Chapter – 5

METHODS

5.1 SELECTION AND SOURCE OF PARTICIPANTS:

5.1.1 Selection criteria for schools:

Those schools with only one teacher for many grades were not selected for this study. Schools were selected if they have adequate teacher to student ratio and have a qualified physical education teacher. Only schools from a specific taluk were selected for the study.

5.1.2 Source of the participants:

The students for this study were recruited from Government schools which were identified for participation by respective taluk coordinators across Karnataka state. A total of ten schools spanning four taluks from Sagara, Shimoga, Kundapura and Udupi were selected for the study. The schools were selected if they satisfied selection criteria and through convenience sampling.

5.1.3 Selection of subjects:

School children in higher primary (7^{th} – 8^{th} class) were recruited for the assessments in this study. Rural schools participating in this yoga shikshana program were randomly selected by block randomization after satisfaction of the selection criteria. These schools were identified for participation by respective taluk coordinators. Further students from each section (either 7^{th} or 8^{th} class) were randomized to receive either yoga or physical training for that section. 40 students from each school were randomly chosen from each section for the study by random numbers generated by computer.

5.1.4 Participants: A total of 802 of which 411students in Yoga group and 391 students in Physical activity group of both sexes were randomized to receive either yoga or physical activity intervention.

5.1.5 SAMPLE SIZE: The study is a randomized controlled two arm trial. Schools were randomized to impart either yoga intervention or physical training daily for an hour, six days a week for a period of 2 months. 10 schools out of 24 with approximately eighty students from each

school were randomly selected for the study. Total 10 schools from four taluks of two districts were selected thereby recruiting 802 students for the study. The sample size for the study was 411 students in Yoga group and 391 students in the physical activity group (Page no.126 Appendices). Cognitive tests used to calculate sample size were SLCT, DLST, TMT-A and TMT-N. (as per comments added)

5.1.6 Sample size calculation:

In an earlier study by (Chaya, Nagendra, Selvam, Kurpad, & Srinivasan, 2012) that compared yoga with physical exercise on cognitive abilities in school children there was an equivocal effect of yoga viz. physical exercise on cognitive function tests with an effect size being .79 on processing speed using six letter cancellation tests. Based on this study the sample size was calculated with power fixed at 95% and an alpha of 0.05. The sample size required for the study was 335 subjects in each arm. Considering 20% dropouts the sample size required for each arm was 402 subjects (sample size for each arm will be 335+67=402 subjects). Randomization was done using random numbers generated using randomizer software for two groups assignment. Block randomization was done with 2 sections from each school being randomized into either yoga or physical training group. Since the class size was unequal across schools and entire class sections was allocated to one intervention; we had 411 in yoga group and 391 in physical activity group.

5.1.7 Students drop outs:

In yoga group out of 412 students (male 196, female 216) dropouts were 25 students and in the physical activity group out of 392 students (male 210, female182) dropouts were 21students.The student's drop outs were due to absenteeism during assessments, not being able to attend classes regularly, time constraints, sickness etc. and lack of interest. These schools were in rural areas and students often commute long distances to reach school.

5.1.8 Selection criteria for subjects:

AYUSH physicians clinically examined Government school children during pre-assessment to rule out any co-morbidities among the children in all the selected 4 taluks of the state. Healthy

children were clinically found with none of the symptoms or features suggesting physical ailments or injuries, mental retardation like epilepsy, cerebral palsy, hearing loss, visual problems, attention deficit and learning problems as stated in exclusion criteria while eliciting their medical history. Tests like Wechsler's memory scale(intelligence test)were also conducted which is standardized for Indian population like digit span forward and backward, Verbal paired associated learning (easy and hard pairs) which was based on conventional scoring and worksheets were prepared changing the digits and words to eliminate serial testing artefacts where retesting was done with 3 trials to rule out any mental retardation.

5.1.8a. Inclusion Criteria:

1. Higher primary and high school children of both sexes
2. Age between 12- 15 years.
3. 40 students randomly from each section and minimum of two sections in each class.

