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Development of a diet pattern assessment tool for coronary heart disease risk reduction

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ABSTRACT

Objective: Existing diet indices have gaps including neglect of the patterns of intake known to affect the final metabolic impact and use of measurement units prone to reporting error, and have applicability that is limited to specific populations. This study sought to develop a tool for diet-pattern assessment (Prudent Approach to Cardiovascular Epidemic, for Indians – Diet Quality Index (iPACE-DQI)) to reduce diet-related coronary-heart-disease (CHD) risk.

Study design: The iPACE-DQI was developed on a 0–100 points scale (higher numeric value healthier). A proof-of-concept analysis was done to examine its construct validity and relation with risk-markers.

Methods: Development of iPACE-DQI was partly guided by 'prudent diet' principles, with assessment focus on quality, quantity, and the pattern of intake. In the second part of the study, construct validity was evaluated by association of iPACE-DQI score with nutrients. Further, relationship of the score with risk-markers high-sensitivity C-reactive protein(hs-CRP), body-mass-index(BMI) and body-fat-percent was examined at single-point-in-time (baseline), and predictive ability of score change on hs-CRP change was evaluated in a proof-of-concept 12-weeks pre-post intervention, among free-living Indians (25–44years,n = 55) in an urban setting.

Results: The iPACE-DQI consists of eight main components. Associations of iPACE-DQI score with mean daily intake of key nutrients were robust and in expected direction [total-dietary-fiber ($r = 0.5$, $p < 0.001$), crude-fiber ($r = 0.6$, $p < 0.001$), protein ($r = 0.5$, $p < 0.001$), total-fat ($r = -0.4$, $p = 0.002$), vitamin-C ($r = 0.5$, $p < 0.001$), total-carbohydrate ($r = 0.3$, $p = 0.017$)]. Trends of hs-CRP, BMI and body-fat-percent across increasing diet-pattern score showed highest degree of abnormality in lowest tertile (≤35). Logistic regression model indicated higher likelihood for hs-CRP reduction (OR: 1.6, 95% CI 0.5–4.9) among those with ≥20% increase in iPACE-DQI score as compared with <20% increase or no-increase over 12-weeks

Conclusion: The iPACE-DQI is a 100-point scale that assesses diet-pattern with respect to CHD-risk. The proposed tool could be useful for researchers/health practitioners to track diet-pattern change and concomitant CHD-risk reduction.

Introduction

Cardiovascular diseases (CVDs) are a leading health concern in nearly all nations [1]. In India, it is characterised by high mortality, upward trajectory, early age of disease onset and rising healthcare costs [2,3]. Dietary risks are a fundamental risk factor for CVD, and therefore crucial for its control and prevention [1,4,5].

Quantitative measurement of diet-pattern change is possibly the first scientific step to determining diet quality and its dynamics with CVD risk. The health practitioner would accurately assess an individual's dietary status, design strategies for outcome-driven diet improvement, and communicate precise dietary guidance to the lay mind – at the clinical and public health levels. This is a strategy that is directly supported by an approach suggested by the pioneering thinker Francis Galton, who is a notable contributor to fields of Statistics and Human Heredity. He stated, "*Wherever you can, count*". He invented measuring devices, where none existed.

The recent focus of nutrition science on the entire diet-pattern for disease prediction, rather than isolated nutrients or isolated foods [6,7], has posed new challenges to *diet assessment*. The roots of diet-pattern

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study lie in multivariate statistical methods of factor analysis and cluster analysis. These analyses follow an inductive approach wherein food consumption patterns are identified, and correlated with beneficial/adverse health outcomes, or alternatively individuals are aggregated into homogenous clusters with similar diets and corresponding disease risk is studied [7,8]. These statistically derived diets at best give broad outlines of healthful and unhealthful diet-patterns. For example, the factors – "prudent diet-pattern" and "Western diet-pattern", the food pattern clusters – "vegetable and fruit pattern" and "fat-reduced foods pattern" [9]. Diet guidance is therefore often limited to this qualitative picture, with evidence-based cutoffs specified only for some diet components. This brings in subjectivity - in diet guidance and assessment by health practitioners, in comprehension of advice by patients, as well as limitation for researchers to build accurate and reliable diet-pattern strategies for examining disease risk reduction during intervention studies.

