.चै
आयुर्वेद महाविद्यालय व संशोधन केंद्र
निगडी, पुणे ४४.
आवक क्र. 3510/2022-23
दिनांक - 3/12/2022
लेखनिक (3)
प्राचार्य

Number of persons attending the event- 23

Mode of event- Offline

Drive Link for Photos-
https://drive.google.com/drive/folders/1fNcy2RB1pwcmyPIHzcESupggMP5_zFMS?usp=share_link

Summary of the event-

As per the e mail of Swasti yoga Centre dated 08/09/2022, visit of students of Swasti yoga Centre was planned at PDEA's college of Ayurveda and research center Nigdi, Pune. Students of Swasti Yoga centre visited on 14/09/2022 between10am – 1 pm. Out of 21 students four students were from other countries.

Dr. Manore welcomed all students & Director of Swasti Yoga Centre Dr. Mr. & Mrs. Chothe. Visit started with Dhanvantari prayer. All students introduced themselves. Dr. Lad gave best wishes to all students. Then students quickly visited to all department of college including Dravyaguna, Agadtantra, Rognidan etc. Afterwards they visited to Swasthavritta department, Sharir Kriya department and Sharir Rachana department for more detailed information. Dr. Madhuri Mahadar from Rachana Department explained basic of Anatomy, various organs & systems on models. Dr. Shweta More from Kriya Department described Prakruti, Tridosha concept, Physiology of systems. Dr. Deepali Manore from Swasthavritta department gave information regarding Diet, Daily regimen, Seasonal regimen, also clarified queries of the students. Visit was coordinated by Dr. Manore.

Dr. P.B. Tople Dr D.B.Naik Dr. M.A. Mahadar, Dr. M.M. Bhanuge

Pune District Education Association's

College of Ayurved & Research Centre

Name of the event- Visit to College of Ayurved & Research Centre, Nigdi, Pune by students of Swasti Yoga Centre, Chinchwad Pune under student exchange programme

Date of the event-14/09/2022





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Nigdi, Pune - 411 044.

Name of the Department: Rachana Sharir	NAAC Metric No. 3.5.1,3.5.2

Pune District Education Association's

College of Ayurved & Research Centre





COLLEGE OF AYURVEDIC RESEARCH * PDEA'S * AKURDI PUNE - 44

Principal

Principal Signature

Stamp

Name of the Department: Rachana Sharir	NAAC Metric No. 3.5.1,3.5.2

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

38. Collaborative activity – Faculty Exchange

SSAM, Hadapsar

26-28/09/2022

Pune District Education Association's

College of Ayurved& Research Centre

Report of IRBR 29/09/2022

Institutional review board for research (IRBR) of MAM's Sumatibhai Shah Ayurved Mahavidyalaya, Hadapsar from 26/09/2022 to 28/09/2022 from 10 am -4.30 pm as research expert was attended. Total 10 members were present Total research seventy two PG projects were discussed &different suggestions were given. After fulfilling the suggestions topics will be approved by committee.

Prof. Dr. Yogini Kulkarni



Name of the Department - Research	NAAC Metric No. 3.5.1

INSTITUTIONAL ETHICS COMMITTEE

Maharashtra Arogya Mandal's,
Sumatibhai Shah Ayurved Mahavidyalaya & Ayurved Hospital - Sane Guruji Arogya Kendra
Malwadi, Hadapsar, Pune - 411 028.
(An ISO 9001 :2015 Certified Mahavidyalaya)
Phone : (020) 29522505 / 29522506, E-mail : ssayu@rediffmail.com

MAM/SS Ayu/ 354 Date :- 14/09/2022

To

Dr. Yogini Kulkarni,
Member,
Institutional Ethics Committee

Sub :- **Regarding IEC Meeting scheduled on 26th to 28th September 2022.**

Respected Madam,

You are esteemed member of MAM'S Sumatibhai Shah Ayurved Mahavidyalaya Institutional Ethics Committee. The role of IEC has a broad scope as it examines and reviews P.G., Ph.D Synopsis and Clinical Trial Projects being undertaken at hospital.

With respect to above Subject I would like to invite you for 35th IEC Meeting from 26th September to 28th September 2022 at 10 a.m. to 4 p.m. Venue for the meeting will be Conference Hall no 7, First Floor, Sumatibhai Shah Ayurved Mahavidyalaya, Hadapsar,Pune.

Agenda will be as follows :-

1. **Welcome of all IEC members by Member Secretary.**
2. **Review and discussion on Pre.M.D Synopsis of all 12 Ayurved Specialties & 5 Ph.D Synopsis for approval.**
3. **Any other Subject with the permission of chair.**

We are sending here with copies of title & synopsis of 67 PG students & 5 Ph.D faculties. Please give your valuable suggestions & bring the copies while coming for the meeting.

Thanking you,

Sincerely Yours,

IEC
Hadapsar, Pune-28

for KVDeshmukh
Member Secretary
Institutional Ethics Committee
MAM'S SSAM Hadapsar, Pune

Member Secretary
, MAM's, S.S.A.M.
& Ayurved Hospital
Sane Guruji Arogya Kendra
Hadapsar, Pune.

Pune District Education Association's

College of Ayurved& Research Centre

Maharashtra Arogya Mandal's

SUMATIBHAI SHAH AYURVED MAHAVIDYALAYA,

Malwadi, Hadapsar, Pune - 411 028.

Phone : (020) 29522505, 29522506, Fax : (020) 26999467,

Web : www.ssayurved.org, E-mail : ssayu@rediffmail.com, ssayucollege@mam.org.in

MAM/SS Ayu/Cert/ 556

Date: 28/09/2022

ATTENDANCE CERTIFICATE

Certified that **Prof. Dr. Yogini Kulkarni** of **Ayurved College & Research Centre, Akurdi, Pune** was present from 26/09/2022 to 28/09/2022 at **MAM's Sumatibhai Shah Ayurved Mahavidyalaya, Hadapsar, Pune** for Institutional Ethics Committee meeting held for Review & discussion of Pre.MD/MS & Ph.D Synopsis for approval.

(Dr. Nilesh M. Phule)
Principal
M. A. M's, Sumatibhai Shah
Ayurved Mahavidyalaya,
Hadapsar, Pune- 411 028.

Name of the Department - Research	NAAC Metric No. 3.5.1

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

39. Collaborative activity – Faculty Exchange

Bharti Vidyapeeth College Of Ayurveda

18/10/2022

Pune District Education Association's
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Phone - 020 - 27653965 / 27659578, Fax :- 020 - 27659578, Website - www.pdeaayurvedcollege.edu.in
E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Matrix no.- 3.5.1

POST EVENT SUMMARY REPORT

Title of collaborative activity-Subject expert in scientific review of research Proposal of M.D. Kauamrbhritya scholars

Date/duration-18/10/2022

Place-Bharati Vidyapeeth College of Ayurveda, Pune

Participant details (student/teachers with numbers)-Teacher -01,
Dr. Madhavi Deodas –as Subject expert

Brief activity details-

Dr. Madhavi Deodas invited as subject expert in scientific review of research Proposal of M.D. Kauamrbhritya scholars organized by scientific research committee, Bharati Vidyapeeth College of Ayurveda, Pune on 18th October 2022.Proposed topics for PG research has been discussed thoroughly in this meeting.

Deodas

Signature

Designation-HOD & Professor

Name- Dr.Madhavi S. Deodas

P.D.E.A.'s College Of Ayurved And Research Centre AKURDI PUNE - 44.

H. O. D.
Dept. of Kaumarbhrutya Tantra
College of Ayurved & Research Centre
Nigdi

Bharati Vidyapeeth
(Deemed to be University)
Pune, India.
Founder Chancellor : Dr. Patangrao Kadam
COLLEGE OF AYURVED, PUNE

★ Accredited with 'A+' Grade (2017) by NAAC ★
★ Category-I University Status by UGC ★
★ NIRF Ranking - 68 ★

"Social Transformation Through Dynamic Education"

Prof. Dr. Shivajirao Kadam
M.Sc., Ph.D.
Chancellor

Prof. Dr. M. M. Salunkhe
M.Sc., Ph.D., F.R.S.C.
Vice Chancellor

Dr. Vishwajeet Kadam
B.Tech., M.B.A., Ph.D.
Pro Vice Chancellor

Dr. Abhijit B. Patil
B.A.M.S., D.T.F.M., Ph.D.
Principal

Ref. No. : BVDU / COA /1330/2022-23

Date : 11-10-2022

To,
Dr. Madhavi Devdas
College of Ayurved & Research Centre,
Akurdi, Pune.

Sub: - Invitation for the Meeting of BV (DU) College of Ayurved- Scientific Research committee regarding.

Respected Madam,

A meeting of BV(DU) College of Ayurved - Scientific Research committee is hereby convened on **18th October 2022 at 10.30 am onwards** in the Conference room of College of Ayurved, Pune.

You are cordially invited to attend the BV (DU) College of Ayurved - Scientific Research committee meeting for the purpose of scientific review of research proposals of M.D. (Kaumarbhritya- Balaroga) scholars.

Kindly make it convenient to attend the said meeting and oblige.

Thanking You,

Yours Faithfully,

Dr. Abhijit B. Patil
PRINCIPAL
Bharati Vidyapeeth
(Deemed to be University)
College of Ayurved
Pune-Satra Road, Pune-43.

Bharati Vidyapeeth
(Deemed to be University)
Pune, India
Founder Chancellor: Dr. Patangrao Kadam
COLLEGE OF AYURVED, PUNE

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★ Category-I University status by UGC ★
★ NIRF Ranking -66 ★

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Prof. Dr. Shivajirao Kadam
M.Sc., Ph. D.
Chancellor

Prof. Dr. M. M. Salunkhe
M.Sc., Ph. D., F.R.S.C.
Vice Chancellor

Dr. Vishwajeet Kadam
B.Tech., M.B.A., Ph. D.
Pro Vice Chancellor

Dr. Abhijit B.Patil
B.A.M.S., D.T.F.M., Ph. D.
Principal

Ref. No. BV (DU)/COA/ 1360 /2022-2023 Date: 18 /10/2022

ATTENDENCE CERTIFICATE

This is certify that **Dr. Madhavi Devdas** has attended for Scientific Review Committee Meeting on **18th October 2022** as a subject expert in the subject of **M.D. (Kaumarbhritya - Balaroga)** at our College of Ayurved, Pune.

Centre of IREC Meeting : Bharati Vidyapeeth
(Deemed to be University)
Pune, India
College of Ayurved,
Pune – 411 043.

Principal

PRINCIPAL
Bharati Vidyapeeth
(Deemed to be University)
College of Ayurved
Pune-Satara Road, Pune-43

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

40. Collaborative Research Project

With

TIMER

15 Nov 2022- 21 March 2023

(4 Months)

1. STATEMENT OF COMPLIANCE

"A Randomized, Multi-center, Prospective, Comparative Clinical Study to evaluate efficacy and safety of AP/VJT/SBO Ayurvedic Hair Oil in mild to moderate Hair loss in females."

Protocol No: AP/VJT/SBO/01/2022, Version no. 2.0 Dated 13th May 2022

We hereby certify the authenticity of the Clinical Study Report and declare that the results are an accurate interpretation of the data; to the best of our knowledge. We also hereby provide assurance that this study was conducted in compliance to the protocol and as per applicable Good clinical Practices and Ethical Guidelines laid down by AYUSH.

Sr. No.	Sponsor/CRO	Represented by	Signature & Date
1	**Sponsor** AYURVED PRATISTHAN Plot no 7/87/8, Kshirsagar Colony, Hirwadi Road, Panchavati, Nasik- 422003. Email: ayurvedpratishthan@gmail.com		
2	**CRO** Target Institute of Medical Education and Research Pvt. Ltd. 402, A/B/C, Jaswanti Allied Business Center, Ramchandra Lane Extn, Malad (West), Mumbai-400064 Email – targetinstitute@yahoo.com	Dr. Sanjay Tamoli	

Sr. No.	Principal Investigator / Co-Investigator	Address of the site	Signature & Date
1.	Dr. Aboli Patil (Phd-Kaumabhritya)	Dr. D. Y. Patil College of Ayurved & Research Centre, OPD No. 01, Department of Kaumarbhritya Floor –Ground floor, Sant Tukaram Nagar, Pimpri Colony, Pimpri-Chinchwad, Pune- 411018 Pune MAHARASHTRA.	
2.	Dr. Jayant Janardan Phadke (MD Ayu and PGDMLS)	Pune District Education Association Pune, College of Ayurveda & Research Center, Agad Tantra Dept. OPD No. 117 B, Ground floor, Sector No. 25, Pradhikaran, Nigdi, Pune-411044, MAHARASHTRA.	
3.	Dr. Shamsunder Agarwal (MBBS, DVD)	The Skin Hair Laser Clinic, Ground Floor, South Main Road, Sukhwari Classic, Koregaon Park, Pune 411001, MAHARASHTRA	

College Of Ayurved And Research Centre AKURDI PUNE - 44

2. EXECUTIVE SUMMARY

2.1	**Protocol Title**	A Randomized, Multi-center, Prospective, Comparative Clinical Study to evaluate efficacy and safety of AP/VJT/SBO Ayurvedic Hair Oil in mild to moderate Hair loss in females.
2.2	**Protocol ID version & date**	AP/VJT/SBO/01/2022, Version no. 2.0 Dated 13th May 2022
2.3	**Study Design**	A Randomized, Multi-center, Prospective, Comparative Clinical Study.
2.4	**Duration of Study product consumption**	The total duration of the study was 60 days.
2.5	**Total no of visits**	Screening/Baseline Visit (Day 0), Visit 1 (Day 15) ± 5 days, visit 2 (Day 30) ± 5 days, visit 3 (Day 45) ± 5 days and Visit 4- End of Study (Day 60)
2.6	**Sample Size**	A total of 66 subjects completed the study (32 subjects in AP/VJT/SBO Hair oil Group and 34 subjects in control group).
2.7	**Investigational Product and Dosage**	There were two groups in the study, one group of participants were assigned to use AP/VJT/SBO Hair Oil while the other group were not given any study product and were infrequent hair oil users. The total duration of the study was 60 days. Subjects were asked to apply approximately 10 ml of hair oil for minimum 3 times a week.
2.8	**Study Objectives**	**Objective:** To evaluate efficacy and safety of AP/VJT/SBO Ayurvedic Hair Oil in mild to moderate Hair loss in females. **Primary Outcomes:** 1. Comparative change in hair fall in AP/VJT/SBO Ayurvedic hair oil by running finger test over a period of 60 days 2. Comparative change in hair breakage in AP/VJT/SBO Ayurvedic hair oil by comb test over a period of 60 days **Secondary Outcomes:** 1. Comparative change in hair fall in AP/VJT/SBO Ayurvedic hair oil by Hair Pull test over a period of 60 days 2. Comparative change in hair growth in AP/VJT/SBO Ayurvedic hair oil by

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		comparing against standard infrequent (applies oil only once or twice week) hair oil users 3. Comparative change in dandruff in AP/VJT/SBO Ayurvedic hair oil in females by standard dandruff evaluation cards 4. Comparative change in quality of hair based on subject questionnaire including effect on greying, hair growth and hair density 5. Global assessment of overall change in hair loss by the physician 6. Global assessment of overall change in hair loss by the subject 7. Assessment of safety by observing episodes, severity and duration of any allergic reactions and adverse events
2.9	**Tools used for Evaluation**	• Run18- Running Finger Test • Comb Test (All-purpose Comb 7″ Fine-teeth) • Pull Test • Standard Dandruff Measurement Cards • Questionnaire based on gradation as per the subject's view • Global assessment of the hair loss by the Investigator • Global assessment of the hair loss by the Subject
2.10	**Inclusion Criteria**	Subjects meeting the following criteria were included in the study 1. Female subjects between the age group of 18- 45 years both inclusive 2. Subjects suffering from mild to moderate hair loss (40-140 Hair by Comb test and Finger Test). 3. Subjects who were infrequent (applies oil only once or twice week) hair oil users 4. Subjects who were willing to give informed consent and ready to comply with the protocol 5. Subjects who were ready to provide regular follow ups till the completion of the Study.
2.11	**Exclusion Criteria**	Subjects meeting any of the following criteria were excluded: 1. Subjects with severe Hair fall due to any clinically significant disorder/s like anemia, thyroid disorders etc. 2. Subject with severe dermatological disorders of the scalp that might interfere with the study evaluation 3. Subjects with recent disease history of malaria, typhoid, jaundice etc. & scalp diseases & subjects who in the opinion of investigator were not eligible for enrollment 4. Subjects who had regularly used anti-hair fall treatment with

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		hair oils over the last 6 months. 5. Subjects who had previously undergone hair transplantation 6. Subjects on systemic steroids for more than 14 days within 2 months prior to enrollment. 7. Subjects on immunosuppressive drugs 8. Known cases of Hypersensitivity to hair oil contents 9. Subjects who had participated in any other clinical study (last 3 months) 10. Subjects who were reported pregnant/planning a pregnancy or lactating. 11. Menopausal Women
2.12	**Methodology**	Female subjects between the age group of 18-45 years (both ages inclusive) were screened for eligibility criteria. On screening visit, a written informed consent was taken. Assessment of inclusion and exclusion criteria was done. Assessment of hair loss was done and those subjects having mild to moderate hair loss (40-140 Hair by Comb test, Running Finger Test) were included in the study. Subjects were also be assessed based on hair pull test. Subject's dandruff score was evaluated on standard dandruff evaluation strip. Subject's clinical examination was done and history of any illness or medicines was recorded. Subjects participating in the study were thoroughly screened on clinical parameters and in case any blood test were required for ascertaining the cause of hair fall the same was done on case-to-case basis. Subjects underwent lab examinations like Hb% and TSH. Subjects with low Hb% and thyroid disorders were excluded from the study. Eligible subjects were then enrolled in the study. Subjects were asked not to take any medication for the treatment of Hair loss except the study medication during the study period. On baseline visit, subject's prakruti evaluation was done. Subject were recruited in the study on meeting all the inclusion criteria. As per computer generated randomization list, subjects were randomized to one of the study groups. There were two groups, one group of participants were provided with AP/VJT/SBO Ayurvedic Hair Oil while the other were assigned to the group who were infrequent (applies oil only once or twice week) hair oil users. Investigational Product dispensing was done to subjects in the AP/VJT/SBO

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		Hair Oil group. Subjects were advised to massage approximately 10 ml hair oil on the scalp with fingertips before going to bed or before bath (2 hours) for minimum 3 times a week. Subjects were asked to do hair wash thrice a week Hair pull test was done in which subjects small section of hair (approximately 20-60 hair) from the proximal portion of the scalp was grasped between the thumb, index and middle fingers from the base of the hairs near the scalp and firmly, but not forcefully, tugged away from the scalp. The number of hairs pulled away from scalp was counted and recorded in CRF. Average length of hair from the Pull test was measured and recorded in CRF. Subject's dandruff score was evaluated on standard dandruff evaluation strip. Clinical examinations, both General and Hair Specific were done. On every follow up visit except last follow up visit, subjects from the AP/VJT/SBO Ayurvedic hair oil group were provided with the hair oil. On every follow up visit, the empty container was collected from the subjects in the AP/VJT/SBO Ayurvedic hair oil and drug compliance was checked. Subjects were called to the investigators site on day 15, 30, 45 for follow up. At every follow up visit subject's clinical examination was done. Subjects were asked for any adverse event during study period. Assessment of Hair loss was done by Running Finger Test (RFT), Comb Test (CT) and Hair pull test in the presence of investigator. Subject's dandruff score was done on dandruff evaluation strip. Average hair length was recorded on each follow-up visit. Average length of hair from the Pull test was measured and recorded in CRF. On all visit subjects were interrogated based on questionnaire to evaluate their quality of hair (both on graded scale and VAS) including effect on dandruff, greying and hair growth. On day 60 i.e., end of treatment visit, clinical examinations were done.