Justification: Inclusion criteria were aimed to recruit maximum number of schools and subjects into the study.

5.1.8b. Exclusion Criteria:

1. Those with congenital heart disease, motor and mental retardation
2. Those with h/o epilepsy, severe exercise induced asthma
3. Fevers or infection at time of screening and recruitment.

Exclusion criteria were chosen to minimize effects of the above confounders on outcome measures. Anyone with history of learning disabilities or features suggestive of mental retardation was identified through interview with students and their teachers. However, being in the higher primary none of the students had any symptoms or features suggesting mental retardation.

5.1.9 Ethical Consideration: (Res/IEC-Svyasa/10/2013, dated 09 Oct'2018)

An approval has been obtained from the Institutional Ethics Committee, S-VYASA University, Bengaluru. All the participants were explained about the study protocol in detail and a signed

written informed consent was obtained in English/Kannada Language from each participant who was willing to participate in the study. (Copies of IEC approval and consent form attached in Annexure)

5.2 DESIGN:

5.2.1 School Sampling: 10 schools out of 24 schools satisfying selection criteria (having minimum of 40 students in each section/class) were selected randomly from 4 taluks have been conveniently sampled. Sections were randomly assigned either to yoga group or physical training group by a draw of lots. Hence, 80 students from 2 sections from each school, total students from 10 schools were randomised in each arm to receive yoga intervention or control intervention (412 students randomised in Yoga group and 392 students in the physical activity group).

In case there were more than 40 students in each section, then 40 students were randomly chosen for the intervention using computer generated random number for each sex. The groups were matched for age and gender.

Plate-1 Children undergoing Yoga training Plate-2

5.2.2 Assessments: were done prior to intervention and after two months after intervention. Field assessments were carried out by AYUSH doctors and clinical psychologist for a week prior to starting the intervention and one week following 2 months of intervention. Assessments were done by Ayush doctors trained in SVYASA and under supervision of a clinical psychologist Dr Vaishna Ruby from HCG.

5.2.3 Tools: All tools used in assessments were scientifically validated. Already for questionnaire we followed like Cronbach's method for different learning skill assessment, mental ability, classroom attention, class room behaviour and others under 6 section heads. Booklets were printed in Kannada and individual students after satisfying selection criteria they were assessed. Pl. See page133-134

5.3 VARIABLES STUDIED:

The word parameter is described as 'characteristic of distribution or relationship in the population which are estimated by statistical analysis of a sample of observations' whereas, the word variable denotes 'measurement or attribute on which observations are made' (Altman, Gore, Gardner, & Pocock, 1983). Hence, in this thesis, the term 'variable' has been used to describe the assessments studied.