Development of the concept of diet quality indices/scoring systems by epidemiologists may be considered as a step towards bringing objectivity to *diet-pattern study*. Some prominent diet indices include the Healthy Eating Index, the Alternative Healthy Eating Index, and the Diet Quality Index [10–12]. Each of the indices have a different set of diet components, and unique scoring criteria – decided á priori, and based partly on diet guidelines, partly on epidemiologic studies or arbitrarily fixed by researchers. Some indices have been able to predict chronic disease incidence/related mortality (based on cohort studies data) but the associations are only modest [11–16]. In addition, applicability of each diet index is limited to specific population groups [11] with specific meal-patterns and therefore different risk-factors. For example, none of the indices above are designed to capture an excess intake of cereals; while cereals are staple foods of most societies, they often become disproportionately high in the Indian diet, resulting in a very high carbohydrate diet – a crucial cardiometabolic risk-factor among Indians [17–20]. Moreover, certain indices have neglected critical foods like added-sugar [12], or the patterns of intake known to affect the final metabolic impact [21] as well as the bioavailability of certain nutrients (like protein) [22], and used measurement units that are prone to reporting error [10].

To address these gaps and limitations, the present research was aimed at constructing a composite diet-pattern scoring system iPACE-DQI (Prudent Approach to Cardiovascular Epidemic, for Indians – Diet Quality Index), geared towards capturing diet-related coronary heart disease (CHD) risk, especially in Indians. Construct validity was evaluated using conventional nutrient measurements, its association with CVD risk-markers at a single point in time and its use in prediction of health parameter change was examined on raw data from a proof-of-concept (POC) study, among a sample of free-living Indian men. "Free-living" in this context implies Indian men who live in uncontrolled conditions that closely approach real-world practice.

Methods

A. Development of iPACE-DQI, its components and scoring. The iPACE-DQI is constructed as a tool for diet-pattern assessment with respect to CHD-risk. It represents the vector sum of diet characteristics - quality, quantity, and pattern of intake. It consists of eight main components: Staple score, Sugar score, Fruit & Vegetable score, Fat consumption score, Diet diversity score, Indicator meals healthiness score, Protein foods, and Smart foods score. The maximum (max.) possible score is 100, and minimum (min.) is 0. According to its scoring protocol, higher scores are considered healthier and desirable for cardiovascular health. The three major dietary domains with respect to disease risk were weighted equally and constituted 20 points each (implying 60 score points out of 100); Staple score (quantity and quality) and Sugar score: $(5 + 5) + 10 = 20$, Fruit & Vegetable score: $10 + 10 = 20$, and Fat consumption score: 20. The remaining 4 components of the index held 10 points each (implying 40 score points out of 100); Diet diversity score: 10, Indicator meals healthiness score: 10, Protein foods: 10, and Smart foods score: 10. The individual scores obtained on each of the eight components were summed for the iPACE-DQI score.

The development of this á priori index was primarily guided by the principles of the "prudent diet-pattern" – defined by higher intake of vegetables, fruits, legumes, whole grains, fish, poultry; and a lower intake of red meat, processed meat, refined grains, sweets/dessert, French fries (potato), and high-fat dairy products [23]. This broad framework was applied to the Indian context complying with its cultural norms and meal-pattern; add-ons included specific flaws recognized in the average Indian diet based on findings from studies on Indian population [17–19,24–26]: including but not limited to a high dietary glycemic load, excess fried snacks and repeated use of same oil for deep frying, excess high-fat dairy foods/*ghee*/high-fat high-sugar Indian sweets, less or nil fish intake except among people belonging to certain communities (so ensuring adequate omega-3 fats is a challenge), and substandard protein *quality* especially among Indian vegetarians. Finally, certain physiological concepts of diet-pattern incorporated in iPACE-DQI design that are known to affect the metabolic response include intake pattern that doesn't promote constant elevation in fatty-acid levels, specific combinations like protein and fiber rich foods for favorable metabolic outcome, effect of post-meal placement of high-sugar high-fat desserts, protein quality and protein distribution over a day for higher bioavailability [20–22,27].