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		Subjects were asked for any adverse event during this period. Assessment of Hair loss was done by Running Finger Test (RFT), Comb Test (CT) and hair pull test in the presence of investigator. Subject's dandruff score was done on dandruff evaluation strip. Average hair length from the Pull test was recorded. Subjects were interrogated based on questionnaire to evaluate their quality of hair (both on graded scale and VAS) including effect on dandruff, greying and hair growth. Global evaluation based on the subject and the investigator were done at the final visit. Subjects were asked to stop study medication and take advice of investigator for further treatment.
2.13	**Statistical method of assessment**	In-house statistician performed the analysis using available version of statistical software. For the analysis of efficacy variables, data was analyzed from the Intent to treat population and per protocol population also. The values of the last visit were considered for final analysis for subjects who did not complete the study schedule (Last Observation Carry Forward) for intent to treat analysis. Safety Analysis was done on all subjects who have administered at least one dose of treatment. The study data generated and collected through clinical study were subjected to statistical analysis for interpretation of results and to draw the unbiased inferences. The demographic data were presented in tables and graphs. The data on discrete variables were represented as n (%) and Median (Range). The data on continuous variables were represented as Mean ± SD. GraphPad InStat Version 3.6 (www.graphpad.com) software was used for statistical analysis of data. The clinical assessment data obtained in the study were subjected to appropriate tests of significance. P value < 0.05 was considered statistically significant. Kolmogrov – Smirnov test was applied to test the normality of data. • Quantitative Parameters - Continuous variables – a. For intra – group comparison (intra – group analysis): Paired t test (if

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		data passed normality test) or Wilcoxon matched-pairs signed-rank test (if data failed normality test) were applied. b. For inter – group comparison between two groups (inter – group analysis): Unpaired t test (if data passed normality test) or Mann – Whitney test (if data failed normality test) were applied. • Quantitative Parameters – Ordinal variables – a. For intra – group comparison (intra – group analysis): Wilcoxon matched-pairs signed-rank test were applied. b. For inter – group comparison between two groups (inter – group analysis): Mann – Whitney test were applied. • Discrete variables: Chi – Square test was applied
2.14	**Results**	A total of 76 subjects were screened in the study. There were 8 screen failures and 68 subjects were randomized with 33 subjects in AP/VJT/SBO Hair oil Group and 35 subjects in control group. There was 1 dropout each in Group A and group B. A total of 66 subjects (32 in group A and 34 in group B) completed the study. **I) Baseline Demography:** There was no significant difference in the demographic parameters like age, Hb and body weight between the two groups, meaning groups were evenly matched. The average age of participants in AP/VJT/SBO Hair Oil group was 31.69 ± 7.92 years while it was 30.41 ± 6.69 years in the control group. The mean Hb% in AP/VJT/SBO group was 11.95 ± 1.04 while in the control arm it was 12.83 ± 1.11. Weight of participants in the AP/VJT/SBO group was 57.35 ± 8.80 kg in AP/VJT/SBO group while in the control arm it was 59.18 ± 9.80 kg. **II) Primary Outcomes:** **A) Comparative assessment of hair fall by RFT (Running Finger Test):** Assessment of hair fall based on running finger test showed that there was a significant reduction in hair fall within the first 15 days of use of AP/VJT/SBO

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		oil from an average of 30.84 ± 10.74 at baseline to 25.41 ± 11.12. This hair fall reduction continued further to 21.25± 8.47 at 30 days, 17.88 ±8.14 at 45 days and 11.66 ±6.41 at the end of the study i.e., 60 days. At the end of 30 days of the study hair fall reduced by 31.10% while at the end of 60 days it reduced to 62.19%. The average hair fall at baseline in control group was 28.91 ± 12.78 which slightly increased to 30.69± 14.07 at the end of 15 days. At the end of 30 days the hair fall was 28.25± 14.26, at the end of 45 days it was 28.25± 14.26 while at the end of the study it was 31.22 ± 14.72. On assessment between the groups, it was observed that AP/VJT/SBO oil application showed significant reduction from baseline to 15 days and further to 30, 45 and 60 days. In terms of times, it can be said that hair fall reduced 2.6 times at the end of 60 days of the study. **B) Comparative Assessment of hair breakage by Comb Test:** Assessment of hair fall based on comb test showed that there was a significant reduction in hair fall within the first 15 days of use of AP/VJT/SBO oil from an average of 31.13± 12.86 at baseline to 23.47± 12.44. This hair fall reduction continued further to 20.13 ± 10.27 at 30 days, 17.31 ± 9.46 at 45 days and 11.78 ± 6.61at the end of the study i.e., 60 days. At the end of 30 days of the study hair fall reduced by 35.34% while at the end of 60 days it reduced to 62.16%. The average hair fall at baseline in control group was 26.63 ± 8.68 which slightly decreased to 25.97 ± 7.84 at the end of 15 days. At the end of 30 days the hair fall was 26.66 ± 6.68, at the end of 45 days it was 24.59 ± 8.11 while at the end of the study it was 26.75 ± 9.50. On assessment between the groups, it was observed that AP/VJT/SBO oil application showed significant reduction from baseline to 15 days and further to 30, 45 and 60 days. In terms of times, it can be said that hair fall reduced 2.6 times at the end of 60 days of the study. **III) Secondary outcomes:** **A) Comparative assessment of hair fall by Hair Pull test:** Assessment of hair fall based on Pull test showed that there was a significant

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		reduction in hair fall within the first 15 days of use of AP/VJT/SBO oil from an average of 4.06 ± 4.10 at baseline to 2.88 ± 3.13. This hair fall reduction continued further to 2.75 ± 2.99 at 30 days, 2.56 ± 4.03 at 45 days and 0.94 ± 1.14 at the end of the study i.e., 60 days. At the end of 30 days of the study hair fall reduced by 32.27% while at the end of 60 days it reduced to 76.85%. The average hair fall at baseline in control group was 4.16 ± 4.93 which increased to 5.66 ± 5.02 at the end of 15 days. At the end of 30 days the hair fall was 5.75 ± 6.89, at the end of 45 days it was 5.00 ± 4.91 while at the end of the study it was 6.31 ± 5.51. On assessment between the groups, it was observed that AP/VJT/SBO oil application showed significant reduction from baseline to 15 days and further to 30, 45 and 60 days. In terms of times, it can be said that hair fall reduced 4.3 times at the end of 60 days of the study. **B) Comparative assessment of hair growth:** The average length of hair at baseline in AP/VJT/SBO group was 40.91 ± 12.97 cm at baseline which increased (non-significant) to 41.91 ± 13.40 cm at the end of 30 days and to 42.91 ± 13.60 cm (significant) at the end of 60 days. The average hair length in control group was 45.18 ± 17.13 cm which decreased to 43.56 ± 17.30 cm at the end of 30 days and to 44.62 ± 16.96 cm (non-significant) at the end of 60 days. On analysis between the group, it was observed that the hair growth was significant in AP/VJT/SBO group as compared to control group at the end of 60 days. **C) Assessment of dandruff on standard dandruff evaluation cards:** Severity of dandruff was assessed using standard dandruff evaluation cards. It was observed that the mean score at baseline in AP/VJT/SBO group was 0.91 ± 0.73 which reduced to 0.81 ± 0.73 at the end of 15 days (non-significant) and further to 0.63 ± 0.66 (significant). Further on day 45 and day 60 the reduction was significant with the score of 0.59 ± 0.56 and 0.38 ± 0.50 respectively. In the control group the baseline score was 0.88 ± 0.72 which reduced slightly to 0.84 ± 0.69 at the end of 15 days (non-significant). The score was recorded as 0.88 ± 0.67 at the end of 30 days, 0.78 ± 0.61 at the end of 45 days and 1.03 ± 0.76 at the end of 60 days. There was an increase in

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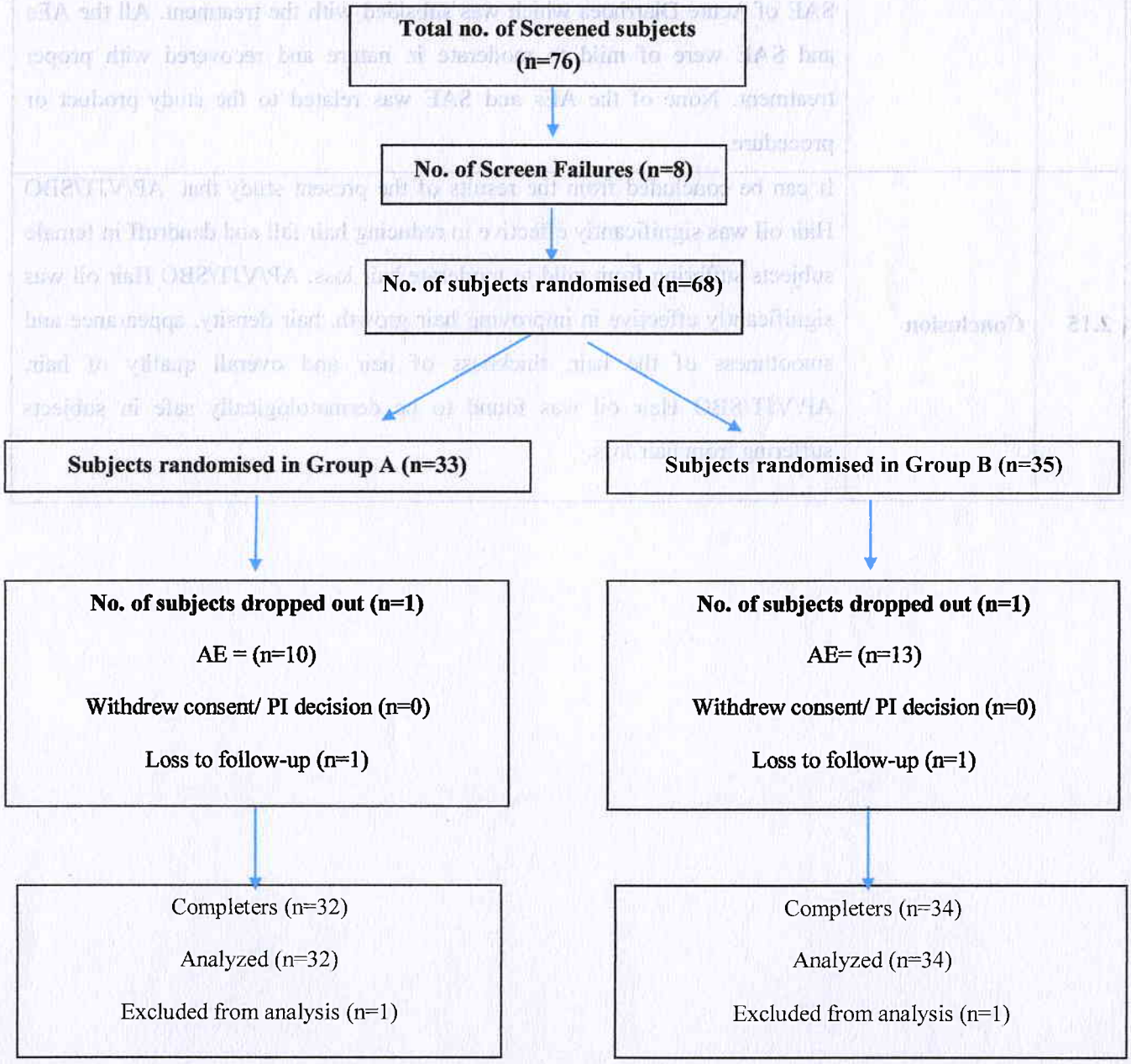
		dandruff score in the control (non-significant). Analysis between the group showed that the decrease in dandruff with the use of AP/VJT/SBO was significant as compared to control from day 30 and continued further. There was a 58.24% reduction in dandruff with the use of AP/VJT/SBO. **D) Comparative assessment of Hair Oil on quality of hair:** It was observed that about 60% of participants reported improvement in reduction of visibility of scalp, 74% reported improvement in hair growth, 72% reported improvement in appearance of hair, more than 90% reported increase in smoothness of hair, more than 92% showed reduction in hair loss while 50% reported increase in thickness of hair. Dandruff reduction was reported by 50% while 15.6% reported in reduction of greying of hair. None of the participant reported improvement on these parameters in the control group while they reported either no change or worsening of their condition. **E) Global assessment of overall change in hair loss by the physician and subject:** As per physician and subject assessment for overall change, 19 (59.37%) subjects reported very much improvement, 11 (34.37%) subjects reported much improvement and 2 (6.25%) subject reported minimal improvement. **F) Global assessment of overall safety by the physician and subject:** In group A, as per physician's and subject's assessment for overall safety, 21 (65.63%) subjects reported excellent overall safety, 11 (34.37%) subjects reported good overall safety. **G) Assessment of Vitals:** In both the groups, no significant change in these parameters was observed from baseline to the end of the study. All the vitals were within normal range at baseline visit and at all the follow up visits. **H) Assessment of AEs:** In group A, 9 subjects had adverse events i.e., headache, severe acidity, cough, cold, vomiting, abdominal pain, bloated abdomen, body pain, stomach pain and calf muscle pain. In group B, 13 subjects had adverse events of



		hyperacidity, cough, cold, headache, tonsilitis, stomatitis, vomiting, low back pain, fever, throat infection and VB-12 Deficiency. In Group B 1 subject had SAE of Acute Diarrhoea which was subsided with the treatment. All the AEs and SAE were of mild to moderate in nature and recovered with proper treatment. None of the AEs and SAE was related to the study product or procedure.
2.15	**Conclusion**	It can be concluded from the results of the present study that AP/VJT/SBO Hair oil was significantly effective in reducing hair fall and dandruff in female subjects suffering from mild to moderate hair loss. AP/VJT/SBO Hair oil was significantly effective in improving hair growth, hair density, appearance and smoothness of the hair, thickness of hair and overall quality of hair. AP/VJT/SBO Hair oil was found to be dermatologically safe in subjects suffering from hair loss.

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SUBJECT DETAILS



* All the subjects who used study product even once were considered for safety evaluation.

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3. ETHICS:

3.1 Ethics Committee approvals:

The study was approved by following ethics committee:

Site 01:

Institutional Ethics Committee, Dr. D.Y. Patil College of Ayurved & Research Centre, Pimpri-Chinchwad, Pune.

Site 02:

Institutional Ethics Committee -II, Pune District Education Association's, College of Ayurved & Research Centre, Nigdi, Pune.

Site 03:

Independent Ethics Committee, Mhaske Hospital and Research Centre Gadital, Hadapsar, Pune.

3.2 Ethical conduct of the study:

The study was initiated after approval from Institutional Ethics Committee of the study site. Study protocol was strictly followed. All the study related activities were conducted under the guidance of Principal Investigators or Co Investigators. All the study persons were given training on AYUSH GCP guidelines for conducting the clinical study in an ethical way. The study was conducted as per approved protocol and AYUSH GCP guidelines given by the department of AYUSH.

3.3 Subject Information and Consent:

Subjects were recruited after signing the Informed Consent Document. Consent was taken after providing complete information to the subject in a written document (Subject Information Sheet). Information was given to the subjects in the language that the subjects could read and write. Subjects were given an opportunity to ask questions and their queries were resolved. In case of illiterate subjects an impartial witness was asked to sign the consent after providing complete information. All the process of Screening/Consent and recruitment were documented by the Clinical Research Coordinator in the Informed consent process document which was approved by the Principal Investigator or Co-Investigator.

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4. CTRI REGISTRATIONS:

The Clinical study is registered on CTRI website with registration number CTRI/2022/04/053630 [Registered on: 23/04/2022]

5. STUDY EVENTS:

Sr. No.	Event	Date
1.	The study was approved by the ethics committee	
	Site 01: Institutional Ethics Committee, Dr. D.Y. Patil College of Ayurved & Research Centre, Pimpri-Chinchwad, Pune.	22/04/2022
	Site 02: Institutional Ethics Committee -II, Pune District Education Association's, College of Ayurved & Research Centre, Nigdi, Pune.	17/05/2022
	Site 03: **Independent Ethics Committee, Mhaske Hospital and Research Centre Gadital, Hadapsar, Pune.**	05/04/2022
2.	CTRI registration	23/04/2022
3.	1st Subject Enrolment date	23/05/2022
4.	Last subject Enrolment date	03/09/2022
5.	Last, follow-up visit of the last subject	03/11/2022

6. STUDY ADMINISTRATIVE STRUCTURE AND INVESTIGATOR:

1. SPONSOR:

AYURVED PRATISTHAN, Plot no 7/87/8, Kshirsagar Colony, Hirwadi Road, Panchavati, Nasik- 422003.

2. CRO:

Target Institute of Medical Education & Research Pvt. Ltd., A wing, 402, A/B/C, Jaswanti allied business Centre, Ramchandra Lane Extension, Kachpada, off link road, Malad West, Mumbai 400064

3. SITE DETAILS:

Sr. No	Principal Investigator / Co-Investigator	Address of the site
1.	Dr. Aboli Patil (Phd-Kaumabhritya)	Dr. D.Y. Patil College of Ayurved & Research Centre, OPD No. 01, Department of Kaumarbhritya Floor –Ground floor, Sant Tukaram Nagar, Pimpri Colony, Pimpri-Chinchwad, Pune- 411018 Pune MAHARASHTRA.
2.	Dr. Jayant Janardan Phadke (MD Ayu and PGDMLS)	Pune District Education Association Pune, College of Ayurveda & Research Center, Agad Tantra Dept. OPD No. 117 B, Ground floor, Sector No. 25, Pradhikaran, Nigdi, Pune-411044, MAHARASHTRA.
3.	Dr. Shamsunder Agarwal (MBBS, DVD)	The Skin Hair Laser Clinic, Ground Floor, South Main Road, Sukhwari Classic, Koregaon Park, Pune 411001, MAHARASHTRA

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7. STUDY INTRODUCTION:

Hair is one of the most defining aspects of our appearance. A healthy head of hair makes us look attractive, youthful, and desirable. Appearance of an individual directly affects her self-image, and one wants to maintain a self-image that is youthful and healthy looking[1].

Hair loss in women is a very common clinical complaint, and is usually associated with severe emotional distress[2]. Hair loss is silent but serious problem which may occur to a healthy person also. It has been regarded as geriatric physiological phenomena, generally after the mid-forties[3]. Hair loss can be caused due to different reasons, such as genetic tendencies, environmental triggers, exposure to chemicals, medicines, nutritional deficiency, extreme stress or long illness etc[4].

Herbal hair oil is more preferred and is used in many ailments of hair. They promote hair growth, improve elegance of hair and prevent hair fall. Hair oil not only promotes hair growth they also provide necessary moisture to the scalp rendering in beautiful hair[5]. Herbal hair oils are one of the most well recognized hair treatments. Herbal hair oils not only moisturize scalp but also reverses dry scalp and dry hair condition. It provides numerous essential nutrients required to maintain normal functions of sebaceous gland and promote natural hair growth[6].

Even thousand years ago in Ayurvedic literature various types of daily regimens for hair care is described in the chapter of Dinacharya and Ritucharya[7]. The Ficus bengalensis tree is a symbol of strength and longevity. In ancient Indian science of Ayurveda, Ficus bengalensis roots shows immense medicinal properties in hair care. AP/VJT/SBO Ayurvedic Hair Oil mainly contains the extracts of Ficus bengalensis Aerial root (Jata). It is very effective in hair fall control, strengthens hair roots and enhances hair growth. AP/VJT/SBO Ayurvedic hair oil contains many useful ayurvedic ingredients like Til oil, Sunthi (Zingiber officinale), Bibhitak (Terminalia bellirica), japapushpa (Hibiscus rosa-sinensis), Jatamansi (Nardostachys jatamansi) which help in hair fall control[8-12]. It helps in imparting natural blackness to hair, preventing premature greying of hair.

A hypothesis was postulated that by virtue of its ingredients AP/VJT/SBO Ayurvedic Hair Oil would be helpful in controlling hair fall and also boost hair growth. To test this hypothesis a clinical study titled –A Randomized, Multi-center, Prospective, Comparative Clinical Study to evaluate efficacy and safety of AP/VJT/SBO Ayurvedic Hair Oil in mild to moderate Hair loss in females‖ was planned.

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8. STUDY OBJECTIVES AND PURPOSE:

To evaluate efficacy and safety of AP/VJT/SBO Hair Oil in mild to moderate Hair loss in females.

8.1 Primary outcomes:

1. Comparative change in hair fall in AP/VJT/SBO Ayurvedic hair oil by running finger test over a period of 60 days
2. Comparative change in hair breakage in AP/VJT/SBO Ayurvedic hair oil by comb test over a period of 60 days

8.2 Secondary outcomes:

1. Comparative change in hair fall in AP/VJT/SBO Ayurvedic hair oil by Hair Pull test over a period of 60 days
2. Comparative change in hair growth in AP/VJT/SBO Ayurvedic hair oil by comparing against standard infrequent (applies oil only once or twice week) hair oil users
3. Comparative change in dandruff in AP/VJT/SBO Ayurvedic hair oil in females by standard dandruff evaluation cards
4. Comparative change in quality of hair based on subject questionnaire including effect on greying, hair growth and hair density
5. Global assessment of overall change in hair loss by the physician
6. Global assessment of overall change in hair loss by the subject
7. Assessment of safety by observing episodes, severity and duration of any allergic reactions and adverse events

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9. TEST PRODUCT DETAILS:

9.1 Product Name: The product was coded as AP/VJT/SBO for the purpose of this clinical study. The product is currently licensed as Ayurvedic Proprietary Medicine with FDA, Maharashtra and is available in the market as AP/VJT/SBO Hair oil and Sandook Banyan Hair Oil (For External use only)

9.2 Ingredients: Each 100 ml processed oil contains:

Sr. No.	Ingredient	Botanical Name	Part Use	Quantity
1	Tila taila	*Sesame oil*	Seeds	100 ml
2	Vata Jata	*Ficus bengalensis*	Aerial Fruit	100 gm
3	Bibhitaki	*Terminalia bellirica*	Fruit	4 gm
4	Japapushpa	*Hibiscus rosa-sinesis*	Flower	2 gm
5	Sunthi	*Zingiber officinale*	Rhizome	0.5 gm
6	Kapur	*Cinnamomum camphora*	Extract	0.75 gm
7	Jatamansi	*Nardostachys jatamansi*	Rhizome	2 gm

This product is available as AP/VJT/SBO Hair oil/Sandook Banyan Hair Oil in the market.

9.3 Dosage form: Apply approximately10 ml oil minimum three times a week for 60 days

10. STUDY METHODOLOGY:

10.1 Study design and Duration:

The study was a Randomized, Multi-center, Prospective, Comparative Clinical study.

10.2 Assessment of Efficacy endpoints:

1. Comparative change in hair fall in AP/VJT/SBO Ayurvedic hair oil by running finger test over a period of 60 days
2. Comparative change in hair breakage in AP/VJT/SBO Ayurvedic hair oil by comb test over a period of 60 days
3. Comparative change in hair fall in AP/VJT/SBO Ayurvedic hair oil by Hair Pull test over a period of 60 days
4. Comparative change in hair growth in AP/VJT/SBO Ayurvedic hair oil by comparing against standard infrequent (applies oil only once or twice week) hair oil users
5. Comparative change in dandruff in AP/VJT/SBO Ayurvedic hair oil in females by standard dandruff evaluation cards
6. Comparative change in quality of hair based on subject questionnaire including effect on greying,

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hair growth and hair density

7. Global assessment of overall change in hair loss by the physician
8. Global assessment of overall change in hair loss by the subject
9. Assessment of safety by observing episodes, severity and duration of any allergic reactions and adverse events

10.3. Inclusion Criteria:

Subjects meeting the following criteria were included in the study-

1. Female subjects between the age group of 18- 45 years both inclusive
2. Subjects suffering from mild to moderate hair loss (40-140 Hair by Comb test and Finger Test).
3. Subjects who were infrequent (applies oil only once or twice week) hair oil users
4. Subjects who were willing to give informed consent and ready to comply with the protocol
5. Subjects who were ready to provide regular follow ups till the completion of the Study.

10.4 Exclusion Criteria:

Subjects meeting any of the following criteria were excluded from the study-

1. Subjects with severe Hair fall due to any clinically significant disorder/s like anemia, thyroid disorders etc.
2. Subject with severe dermatological disorders of the scalp that might interfere with the study evaluation
3. Subjects with recent disease history of malaria, typhoid, jaundice etc. & scalp diseases & subjects who in the opinion of investigator were not eligible for enrollment
4. Subjects who had regularly used anti-hair fall treatment with hair oils over the last 6 months.
5. Subjects who had previously undergone hair transplantation
6. Subjects on systemic steroids for more than 14 days within 2 months prior to enrollment.
7. Subjects on immunosuppressive drugs
8. Known cases of Hypersensitivity to hair oil contents
9. Subjects who had participated in any other clinical study (last 3 months)
10. Subjects who were reported pregnant/planning a pregnancy or lactating.
11. Menopausal Women

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11. ASSESSMENT PARAMETERS:

11.1 Assessment of Efficacy Parameters:

The study involved the use of various scales for assessment of symptoms, overall change, and safety. The investigator assisted /explained /guided/helped the subject in filling up the scores in these scales wherever required.