5.3.1 Primary Outcome Measures: (Tests for executive function/ Psychomotor)

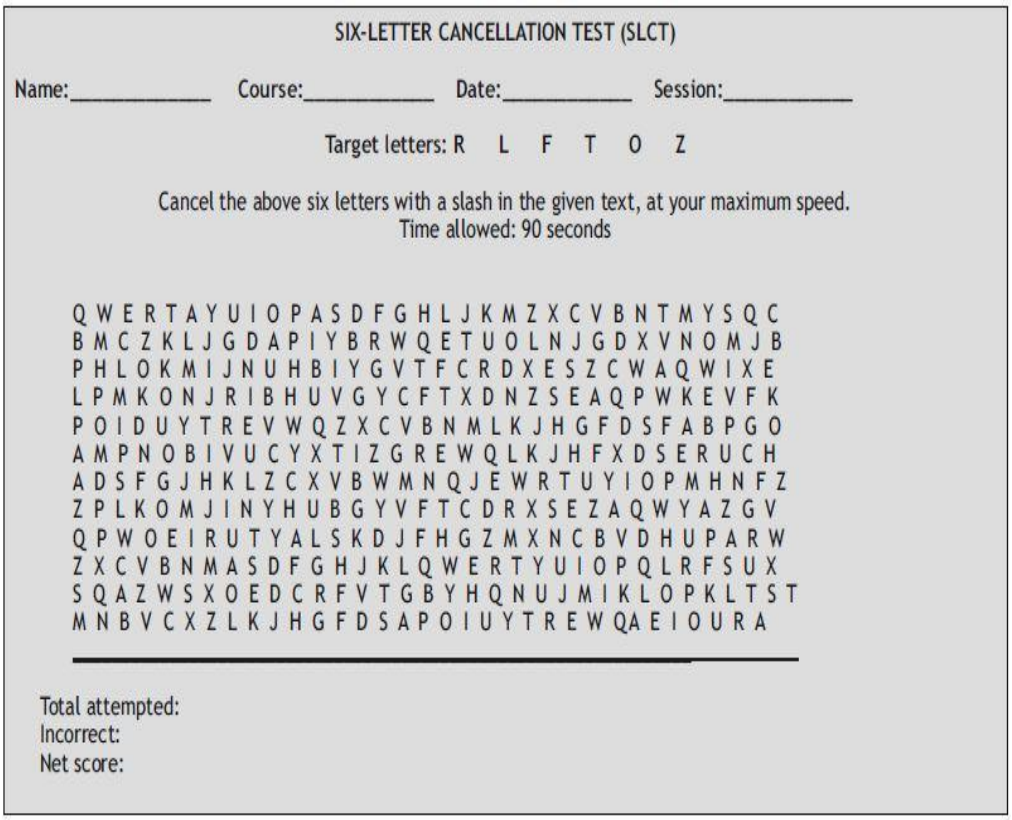
a. Six Letter Cancellation Test (SCLT)

b. Digit Letter Substitution Test (DLST)

c. Trail Making Test (TMT-N and TMT-A)

5.3.1a. Six Letter Cancellation Test (SLCT)

Figure 1: The six-letter cancellation test



SIX-LETTER CANCELLATION TEST (SLCT)

Name:_____ Course:_____ Date:_____ Session:_____

Target letters: R L F T O Z

Cancel the above six letters with a slash in the given text, at your maximum speed.
Time allowed: 90 seconds

Q W E R T A Y U I O P A S D F G H L J K M Z X C V B N T M Y S Q C
B M C Z K L J G D A P I Y B R W Q E T U O L N J G D X V N O M J B
P H L O K M I J N U H B I Y G V T F C R D X E S Z C W A Q W I X E
L P M K O N J R I B H U V G Y C F T X D N Z S E A Q P W K E V F K
P O I D U Y T R E V W Q Z X C V B N M L K J H G F D S F A B P G O
A M P N O B I V U C Y X T I Z G R E W Q L K J H F X D S E R U C H
A D S F G J H K L Z C X V B W M N Q J E W R T U Y I O P M H N F Z
Z P L K O M J I N Y H U B G Y V F T C D R X S E Z A Q W Y A Z G V
Q P W O E I R U T Y A L S K D J F H G Z M X N C B V D H U P A R W
Z X C V B N M A S D F G H J K L Q W E R T Y U I O P Q L R F S U X
S Q A Z W S X O E D C R F V T G B Y H Q N U J M I K L O P K L T S T
M N B V C X Z L K J H G F D S A P O I U Y T R E W Q A E I O U R A

Total attempted:
Incorrect:
Net score:

Procedure:

The Six Letter Cancellation task was presented on a work sheet which specifies the six target letters to be cancelled and had a 'working section' of letters of the alphabet arranged randomly in 22 rows and 14 columns. Participants were asked to cancel as many of the target letters as possible in 90 seconds. They were instructed that there would be two possible strategies. i.e., (i) marking all six letters at a time or (ii) selecting any one target letter of the six, and they could follow a horizontal, vertical, or a random path according to their choice. The total number of cancellations and wrong cancellations scored, and the net scores was calculated by deducting wrong cancellations from the total cancellations attempted (Nagendra & Pradhan, 2008). Mean of 3 assessments was considered as an outcome measure for the assessment. The Six letter cancellation test retest reliability was found (r= 0.781, P=0.002) (Sarang and Telles, 2007). Normative data for six letter cancellation tasks (Nagendra & Pradhan, 2008) in school children.