The iPACE-DQI with its components and scoring criteria is presented in Table 1. The detailed criteria for each component is evidence based. Key features of the iPACE-DQI components are explained here. "Staple score" has two subcomponents – quantitative and qualitative. Quantitative subcomponent counts the total *staple* servings (cereal grains {whole and refined} and potato) proportionate to daily total energy (kilocalories) intake. Serving/1000 kilocalories (max. score) $\leq$5, (min. score) >5 or nil. Here, a *serving* refers to (starchy) staple food equivalent to 15 g carbohydrate, approximately 70–80 kilocalories based on food-exchange system [28–30]. Example, a serving (one exchange) equals: 1 bread slice (white/whole wheat), 1/3rd-cup cooked rice (approximately 20 g rice), 1 small thin *Indian* 'roti' (approx. 23 g whole wheat flour), 1 medium-sized potato (uncooked, approx. 100 g); these amounts have similar nutritional content. While the present research used the aforementioned cereal/starch exchange system based on a specified carbohydrate content as *constant* (or unit of measurement) for equivalent *staple* servings, some other studies have used a specified weight of a 'whole grain' as unit of measurement for determining equivalent servings of different grain-based food items [31,32]. The cut-off in the current subcomponent defined as '$\leq$5', would constitute approximately 35% of total energy. Standard diets proposed by certain agencies recommend 2.5 to 3 servings/1000 kilocalories (one serving = a bread slice), with not more than half as refined starches, and with no upper limit indicated for the whole grain part; while Harvard's famous 'plate' shows a relative section size for *grains* and does not define the number of servings or kilocalories proportion [33–35]. Dose-response studies indicate stronger cardiovascular-risk reduction from no whole grain to up to 3 servings/day, and a less steep but continued risk reduction only up to 7.5 servings/day (here, a serving = one bread slice) [32,36]. It is therefore rational to factor in an upper limit to intake of grain foods (and potato), especially in context of specific population groups (example: Indians, Koreans etc.) where these foods can become disproportionately high in diets posing a 'risk' at other end of the spectrum of grain consumption – an excess intake [37–39]. This can result in high carbohydrate diet (even 70–80% of total kilocalories) and high glycemic load, that adversely impact plasma triacylglycerol, HDL-cholesterol (HDL-C), and small-dense LDL particles [39–41]. The other subcomponent – qualitative, determines percentage of total *staple* consumed as refined grains/potato, with max. score when atleast 50% of total *staple* is whole grain [42,43]. Potato (rapidly digested high carbohydrate), is widely classified with refined grains and strongly associated with adverse metabolic implications [23,33,35,44–47]. "Sugar score" measures

Table 1
iPACE Diet Quality Index - a snapshot of diet-related CVD risk.