11.1.1 Comparative Assessment of hair fall in AP/VJT/SBO Ayurvedic hair oil by running finger test over a period of 60 days:

At site, subjects were asked to run finger before washing the hair from upward to downward direction for about 10 min covering the entire scalp. All the hair were collected in plastic bags and then counted. Hair less than 1 cm were not considered for counting. No. of hair collected by running finger test at each visit then were compared with Baseline value and between the groups.

11.1.2 Comparative Assessment of hair breakage in AP/VJT/SBO Ayurvedic hair oil by comb test over a period of 60 days:

At site, subjects were asked to collect hair by combing which was done for about 1 min covering the entire scalp. No. of hair collected by comb test at each visit then were compared with Baseline value and between the groups.

11.1.3 Comparative Assessment of efficacy of AP/VJT/SBO Ayurvedic hair oil in mild to moderate hair loss in females (by pull test):

At site, on every follow up visit, subject's small section of hair (approximately 20-60 hairs) from the proximal portion of the scalp were grasped between the thumb, index and middle fingers from the base of the hairs near the scalp and firmly, but not forcefully, tugged away from the scalp. The number of hairs pulled away from scalp were counted and recorded in CRF. Also, average length of hair from Pull test were measured and recorded in the CRF.

11.1.4 Comparative assessment of Hair growth of AP/VJT/SBO Ayurvedic hair oil in females:

At site from hairs collected from subject's hair pull test, average length of hair was measured and recorded in CRF. Subjects from the infrequent (applies oil only once or twice week) hair oil users were asked to visit site on follow-up visits. Hair from proximal portion of scalp were pulled. Length of the collected hair was measured and average was calculated and was compared with study group subject's hair length.

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11.1.5 Comparative Assessment on dandruff of AP/VJT/SBO Ayurvedic hair oil in females:

Measuring dandruff score on Standard dandruff evaluation strip was done on each follow up visit as per the attached annexure. Dandruff evaluation score at each follow visit then was compared to baseline score and between the groups.

11.1.6 Assessment of effect of AP/VJT/SBO Ayurvedic hair oil on quality of hair based on subject questionnaire including effect on greying, hair growth and hair density

Assessment of effect of hair_oil on quality of hair based on subject questionnaire was done on each follow up visit. Score at each visit then was compared to the baseline visit and between the groups. Assessment of effect of hair oil on quality of hair based on subject questionnaire was as follows.

1. Since the start of the study, how much of your visibility of scalp is getting lesser?

ss(On a VAS Scale of -10 to 10, where 0 represents no change, -10 maximum worsening and +10 maximum improvement).

2. Ever since the start of the study how would you describe the growth of your hair?

-3 = Severe Worsening	0 = No Change	+ 1 Slight improvement
-2 = Moderate Worsening		+2= Moderate improvement
-1 = Mild Worsening		+3 = Marked improvement

3. Compared to beginning of the study, how satisfied are you with the appearance of your hair?

-3 = Severe Worsening	0 = No Change	+ 1 Slight improvement
-2 = Moderate Worsening		+2 = Moderate improvement
-1 = Mild Worsening		+3 = Marked improvement

4. How would you rate your hair in terms of smoothness as compared to beginning of study?

(On a Scale of -10 to 10 where -10 represents extremely rough 0 represents no change and 10 extremely smooth).

5. How effective do you think the treatment has been in slowing down your hair loss?

-3 = Severe Worsening	0 = No Change	+ 1 Slightly effective
-2 = Moderate Worsening		+2 = Moderately effective
-1 = Slightly worsened		+3 = Extremely effective

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6. Because of the treatment you have received since the start of the study, how would you rate thickness of your Hair enhanced?
(On a Scale of -10 to 10 where -10 represents extremely thin 0 represents no change and 10 extremely dense and thick).

7. Since the start of the study, do you feel difference in dandruff of hair/scalp?

-3 = Severe Worsening	0 = No Change	+ 1 Slight improvement
-2 = Moderate Worsening		+2 = Moderate improvement
-1 = Mild Worsening		+3 = Marked improvement

8. Since the start of the study do you feel any change in greying of your hair?

-3 = Severe Worsening	0 = No Change	+ 1 Slight improvement
-2 = Moderate Worsening		+2 = Moderate improvement
-1 = Mild Worsening		+3 = Marked improvement

11.1.7 Global assessment of overall change in hair loss by the physician:

The CGI-I is a global assessment scale used by physician/investigator to provide a brief, standalone assessment of the Subject's global functioning prior to and after initiating a study medication including a knowledge of the Subject's history, psychosocial circumstances, symptoms, behaviour, and the impact of the symptoms on the Subject's ability to function. CGI-I was recorded/filled at the end of the study. The CGI is rated on a 7-point scale, with the severity of illness scale using a range of responses from 1 (very much improved) to 7 (very much worse). Each component of the CGI is rated separately; the instrument does not yield a global score. Investigator rates the total change, whether, it is entirely due to product treatment compared to Subject's condition at admission to the study and how much has she changed

0 = Not assessed	4 = No change
1 = Very much improved	5 = Minimally worse
2 = Much improved	6 = Much worse

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3 = Minimally improved	7 = Very much worse

11.1.8 Global assessment of overall change in hair loss by the subject

The subject rates the overall change in the hair loss, whether or not, it is entirely due to product treatment compared to her condition at admission to the study and how much has it changed.

0 = Not assessed	4 = No change
1 = Very much improved	5 = Minimally worse
2 = Much improved	6 = Much worse
3 = Minimally improved	7 = Very much worse

11.1.9 Assessment of safety by observing episodes, severity and duration of any allergic reactions and adverse events

Assessment of safety by observing episodes, severity and duration of any allergic reactions and adverse events during the study period measured in day(s) based on investigators clinical examination was done on each follow up visit.

11.2 Assessment of Safety:

Safety was assessed by clinical review of all safety parameters, including the following:

a. Adverse event reporting, as applicable

b. Vital signs including allergic reactions, skin infections etc.

c. Assessment of Overall Safety and Tolerability of the product by the physician and subject on global assessment scale by the investigator and by subject herself. The criterion for the global assessment of overall safety was as follows:

1 = **Excellent Overall safety** (No adverse event/s reported)

2 = **Good Overall safety** (Mild adverse events (s) reported which subside with or without medication)

3 = **Fair Overall safety** (Moderate to severe adverse event(s) reported which subside with or without medication and do not necessitate stoppage of study treatment)

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4 = **Poor Overall safety** (Severe or serious adverse event(s) which necessitate stoppage of study.)

Safety variables were listed individually for detailed clinical review, when needed. Additional tables shall summarized adverse events by severity and relationship to study product as well as leading to SAEs and withdrawal of the subjects from the trial.

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APPENDIX I- TABLE OF ASSESSMENT

Sr. No.	Activity	Screening Visit	Baseline Visit	1st follow up (Day 15)	2nd follow up (Day 30)	3rd follow up (Day 45)	4th follow up (Day 60)
1	Informed Consent	√	×	×	×	×	×
2	Assessment of Inclusion/Exclusion	√	×	×	×	×	×
3	Medical History	√	×	×	×	×	×
4	Prior Treatment	√	×	×	×	×	×
5	Clinical examination	√	√	√	√	√	√
6	Clinical examination (Hair Specific: Running finger test, Comb test, Hair Pull test, Subject Questionnaire, Dandruff evaluation)	√	√	√	√	√	√
7	Hb% and TSH	√	×	×	×	×	×
8	Randomization	×	√	×	×	×	×
9	Drug dispensing	×	√	√	√	√	×
10	Adverse Event	√	√	√	√	√	√
11	Concomitant Treatment	√	√	√	√	√	√
12	Compliance	×	×	√	√	√	√
13	Global assessment by Investigator and Subject	×	×	×	×	×	√
14	Completion	×	×	×	×	×	√



12. STUDY VISIT DETAILS:

12.1. Study population and pre-study screening evaluation

Written informed consent was obtained from the subject/ LAR of subjects prior to screening for possible inclusion in the study. During Informed consent process, subjects were given enough time to read the Informed Consent Document which was printed in the languages best understood by them. Subjects/ LAR were given freedom to ask the questions and all questions were answered by the Investigator or by other study staff. If subject agreed to participate in the study, a written informed consent for the same was obtained from her.

The screening phase was designed to confirm that the subject fulfilled all inclusion and exclusion criteria. The baseline evaluations were completed prior to the initiation of study treatments. A screening log was maintained at the site where all the subjects screened for possible inclusion were enlisted, irrespective of whether or not the subjects were finally enrolled into the study. Those who did not fulfill the inclusion/exclusion criteria were recorded as 'screening failures.

The following activities were performed at this stage:

1. Female subjects were screened for eligibility criteria.
2. On screening visit, a written informed consent was obtained from subjects for their participation in the study.
3. Demographic details were recorded. General Physical and clinical examination were done.
4. Clinical symptoms, if any were noted in the CRF.
5. Subjects were asked to do a Running Finger Test (RFT) and Comb Test (CT) in the presence of investigator/Study Personal and the hair samples were collected in plastic bag and documented in the CRF.
6. Subjects were also assessed based on hair pull test.
7. Subject's dandruff score was evaluated on standard dandruff evaluation strip.
8. If required, subjects underwent lab examinations like Hb% and TSH. Subjects with low Hb% and thyroid disorders were excluded from the study.

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9. Eligible subjects were enrolled in the study.
10. Subjects were asked not to take any medication for the treatment of Hair loss except the study medication during the study period.
11. Subjects were asked to continue their usual routine diet and exercise/activity regimen, which they were already following, during the entire study period. Subjects were asked to come to hospital/site for baseline visit within three days after screening visit.

12.2. Procedures performed during the study period

A) Baseline Visit (Day 0):

On baseline visit, subjects were recruited in the study on meeting all the inclusion criteria. As per computer generated randomization list, subjects were randomized to one of the two study groups. Investigational Product dispensing was done to Subject's in the AP/VJT/SBO oil group Subjects were given a HDPE bottle containing 150mL of Hair oil. Subjects were asked to apply approximately 10 ml oil. Oil application was asked minimum 3 times a week for 60 days.

Subjects prakruti evaluation was done and they underwent general and systemic examinations. Subject's Clinical symptoms were noted in the CRF. Subjects were asked to do a Running Finger Test (RFT) and Comb Test (CT) in the presence of investigator and the hair samples were collected in plastic bag and documented in the CRF. Subjects small portion of hair (approximately 20-60 hairs) from the proximal portion of the scalp were grasped between the thumb, index and middle fingers from the base of the hairs near the scalp and firmly, but not forcefully, tugged away from the scalp. The number of hair pulled away from scalp were counted and recorded in CRF. Average length of hair from Pull test were measured and recorded in CRF. Subject's dandruff score was evaluated on standard dandruff evaluation strip. Subjects were interrogated based on questionnaire to evaluate their quality of hair (both on graded scale and VAS).

Subjects were asked not to take any medication for the treatment of Hair loss during the study period. The subjects were asked to continue with their usual regular daily diet and activity regimen as they were taking earlier.

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Subject were asked for any AE/SAE occurred. If subject had AE/SAE, the details of the incidence was documented in the source document and CRF. SAE, if any, was reported to the IEC in a SAE reporting form. Rescue medication used, if any, was recorded in the CRF.

Subjects were asked to massage with 5 to 10 ml hair oil maximum 3 times a week on the scalp with fingertips before going to bed in night or before bath. Subjects were asked to apply hair oil daily and do hair wash thrice a week. Subject were then asked to come for subsequent follow ups on day 15, 30, 45 and 60.

B) Follow up Visits: Visit 1 (Day 15), Visit 2 (Day 30) and Visit 3 (Day 45) ± 5 days:

Subjects underwent general and systemic examinations. Clinical symptoms were noted in the CRF. Assessment of Hair loss was done by Running Finger Test (RFT), Comb Test (CT) and Hair pull test in the presence of investigator. Assessment of dandruff was done on dandruff evaluation strip in the presence of investigator. Subjects were interrogated based on questionnaire to evaluate their quality of hair (both on graded scale and VAS) on every Follow up. Assessment of hair growth was done by measuring subject's average hair length. On same follow up visit's subjects from infrequent hair oil users' group were asked for measuring standard hair length for evaluating hair growth.

On every follow up visit except last follow up visit, subjects from the NANSHO Hair Oil group were provided with study medicine. On every follow up visit, the empty container was collected from the subject and drug compliance was checked. Subjects were asked for any AE/SAE occurred. If subject had AE/SAE, the details of the incidence was documented in the source document and CRF. SAE, if any, was reported to the IEC in a SAE reporting form. Rescue medication used, if any, was recorded in the CRF.

C). Visit 4- End of Study (Day 60):

Assessment of Hair loss was done by Running Finger Test (RFT), Comb Test (CT) and Pull test in the presence of investigator. Assessment of dandruff was evaluated on dandruff evaluation strip in the presence of investigator. Subjects were interrogated based on questionnaire to

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evaluate their quality of hair (both on graded scale and VAS). Overall safety of the trial Hair oil was assessed on global assessment scale by the investigator and by subject herself. Assessment of hair growth was done by measuring subject's average hair length. On same follow up visit subjects from infrequent (applies oil only once or twice week) hair oil group were asked for measuring standard hair length for evaluating hair growth in infrequent (applied oil only once or twice week) hair oil users. Subjects were asked for any adverse event during this period. If subject had AE/SAE, the details of the incidence were documented in the source document and CRF. SAE, if any, were reported to the IEC in a SAE reporting form. Rescue medication used, if any, was recorded in the CRF. Subjects were asked to stop trial medication and take advice of investigator for further treatment.

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13.STUDY POPULATION:

A total of 76 subjects were screened in the study. There were 8 screen failures and 68 subjects were randomized with 33 subjects in AP/VJT/SBO Hair oil Group and 35 subjects in control group. There was 1 dropout each in Group A and group B. A total of 66 subjects (32 in group A and 34 in group B) completed the study. Also, all the cases who took at least one dose of the study drug were considered as —Safety population‖ and were evaluated.

14.OBSERVATIONS AND RESULTS:

I) Baseline Demography:

There was no significant difference in the demographic parameters like age, Hb and body weight between the two groups, meaning groups were evenly matched. The average age of participants in AP/VJT/SBO Hair Oil group was 31.69 ± 7.92 years while it was 30.41 ± 6.69 years in the control group. The mean Hb% in AP/VJT/SBO group was 11.95 ± 1.04 while in the control arm it was 12.83 ± 1.11. Weight of participants in the AP/VJT/SBO group was 57.35 ± 8.80 kg in AP/VJT/SBO group while in the control arm it was 59.18 ± 9.80 kg.

Table 1: Baseline Demography and Lab test in the two study groups

	Age in years	Hb%	Weight	BMI
AP/VJT/SBO Group (n=32)	31.69 ± 7.92	11.95 ± 1.04	57.35 ± 8.80	23.65 ± 3.51
Control Group (n = 34)	30.41 ± 6.69	12.83 ± 1.11	59.18 ± 9.80	24.84 ± 4.45
p-value between the Groups	p>0.05 (NS)	p>0.05 (NS)	p>0.05 (NS)	p>0.05 (NS)

II) Primary Outcomes:

A) Comparative assessment of hair fall by RFT (Running Finger Test):

Assessment of hair fall based on running finger test showed that there was a significant reduction in hair fall within the first 15 days of use of AP/VJT/SBO oil from an average of 30.84 ± 10.74 at baseline to 25.41 ± 11.12. This hair fall reduction continued further to 21.25± 8.47 at 30 days, 17.88 ±8.14 at 45 days and 11.66 ±6.41 at the end of the study i.e., 60 days. At the end of 30

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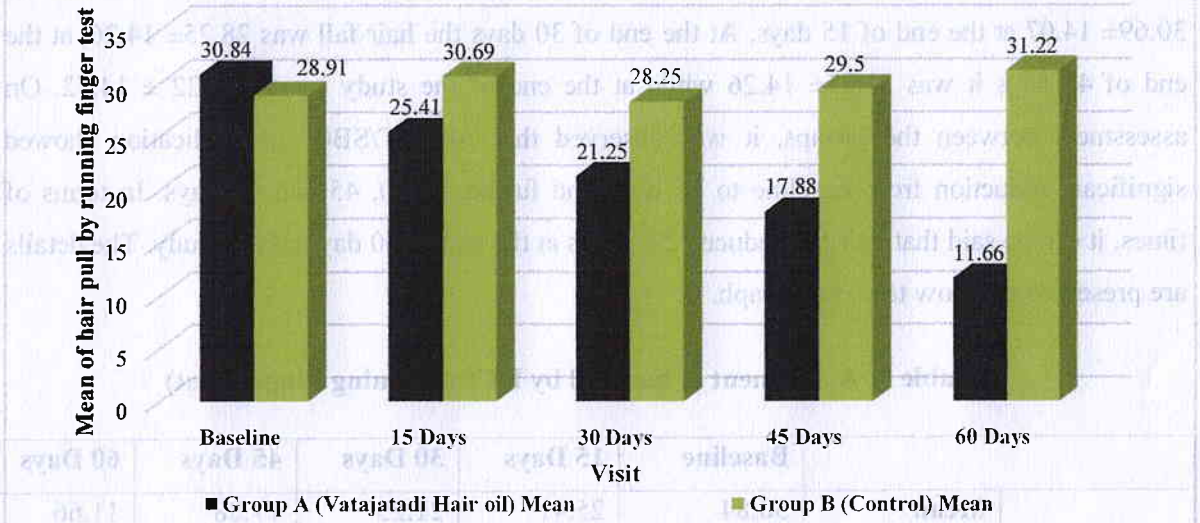
days of the study hair fall reduced by 31.10% while at the end of 60 days it reduced to 62.19%. The average hair fall at baseline in control group was 28.91 ± 12.78 which slightly increased to 30.69± 14.07 at the end of 15 days. At the end of 30 days the hair fall was 28.25± 14.26, at the end of 45 days it was 28.25± 14.26 while at the end of the study it was 31.22 ± 14.72. On assessment between the groups, it was observed that AP/VJT/SBO oil application showed significant reduction from baseline to 15 days and further to 30, 45 and 60 days. In terms of times, it can be said that hair fall reduced 2.6 times at the end of 60 days of the study. The details are presented in below table and graph.

Table 2: Assessment of hair fall by RFT (Running Finger Test)

		Baseline	15 Days	30 Days	45 Days	60 Days
AP/VJT/SBO Group (n = 32)	**Mean**	30.84 ± 10.74	25.41 ± 11.12	21.25 ± 8.47	17.88 ± 8.14	11.66 ± 6.41
	p-value	-	p<0.05	p<0.05	p<0.05	p<0.05
	% Change from baseline	-	17.58%	31.10%	42.02%	62.19%
Control Group (n = 34)	**Mean**	28.91 ±12.78	30.69 ± 14.07	28.25 ± 14.26	29.50 ± 14.02	31.22 ± 14.72
	p-value	-	p>0.05	p>0.05	p>0.05	p>0.05
	% Change from baseline	-	-6.16%	2.28%	-2.04%	-7.99%
p-value between Groups		p>0.05	p<0.05	p<0.05	p<0.05	p<0.05

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Graph 1: Assessment of hair fall by RFT (Running Finger Test)



B) Comparative Assessment of hair breakage by Comb Test:

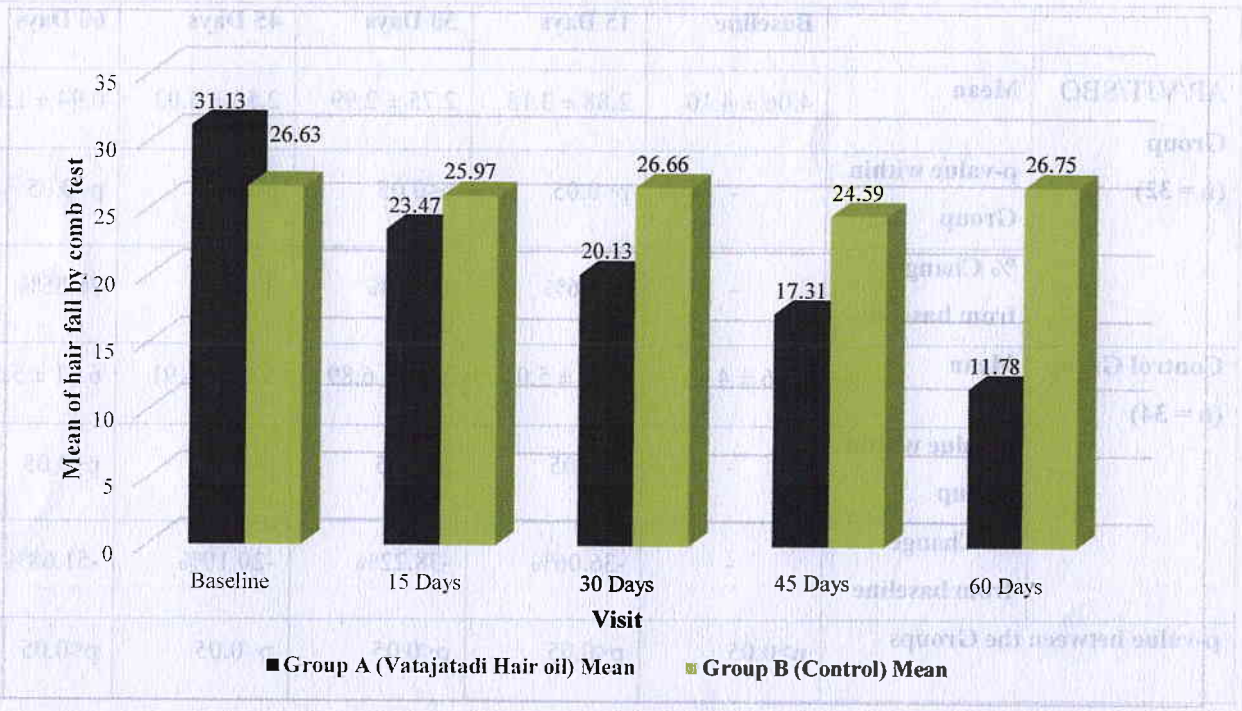
Assessment of hair fall based on comb test showed that there was a significant reduction in hair fall within the first 15 days of use of AP/VJT/SBO oil from an average of 31.13± 12.86 at baseline to 23.47± 12.44. This hair fall reduction continued further to 20.13 ± 10.27 at 30 days, 17.31 ± 9.46 at 45 days and 11.78 ± 6.61at the end of the study i.e., 60 days. At the end of 30 days of the study hair fall reduced by 35.34% while at the end of 60 days it reduced to 62.16%. The average hair fall at baseline in control group was 26.63 ± 8.68 which slightly decreased to 25.97 ± 7.84 at the end of 15 days. At the end of 30 days the hair fall was 26.66 ± 6.68, at the end of 45 days it was 24.59 ± 8.11 while at the end of the study it was 26.75 ± 9.50. On assessment between the groups, it was observed that AP/VJT/SBO oil application showed significant reduction from baseline to 15 days and further to 30, 45 and 60 days. In terms of times, it can be said that hair fall reduced 2.6 times at the end of 60 days of the study. The details are presented in below table and graph.