Tests for information processing and mental speed:

Information processing speed refers to the brain's ability to rapidly process simple and complex information. Because input of information may be tactile, auditory, verbal, or visual, this domain is inter-related with all of other domains of cognitive function and may have a direct influence on people's ability to store such information into memory. Mean of 3 assessments was considered as an outcome measure for assessment.

5.3.1b. Digit Letter Substitution Test (DLST):

Appendix: Digit letter substitutions test

Instructions:
Substitute the digits with corresponding letter as per the given key.
Substitute as many possible within the given time.
Start and stop only when told.

Substitute Letters:

1	2	3	4	5	6	7	8	9			
L	H	Y	N	R	E	D	T	J			
6	2	4	1	5	7	9	3	2	6	8	5
5	4	7	8	1	2	3	4	9	6	3	7
2	4	6	7	8	9	3	1	2	3	7	4
2	9	4	6	8	1	2	5	9	3	4	7
9	7	4	2	3	8	1	5	6	2	9	1
8	6	2	3	9	4	5	7	1	4	3	9
3	5	9	1	2	5	6	2	7	8	9	1
5	4	9	2	7	1	3	2	8	9	5	6

Figure-2

Procedure:

The Digit Symbol Substitution Test Natu, (2002) is a test of visual motor coordination, motor persistence, sustained attention and response speed. Rapid information processing is required to substitute the symbols accurately and quickly. The test consists of a sheet in which numbers 1-9 are randomly arranged in 4 rows of 25 squares each. The student's substitutes each with a letter using a number. This test is not administered on illiterate students. Mean of 3 assessments was considered as an outcome measure for assessment. The reliability of the test for DLST was r =0.76 (Langdon, DW, 2011).

5.3.1c. Trail Making Test (TMT-N and TMT-A):

Procedure:

The TMT provides information on visual search, scanning, speed of processing, mental flexibility, and executive functions in the Halstead–Reitan Battery (Reitan & Wolfson, 1985). The TMT consists of two parts. TMT-A requires an individual to draw lines sequentially connecting 25 encircled numbers distributed on a sheet of paper. Task requirements are similar for TMT-B except the person must alternate between numbers and letters (e.g., 1, A, 2, B, 3, C, etc.). The score on each part represents the amount of time required to complete the task. Normative data for trail making tests are available that show cut-off beyond which there is likely to be neuropsychological impairment (Reitan & Wolfson, 1985). Mean of 3 assessments was considered as an outcome score for assessment. The reliability of the test reported was r=0.94 for TMTA and r=0.97 for TMTN respectively (Fals-Stewart W, 1992).

5.3.2 Secondary Outcome Measures:

a. Beep Test

b. Flamingo Balance Test (FBT)

c. Standing Broad Jump Test (SBJ)

5.3.2a. Beep Test:

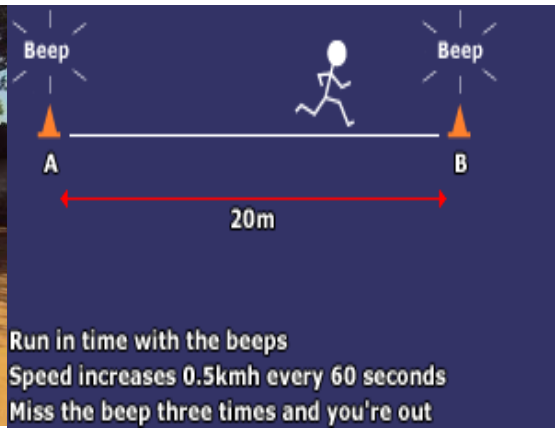


Plate-3 Children participating in Beep Test Run Plate-4

a) The Beep Test is performed over a distance of 20-meters; this distance is marked out with two cones which are placed exactly 20-meters apart.