	Index Component	Sub-Component	Max.Score Value	Scoring & Criteria,Data Source[a] (DS)
1	Diet Diversity Score	–	10	**10**: ≥7; [b]**5**: 4–6; **0**: <4 food groups[c]/d *DS: 24-h recall*
2	Staple score (Quantity & Quality)	Quantity: Total *staple* servings (cereal grain {whole & refined} + potato)	5	**5**: ≤5; **0**: 0 or >5 servings/1000 kilo calories *DS: 24-h recall*
		Quality: Refined grain and potato servings	5	**5**: ≤50%; **0**: >50% of total staple servings as refined grain and potato *DS: 24-h recall*
3	Sugar score	Sugar-sweetened beverages (SSBs)[d]	5	**5**: ≤2; **0**: >2 SSBs/d *DS: 24-h recall*
		Sweet dessert post-meal	5	**5**: ≤1; **0**: ≥2 in the last three days *DS: Dietary Question*
4	Fruit & Vegetable score[e]	Fruit	10	**10**: ≥1.5; [b]**6**: 1; [b]**3**: ≤0.5; **0**: 0 servings/1000 kilo calories/d *DS: 24-h recall*
		Vegetable (non-potato)	10	**10**: ≥2; [b]**6**: 1–1.5; [b]**3**: ≤0.5; **0**: 0 servings/1000 kilo calories/d *DS: 24-h recall*
5	Fat consumption score	Total fat consumption (invisible fat + estimated/day visible fat[f] intake)	5	**5**: ≤30%; [b]**2.5**: 30.1%–35%; **0**: >35% of total energy intake *DS: 24-h recall & Dietary Question*
		Milk type[g] (milk & milk products)	5	**5**: skim or double-toned; [b]**2.5**: toned milk; **0**: whole milk *DS: Dietary Question*
		Visible fat profile	5	**5**: ≥2 oils with/without butter/*ghee*; [b]**2.5**: 1 oil with/without butter/*ghee*; **0**: butter/*ghee* only, or 'a *trans*-fat (like *vanaspati*) with/without any other fat' *DS: Dietary Question*
		Omega-3 PUFA sources i. fish, ≥2/week ii. flaxseed (ground)/walnut, daily iii. mustard/canola oil iv. fish oil supplements	5	**5**: ≥2; [b]**2.5**: 1; **0**: 0 of the four sources *DS: Dietary Question*
6	Indicator meals healthiness score [@ *protein quantity, protein quality, fiber*]	Three indicator meals • Breakfast • Snack 1 • Snack 2	10[h] [10= 3 + 3+4]	*Protein quantity*. **3**: ≥5 g; [b]**2**: 3–4.9 g; [b]**1**: 2–2.9 g; **0**: <2 g *Protein quality*. **3**: milk & milk product or animal food or mutually supplemented protein; **0**: none of the three *Fiber*. **4**: ≥3 g; [b]**2**: 2–2.9 g; [b]**1**: 1–1.9 g; **0**: <1 g *DS: 24-h recall*
7	Protein foods		10	Non-vegetarians: **10**: Mostly Fish (≥2/week); [b]**5**: Mostly Poultry (≥3/week); **0**: Mostly Red Meat[i] (≥3/week) Vegetarians: **10**: Mostly pulses/beans & 'paneer'/curd (≥6/week); [b]**5**: Mostly pulses/beans only or 'paneer'/curd only (≥6/week); **0**: Neither pulse/bean nor 'paneer'/curd (≥6/week) *DS: Dietary Question*
8	Smart foods score	Smart foods i. turmeric supplement ii. soluble fiber supplement iii. green tea iv. olives/extra-virgin olive oil	10	**10**: ≥2; [b]**5**: 1; **0**: 0 of these foods, consumed daily *DS: 24-h recall, Dietary Question*
Maximum Total Score			100	

[a] Data Source: 24-h recall. An interview record of food ate/drank the previous day during the day & night, whether at home or outside the home [must be ascertained to be a typical day]; Dietary Question. Six specific dietary questions to elicit information on: post-meal dessert consumption over the past three days; monthly household consumption of visible fat quantity and types, and family profile (in terms of age and gender) including pets to determine consumption units; type of milk and its average daily quantity consumed; omega-3 food sources' (listed in table above) frequency and quantity of intake; protein foods: for non-vegetarians, fish/poultry/red meat intake frequency and quantity, and for vegetarians, pulses/beans/'paneer'/curd intake frequency and quantity; Smart foods' (listed in table above) frequency of intake for checking daily consumption.