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Table 3: Assessment of hair fall by CT (Comb Test)

		Baseline	15 Days	30 Days	45 Days	60 Days
AP/VJT/SBO Group (n = 32)	Mean SD	31.13 ± 12.86	23.47 ± 12.44	20.13 ± 10.27	17.31 ± 9.46	11.78 ± 6.61
	p-value	-	p<0.05	p<0.05	p<0.05	p<0.05
	% Change from baseline	-	24.61%	35.34%	44.40%	62.16%
Control Group (n = 34)	Mean SD	26.63 ± 8.68	25.97 ± 7.84	26.66 ± 6.68	24.59 ± 8.11	26.75 ± 9.50
	p-value	-	p>0.05	p>0.05	p>0.05	p>0.05
	% Change from baseline	-	2.48%	-0.11%	7.66%	-0.45%
p-value between Groups			p<0.05	p<0.05	p<0.05	p<0.05

Graph 2: Assessment of hair fall by comb test



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III) Secondary outcomes:

A) Comparative assessment of hair fall by Hair Pull test:

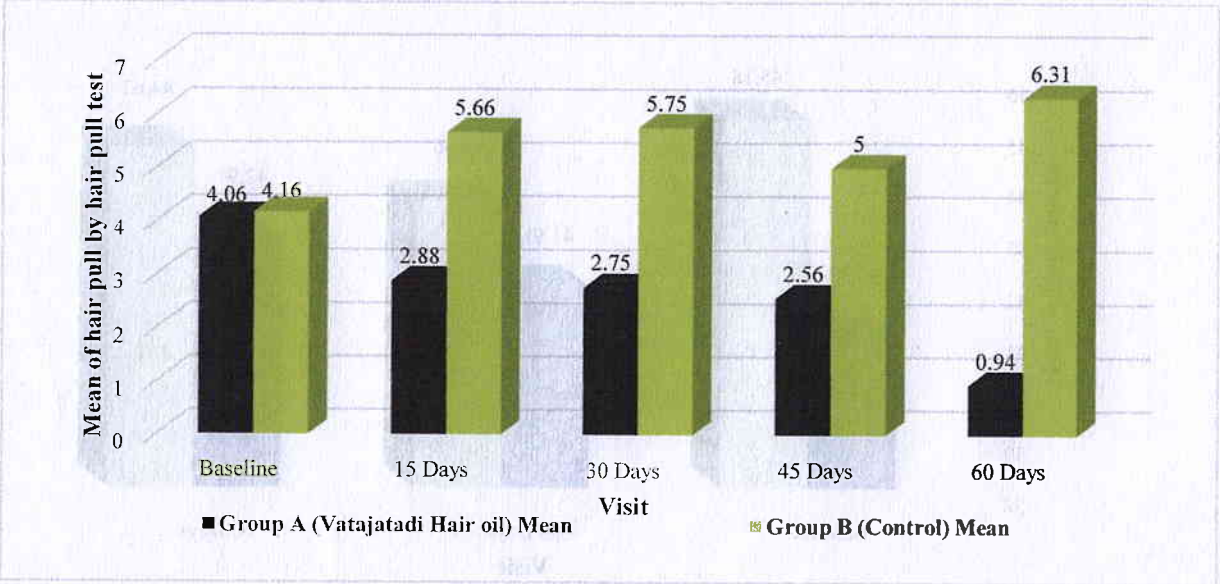
Assessment of hair fall based on Pull test showed that there was a significant reduction in hair fall within the first 15 days of use of AP/VJT/SBO oil from an average of 4.06 ± 4.10 at baseline to 2.88 ± 3.13. This hair fall reduction continued further to 2.75 ± 2.99 at 30 days, 2.56 ± 4.03 at 45 days and 0.94 ± 1.14 at the end of the study i.e., 60 days. At the end of 30 days of the study hair fall reduced by 32.27% while at the end of 60 days it reduced to 76.85%. The average hair fall at baseline in control group was 4.16 ± 4.93 which increased to 5.66 ± 5.02 at the end of 15 days. At the end of 30 days the hair fall was 5.75 ± 6.89, at the end of 45 days it was 5.00 ± 4.91 while at the end of the study it was 6.31 ± 5.51. On assessment between the groups, it was observed that AP/VJT/SBO oil application showed significant reduction from baseline to 15 days and further to 30, 45 and 60 days. In terms of times, it can be said that hair fall reduced 4.3 times at the end of 60 days of the study. The details are presented in below table and graph

Table 4: Assessment of hair fall by hair pull test

		Baseline	15 Days	30 Days	45 Days	60 Days
AP/VJT/SBO Group (n = 32)	Mean	4.06 ± 4.10	2.88 ± 3.13	2.75 ± 2.99	2.56 ± 4.03	0.94 ± 1.14
	p-value within Group	-	p<0.05	p<0.05	p<0.05	p<0.05
	% Change from baseline	-	29.06%	32.27%	36.95%	76.85%
Control Group (n = 34)	Mean	4.16 ± 4.93	5.66 ± 5.02	5.75 ± 6.89	5.00 ± 4.91	6.31 ± 5.51
	p-value within Group	-	p<0.05	p<0.05	p<0.05	p<0.05
	% Change from baseline	-	-36.06%	-38.22%	-20.19%	-51.68%
p-value between the Groups		p>0.05	p<0.05	p<0.05	p<0.05	p<0.05

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Graph 3: Assessment of Hair fall by Hair pull test



B) Comparative assessment of hair growth:

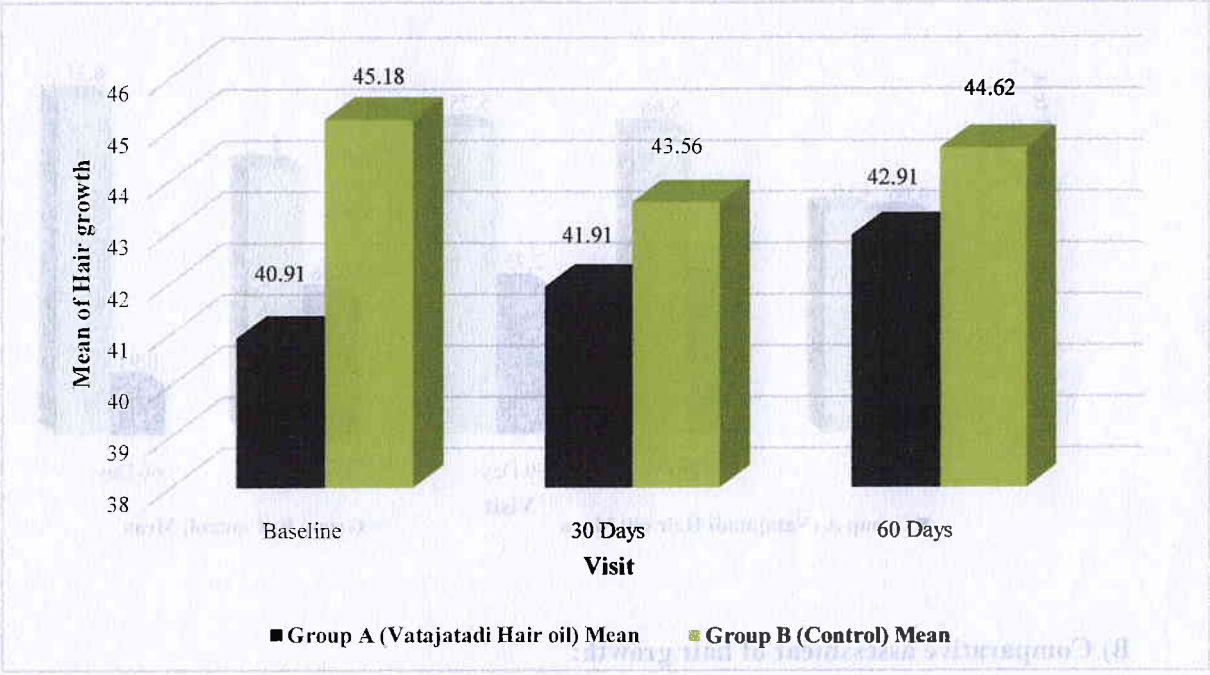
The average length of hair at baseline in AP/VJT/SBO group was 40.91 ± 12.97 cm at baseline which increased (non-significant) to 41.91 ± 13.40 cm at the end of 30 days and to 42.91 ± 13.60 cm (significant) at the end of 60 days. The average hair length in control group was 45.18 ± 17.13 cm which decreased to 43.56 ± 17.30 cm at the end of 30 days and to 44.62 ± 16.96 cm (non-significant) at the end of 60 days. On analysis between the group, it was observed that the hair growth was significant in AP/VJT/SBO group as compared to control group at the end of 60 days.

Table 5: Comparative assessment of hair growth

Group	**Parameter**	**Baseline**	**30 Days**	**60 Days**
AP/VJT/SBO	**Mean SD**	40.91 ± 12.97	41.91 ± 13.40	42.91 ± 13.60
Group (n = 32)	**p-value**	-	p>0.05	p<0.05
Control Group	**Mean SD**	45.18 ± 17.13	43.56 ± 17.30	44.62 ± 16.96
(n = 34)	**p-value**	-	p>0.05	p>0.05
p-value between the Groups		p>0.05	p>0.05	p<0.05

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Graph 4: Comparative assessment of hair growth



C) Assessment of dandruff on standard dandruff evaluation cards:

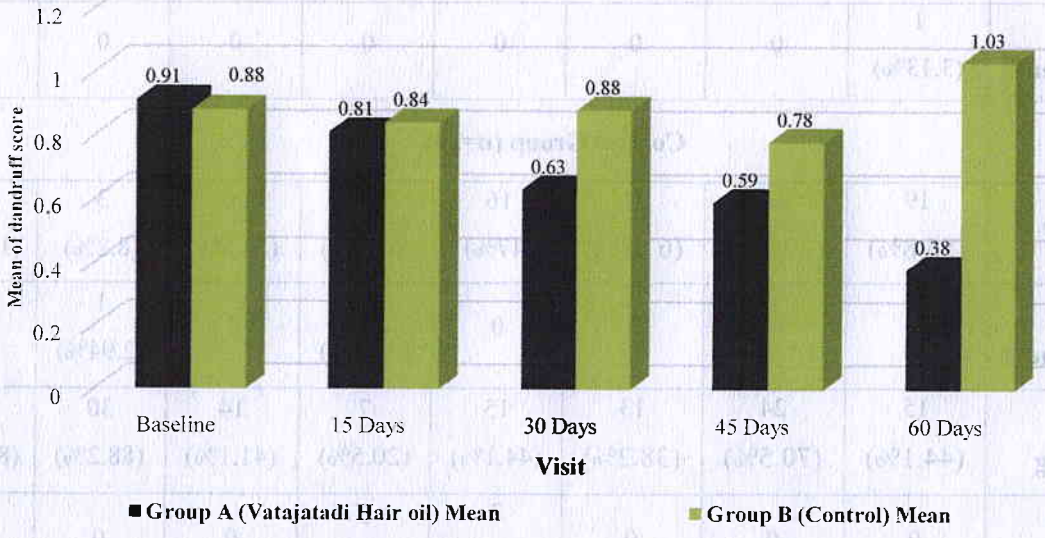
Severity of dandruff was assessed using standard dandruff evaluation cards. It was observed that the mean score at baseline in AP/VJT/SBO group was 0.91 ± 0.73 which reduced to 0.81 ± 0.73 at the end of 15 days (non-significant) and further to 0.63 ± 0.66 (significant). Further on day 45 and day 60 the reduction was significant with the score of 0.59 ± 0.56 and 0.38 ± 0.50 respectively. In the control group the baseline score was 0.88 ± 0.72 which reduced slightly to 0.84 ± 0.69 at the end of 15 days (non-significant). The score was recorded as 0.88 ± 0.67 at the end of 30 days, 0.78 ± 0.61 at the end of 45 days and 1.03 ± 0.76 at the end of 60 days. There was an increase in dandruff score in the control (non-significant). Analysis between the group showed that the decrease in dandruff with the use of AP/VJT/SBO was significant as compared to control from day 30 and continued further. There was a 58.24% reduction in dandruff with the use of AP/VJT/SBO oil.

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Table 6: Assessment of dandruff by standard dandruff evaluation cards

Group	Parameter	Baseline	15 Days	30 Days	45 Days	60 Days
AP/VJT/SBO Group (n = 32)	Mean	0.91 ±0.73	0.81 ± 0.73	0.63 ± 0.66	0.59 ± 0.56	0.38 ± 0.50
	p-value	-	p>0.05	p<0.05	p<0.05	p<0.05
	% Change from baseline	-	10.99%	30.77%	35.17%	58.24%
Control Group (n = 34)	Mean	0.88 ±0.72	0.84 ± 0.69	0.88 ± 0.67	0.78 ± 0.61	1.03 ± 0.76
	p-value	-	p>0.05	p>0.05	p>0.05	p>0.05
	% Change from baseline	-	4.54%	0%	11.36%	-17.04%
p-value between the Groups			p>0.05	p<0.05	p<0.05	p<0.05

Graph 5: Assessment of dandruff by standard dandruff evaluation cards



D) Comparative assessment of Hair Oil on quality of hair:

The table below shows change in hair quality based on questionnaire assessment (8 questions) as per the participant at the end of the study. It was observed that about 60% of participants reported improvement in reduction of visibility of scalp, 74% reported improvement in hair growth, 72% reported improvement in appearance of hair, more than 90% reported increase in

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smoothness of hair, more than 92% showed reduction in hair loss while 50% reported increase in thickness of hair. Dandruff reduction was reported by 50% while 15.6% reported in reduction of greying of hair. None of the participant reported improvement on these parameters in the control group while they reported either no change or worsening of their condition.

Table 7: Comparative assessment of Hair Oil on quality of hair

AP/VJT/SBO Hair oil Group (n = 32)								
Assessment	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**	**Q8**
No change	13 (40.6%)	8 (25%)	9 (28.1%)	3 (9.3%)	3 (9.3%)	16 (50%)	24 (75%)	27 (84.3%)
Slight Improvement	17 (53.1%)	14 (43.7%)	21 (65.6%)	22 (68.7%)	10 (31.2%)	16 (50%)	8 (25%)	5 (15.6%)
Moderate Improvement	1 (3.1%)	10 (31.2%)	2 (6.2%)	7 (21.8%)	19 (59.3%)	0	0	0
Marked Improvement	1 (3.13%)	0	0	0	0	0	0	0
Control Group (n=34)								
No change	19 (55.8%)	10 (29.4%)	21 (61.7%)	16 (47%)	21 (61.7%)	20 (58.8%)	3 (8.2%)	4 (11.7%)
Slight Improvement	0	0	0	0	1 (2.94%)	0	1 (2.94%)	0
Mild Worsening	15 (44.1%)	24 (70.5%)	13 (38.2%)	15 (44.1%)	7 (20.5%)	14 (41.1%)	30 (88.2%)	30 (88.2%)
Moderate Worsening	0	0	0	3 (8.8%)	5 (14.7%)	0	0	0

Q1- visibility of scalp, Q2- Growth of hair, Q3- Appearance of hair, Q4- Smoothness of hair, Q5- Hair loss, Q6- Thickness of hair, Q7- Dandruff, Q8- Greying of Hair

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E) Global assessment of overall change in hair loss by the physician and subject:

As per physician and subject assessment for overall change, 19 (59.37%) subjects reported very much improvement, 11 (34.37%) subjects reported much improvement and 2 (6.25%) subject reported minimal improvement.

Table 8: Global assessment of overall change in hair loss by the physician and subject

	Scale	AP/VJT/SBO Group (n = 32)
Physician	0 (Not Assessed)	0
	1 (Very Much Improved)	19 ((59.37%)
	2 (Much Improved)	11 (34.37%)
	3 (Minimally Improved	2 (6.25%)
	4 (No Change)	0
	5 (Minimally Worse)	0
	6 (Much Worse)	0
	7 (Very Much Worse)	0
Subject	0 (Not Assessed)	0
	1 (Very Much Improved)	19 ((59.37%)
	2 (Much Improved)	11 (34.37%)
	3 (Minimally Improved	2 (6.25%)
	4 (No Change)	0
	5 (Minimally Worse)	0
	6 (Much Worse)	0
	7 (Very Much Worse)	0

F) Global assessment of overall safety by the physician and subject:

In group A, as per physician's and subject's assessment for overall safety, 21 (65.63%) subjects reported excellent overall safety, 11 (34.37%) subjects reported good overall safety.

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G) Assessment of Vitals:

In both the groups, no significant change in these parameters was observed from baseline to the end of the study. All the vitals were within normal range at baseline visit and at all the follow up visits.

Table 9. Assessment of Vitals

Parameter	AP/VJT/SBO Group (n = 32)			Control Group (n = 34)		
	Baseline	**30 Days**	**60 Days**	**Baseline**	**30 Days**	**60 Days**
Pulse	76.50 ± 4.33	76.16 ± 3.57	76.97 ± 4.25	76.12 ± 4.40	73.15 ± 3.58	73.50 ± 3.71
RR	17.91 ± 1.77	18.41 ± 2.08	18.84 ± 2.42	18.68 ± 2.04	17.97 ± 1.99	18.21 ± 2.17
Temp	97.83 ± 0.37	97.85 ± 0.50	97.90 ± 0.54	97.66 ± 0.56	94.97 ± 0.41	94..93 ± 0.45
BP(S)	121.38 ± 5.04	119.44 ± 6.23	119.56 ± 6.24	118.59 ± 6.41	115.18 ± 6.74	116.06 ± 5.72
BP(D)	82.06 ± 5.53	78.22 ± 13.77	79.50 ± 6.43	79.12 ± 5.46	76.53 ± 5.77	77.18 ± 4.44

H) Assessment of AEs:

In group A, 9 subjects had adverse events i.e., headache, severe acidity, cough, cold, vomiting, abdominal pain, bloated abdomen, body pain, stomach pain and calf muscle pain. In group B, 13 subjects had adverse events of hyperacidity, cough, cold, headache, tonsilitis, stomatitis, vomiting, low back pain, fever, throat infection and VB-12 Deficiency. In Group B 1 subject had SAE of Acute Diarrhoea which was subsided with the treatment. All the AEs and SAE were of mild to moderate in nature and recovered with proper treatment. None of the AEs and SAE was related to the study product or procedure.

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15. DISCUSSION:

The present study was conducted to evaluate efficacy and safety of AP/VJT/SBO Ayurvedic Hair Oil / AP/VJT/SBO Hair Oil group in mild to moderate Hair loss in females. A total of 66 subjects (32 in group A and 34 in group B) completed the study. There was no significant difference in the demographic parameters like age, Hb% and body weight between the two groups, meaning groups were evenly matched. The average age of participants in AP/VJT/SBO Hair Oil group was 31.69 ± 7.92 years while it was 30.41 ± 6.69 years in the control group.

In AP/VJT/SBO group, hair fall as assessed using running finger test reduced 2.6 times (significant) at the end of 60 days of the study compared to control group. As per comb test, hair fall significantly reduced 2.6 times at the end of 60 days of the study compared to control group. It was observed in assessment of hair fall based on pull test that hair fall reduced (significant) 4.3 times at the end of 60 days of the study compared to the control group. On analysis between the group, it was observed that the hair growth was significant in AP/VJT/SBO group as compared to control group at the end of 60 days. Significant reduction in dandruff with the use of AP/VJT/SBO was observed from day 30 onwards till the end of the study as compared to control. There was a 58.24% reduction in dandruff with the use of AP/VJT/SBO oil.

It was observed that about 60% of participants reported improvement in reduction of visibility of scalp, 74% reported improvement in hair growth, 72% reported improvement in appearance of hair, more than 90% reported increase in smoothness of hair, more than 92% showed reduction in hair loss while 50% reported increase in thickness of hair. Dandruff reduction was reported by 50% while 15.6% reported in reduction of greying of hair. None of the participant reported improvement on these parameters in the control group while they reported either no change or worsening of their condition. As per global assessment of overall change, majority of the subjects in AP/VJT/SBO group showed very much improvement in hair fall at the end of the study.

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It is evident from the above results that AP/VJT/SBO significantly reduced hair fall and dandruff, increased hair growth, improved hair appearance, smoothness of hair and thickness of hair. AP/VJT/SBO also helps in reduction in greying of hair. Ingredients present in AP/VJT/SBO, strengthen the roots, promote hair growth, reduce dandruff, and also help in smoothness of hair. Ingredients also possess 5α-reductase inhibitory activity that helps increase hair growth in subjects suffering from hair loss.[13-17] Synergistic activities of the ingredient present in AP/VJT/SBO could have helped subjects in reduction of hair fall and dandruff and increase in hair growth.

Majority of the subjects in AP/VJT/SBO group showed excellent overall safety. In both the groups, no significant change in vital parameters was observed from baseline to the end of the study. All the vitals were within normal range at baseline visit and at all the follow up visits. In group A, 9 subjects had adverse events, while in group B, 13 subjects had adverse events. In Group B, 1 subject had SAE of acute diarrhoea. All the AEs and SAE were of mild to moderate in nature and recovered with proper treatment. None of the AEs and SAE was related to the study product or procedure. These results established safety of use of AP/VJT/SBO in subjects suffering from hair loss.



16. CONCLUSION:

It is evident from the results of the present study that AP/VJT/SBO Hair oil was significantly effective in reducing hair fall and dandruff in female subjects suffering from mild to moderate hair loss. AP/VJT/SBO Hair oil was significantly effective in improving hair growth, hair density, appearance and smoothness of the hair, thickness of hair and overall quality of hair. AP/VJT/SBO Hair oil was found to be dermatologically safe in subjects suffering from hair loss.