b) There are 21-levels on the beep test and each level has a set amount of stages to complete. The higher the level the greater the number of stages to complete e.g. Level -1 has 7 stages, level -11 has 12 stages and the final level -21 has 16 stages. Each level goes for approximately 1-minute. Each increase in level is accompanied by an increase in the beep tempo (beeps get closer together). The test starts at 8.5 km/hr. (level 1) and increases by 0.5km/hr. at each level.

c) Your end score will be based on the amount of stages you were able to complete at a set level, for example at level -7 you were able to complete 8 stages, and your final test score would then be level-7 / stage-8 (7/8)

d) "THE ACTUAL TEST" The participant turns their "Beep Test" on and positions themselves adjacent to one of the cones. The participant then starts on the starters command and must continually touch the opposite cone, keeping in tempo with the beeps.

e) Once the participant is unable to get to the next cone before the scheduled beep, the test then continues for one more beep/cone, if the participant is successful in playing "catch up" and can reach the next cone before the next beep, then the test continues, however if the participant fails two consecutive beeps/cones, then the test ends and their final score reverts back to the last successful cone attempt (Tomkinson & Grant, 2003).

Procedure:

Selected students for test were involved to continuously run between two lines 20m apart in time to recorded beeps. For this reason, the test is also often called the 'beep' or 'bleep' tests. The test subjects stand behind one of the lines facing the second line and begin running when instructed by the CD or tape. The speed at the start is quite slow. The student continues running between the two lines, turning when signaled by the recorded beeps. After about one minute, a sound indicates an

increase in speed, and the beeps will be closer together. This continues each minute (level). If the line is not reached in time for each beep, the student must run to the line turn and try to catch up with the pace within 2 more beeps. Also, if the line is reached before the beep sounds, the student must wait until the beep sounds. The test is stopped if the student fails to reach the line (within 2 meters) for two consecutive ends. There are several versions of the test, but one commonly used version has an initial running velocity of 8.5 km/hr., which increases by 0.5 km/hr. each minute one attempt was allowed. Selected students allowed for assessments underwent single attempt of tests and was considered for the final assessment. Beep test done only once calculating the number of levels and rounds completed (Jürimäe, Volbekiene, Jürimäe, & Tomkinson, 2007).

5.3.2b. Flamingo Balance Test (FBT):

It is a total body balance test, and forms part of the Euro fit Testing Battery (Ingunn, 2001). This single leg balance test assesses the strength of the leg, pelvic, and trunk muscle as well as dynamic balance.

Plate-5 Flamingo Balance Test Plate-6

Procedure:

Selected students for test were made to stand on the beam with shoes removed. Keep balance by holding the instructor's hand. While balancing on the preferred leg, the free leg is flexed at the knee and the foot of this leg held close to the buttocks. Start the watch as the instructor lets go. Stop the stopwatch each time the person loses balance (either by falling off the beam or letting go of the foot being held). Start over, again timing until they lose balance. Count the number of falls in 60 seconds of balancing. If there are more than 15 falls in the first 30 seconds, the test is

terminated and a score of zero is given. Selected students allowed for assessments underwent 3 attempts of tests and the best of 3 was considered for the final assessment.

5.3.2c. Standing Broad Jump Test (SBJ):

The Standing long jump, also called the Broad Jump, is a common and easy test to measure explosive leg power. It is one of the fitness tests in the NFL Combine. The standing long jump was also once an event at the Olympic Games, and is also an event in Sports Hall competitions in the UK (Davies, 1990).

Procedure:

Selected students for test were made to stand behind a line marked on the ground with feet slightly apart. A two-foot take-off and landing is used, with swinging of the arms and bending of the knees to provide forward drive. The subject attempts to jump as far as possible, landing on both feet without falling backwards. Three attempts were allowed. Selected students allowed for assessments underwent 3 attempts of tests and the best of 3 was considered for the final assessment.