[b] Apart from the 'intakes' determining maximum and minimum scores in the table above, for some iPACE-DQI components there are 'transitional intakes' that are given intermediary scores. In such cases these are also given in the scoring & criteria column.

[c] Food groups: (1)Starchy staples (cereal grains + potato), (2)Dark green vegetables, (3)Red & orange vegetables, (4)Other vegetables, (5)Fruits, (6)Milk/milk products, (7)Pulses & Soyabean or Chicken/fish/meat/egg, (8)Oils & fat, (9)Nuts & seeds.

[d] SSBs including tea/coffee, aerated drinks, packed juices, 'sharbats' etc.

[e] 1 cup of fresh fruit juice or vegetable juice to be counted as ½ serving, since it has lost the edible fiber. Packed juices not to be counted.

[f] To estimate an individual's visible fat intake the monthly household visible fat consumption in grams is divided by the sum of the family's consumption units (relative consumption coefficients for different age groups, gender, and physical activity level) and subsequently multiplied by the consumption unit of the person in question; the consumption unit standard for Indians is given by National Institute of Nutrition (Hyderabad, India) [97].The visible fat in cooked-food procured from outside the household either cancels off by equivalent intake by visitors, or else accounted for, at the discretion of the scorer. (Invisible fat intake is calculated using food compositional databases).

[g] If two types of milk used, then the type consumed in greater quantity to be considered for assigning a score.

[h] Each of the three meals scored out of 10 (max. scores for protein quantity, quality, and fiber are 3, 3, and 4 respectively); missed meal scored 0 since long no-food gaps not advised, and also such meal-patterns are associated with high diet quality [63]; average value of the three meals obtained for determining the Indicator meals healthiness score.

[i] Red meat is considered to include beef, lamb, mutton, pork, and processed meat[45,98]