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18. ANNEXURES:

1. World Medical Association Declaration of Helsinki
2. SOP for hair fall tests and Standard dandruff evaluation test.
3. Instructions for hair wash

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3.5.1

41. Collaborative activity

Student exchange

Dy Patil Pharmacy College Akurdi

30/11/2022

Pune District Education Association's

College of Ayurved & Research Centre

Post event summary report **Date- 30/11/2022**

Name of the event- Visit to College of Ayurved & Research Centre, Nigdi, Pune by students of Dr D Y Patil Institute of Pharmacy Ravet Pune under student exchange programme

पु.जि.शि.मं.चे
आयुर्वेद महाविद्यालय व संशोधन केंद्र
आवक क्र. 3509/2022-23
दिनांक 3/12/2022
लेखनिक
प्राचार्य

Date of the event-30/11/2022

Organising department- Rachana Sharir

Location of the event- College of Ayurved & Research Centre, Nigdi, Pune

Number of persons attending the event- 45

Mode of event- Offline

Drive Link for Photos-
https://drive.google.com/drive/folders/1Cqh0k1oAIjFUignAKmfiU9Wsvkl3tDcB?usp=share_link

Summary of the event-

As per the e mail and request letter from Dr D Y Patil Institute of Pharmacy Ravet dated 17/11/2022, visit of students of Dr D Y Patil Institute of Pharmacy students was planned at PDEA's college of Ayurveda and research center Nigdi, Pune. Students of Dr D Y Patil Institute of Pharmacy Ravet visited on 30/11/2022 between10am – 2 pm. Out of 45 students along with Vice Principal Mrs Bhavana Kapse and Mrs Aishwarya Ambekar madam.

Dr. Topale welcomed all students & Vice Principal Mrs. Bhavana Kapse and Mrs Aishwarya Ambekar madam. Visit started with Dhanvantari prayer. All students introduced themselves. Dr. Naik gave best wishes to all students. Then students visited Rachana Sharir department of college including Herbal Garden and Dravyaguna Department.

Dr. Madhuri Mahadar and Dr Manisha Bhanage from Rachana Department explained basic of Anatomy, various organs & systems on models. Mr Ajay Bandwal explained the mounting and preservation of wet specimen and also took photographs of students.

Dr. P.B.Tople **Dr. D.B.Naik** **Dr. M.A.Mahadar** **Dr. M.M.Bhange**

Name of the Department	Rachana Sharir	NAAC Metric No. 5.4.2

Pune District Education Association's

College of Ayurved & Research Centre





Principal
P.D.E.A'S
College of Ayurved And Research Centre
Nigdi, Pune - 411 044.

Name of the Department	Rachana Sharir	NAAC Metric No. 5.4.2

Pune District Education Association's

College of Ayurved & Research Centre

Name of the event- Visit to College of Ayurved & Research Centre, Nigdi, Pune by Dr D Y Patil Institute of Pharmacy Ravet of students under student exchange programme

Date of the event-30/11/2022





Principal
P.D.E.A'S
College of Ayurved And Research Centre
Nigdi, Pune - 411 044.

Name of the Department	Rachana Sharir	NAAC Metric No. 5.4.2

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3.5.1

42. Collaborative activity

Student exchange

Punarvasu Aushadhshala PVT.LTD.

02/01/2023 to 03/02/2023

Pune District Education Association's,

College of Ayurved & Research Centre

(I.D.No. P.U./P.N./AYU./081/1990)

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Governing Council

President-Ajit Pawar, Vice President -Rajendra Ghadge ,Secretary-Sandeep Kadam, ,

Treasurer-Adv. Mohanrao Deshmukh, Asst. Secretary-L.M.Pawar, Principal-Dr.R.R. Patil

O.No. - 2038/2022-23

Date :- 02 JAN 2023

To,

The Director,

Punarvasu Aushadhshala,

Shivane, Pune.

Subject- Regarding Pharmacy Training of Post Graduate Students.

Respected Sir,

As per subject cited above,GMP approved Pharmacy training is mandatory for post-graduate students of Rasashastra and Bhaishajya Kalpana Subject. The previous students of respective Dept. of CARC, Nigdi have attended such training at your Pharmacy.

So, requesting you to allow following students of Rasashastra and Bhaishajya Kalpana Dept. of our college to attend the 1 month pharmacy training (15 days AushadhNirman Dept., 15 days Quality Control Dept.) at Punarvasu Aushadhshala.

1) Dr. Jui Tamhankar	2) Dr. PrajktaDahiphale	3) Dr. AnujaWatve
4) Dr. Gargi Vaidya	5) Dr. Pallavi Parakhi	6) Dr. SayaliKathane

Thanking you.

Yours Sincerely,

(Dr. Mrs. R. R. Patil)
Principal

Principal
P.D.E.A'S
College of Ayurved And Research Centre
Nigdi, Pune - 411 044.

Punarvasu Aushadhshala Pvt. Ltd.

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Date : / / 20

Date: 03/02/2023

CERTIFICATE OF ATTENDANCE / VISIT

This is to certify that

Dr. GARGI VAIDYA

Who is student of last year M.D. Rasashastra and Bhaishjya kalpana,

College of Ayurved and research centre, Akurdi, Pune

worked / taken training in our Aushadhshala from 02/01/2023 to 03/02/2023

She experienced various preparations like Guggul Kalpana,

Granulation for Gutu Vati , Gandhak shodhan , Khaalvi rasayan preparation , Avaleha

Kalpana with Quality control of various medicines prepared in our Aushadhshala.

I wish her all the best in the future.

Vd. Vivek D. Sane,

PUNARVASU AUSHADHSHALA PVT. LTD.
S.No. 78/1, Shiv-Kamal Industrial Estate,
Shed No. 11, Shivane, Pune - 411 023.

Director,

Punrvasu Aushadhshala Pvt. Ltd. Pune

COLLEGE OF AYURVEDIC RESEARCH AKURDI PUNE - 44

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She experienced various preparations like Guggul Kalpana,

Granulation for Gutu Vati , Gandhak shodhan , Khaalvi rasayan preparation , Avaleha Kalpana with Quality control of various medicines prepared in our Aushadhshala.

I wish her all the best in the future.

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Date : / / 20

Date: 03/02/2023

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Date-6/2/2023

POST EVENT SUMMARY REPORT

Name of the collaborative activity

Industrial training at Punarvasu Aushdhashala Pvt. Ltd, Shivane,Pune.

Date/ Duration

2/1/2023 to 3/2/2023

Place: Punarvasu Aushdhashala Pvt. Ltd, Shivane,Pune.

Participants Details: Final Year PG Students - 04

Organising department/ committee- Rasashastra evam Bhaishajya Kalpana

Brief Activity Details:

- Standardization of ASU drugs
- Standardization of Raw materials, manufacturing process and finished products for ASU drugs
- Preparation of various Guggulu Kalpas
- Preparation of various Kharliya Rasayan
- Preparation of various Kupipakwas like Suvarnaraj vangeshwar,Roupyasindur and Rasmanikya
- Hands on training of Quality control measures for different formulations.

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HOD
Department of Rasashastra Bhaishajyakalpana
College of Ayurved & Research Centre, Akurdi Pune 44

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43. Collaborative activity

Student exchange

Marathwada Mitramandal's College of Pharmacy, Thergaon

23/01/2023

Pune District Education Association's
College of Ayurved & Research Centre
(I.D.No. P.U./P.N./AYU. /081/1990)
Sector No. 25, Pradhikaran, Nigdi, Pune-411 044 (Maharashtra State), India.
Phone - 020 - 27653965 / 27659578, Fax: - 020 - 27659578, Website - www.pdeaayurvedcollege.edu.in
E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Date:03/02/2023

Report of Student exchange activity at CARC

Name of the event:	Authentication of Herbal samples given by students of Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune as collaborative & students exchange activity
Organizing Departments:	Dept. of Dravyaguna, CARC and Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune
Date:	03/02/2023
Location / Place:	Department of Drayaguna, College of Ayurved & Research Centre, Nigdi, Pune
Mode of event -	Offline
No. of students –	03 students (M. Pharm. students)

Brief summary of the event:
Under collaborative & student exchange activities Dr. Meenal Lad issued authentication certificate to the M. pharm. students Mr. Sameer Shaikh,Ms. Prachi Bhapkar & Ms. Sarika Kamle after studying samples. After studying samples, it was found that first sample was Ashok (*Saraca asoca* Roxb.), second sample was Shivlingi (*Byonia laciniosa* Linn.) & third sample was Tirphal (*Zanthoxylum armatum* DC.)

HOD
Dept. of Dravyaguna
Dr. Meenal D. Lad
M. D. , Ph. D. (Ayu.)
Prof. & H.O.D.
Dept. of Dravya guna C.A.R.C, Akurdi

MARATHWADA MITRA MANDAL'S COLLEGE OF PHARMACY

(D. Pharm., B. Pharm., M. Pharm., Ph.D.)
Approved by AICTE, PCI & Recognized by DTE (GOM)
Permanently Affiliated to Savitribai Phule Pune University, Pune & MSBTE
Recognized Under Section 2 (f) and 12 (B) of the UGC Act, 1956
Accredited by NBA (B. Pharm) & NAAC with A+ Grade
Recipient of Best College Award (Professional-Urban) by SPPU, Pune

Shri. Shivajirao D. Ganage	**Prin. Bhausaheb G. Jadhav**	**Shri. Kishor H. Mungale**
President	Exec.President	Secretary

Ref: MM / COP/Sample/2022-23/3099. *Date:* 23/01/2023

To,
Dr. Minal Lad,
Head of Dept. (Dravyaguna Vibhag)
PDEA'S College of Ayurved and Research Centre,
Sector No, 27, Nigdi Pradhikaran,
Pimpri Chinchwad, Pune411044

पु.ज्ञि.शि.मं.चे
आयुर्वेद महाविद्यालय व संशोधन केंद्र
आवक क्र. 437/2022-23
दिनांक - 25/1/2023
लेखनिक
प्राचार्य

Subject- Request to avail authentication of Herbal Drug samples for research work

Respected Sir,

Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune-33, was established in academic year 2006-07. The college is progressive, student centered, and committed to high quality education and for creating excellent teaching learning facilities.

I undersigned Dr. Rahul H. Khiste, Associate Professor & Dean, Training, Placement, Industry-Institute Interaction Cell, EDC of the Institute request you to kindly avail authentication of Herbal Drug samples for research work to be carried out by Mr. Sameer Shaikh, M. Pharm- Pharmacognosy-Semester-III, under the guidance of Dr. Prasad V. Kadam, Associate Professor, Pharmacognosy.

Sr. No.	Particulars	Quantity
1	Authentication of Herbal Drug Samples	03 No.

You are requested to kindly do the needful and oblige.
Thanking you,

Marathwada Mitra Mandal's College of Pharmacy Estd. 2006 Thergaon, Pune-33

Yours Faithfully,

Dr. Rahul H. Khiste
Dean, Training, Placement, Industry-Institute Interaction, EDC

Dr. Manohar J. Patil
Principal
PRINCIPAL
Marathwada Mitra Mandal's
COLLEGE OF PHARMACY
Thergaon (Kalewadi), Pune-411 033

HOD Dept. Dravyaguna

S. No. 4/17, Sector No. 34, PCNTDA, Thergaon, Pune – 411 033 (MS)
Ph. No. 8446060841, E – mail : mmcopharm@yahoo.co.in Website : www.mmcop.edu.in

P.D.E.A.'s

COLLEGE OF AYURVED AND RESEARCH CENTRE

Sector No. 25, Pradhikaran, Nigdi, Pune-411044. (M.S.)

Department of Dravyagunavigyan

Certificate

ओषधद्रव्य-नि० -2403-A/22-23

This is to certify that , the samples submitted by Mr. Sameer Shaikh, student of M. Pharma (Pharmacognosy), MarathwadaMitra Mandal College of Pharmacy, Pune , was identified and authenticated by using floras and other tools of taxonomy and it's details are given as follows,

Name	Scientific Name	Part
Ashok	*Saracaasoca*, Roxb.	Bark

The drug was authenticated by using organoleptic/macroscopic characters.

The plant nomenclature of the given plant is as per IPNI(www.ipni.org). The certificate is given as per his request and strictly for academic purpose.

Dr. Lad Meenal Deepak

Head of the Department,

Dravyaguna

Dr. Meenal D. Lad
M. D., Ph. D. (Ayu.)
Prof. & H.O.D.
Dept. of Dravya guna C.A.R.C. Akurdi

Sameer

Received - Sameer shaikh

P.D.E.A.'s College Of Ayurved And Research Centre * NIGDI PUNE-44

P.D.E.A.'s

COLLEGE OF AYURVED AND RESEARCH CENTRE

Sector No. 25, Pradhikaran, Nigdi, Pune-411044. (M.S.)

Department of Dravyagunavigyan

Outward No.: 2403-B/22-23 Date:03/02/2023

Certificate

This is to certify that , the samples submitted by Miss.Prachi Bhapkar student of M. Pharma (Pharmacognosy), MarathwadaMitra Mandal College of Pharmacy, Pune , was identified and authenticated by using floras and other tools of taxonomy and it'sdetails are given as follows,

Name	Scientific Name	Part
Shivlingi	*Bryonialaciniosa*, linn.	Seeds

The drug was authenticated by using organoleptic/macroscopic characters.

The plant nomenclature of the given plant is as per IPNI(www.ipni.org). The certificate is given as per her request and strictly for academic purpose.

Dr. Lad Meenal Deepak

Head of the Department,

Dravyaguna

Dr. Meenal D. Lad
M. D., Ph. D. (Ayu.)
Prof. & H.O.D.
Dept of Dravya guna C.A.R.C. Akurdi

Received → Prachi Bhapkar

P.D.E.A.'s College Of Ayurved And Research Centre NIGDI PUNE-44

P.D.E.A.'s

COLLEGE OF AYURVED AND RESEARCH CENTRE

Sector No. 25, Pradhikaran, Nigdi, Pune-411044. (M.S.)

Department of Dravyagunavigyan

Outward No.: 2404-C/22-23 Date: 03/02/2023

Certificate

This is to certify that , the samples submitted by Miss. SarikaKamblestudent of M. Pharma (Pharmacognosy), MarathwadaMitra Mandal College of Pharmacy, Pune , was identified and authenticated by using floras and other tools of taxonomy and it's details are given as follows,

Name	Scientific Name	Part
Tejbal/Tirphal	*Zanthoxylumarmatum*DC.	Fruits

The drug was authenticated by using organoleptic/macroscopic characters.

The plant nomenclature of the given plant is as per IPNI(www.ipni.org). The certificate is given as per her request and strictly for academic purpose.

Dr. Lad Meenal Deepak 04/2/23

Head of the Department,

Dravyaguna

Dr. Meenal D. Lad
M. D., Ph. D. (Ayu.)
Prof. & H.O.D.
Dept. of Dravya guna C.A.R.C, Akurdi

Kamble

Received - Sarika Kamble

P.D.E.A's College Of Ayurved And Research Centre NIGDI PUNE-44

Pune District Education Association's
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(I.D.No. P.U./P.N./AYU./081/1990)
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3.5.1

44. Collaborative activity

Faculty exchange

NCISM, New Delhi

01/02/2023 -03/02/2023

Pune District Education Association's
College of Ayurved & Research Centre
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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Report of teacher exchange on 1st Feb 2023 to 3rd Feb 2023

Time and Date – 1st Feb 2023 to 3rd Feb 2023 9.30 am to 6. 30 pm

Place – NCISM office Block 'D' Janakpuri New Delhi

Brief about activity –

All three days syllabus formulation work started with assigned teams with development of CO and mapping with PO

Syllabus content were listed with CO, TL methods and assessment methods, domains etc.

Signature

Dr. Yogini R. Kulkarni

भारतीय चिकित्सा पद्धति राष्ट्रीय आयोग
आयुष मंत्रालय, भारत सरकार
कार्यालय: 61-65, संस्थानिक क्षेत्र, जनकपुरी, डी-ब्लाक नई दिल्ली - 110058
National Commission for Indian System of Medicine
Ministry of Ayush, Govt. of India
Office: 61-65, Institutional Area, Janakpuri, D-Block, New Delhi - 110085

दूरभाष/Phone
अध्यक्ष/Chairman: 28525156
सचिव/Secretary: 28525847
कार्यालय/Office: 28525464
पंजीयन/Registration: 28522519
फैक्स/Fax: 28520878
www.ncismindia.org
secretary@ncismindia.org

क्रमांक/Ref. No.BOA/SYLLABUS/31/2/2022 दिनांक/Dated.24.01.2023

To,

Dr Yogini Kulkarni
Professor
Poona District Education Association's, College of Ayurved & Research Centre,
Sector No. 25, Pradhikaran, Akurdi, Nigadi, Tal. Haveli, Distt. Pune –411044, Maharashtra
Email ID: dryoginik01@gmail.com

Greetings from NCISM

NCISM is committed to quality education in Ayurveda. To bring transformation in Ayurveda education, NCISM successfully implemented Competency Based /Outcome Based Medical Education (CBME/OBME) for 1st Professional BAMS students. Now this is the time to develop CBME/OBME for Second Professional BAMS subjects.

With this background, NCISM is organising a workshop for 'Development of Syllabus for Second Professional BAMS subjects from 1st to 3rd February 2023.

You are requested to attend the workshop as a **'Expert'** for the above said workshop and to make available physically from 1stto 3rd February 2023. Please plan to arrive to the venue on 31st January 2023 (Tuesday) and to depart on 04th February 2023 (Saturday).

You will be provided economy air fare (tickets are to be booked from IRCTC or Airline websites only) or second AC train fare to and fro and accommodation during workshop.

Please bring laptop, and pendrive.

For further details please refer program schdeule copy enclosed along with this letter.

Dr B. S. Prasad
President, BoA, NCISM

Copy to:-

1. The Chairman, NCISM, New Delhi-110058
2. Director/Dean/Principal of respective college for information and to depute the faculty as on duty
3. Guard file

Dr B. S. Prasad
President, BoA, NCISM

National Commission for Indian System of Medicine
New Delhi
Development of Syllabus for Second Professional BAMS Subjects Workshop (Physical Mode) -1st to 3rd February 2023

SCHEDULE OF PROGRAM

Day 0 (Tuesday, 31st January 2023)	
Arrival to Venue IIIT-Delhi Sonipat Campus, Khewra, Haryana (Near Ashoka University) (Around 60kms from IGI Airport, Delhi) Click for Location (Google Maps)	
DAY 1 (Wednesday, 1st February 2023) (Parallel Group Meetings- Subject wise)	
10.00-13.00	• Prayer • Opening remarks by respective group Chairman • Writing Course outcomes of the subject/course. • Mapping of Program outcomes (PO) and CO. • Identification of 'Not to teach in UG' topics in the existing UG syllabus • Finalization of PO-CO
13.00-14.00	LUNCH
14.00- 16.00	• Master topics list finalization • Topic List- term wise Distribution & weightage of marks.
16.00-18.00	• Allotment of topics to experts • Experts working - as per distributed syllabus points (writing Objectives, CO, Domains, Levels, TL methods etc.)

DAY 2 (Thursday, 2nd February 2023) (Parallel Group Meetings- Subject wise)	
09.00-13.00	• Continuation (as per distributed syllabus points) (Writing Objectives, CO, Domains, Levels, TL methods, etc.)
13.00-14.00	LUNCH
14.00-16.00	• Finalization of Practicals • Continuation (as per distributed syllabus points) (Writing Objectives, CO, Domains, Levels, TL methods, etc.)
16.00-16.30	Visit to Atal incubation center and start-ups
16.30-18.00	• Continuation (as per distributed syllabus points) (Writing Objectives, CO, Domains, Levels, TL methods, etc.)

भारतीय चिकित्सा पद्धति राष्ट्रीय आयोग
आयुष मंत्रालय, भारत सरकार
कार्यालय: 61 65, संस्थानिक क्षेत्र, जनकपुरी, डी.ब्लाक नई दिल्ली - 110058
National Commission for Indian System of Medicine
Ministry of AYUSH, Govt. of India
Office: 61-65, institutional Area, Janakpuri, D-Block, New Delhi - 110058

प्राणाभिसरः प्राणायतनानाम्

दूरभाष/ Phone
अध्यक्ष / Chairman: 28525156
सचिव / Secretary: 28525847
कार्यालय /Office: 28525464
पंजीयन / Registration: 28522519
फैक्स / Fax: 28520878
www.ncismindia.org
secretary@ncismindia.org

क्रमांक/ **Ref. No. BOA/SYLLABUS/31/2/2022** दिनांक/ **Dated 03.02.2023**

CERTIFICATE

It is certified that **Dr. Yogini Kulkarni, Professor**, Poona District Education Association's, College of Ayurved & Research Centre, Sector No. 25, Pradhikaran, Akurdi, Nigadi, Tal. Haveli, Distt. Pune –411044, Maharashtra has attended three days workshop on "Development of Syllabus for Second Professional BAMS Subjects" from 01.02.2023 to 03.02.2023 as a Chairman of Expert Committee for the subject Dravyaguna organized by NCISM at the office of IIT Delhi Sonipat Campus, SH 11, Khewra, Haryana.

3/2/23

Dr. B. S. Prasad
President, Board of Ayurveda
NCISM

Copy to:-

1. Office copy

Pune District Education Association's
College of Ayurved & Research Centre
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3.5.1

45. Collaborative activity

Student exchange

Vidyarthi mitra,

Vaidya M.V. Kolatkar Ayurved Pratisthan

03/02/2023 - 04/03/2023

Pune District Education Association's

College of Ayurved& Research Centre

(I.D.No. P.U./P.N./AYU./081/1990)
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Date :- 10/02/23

Metric No. 3.5.1

Vidyarthi Mitra, Vaidya M.V. Kolhatkar Ayurved Pratisthana – Gurukul Certificate course.

Duration - 03/02/2023 - 04/02/2023

Place - Pune

Participant details as student - 1

Activity detail

Students were trained in Samhita Adhyayan based on Ashtanga Hrudaya. Students had an opportunity to learn from more than 40 practitioners from Maharashtra. They also participated in vanaspati darshan and Aushadhi Nirman.