5.3.3 Others: (Tests for flexibility and strength)

a. Sit and Reach Test (SR)

b. Hand Grip Test (HGT)

c. Back and Leg Dynamometer (BLD)

5.3.3a. Sit and Reach Test (SR):

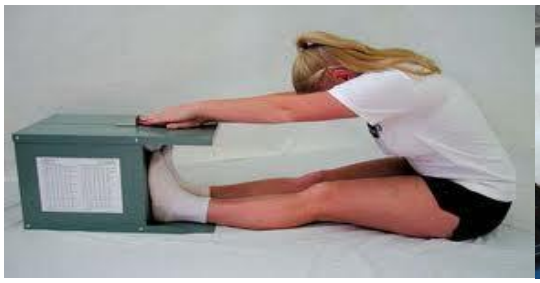


Plate-7 Sit and Reach Test Plate-8

The sit and reach test is a common measure of flexibility, and specifically measures the flexibility of the lower back and hamstring muscles. This test is important as because tightness in this area is implicated in lumbar lordosis, forward pelvic tilt and lower back pain. This test was first described by Wells and Dillon (1952) and is now widely used as a general test of flexibility.

Procedure:

The sit-and-reach test was performed using a commercially available metal sit and- reach box. The children were made to sit on the floor in the long sitting position with knees straight and with the soles of their feet (socks on) against the box with the palms facing downwards, and the hands on top of each other or side by side, the subject reaches forward along the measuring line as far as possible ensuring their hands remain at the same level, not one reaching further forward than the other. After some practice reaches, the subject reaches out and holds that position for at least one-two seconds while the distance is recorded without any jerky movements, the box is made with 9 inches (23 cm) at the level of the feet, so reaching two inches past the toes is recorded as 11 inches and repeat the same conditions for each time the test is conducted and perform the test according to ACSM guidelines (Baechle & Thomas, 2008). The score was recorded to the nearest centimeter or half inch as the distance reached by the hand. Students for assessments underwent 3 attempts of tests to reach 2 inches and the best of 3 was considered for the final assessment.

5.3.3b. Hand Grip Test (HGT):

Plate-9 Hand Grip Test Equipment

Portable and convenient Hand Grip test dynamometer used to assess the isometric exercise in

school. It strengthens hand, fingers, wrist, forearms, and release pressure anywhere and anytime. It helps in evaluation of circulatory alterations during sustained isometric muscle contractions is a useful method to assess cardiac function. Hence, handgrip dynamometer test was performed to elicit the sympathetic cardiovascular functions during the isometric exercise. The baseline systolic and diastolic blood pressure values are to be recorded.

Procedure:

Selected each student for test was made to stand and is allowed to hold the hand grip dynamometer. The student was asked to perform Maximal Voluntary Contraction (MVC) by gripping the handgrip dynamometer, as hard as possible for few seconds and the maximum force exerted was noted down. After giving rest for a few minutes, the student was made to perform isometric exercise at 30% of the maximal voluntary contraction to the point of fatigue. A (i) Systolic blood pressure (SBP) in mmHg and (ii) Diastolic blood pressure (DBP) in mmHg recording was taken at intervals of each minute during the period of exercise. The mean systolic and diastolic blood pressure, the increase in systolic and diastolic blood pressure during the isometric exercise was calculated and the maximal values of systolic and diastolic BP achieved during exercise was noted down (Häger-Ross & Rösblad, 2002). Students for assessments underwent 3 attempts of tests and the best of 3 was considered for the final assessment.

5.3.3c. Back and Leg Dynamometer: (BLD)

Plate-10 Student using BLD instrument for his assessment

Plate-11 BLD instrument

Portable and convenient Back and Leg Dynamometer was used to assess the isometric exercise in school.

Procedure:

Students were made to stand on footrest of wooden plank and hold the hand bar fixed to the BL Dynamometer and stretch bar upwards attached to the plank without bending the knees. Stretching exercise measures the Strength and flexibility of lower back, hamstring thigh, leg and calf muscles. It helps in evaluation of circulatory alterations during sustained isometric muscle contractions is a useful method to assess cardiac function. Hence, Back leg dynamometer test was performed to elicit the sympathetic cardiovascular functions during the isometric exercise. The baseline systolic and diastolic blood pressure values in mm Hg were recorded. Students for assessments underwent 3 attempts of tests and the best of 3 was considered for the final assessment.