P.D.E.A.'S College Of Ayurved And Research Centre NIGDI PUNE - 44

H.O.D.
Dept of Ayurved Samhita Siddhant
College of Ayurved & Research Centre
Nigdi, Pune

Pune District Education Association's
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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook-acrc_akurdi@pdeapune.org

This certificate was received to student at Gurukul on 03/02/2023 to 04/03/2023

विद्यार्थीमित्र-वैद्य-मा-वा-कोल्हटकर-आयुर्वेद-प्रतिष्ठानम्

श्रीमाधवाचार्य गुरुकुलम्



प्रमाणपत्रम्



~~श्रीमान्~~ / ~~श्रीमती~~ / कु. पाटोदकरकुलोत्पन्ना सुप्रभारावतनया शबरी

अनेन/अनया श्रीमाधवाचार्यगुरुकुलेन (०३.०२.२०२३ - ०४.०३.२०२३) संचालितः निवासी पाठ्यक्रमोऽभ्यस्तोऽस्ति । निदानस्थानादारभ्य सम्पूर्णं अष्टाङ्गहृदयम् तस्मिन् पठितमस्ति । सूत्रनिदानस्थानयोः केषाञ्चित् अध्यायानां कण्ठस्थीकरणम्, टीकावाचनम्, वनस्पतिदर्शनं, औषधनिर्माणं च अस्मिन् समाविष्टमासीत् । तदर्थं एतत् प्रमाणपत्रं प्रदीयते ।

वैद्यः गाडगीलकुलोत्पन्नः दिलीपः
अध्यक्षः

वैद्यः कोल्हटकरकुलोत्पन्नः वेधस्-शर्मा
सचिवः

Pune District Education Association's
College of Ayurved & Research Centre
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3.5.1

46. Collaborative activity

Student Exchange

Shri Vishwagandha Gurukul Pariwar

27/02/2023- 01/03/2023

Pune District Education Association's
College of Ayurved& Research Centre
(I.D.No. P.U./P.N./AYU./081/1990)
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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook-acrc_akurdi@pdeapune.org

Date :- 10/03/23

Metric No. 3.5.1

Shri Vishwagandha Gurukul by Shri Vishwagandha Gurukul Pariwar Gurukul Certificate course.

Duration - 27/02/2023- 01/03/2023

Place – Newasa.

Participant details as student - 1

Activity detail

Students were trained in Yakrut Vikar Vidnyan based on Ashtanga Hrudaya. Students had an opportunity to learn from more than 10 practitioners from Maharashtra.

P.D.E.A.'S College Of Ayurved And Research Centre NIGDI PUNE - 44

H.O.D.
Dept of Ayurved Samhita Siddhant
College of Ayurved & Research Centre
Nigdi, Pune

Pune District Education Association's
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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook-acrc_akurdi@pdeapune.org

This Trophy was received to student at Gurukul on 27/02/2023 to 01/03/2023


श्री विश्वगंध गुरुकुलम्
आयोजित
श्री विश्वगंध गुरुकुलम्
प्रथम पुष्प २०२३
श्री क्षेत्र देवगड संस्थान, नेवासा, अहमदनगर.
यकृत विकार विज्ञान
दि.२७/०२/२०२३ ते दि.०१/०३/२०२३
सन्मानचिन्ह
वैद्य अक्षय अंकुश महामुलकर

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

3.5.1

47. Collaborative activity

Student Exchange

Marathwada Mitramandal's College of Pharmacy, Thergaon

07-06-2023

Pune District Education Association's
College of Ayurved & Research Centre
(I.D.No. P.U./P.N./AYU. /081/1990)
Sector No. 25, Pradhikaran, Nigdi, Pune-411 044 (Maharashtra State), India.
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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Date:08/06/2023

Report of Student exchange activity at CARC

Name of the event:	Authentication of Herbal samples given by students of Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune as collaborative & students exchange activity
Organizing Departments:	Dept. of Dravyaguna, CARC and Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune
Date:	08/06 2023
Location / Place:	Department of Drayaguna, College of Ayurved & Research Centre, Nigdi, Pune
Mode of event -	Offline
No. of students –	02 students (M.Pharm. students)

Brief summary of the event:
Under collaborative & student exchange activities Dr. Meenal Lad issued authentication certificate to the M. pharm. students Mr. Gajanan Kulkarni & Mr. Ashutosh Shewale after studying samples. After studying samples, it was found that first sample was Gulabi Shirish/ Rain tree (*Samania saman* Merr.) and second sample was Jackfruit (*Artocarpus heterophyllus* Lam.)

HOD

Dept. of Dravyaguna

Dr. Meenal D. Lad
M. D., Ph. D. (Ayu.)
Prof. & H.O.D.
Dept. of Dravya guna C.A.R.C, Akurdi

MARATHWADA MITRA MANDAL'S
COLLEGE OF PHARMACY

(D. Pharm., B. Pharm., M. Pharm., Ph.D.)
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Accredited by NBA (B. Pharm) & NAAC with A+ Grade
Recipient of Best College Award (Professional-Urban) by SPPU, Pune

Shri. Shivajirao D. Ganage	**Prin. Bhausaheb G. Jadhav**	**Shri. Kishor H. Mungale**
President	Exec.President	Secretary

Ref: MM / COP/ संशो/2022-23/3570.

Date: 07/06/2023

To,
Dr. Minal Lad,
Head of Dept. (Dravyaguna Vibhag)
PDEA'S College of Ayurved and Research Centre,
Sector No, 27, Nigdi Pradhikaran,
Pimpri Chinchwad, Pune411044

पु.जि.शि.मं.चे
आयुर्वेद महाविद्यालय व संशोधन केंद्र
निगडी, पुणे-४११०४४.
आवक क्र. 906/23-24
दिनांक - 8/6/2023
लेखनिक
आचार्य

Subject- Request to avail authentication of Herbal samples for research work

Respected Sir,

Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune-33, was established in academic year 2006-07. The college is progressive, student centered, and committed to high quality education and for creating excellent teaching learning facilities.

I undersigned Dr. Rahul H. Khiste, Associate Professor & Dean, Training, Placement, Industry-Institute Interaction Cell, EDC of the Institute request you to kindly avail authentication of Herbal samples for research work to be carried out by Mr. Gajanan Kulkarni and Mr. Ashutosh Shewale, M. Pharm-Pharmaceutics-Semester-IV, under the guidance of Dr. Avinash R. Tekade, Professor, Pharmaceutics.

Sr. No.	Particulars	Quantity
1	Authentication of Herbal Fruit Sample	01 No.
2	Authentication of Herbal Seed Sample	01 No.

You are requested to kindly do the needful and oblige.
Thanking you,

Yours Faithfully,

Dr. Rahul H. Khiste
Dean, Training, Placement, Industry-Institute Interaction, EDC

Dr. Manohar J. Patil
Principal

PRINCIPAL
Marathwada Mitra Mandal's
COLLEGE OF PHARMACY
Thergaon (Kalewadi), Pune-411 033

Mr. More P.
take. 5 gms each sample

S. No. 4/17, Sector No. 34, PCNTDA, Thergaon, Pune – 411 033 (MS)
Ph. No. 8446060841, E – mail : mmcopharm@yahoo.co.in Website : www.mmcop.edu.in

P.D.E.A.'s

COLLEGE OF AYURVED AND RESEARCH CENTRE

Sector No. 25, Pradhikaran, Nigdi, Pune-411044. (M.S.)

Department of Dravyagunavigyan

Outward No.: 515/2023-24 Date: 08/06/2023

Certificate

This is to certify that, the samples submitted by Mr. Gajanan Kulkarni student of M. Pharma (Pharmaceutics), Marathwada Mitra Mandal's College of Pharmacy, Pune , was identified and authenticated by using floras and other tools of taxonomy and it's details are given as follows,

Name	Scientific Name	Synonyms	Parts
Gulabi shirish Saman/ Rain tree	***Samanea saman* Merr.**	**Albizia saman f.** **Acacia propinqua A.Rich** **Mimosa saman Jacq.**	**Pod, Branch with flower, Leaves**

The drug (Part used is seeds) was authenticated by using organoleptic/macroscopic characters.

The plant nomenclature of the given plant is as per IPNI(www.ipni.org). The certificate is given as per his request and strictly for academic purpose.

Dr. Lad Meenal Deepak

Dr. Meenal D. Lad
M. D., Ph. D. (Ayu.)
Prof. & H.O.D.
Dept. of Dravya guna C.A.R.C, Akurdi.

Received
Gajanan

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Sector No. 25, Pradhikaran, Nigdi, Pune-411044. (M.S.)
Department of Dravyagunavigyan

Outward No.: 516/2023-24

Date: 08/06/2023

Certificate

This is to certify that, the samples submitted by Mr. Ashutosh Shewale student of M. Pharma (Pharmaceutics), Marathwada Mitra Mandal's College of Pharmacy, Pune , was identified and authenticated by using floras and other tools of taxonomy and it's details are given as follows,

Name	Scientific Name	Synonym	Part
Jackfruit	*Artocarpus heterophyllus* Lam.	*Artocarpus brasiliensis* Ortega *Artocarpus maximus* Blanco	Fruit

The drug (Part used fruit) was authenticated by using organoleptic/macroscopic characters.

The plant nomenclature of the given plant is as per IPNI(www.ipni.org). The certificate is given as per his request and strictly for academic purpose.

Dr. Lad Meenal Deepak
Dr. Meenal D. La
M. D., Ph. D. (Ayu.)
Prof. & H.O.D.
Dept. of Dravya guna C.A.R.C. Akurdi

Received

P.D.E.A.'S College Research Centre * NIGDI PUNE-44

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3.5.1

48. Collaborative activity

Faculty Exchange

MIMER Physiotherapy College Talegaon

07-06-2023

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Date :- 08/ 06/2023

Metric No.3.5.1

Collaborative activity as Faculty exchange event report

Name of the event: Basic Research Methodology workshop at MIMER Physiotherapy College

Date:07/06/2023

Time and Place: 10.00-15.00 MIMER Physiotherapy College Talegaon Dabhade

Participants: Twenty nine 1st year PG students of Physiotherapy, three teachers of Physiotherapy & three Ph.D students of Homeopathy

Brief description of the event:

Basic RMW workshop was organized by MIMER Physiotherapy College Talegaon Dabhade from 07-09 June 2023. They have invited me as guest speaker for 1st day. Twenty nine 1st year post graduate students of physiotherapy, three faculties of physiotherapy & Three Ph.D students from Homeopathy were registered from various colleges. Timings 10.00 -15.00

Lectures delivered with group activity as follows-

1) Descriptive study designs – Cross sectional and longitudinal study designs
2) Analytical study designs – Case Control and Cohort Study designs





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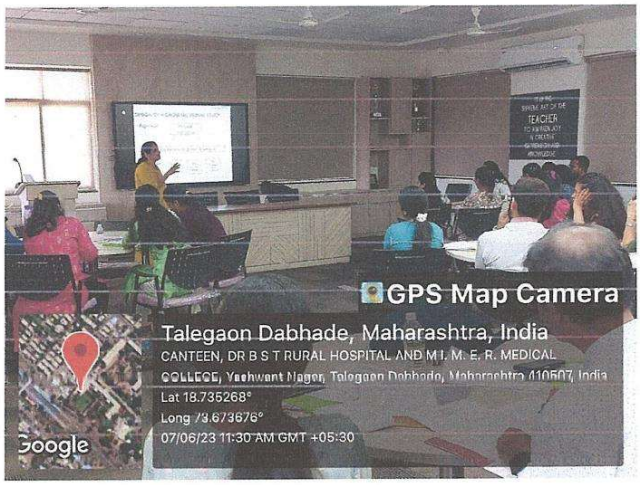
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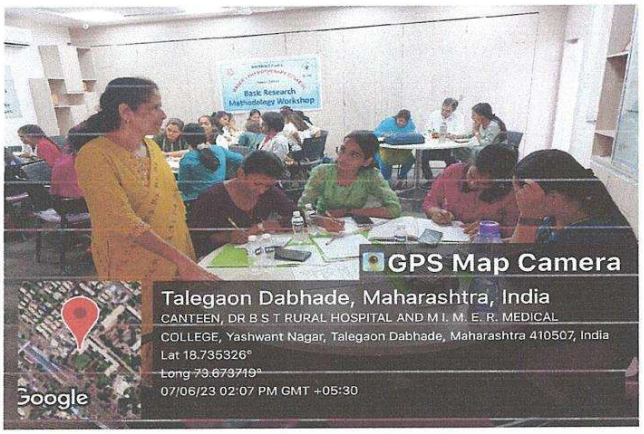
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Date :- 08/ 06/2023

Metric No.3.5.1





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3.5.1

49. Collaborative workshop With MUHS Nashik

03/07/2023 to 05/07/2023

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Date :- 06 / 07/2023
Metric No. 3.2.2

Report of Research Methodology workshop

3th - 5th July 2023

The workshop on Research methodology was organized by our institute on 3rd July to 5 July 2023 at P.D.E.A's College of Ayurved and Research Centre Nigdi Pune 44. As per MUHS/URD guidelines the sessions were organised for three days from morning 09.30- 17.00.

The thirty delegated were registered & attended the workshop. The detailed list is attached with the report.

Sr. no	College name	Number of delegates attended
1	**P.D.E.A'S COLLEGE OF AYURVED AND RESEARCH CENTRE NIGDI PUNE 44**	48
2	**K.C. Ajamera Ayurvedic college Dhule**	01
3	**Nandha Ayurveda Medical College and Hospital, Erode**	01

Seven faculty members were invited as resource person for workshop. Myself from our college Pune; Dr. Hrishikesh Rangnekar from Pt. Dr. Shiv Shaktilal Sharma Ayurveda Medical College, Ratlam ; Dr. Pranita Joshi from SSAM Hadapsar Pune; Dr. Prasad Pore from BVDU's Medical college, katraj, Pune; Mr. D. R. Basannar from AFMC College Pune, Dr. Suvarna Joshi madam from B. J. Medical college Pune & Dr. Madhav Mutalik from SSPM Medical college Padave, Oros ,Sindhdurga; Previously the instruction was given to students that bring your synopsis titles and problems regarding synopsis so,the workshop became more interactive and fruitful to them. For group activity heterogeneous groups were performed. Pre MCQ test was taken for 30 marks. Dr.Tejal Sharma from Balroga department by 21 marks rank 1st in pre-test & Dr. Swati Pawar from Dravyaguna department by 19 marks rank 2nd in pre-test & Dr. Renuka Palliwal from Rasashastra department & Dr. Shivani Gadewar from shalakya department by 18 marks rank 3rd in pre-test.

Before starting the inaugural session online Pre-test was conducted twenty minutes were given to complete. The responses were collected through goggle form. The workshop was started with Dhanwantari poojan and stawan. The first day session was started sharp at 09.30- 10.00 by lecture taken by myself from our college on the topic "Introduction to research methodology and formulation of RQ and Hypothesis. Next session were taken on observational study designs descriptive and analytical. After analytical study design tea break was given, then session was continued by Dr. Hrishikesh Rangnekar on experimental study design up to 1 pm. The post lunch

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Date :- 06 / 07/2023
Metric No. 3.2.2

session was started on 1.30 pm. with group activity taken by me. Five groups were prepared each group with 10 members and five problems were given. The details as follows-

Group no.	Topics given for study design group activity	Instructed to formulate as per following points
1	Study of young adult population to identify the risk factors for greying of hairs- Dr. Bhagyash Kare	1) Formulate the title 2) Choose appropriate study design 3) Research question with FINER& Hypothesis if necessary 4) Aims and objectives of the study 5) Independent and dependent variable 6) objectives
2	Study the association of Atilavan Amla sevan and graying of hairs in adult young population- Dr. Siddhi Purohit	
3	Calculation of incidence of anemia in pregnant women population- Dr. Rupali naik	
4	To find out multiple risk factors responsible for amanita in company workers- Dr. Snehal Bhorkute	
5	Efficacy study of Sinhanad Guggulu and Vatari Guggulu in Amavata Dr. chaithanya	

Next lecture was taken on literature search with online demo by me was completed on 4.00 First day ended at 05.00 p.m.by lecture on qualitative research by Dr Pranita Joshi from SSAM college Hadapsar 1st days feedback link was shared on their personal mails and collected the responses on goggle form.

The second day was started with Dhanwantari Poojan and Stawan followed by lecture on Data and data presentation was taken by Dr. Prasad Pore sir from BUDU College, Katraj Pune from 9.30am-11.00 am.. Next session was taken by sir on "Sampling & sample size with group activity the session ends at 12.45 am. Then lunch break was given

After the lunch break the sessions were started on inferential statistics by Mr. D. R. Basannar from AFMC Pune. The group activity was taken on selecting the appropriate test for given problems to each table. The session was ended on 3.30 pm.

For next session every delegate was requested to download EPI info 7 on their laptops and one excel data file was shared with delegates so that the "computer assistance in data analysis on Excel, epi info" with Demo was completed up to 5 pm. 2nd days feedback link was shared on their personal mails and collected the responses on goggle form.



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The third day was started at 9.30 am with Dhanwantari Poojan and Stawan followed by lecture delivered on ethics in medical research by Dr. Suvarna Joshi madam from B. J. Medical College Pune and group activity was taken by on given topics as follows

Group no.	Protocol and Ethical issues on following topics	Presenter from the group
1	Study of young adult population to identify the risk factors for greying of hairs-	Dr. Lanjewar
2	Study the association of Atilavan Amla sevan and greying of hairs in adult young population-	Dr. Purohit
3	Calculation of incidence of anemia in pregnant women population-	Dr. Naik
4	To find out multiple risk factors responsible for amanita in company workers-	Dr. Mahale
5	Efficacy study of Sinhanad Guggulu and Vatari Guggulu in Amavata	Dr. Chaithanya

Session was end up at 11.30 am. Ten minutes tea break was given. Second lecture was stated on protocol writing with group activity ended at 1 pm.

After lunch Dr. Madhav Mutalik from SSPM Medical college Padave, Oros ,Sindhdurga had taken sessions online on zoom platform because of personal problem. Article and evaluation check list was mailed to all delegates 1st session was taken on diagnostic test completed on 14.00 pm. Next session was taken by Dr. Madhav Mutalik on questionnaire designing completed session 3.30 pm. Sir had taken very interactive and informative lecture. Next session was started on 3.30 pm on critical journal article evaluation ended on 5 pm by group activity. Article was shared to every delegate and also checklist also shared for evaluation before one day of session so that everyone can read the article for critical evaluation.

Post workshop evaluation MCQ test was taken. Three best improved delegates were declared and felicitated with Pen set, first topper Dr. Rupali Naik from Kayachikista department by 30 marks, second topper from Dr Vaibhav Eknar from Kayachiksta department by 29 marks and third toppers Dr. Aditi Khadamkar from Balrog department by 28 marks of our college. Study material given in soft copy to all delegates. After felicitation delegates. The valedictory function ended with vote of thanks.

The daily evaluation and whole program evaluation sheets were filled by delegates. The analysis of program evaluation is given asfollows-



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Some comments given by delegates are as follows-

1) Workshop duration should be increased.
2) Workshop is fruitful especially with group activities
3) Time management and organization of workshop is very good
4) Majority of delegates very much satisfied with group activities.
5) The continuous lectures should not be kept, 5 minutes rest should be given after each session.
6) Dr. Prasad Pore, D. R. Basannar & Dr. Suvarna Joshi are the best faculty members mentioned by all most all delegates.

1st days feedback analysis -

Dr. Yogini Kulkarni A	166.5
B	165.1
C	164
Dr. Hrishikish Rangnekar D	154.1
Dr. Yogini GA E	164.1
F	161.3
Dr. Praneta Joshi G	161.6

2nd days feedback analysis –

	183.43
B	181.14
C	182
Mr. D. R. BasannarD	181.86
E	182
F	181.14

3rd days feedback analysis –

Dr. Suvarna Joshi A	178.14
B	174
C	170.57
D	167.71

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Dr. Madhav Mutalik E	167
F	168.14
G	164.29

Important suggestions by coordinator as –

1) Group activities are more effective in well-equipped digital lab of computers.
2) Online attendance of delegates is more time taking so should be continued with previous method
3) If the organized college delegates only allowed by MUHS MET cell then such instructions should circulated to all medical colleges because more phone calls to coordinator form other college students

The activity started by M.U.H.S. and MET is really very much necessary and useful for up-gradation of knowledge of Research techniques to post graduate students and teachers.Thanking you,

Dr. Yogini R. Kulkarni (Coordinator)

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Research Methodology
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Akurdi. Pune - 411 044

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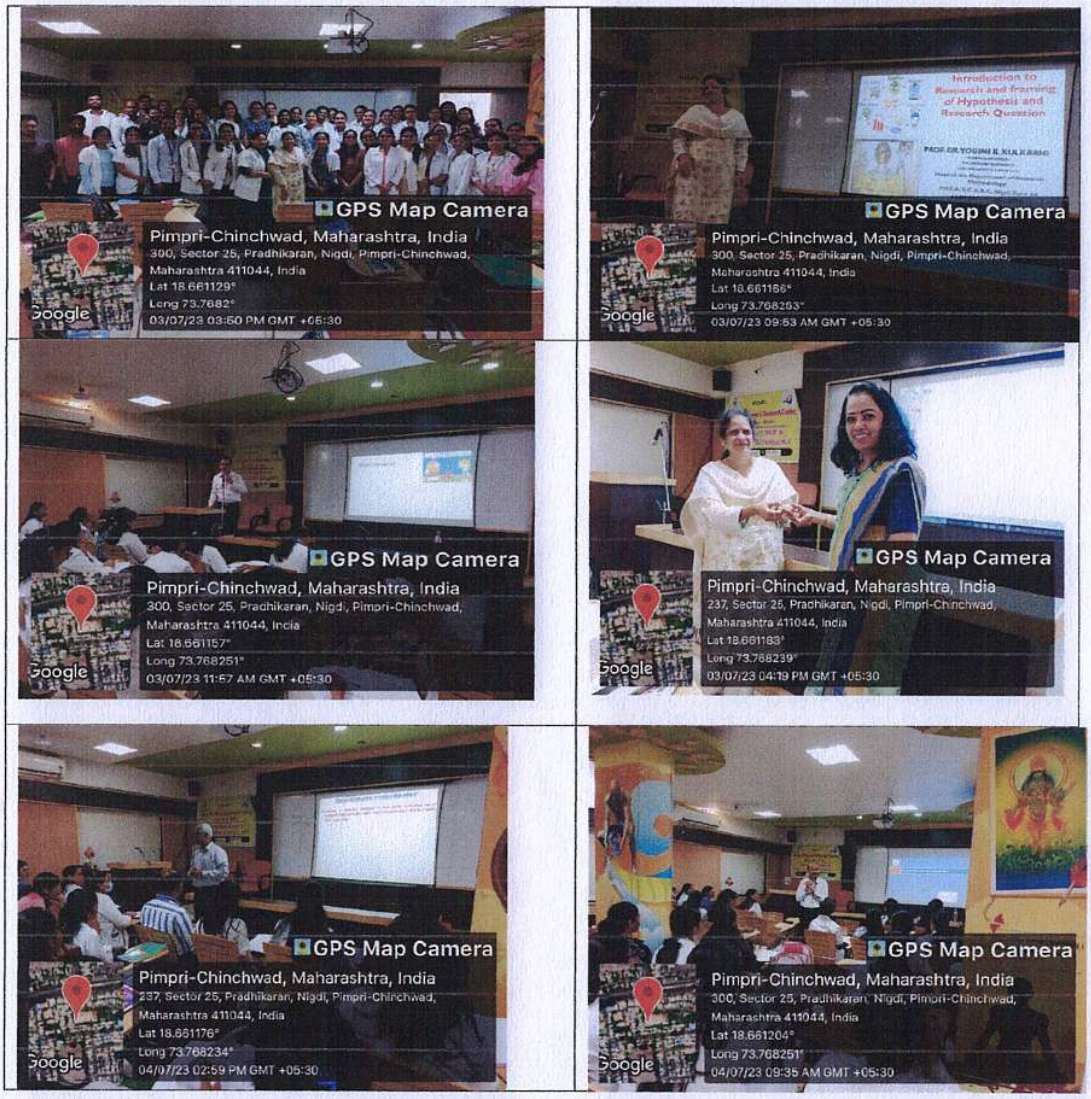
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50. Collaborative activity - Faculty Exchange

Ayurved Mahavidyalaya

Wagholi

Pune

08-07-2023

Bharatiya Sanskriti Darshan Trust's
AYURVED MAHAVIDYALAYA
Wagholi, Tal: - Haveli. Dist: - Pune. 412207.
Maharashtra, India

FOUNDER
ParampujyaShri P. K. Sardeshmukh Maharaj

PHONE: (020) 67346152
Email ID : bsdtam@gmail.com

PRINCIPAL:
Dr. A.B. KULKARNI
Ph.D(Ayurved)

O. No. : BSDTAM / 23
DATE . : 30/06/2023

Invitation Letter

To,
Dr. Yogini Kulkarni
Professor
PDEA's CARC, Nigdi, Pune.

Respected Madam,

Our college is conducting a three-day **Basic Research Methodology Workshop** of Maharashtra University of Health Sciences, Nashik. from July 6th to 8th 2023.

We are pleased to invite you as a resource person for the same. Your Lecture schedule is as follows

Sr. No	Date and Time	Name of Topic
1	08/07/2023 10.00 am - 11.15 am	Ethical Issues in Medical Research
2	08/07/2023 11.15am – 12.15pm	Writing a research protocol

Kindly accept the invitation. We look forward to your presence at the workshop.

You are requested to confirm your availability and forward your CV to **bsdtamacademic @gmail.com**

Thanking You

Workshop Coordinator

Principal
PRINCIPAL
Dr. Anand. B. Kulkarni
B.S.D.T'S Ayurved Mahavidyalaya

Bharatiya Sanskriti Darshan Trust's

AYURVED MAHAVIDYALAYA

Wagholi, Tal: - Haveli. Dist: - Pune. 412207.
Maharashtra, India

FOUNDER
Parampujya Shri P. K. Sardeshmukh Maharaj

PHONE: (020) 67346152
Email ID : bsdtam@gmail.com

PRINCIPAL:
Dr. A.B. KULKARNI
Ph.D(Ayurved)

O. No. : BSDAM /2023
DATE :- 08/07/2023

ATTENDANCE CERTIFICATE

This is to certify that **Dr. Yogini Kulkarni,** Professor, PDEA's CARC, Nigdi, Pune has participated as a resource faculty on 08/07/2023 in 3 days Basic Research Methodology Workshop organized by B.S.D.T's Ayurved Mahavidyalaya Wagholi Pune, approved by Maharashtra University of Health Sciences, Nashik.

Workshop Coordinator

Principal

PRINCIPAL
Dr. Anand. B. Kulkarni
B.S.D.T'S Ayurved Mahavidyalaya
At Post-Wagholi, Tal-Haveli, Dist-Pune.

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Date:- 10/07/2023

Metric No. – 3.5.1

Collaborative activity as Faculty Exchange Event Report

Name of the Event- Basic Research Methodology workshop at Ayurveda Mahavidyalaya, Wagholi, Pune.

Date – 08/07/2023

Time and Place- 9.00am to 1.00 pm, Ayurveda Mahavidyalaya, Wagholi, Pune.

Number of Participants- 50

Mode of the Program (Online/Offline)- Offline

Brief Report of the Event-
Basic Research Methodology workshop was organised by Ayurveda Mahavidyalaya, Wagholi, Pune from 6th July to 8th July 2023. They have invited me as a guest speaker for third day. Total 50 delegates were attending this workshop. Among them some were pre MD and PhD students of Ayurved and Homeopathy and some were faculties.

Lectures delivered with group activity as follows:

1. Ethical issues in Medical Research
2. Writing a research Protocol

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निगडी, पुणे-४११०४४.
आवक क्र 1504/2022-23
दिनांक - 12/7/23
लेखनिक
आचार्य

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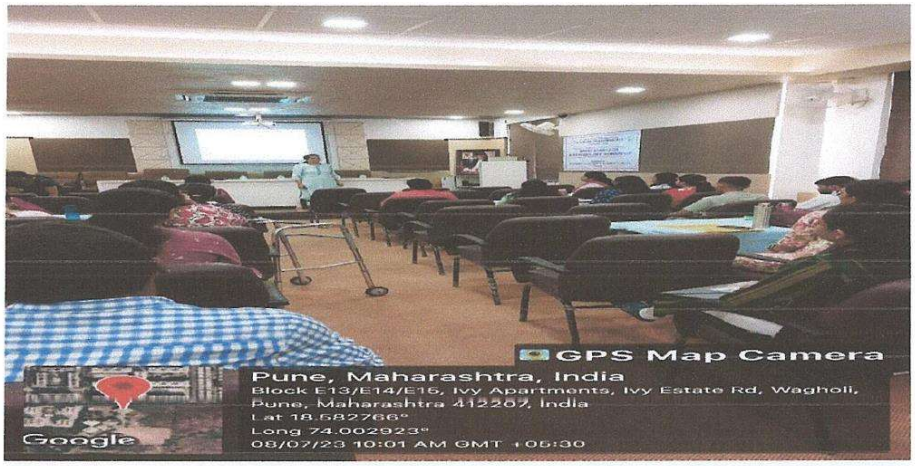
Pune District Education Association's

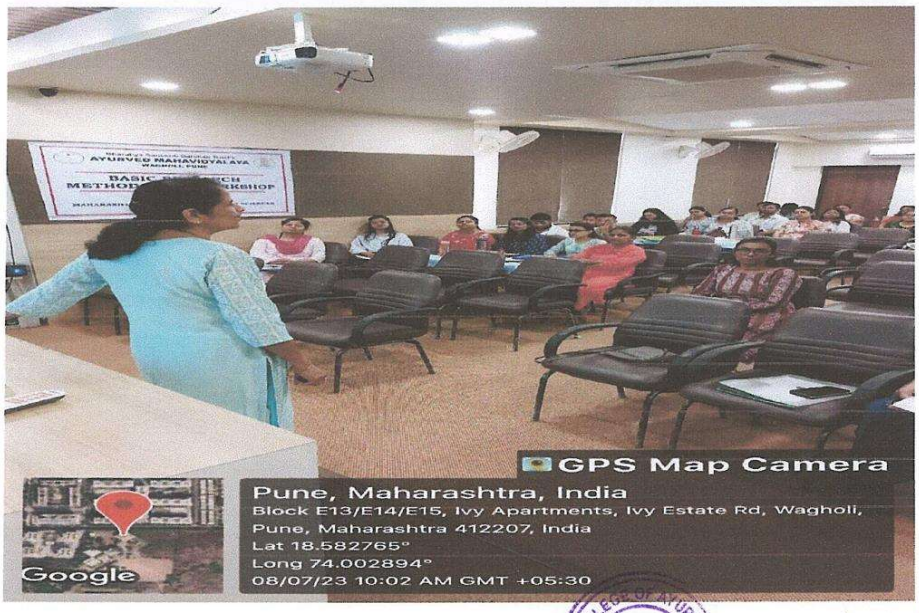
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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook-acrc_akurdi@pdeapune.org

Date:- 10/07/2023

Metric No. – 3.5.1





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Principal
P.D.E.A'S
College of Ayurved And Research Centre
Nigdi, Pune - 411 044.

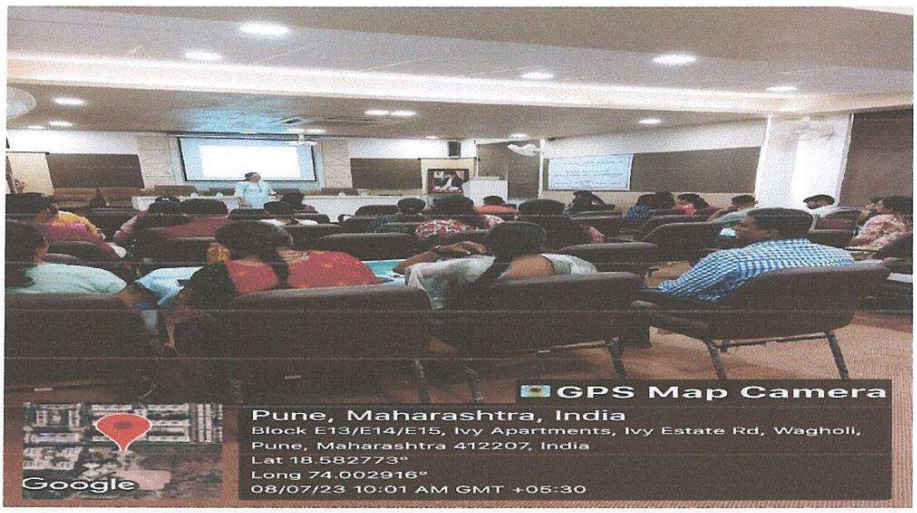
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Bharatiya Sanskriti Darshan Trust's

AYURVED MAHAVIDYALAYA

Vishwashanti Dham, Kesnand Road, Wagholi, Pune, M.S., INDIA.

Certificate of Appreciation

This certificate is presented to

Dr. Yogini Kulkarni

for sharing her valuable knowledge as a Resource Person

in BASIC RESEARCH METHODOLOGY WORKSHOP

organised by BSDT's Ayurved Mahavidyalaya, Wagholi, Pune approved by MUHS, Nashik

conducted from 06/07/2023 to 08/07/2023.

Workshop Co-ordinator
BSDT's Ayurved Mahavidyalaya, Wagholi, Pune

Principal
P.D.E.A's
College of Ayurved And Research Centre
Nigdi, Pune - 411 044.

Principal
BSDT's Ayurved Mahavidyalaya, Wagholi, Pune

www.ayurvedcollegewagholi.com

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3.5.1

51. Collaborative activity - Student Exchange

Lokmanya Homeopathic Medical College Chinchwad Pune

08-07-2023

LATE SHREE FAKIRBHAI PANSARE EDUCATION FOUNDATION's
LOKMANYA HOMOEOPATHIC MEDICAL COLLEGE
Near Elpro Company, Behind Prof. Ramkrishna More Auditorium, Chinchwad, Pune - 411033.
Ph.: (020) 27357552, Fax : (020) 27352503, E-mail : chinchom@rediffmail.com
P.T.R. No. : F/37677/PUNE
Affiliated to Maharashtra University of Health Science, Nashik, Recognised by C.C.H., New Delhi.

Outward No.: LSFPEF's-LHMC/ 205A/2023 Date:- 35

To,

Dr. Lad

PDEA'S Ayurveda College

Nigdi Pune 411044

Date : 21/06/23

Sub- Request to conduct Guest lecture

Respected Madam,

This is to request you to conduct guest lecture for our 1st BHMS students (Batch-2023-24) related to the subject of Homoeopathic Pharmacy.

Kindly find the details of the lecture to be conducted :

Topic: Pharmacognosy and identification of medicinal plants

Date :08/7/23

Day Saturday

Time- between 2.00pm to 4.00pm.

We will be obliged!

Thanking You,

21/06/23

Yours Sincerely

Dr A.S Khaladkar

HOD & PROFESSOR
Dept. of Pharmacy
L.S.F.P.E.F.'s L.H.M.C.
Chinchwad, Pune-33

21/6/23

Dr S.B Shitole

LECTURER
Dept. of Pharmacy
L.S.F.P.E.F.'s L.H.M.C.
Chinchwad, Pune-33

Copy to The Principal PDEA'S Ayurveda College Nigdi Pune 411044

LSFPEF'S LHMC
Dept. of Hom.
Pharmacy

Pune District Education Association's

COLLEGE OF AYURVED & RESEARCH CENTRE

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Sector No. 25, Pradhikaran, Nigadi, Pune - 411044 (Maharashtra) India
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Managing Trustee

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Ajit Pawar

Vice President
Rajendra Bhadge

Hon. Secretary
Adv. Sandeep Kadam
Senate Member
Savitribai Phule Pune University, Pune

Treasurer
Iv. Mohanrao Deshmukh

Dy. Secretary
. M. Pawar

Principal
Dr. Ragini Patil

Ref. No. 741/223-24

Date : 08 JUL 2023

To

The Principal

LSFPEFLHMC Chinchwad PUNE

Subject: - **VISIT OF IST BHMS STUDENTS (BATCH 2023-24) TO OUR BOTANICAL GARDEN**

Dear Madam,

This is to certify that 80 students from IST BHMS and 03 staff from LSFPEF LHMC Chinchwad had visited our botanical garden on 08/07/2023.

We confirm that they were conducted by our experienced staff around all aspects of our Botanical garden and brief description of medicinal plants were explained to them.

Thanking you once again and would look forward for similar visits in future.

Akhalaakar
08/07/2023
Received with thanks!

COLLEGE OF AYURVEDIC RESEARCH AKURDI PUNE - 44

Principal
College of Ayurved And Research Centre
Nigdi, Pune - 411 044.

LATE SHREE FAKIRBHAI PANSARE EDUCATION FOUNDATION's
LOKMANYA HOMOEOPATHIC MEDICAL COLLEGE
Near Elpro Company, Behind Prof. Ramkrishna More Auditorium, Chinchwad, Pune - 411033.
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P.T.R. No. : F/37677/PUNE
Affiliated to Maharashtra University of Health Science, Nashik, Recognised by N.C.H., New Delhi.

Outward No.: LSFPEF's-LHMC/228/2023

Thankyou Letter

To,

Date : 08/07/23

The Principal Dr. Mrs .Ragini Patil

PDEA'S Ayurveda College

Nigdi Pune 411044

Respected Madam,

Thank you for granting permission for the botanical garden visit to our students which is a mandatory activity in our syllabus.We also thank Dr M.D Lad Madam Dept oif Drvyaguna -HOD &Prof who conducted guest lecture to students about topic: **Pharmacognosy and identification of medicinal plants.**The students who attended today's guest lecture really enjoyed your presentation especially the identification part. We appreciate you making time in your busy schedule to speak to our students and department staff members.

A special thanks to Dr Mrs Ila Bhor Madam for her cooperation to put up the entire event .

We look forward to organise such visits and informative lectures in the future!

This visit was coordinated by the Dept of Homoeopathic Pharmacy of our college.

Thank you again !

With kind regards

6.7.2023

Dr Mrs N.S Joshi

Dr.Mrs.N.S.Joshi
PRINCIPAL
L.S.F.P.E.F.'s Lokmanya
Homoeopathic Medical College
Chinchwad,Pune-411033

Dr. Meenal D. Lad
M. D., Ph. D. (Ayu.)
Prof. & H.O.D.
Dept. of Dravya guna C.A.R.C. Akurdi

L.S.F.P.E.F.'s Lokmanya Homoeopathic Medical College Chinchwad,Pune-33

P.D.E.A.'S COLLEGE OF AYURVEDIC RESEARCH AKURDI PUNE - 44

Received
Dr 2/9 Bhor

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Date: - 15/07/2023

Metric No.3.5.1

Post event Summary

Student & Faculty exchange activity at CARC

Name of the event: Guest lecture given & CARC Herbal Garden visit of 1st year BHMS students as collaborative & students & faculty exchange activity

Organizing Departments: Dept of Dravyaguna- CARC, & Lokmanya Homoeopathy Medical College, Chinchwad,Pune

Date: 08/07/2023

Location / Place: Herbal Garden of Dept of Dravyaguna, & College of Ayurved & Research Centre, Nigdi, Pune

Mode of event - Offline

No of attendees – 73 (out of 82 students) +2 staff members

Drive link for photos share link-
https://drive.google.com/drive/folders/1amSYg_Ygx9WW3bJ11qDx_di4mq_FgNsV?usp=drive_link

Brief summary of the event:

Under collaborative & student & faculty exchange activities Teaching staff of Dravyaguna dept- Dr M.D.Lad, Dr Ila Bhor, Dr Shivani Sonar had given demo of medicinal plants with their descriptions and to 1st year students of Lokmanya Homoeopathy Medical College,, Chinchwad, Pune on 08/07/2023, 1.30 - 4.00 pm.
Dr M.D.Lad has given lecture on Pharmacognocy & identification of medicinal plants after garden visit in the college classroom.
With this activity pharmacognostical & pharmacological aspect of some important medicinal plants has explained to the students as per their syllabus accordingly.

पु.जि.शि.मं.चे
आयुर्वेद संशोधन केंद्र
आवक क्र. 1824172374
दिनांक - 21/07/23
लेखनिक
प्राचार्य

Dr. Meenal D. La
M. D., Ph. D. (Ayu.)
Prof. & H.O.D.
Dept. of Dravya guna C.A.R.C. Akurdi

COLLEGE OF AYURVEDIC RESEARCH AKURDI PUNE-44 P.D.E.A.'S

Principal
P.D.E.A'S
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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Date: - 15/07/2023

Metric No.3.5.1

Photos of the event: Student & Faculty exchange activity at CARC



HOD
Dept of Dravyaguna

Dr. Meenal D. Lad
M.D., Ph.D. (Ayu.)
Prof. & H.O.D.
Dept. of Dravyaguna C.A.R.C. Akurdi

Principal
CARC, Nigdi

Principal
P.D.E.A'S
College of Ayurved And Research Centre
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3.5.1

52. Collaborative activity - Student Exchange

Swasti Yoga Centre

Pune

08-07-2023

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Date :- 17/ 7 /23
Metric No. **3.5.1,3.5.2**

Post event summary report

Name of the event- Visit to College of Ayurved & Research Centre, Nigdi,Pune by students of Swasti Yoga Centre, Chinchwad Pune under student exchange programme

Date of the event- 8/07/2023

Organising department- Rachana sharir

Location of the event- College of Ayurved & Research Centre, Nigdi, Pune

Number of persons attending the event- 25

Mode of event- Offline

Drive Link for Photos-
https://drive.google.com/drive/folders/1fNcy2RB1pwcmyPIHzcESupggMP5_zFMS?usp=share_link

Summary of the event-

As per the e mail of Swasti yoga Centre dated 4/07/2023, visit of students of Swasti yoga Centre was planned at PDEA's college of Ayurveda and research center Nigdi, Pune. Students of Swasti Yoga centre visited on 8/07/2023 between11am – 1 pm. Out of 25 students one student was from other countries.

Dr. Manore welcomed all students & Director of Swasti Yoga Centre Dr. Mr. & Mrs. Chothe. Visit started with Dhanvantari prayer. All students introduced themselves.

Students visited, Sharir Rachana department for more detailed information. Dr. Dinesh Naik from Rachana Department explained basic of Anatomy, various organs & systems on models.. Dr. Deepali Manore from Swasthavritta department gave information regarding Diet, Daily regimen, Seasonal regimen, also clarified queries of the students. Visit was coordinated by Dr. Manore.

पु.ज्ञि.शि.मं.चे
आयुर्वेद महाविद्यालय व संशोधन केंद्र
निगडी, पुणे-४११०४४.
आवक क्र 1602/2023-24
दिनांक - 17/7/2023
लेखनिक Uniti
प्राचार्य

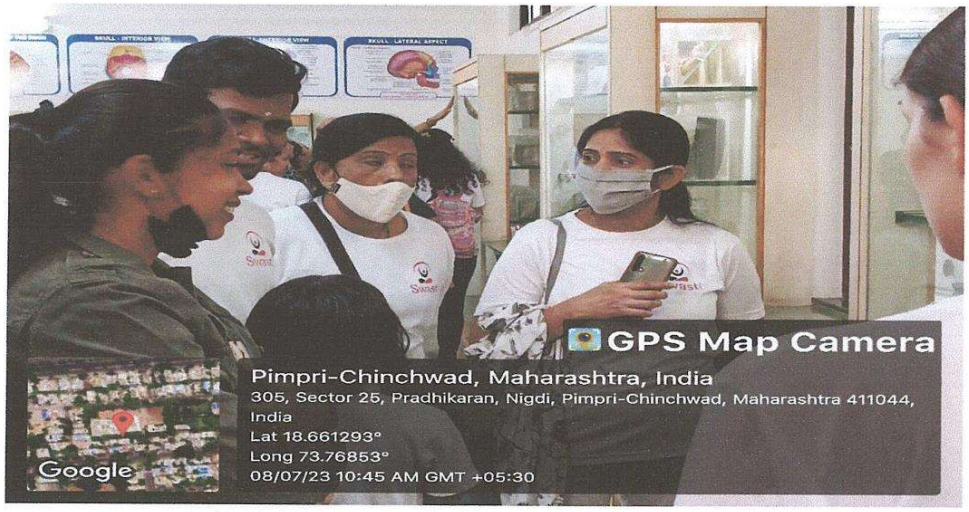
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Principal
P.D.E.A'S
College of Ayurved And Research Centre
Nigdi, Pune - 411 044.