5.3.4 2017 Consort Checklist: of information to include when reporting a randomized trial assessing non-pharmacologic treatments (NPTs)*. Modifications of the extension appear in italics and blue.

Section/Topic Item	Checklist item no.	CONSORT item	Extension for NPT trials
Title and abstract			
	1a	Identification as a randomized trial in the title	✓
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	✓
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	✓

	2b	Specific objectives or hypotheses	✓
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	✓
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	✓
	4b	Settings and locations where the data were collected	✓Shimoga, Sagara, Kundapura, Udupi
Interventions†	5	The interventions for each group with enough details to allow replication, including how and when they were administered	Yoga and physical exercise
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	□
	6b	Any changes to trial outcomes after the trial commenced, with reasons	□ **Sit ups could not be done in the school setting**
Sample size	7a	How sample size was determined	✓
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomization:			
- Sequence generation	8a	Method used to generate the random allocation sequence	✓
	8b	Type of randomization; details of any restriction (such as blocking and	✓

		block size)	
- Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Block Allocation with the sections in each school with 40 students being randomized
- Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	✓
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Those assessing outcomes were blinded to interventions.
Statistical methods	11b	If relevant, description of the similarity of interventions	NA
	12a	Statistical methods used to compare groups for primary and secondary outcomes	✓
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	✓ ITT analyses done
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	✓
	13b	For each group, losses and exclusions after randomization, together with reasons	✓

	New	**Details of the experimental treatment and comparator as they were implemented**	✓
Recruitment	14a	Dates defining the periods of recruitment and follow-up	☐
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	✓
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	✓
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	✓
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All-important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	✓
Discussion			✓
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if	NA

		relevant, multiplicity of analyses	
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	✓
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	✓
Other information			
Registration	23	Registration number and name of trial registry	NA
Protocol	24	Where the full trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Dept. of AYUSH, Dept. of Education, Govt of Karnataka

**Additions or modifications to the 2010 CONSORT checklist. CONSORT = Consolidated Standards of Reporting Trials*

†The items 5, 5a, 5b, 5c, 5d are consistent with the Template for Intervention Description and Replication (TIDieR) checklist

5.4 INTERVENTIONS:

The intervention group with yoga received daily yoga classes on working days for a period of 2 months of the study while the physical training group received a standard test of physical exercises to maintain physical fitness.

5.4a Yoga Intervention: the intervention program involves a series of asanas, pranayama, meditation and relaxation given over a one-hour period daily 6 days a week for 2 months. The intervention was imparted by teachers who are trained in the yoga program and monitored by AYUSH physicians and Yoga qualified coordinators. The yoga and physical activity class was scheduled between 3pm-4pm two hours post lunch every week day in the last period. As per comments added separately. For details please see (Annexure 1Page nos.122-132).

Measures to prevent if any side effects on yoga: Students of Government Higher primary and Highschool have undergone inclusion and exclusion criteria to rule out any comorbidities and are clinically tested by AYUSH physicians for any health issues. Students are trained by qualified yoga instructors and those teachers who were also undergone prior yoga training in TOT and further in camps were updated about yoga benefits of *asanas, pranayamas, Dhyana,* relaxations techniques etc, and about the intervention in parameter study. Necessary precautions to be taken like providing yoga mats, intervals of relaxation between *Yogasanas,* duration of each *asana,* Diet timings etc., in case of exhaustion all such preventive measures as suggested by Ayush physicians and they were supervised by yoga coordinators deputed by AYUSH. With all these measures in place there were no any side effects from yoga practices.

5.4b Control Intervention: Involves one hour of physical training and play daily 6 days a week for 2 months. The intervention was imparted by the physical education teachers in each school. for details please see (Annexure 1Page nos.133-137).

5.5 DATA EXTRACTION:

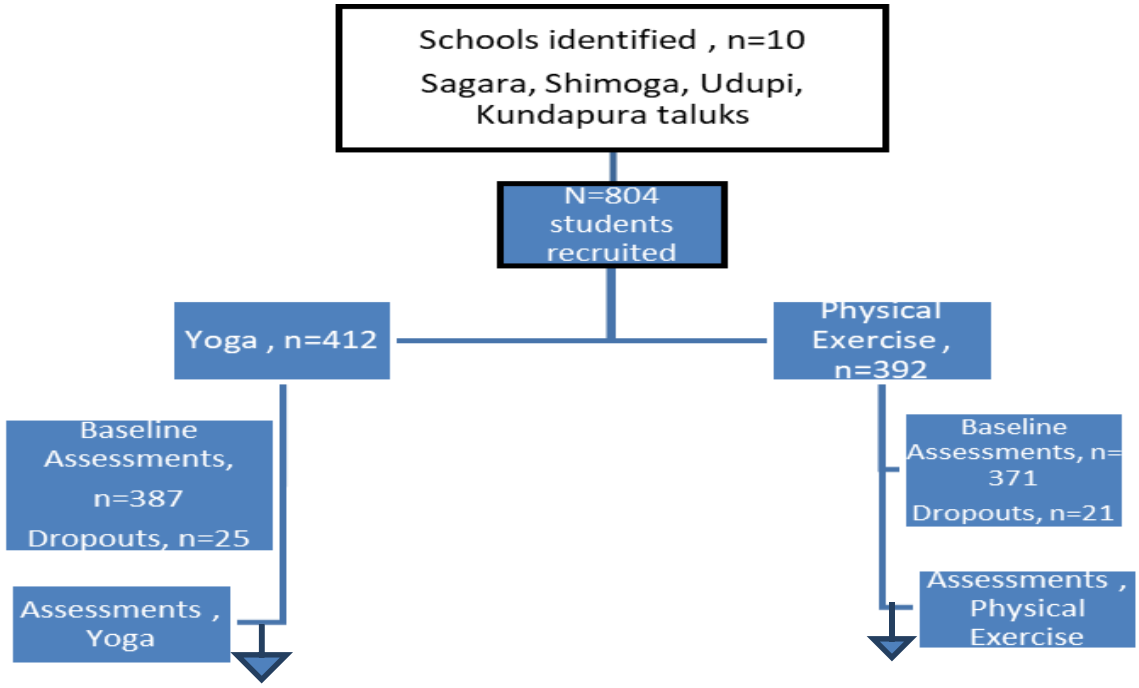
Data Extraction: the data was extracted using case report form developed for the study by field personnel involved in the study.

5.6 DATA ANALYSIS:

The Data was analyzed using **Statistical Packages for Social Sciences (SPSS), version 18.0** for Windows. Both descriptive and inferential statistics were used to describe data and infer hypothesis. The data were found to be normally distributed and hence a **"parametric independent samples t tests"** on change score following intervention between groups was carried out. The data were analyzed using intention to treat principle by substituting the missing values with their respective group mean average. An Alpha of 0.05 was considered significant. The within group analysis was done using **"paired samples t test".**

5.7 CONSORT TABLE:

TRIAL PROFILE:



Assessments	pre, n	post, n
Beep test, VO2Max	377	371
SLCT	387	372
DLST	384	370
Trail making Test	291	283
Standing Broad Jump	338	338
Flamingo Balance	365	245
Sit and reach	370	355
Hand Grip	370	324
Back leg dynamometer	371	331

Assessments	Pre, n	post, n
Beep test, VO2Max	371	363
SLCT	363	363
DLST	352	346
Trail making Test	322	311
Standing Broad Jump	328	323
Flamingo Balance	332	264
Sit and reach	363	312
Hand Grip	359	308
Back leg dynamometer	356	299

SLCT- Six letter cancellation test, DLST- Digit letter substitution test