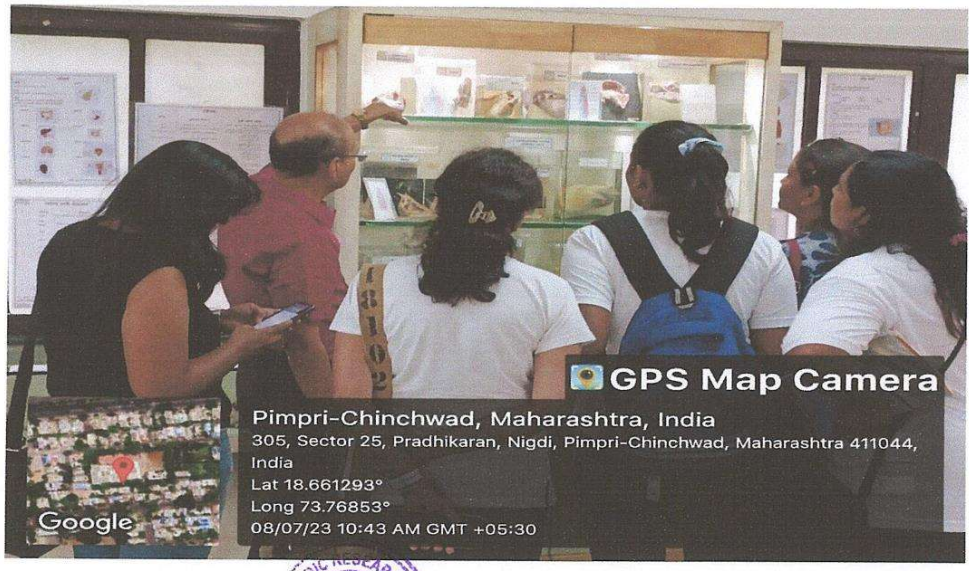
Pune District Education Association's

College of Ayurved & Research Centre

Name of the event- Visit to College of Ayurved & Research Centre, Nigdi, Pune by students of Swasti Yoga Centre, Chinchwad Pune under student exchange programme

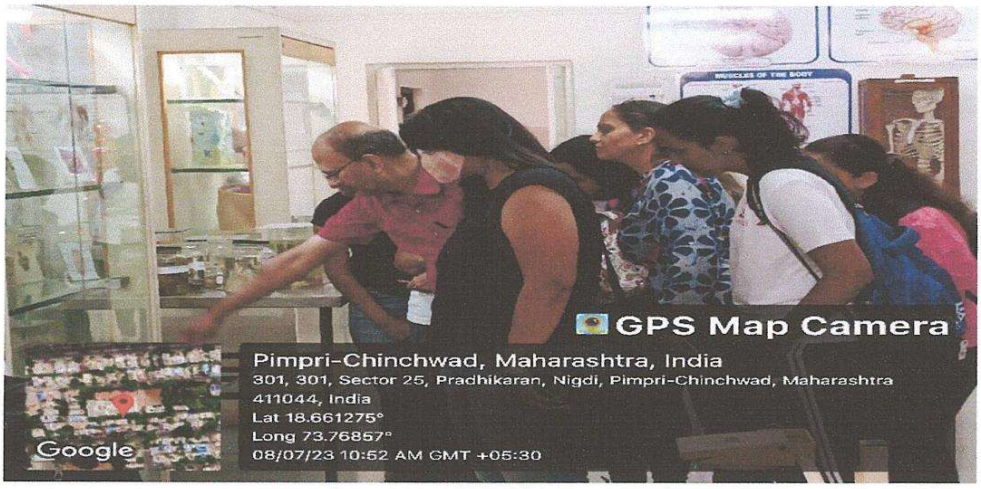
Date of the event-8/07/2023

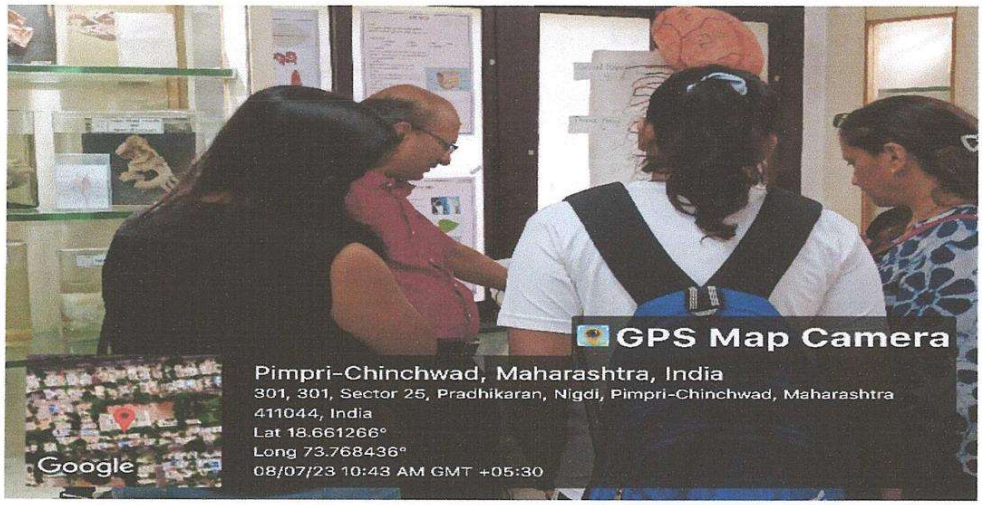




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College of Ayurved And Research Centre
Nigdi, Pune - 411 044.

Name of the Department: Rachana Sharir **NAAC Metric No. 3.5.1,3.5.2**





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Name of the Department: Rachana Sharir	NAAC Metric No. 3.5.1,3.5.2

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3.5.1

53. Collaborative Workshop with MUHS Nashik

10/07/2023 to 12/07/2023

Pune District Education Association's

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Date :- 17/07/2023

Metric No. 3.2.2

Report of online Research Methodology workshop

10th - 12th July 2023

The online workshop on Research methodology was organized by P.D.E.A's College of Ayurved and Research Centre Nigdi Pune 44 on zoom platform from 10th July to 12th July 2023. As per MUHS/URD guidelines the sessions were organised online for three days from morning 09.30- 17.00.

The Fifty delegates were registered in those 13 teachers and 37 PG & Ph.D. students & attended online the workshop. The detailed list is attached with the report.

Sr. no	College name	Number of delegates attended
1	P.D.E.A'S COLLEGE OF AYURVED AND RESEARCH CENTRE NIGDI PUNE 44 (students)	20
	P.D.E.A'S COLLEGE OF AYURVED AND RESEARCH CENTRE NIGDI PUNE 44 (teachers)	06
2	K.C. Ajamera Ayurvedic college Dhule	03
3	SSAM hadapsar Ayurveda college Pune	01
4	Kakasaheb Mhaske Homoeopathic Medical College & Hospital & Post Graduate Institute, Ahmednagar [Homoeopathy]	02
5	Yashwant Ayurvedic College Kodoli	02
6	Guru Mishri Homoeopathic Medical College & Hospital, Jalna [Homocopathy]	01
7	LSFPEF's Lokmanya HMC Chinchwad Pune (Teachers)	05
8	LRP Ayuervedic medical college and hospital, post graduate institute and research centre islampur.	02
9	MGM Dental College and Hospital, Navi Mumbai	01
10	Manjra Ayurvedic medical College Latur	01
11	Dr. Vedprakash Patil Ayurved Medical College and Research Institute, Jalna (Teacher)	01
12	Government Ayurved College Baramat Pune (teacher)	01
13	School Of Dental Sciences, Karad	01
14	Late Kedari Redekar Ayurved Mahavidyalaya, Gadhinglaj, Kolhapur [Ayurved]	02

Seven faculty members were invited as resource person for workshop. Myself from our college Pune; Dr. Hrishikesh Rangnekar from Pt. Dr. Shiv Shaktilal Sharma Ayurveda Medical College, Ratlam ; Dr. Pranita Joshi from SSAM Hadapsar Pune; Dr. Pradip Borle from B. J. Medical college, Pune; Mrs. Swati Raje from MIMER Medical College Talegaon Pune, Dr. Suvarna Joshi madam from B. J. Medical college Pune & Dr. Madhav Mutalik from SSPM Medical college Padave, Oros

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Date :- 17/07/2023

Metric No. 3.2.2

,Sindhdurga; Previously the instruction was given to students that be ready with synopsis titles and problems regarding synopsis so, that it can be discussed in the workshop, so that workshop became more interactive and fruitful to them. For group activity heterogeneous groups were performed. Pre MCQ test was taken for 30 marks. Dr. Bhanushali Divya Bhavesh from **Guru Mishri Homoeopathic Medical College & Hospital, Jalna [Homoeopathy] by 17marks out of 30** and stood 1st rank in pre-test. Five participants got 16 marks out of 30 so other ranks not declared. Before starting the inaugural session online Pre-test was conducted twenty minutes were given to complete. The responses were collected through goggle form.

The workshop was started by Dhanwantari stawan. The first day session was started sharp at 09.30- 11.00 by lecture taken by Dr. Hrishikesh Rangnekar from Pt. Dr. Shiv Shaktilal Sharma Ayurveda Medical College, Ratlam on experimental study design. Sir has taken a very nice informative session with many newer designs, ended the session on 11 am. After this session I had taken the sessions on the topic "Introduction to research methodology and formulation of RQ and Hypothesis. Next session were taken on observational study designs descriptive and analytical. Session completed by me up to 1 pm. The post lunch session was started on 1.30 pm. with group activity taken by me. Five groups were prepared each group with 10 members and five problems were given. The details as follows-

Group no.	Topics given for study design group activity	Instructed to formulate as per following points
1	Anthropometric measurements and grip strength in auto rickshw drivers between age group of 20-40 years- Dr. Poonam Yadav	1) Formulate the title 2) Choose appropriate study design 3) Research question with FINER& Hypothesis if necessary 4) Aims and objectives of the study 5) Independent and dependent variable 6) objectives
2	Correlation of anthropometric measurements and grip strength in auto rickshw drivers between age group of 20-40 years -Dr. Prerana	
3	Calculation of incidence of cervical Spondylosis in Auto rikshw driver population- Dr Janaki Doshi	
4	To find out multiple risk factors responsible for obesity in company workers- Dr. Priya Banger	
5	Study of multiple effects of longer time driving in Auto Rikshw drivers population- Dr. Murde	

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E-mail - carc2006@rediffmail.com / carcakurdi@gmail.com Outlook- acrc_akurdi@pdeapune.org

Date :- 17/07/2023

Metric No. 3.2.2

Next session was taken on qualitative research by Dr Pranita Joshi from SSAM College Hadapsar last session was taken on literature search with online demo by Dr. Pranita Joshi madam. 1st days feedback link was shared on their personal mails and collected the responses on goggle form.

The second day was started with Dhanwantari Stawan followed by lecture on Data and data presentation was taken by Mr. pradip Borle sir from B. J. Medical College Pune from 9.30am-11.00 am. Next session was taken by sir on "Sampling & sample size with group activity the session ends at 12.45 am. Activity presented by every group by a group leader details were as follows

Group no.	Topics given for Sampling and sample size calculations group activity	Instructed to formulate as per following points
1	Anthropometric measurements and grip strength in auto rickshw drivers between age group of 20-40 years- Dr. Poonam Yadav	• Title • Study design • Sample size • Sampling method
2	Correlation of anthropometric measurements and grip strength in auto rickshw drivers between age group of 20-40 years -Dr. Amrapali Lade	
3	Calculation of incidence of cervical Spondylosis in Auto rikshw driver population- Dr Anuja Wadekar	
4	To find out multiple risk factors responsible for obesity in company workers- Dr. Janaki Doshi	
5	Study of multiple effects of longer time driving in Auto Rikshw drivers population- Dr. Murde	

After the lunch break the sessions were started on inferential statistics by Dr. Swati Raje madam from MIMER medical college Talegaon Pune. The group activity was taken on selecting the appropriate test for given problems to each table. The session was ended on 3.30 pm.

For next session every delegate was requested to download EPI info 7 on their laptops and one excel data file was shared online so that the "computer assistance in data analysis on Excel, epi info" with Demo was explained up to 5 pm. 2nd days feedback link was shared on their personal mails and collected the responses on goggle form.

The third day was started at 9.30 am with Dhanwantari Stawan followed by Dr. Madhav Mutalik from SSPM Medical college Padave, Oros ,Sindhdurga, 1st session was taken on diagnostic test completed on 10.30 am. Next session was taken by Dr. Madhav Mutalik on questionnaire

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designing completed session 11.30 am . Sir had taken very interactive and informative lecture. Next session was started on 11.45 am on critical journal article evaluation ended on 1 pm by group activity. Article was shared to every delegate and also checklist also shared for evaluation before one day of session so that everyone can read the article for critical evaluation. Every group presented their opinion about the article. Then session was completed.

Post lunch session lecture was delivered on ethics in medical research by Dr. Suvarna Joshi madam from B. J. Medical College Pune and group activity was taken on given topics but due to internet problem participants not presented but submitted by email.

After Ten minutes tea break, second lecture was stated on protocol writing with group activity ended at 16.30pm.

Post workshop evaluation MCQ test was taken. Three best improved delegates were declared first Dr. Anuja Waddekar & Dr. Priya Bangar 1st rank by 28 marks, 2nd rank Dr. Sharada Chikurte by 27 marks

Study material given in soft copy to all delegates. Workshop was ended with vote of thanks.

The daily evaluation and whole program evaluation sheets were filled by delegates. The analysis of program evaluation is given asfollows-

Some comments given by delegates are as follows-

1) Online Workshop should be with good internet connection of host and speakers
2) Workshop duration should be increased.
3) Workshop is fruitful especially with group activities
4) Time management and organization of workshop is very good
5) Majority of delegates very much satisfied with group activities.
6) Mr. Pradip Borle, Dr. Madhav Mutalik Dr. Swati Raje are the best faculty members mentioned by all most all delegates.

1st day's feedback analysis -

Dr. Yogini Kulkarni A	165.85
B	164.42
C	166.28
Dr. Rangnekar D	162
Dr. Yogini GA E	163
F	158.5
Dr. Praneta Joshi G	158.4

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2nd day's feedback analysis –

Mr. Pradip Borle A	176.71
B	176.4
C	176.4
Dr. Swati Raje D	174.21
E	174.42
F	174

3rd day's feedback analysis –

Dr. Suvarna Joshi A	159.14
B	160.17
C	157.85
D	166.28
Dr. Madhav Mutalik E	175.28
F	173.85
G	171.42

Suggestions by coordinator as –

1) Group activities are more effective in well-equipped digital lab of computers.
2) Online attendance of delegates is more time taking so should be continued with previous method

The activity started by M.U.H.S. and MET is really very much necessary and useful for up-gradation of knowledge of Research techniques to post graduate students and teachers.Thanking you,

Dr. Yogini R. Kulkarni (Coordinator)

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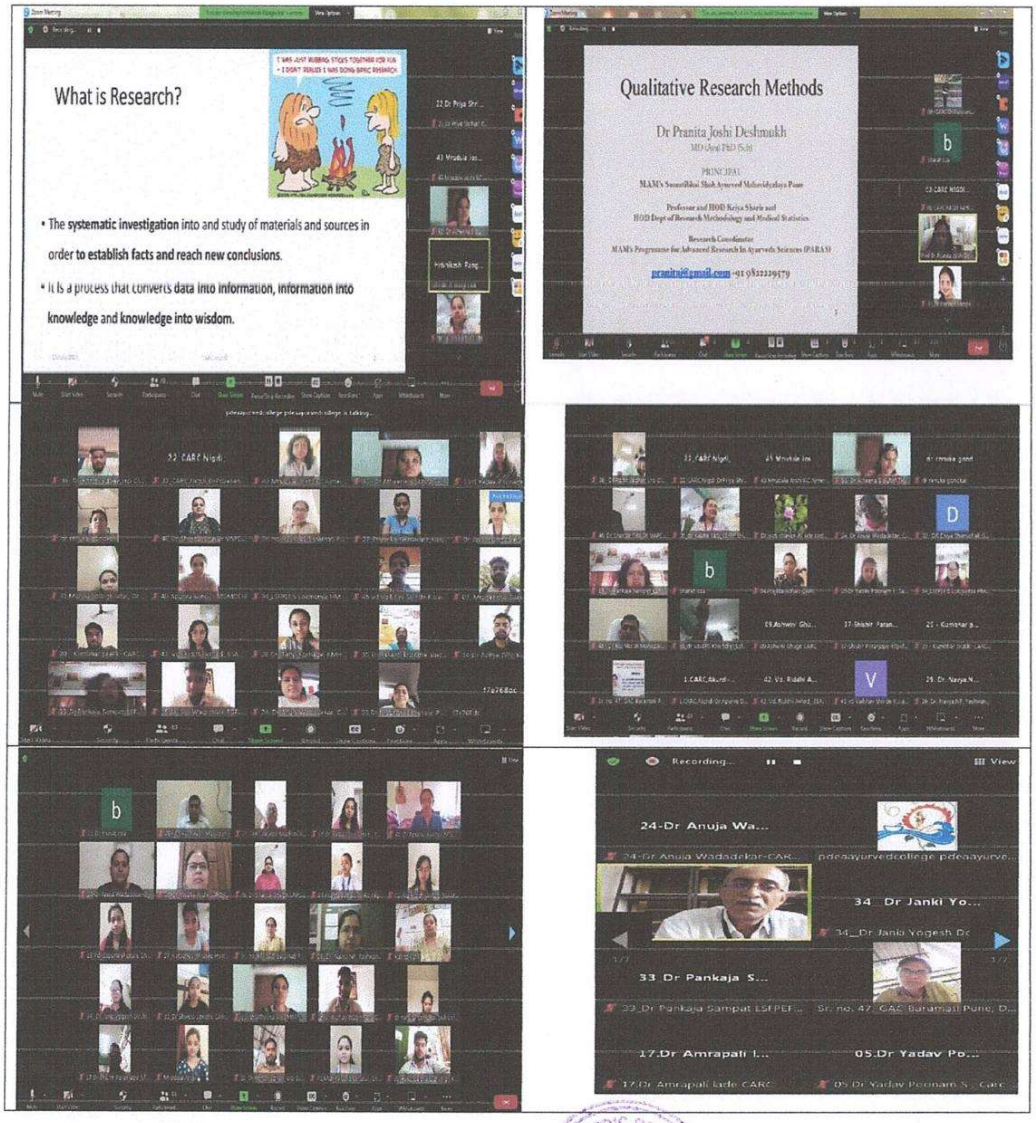
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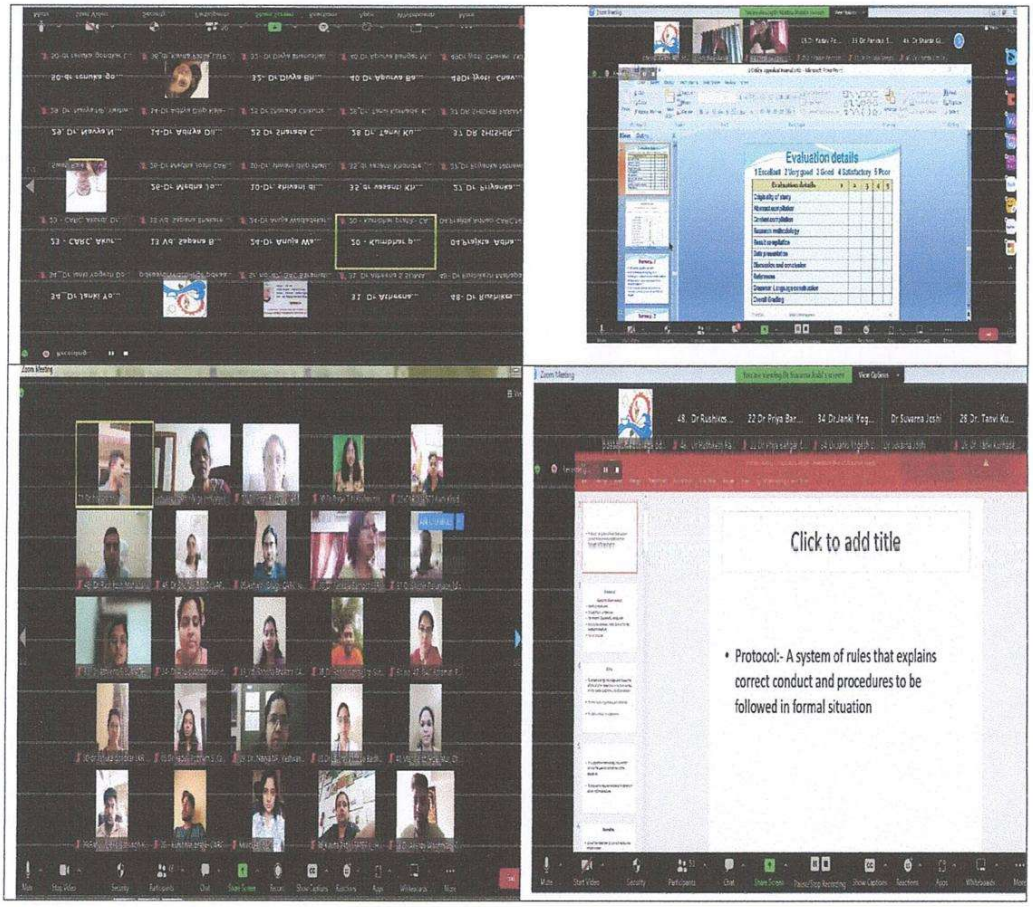
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3.5.1

54. Collaborative activity – Faculty Exchange

NCISM
New Delhi
13/07/2023 - 14/07/2023

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Report of teacher exchange on 13th July 2023 to 14th July 2023

Time and Date – 13th July 2023 to 14th July 2023 9.30 am to 6. 30 pm

Place – NCISM office Block 'D' Janakpuri New Delhi

Brief about activity –

On 13th July 2023 the meeting was started at 9.30 am at NCISM office new Delhi, Preparation of 2nd year syllabus presentation completed as per instructions. Presentation was started by me as chairman in front of Dr. B.S. Prasad, President Board of Ayurveda, Dr. Jayant Deopujari, Chairman NCISM & coordinator Dr. Mohan Joshi on 2nd year revised Dravyaguna syllabus, as content of paper 1, paper 2 & practical with non-lecture activities. The practical marks distribution and blue print of question papers also presented. Some suggestions given by authorities.

On next day 14th July 2023Dravyaguna syllabus was presented with corrections before same committee. Approved copy of syllabus handed over to the authorities at 6.30 pm

Invitation & attendance letter is attached with this report

Signature
Dr. Yogini R. Kulkarni

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