intake of added-sugar using two proxies – daily intake of *sugar--sweetened-beverages (SSBs)* (score max.: ≤2 SSBs/day, min.: >2 SSBs/day), and *post-meal sweet-dessert* intake trend in preceding three days (score max.: ≤1, min.: ≥2 in the last 3 days). Added-sugar is a highly refined carbohydrate containing glucose and fructose, with adverse metabolic implications [33,48,49]. In addition, 'liquid' SSBs are prone to excess consumption due to low satiation [50]. In case of post-meal sweet-dessert, added points that magnify the metabolic response include its typically high fat and high kilocalories, besides being a rich added-sugar source, and its "post-meal" placement [17,27]. Scoring basis is consistent with studies of incident CHD and intermediate cardiovascular risk-factors [48,51]. In "Fruit and Vegetable score", daily consumption is measured on a graded scale, with scores attributed to ideal intake and transitional intakes consistent with evidence showing incremental benefit for every added serving (+1/day) [52]. For fruit: serving/1000 kilocalories (max. score) ≥1.5, (min. score) nil, (intermediary scores) 1 and ≤ 0.5; for vegetable: serving/1000 kilocalories (max. score) ≥2, (min. score) nil, (intermediary scores) 1–1.5 and ≤ 0.5; transitional intakes to round-off into multiples of 0.5. Here, a fruit serving was equivalent to one medium-sized fruit or two small-sized fruits (example: apple, banana, plum), or half-cup of cut-fruit (example: papaya, muskmelon); a vegetable serving on the other hand was half-cup of cut-vegetable in raw state or cooked, or one-cup of raw green-leafy-vegetable. This standard serving is based on the metric (volume and average-weight based) suggested by He et al., also used by other authors [33,53,54]. Cut-off values were decided after examining literature including dose-response analyses [16,33,35,52,54]. In the present tool however, a cup of fruit or vegetable juice (fresh) is counted as half serving of fruit or vegetable, since it has lost the edible fiber; packed juices are not counted at all – apart from the lost edible fiber, even micronutrient content is generally compromised in packed juices. They are also generally higher in calories and to be counted as SSBs (under Sugar score). "Fat consumption score" (FCS) has four sub-components covering quantitative and qualitative elements of fat intake that are crucial to cardiovascular health. One subcomponent checks the total-fat consumed in a day: invisible fat inherent in foods and an estimation of visible fat consumed over a day in the form of cooking-oils, butter and *ghee* (recommended method of calculation in footnote of Table 1). Total daily fat intake ≤30% and >35% of total energy intake would get max. and min. scores respectively, while transitional intakes get intermediary score. These cutoffs are based on World Health Organization norms, consistent with other healthful eating-patterns [34,35,55]. The remaining three subcomponents are *indicators* of overall fat quality. First, the milk type, which is a helpful proxy for saturated fat and total-fat consumption [56]; (max. score) consuming greater amounts of skimmed or double-toned milk, (intermediary score) toned milk, (min. score) primary use of whole milk. Next, the visible fat profile, which is devised as a simple food-based marker of the fatty-acid profile of the diet; (max. score) ≥2 oils with or without saturated fat (for example: canola oil, groundnut oil, extra-virgin olive oil, butter, *ghee*), (intermediary score) single oil with or without saturated fat, (min. score) sole use of saturated fat (for example: butter or *ghee* only) or any use of a *trans*-fat (for example: *vanaspati*) in diet [33,57]. The last sub-component, omega-3 polyunsaturated fatty-acid (PUFA) rich sources, checks the presence and consumption pattern of fish [23,33,58], flax seeds [58–60], walnuts [33,58], mustard oil [57,58,61], canola oil [57,58], and fish oil supplements [33,58,62] (scoring detailed in Table 1). "Indicator meals healthiness score" (IMHS) has three indicator meals - breakfast, snack1 (mid-morning) and snack2 (evening) which are rated for protein quantity, protein quality and fiber content. These three meals were taken as important indicators of overall diet quality [63,64]. They will also be most amenable to 'immediate' change post dietary-counseling, since they can remain largely independent of the household dietary beliefs, procurement, cooking, and (habitual) family meal-patterns [65,66]. Further, protein- and fiber-rich foods are promoted since existing research indicates that combination of foods rich in

these nutrients lead to favorable metabolic outcomes [21,64,67,68]. On the other hand, foods typically consumed at snack time in several countries are grain-based, high fat, heavily salted, and sweetened [69]. To assess IMHS, each of these three meals is scored out of 10 (max. scores for protein quantity, quality, and fiber are 3, 3, and 4 respectively); missed meal scored 0 since long no-food gaps are not advised, and also such meal-patterns are associated with high diet quality [63]; average value of the three meals is the IMHS. Scoring detailed in Table 1. "Protein foods score" checks the quality (of protein and fat inherent in food) and adequacy of protein consumption, mainly in lunch and dinner. Inadequacy of protein is a particular concern in some diets [24,70], and encouraging protein distribution over a day leads to higher bioavailability [22]. Scoring detailed in Table 1. The component "Diet diversity score" is a simple count of food-groups (and subgroups) consumed over preceding 24 hours. Nine food-group categories included in this score are listed in Table 1. This variety score and its measurement protocol is based on Food and Agriculture Organization's guidelines and other notable publications [43,71,72]. Prospective data suggest that diet diversity has a bearing on cardiac risk-factors and mortality [71], is a proxy of micronutrient adequacy [43,72], and an indicator of individual *access* to food (a correlate of the socioeconomic situation [72] and health awareness). The final component, "Smart foods score", considers cardio-protective role of certain supplementary foods: turmeric [73–75], soluble-fiber supplement [76–78], olives or extra-virgin olive oil [79,80], and green tea [74,75,81]; scoring criteria in Table 1.

In iPACE-DQI, an attempt was also made to have simple, reliable diet measurements, with greater accuracy, and reduced cumbersomeness which is otherwise inherent in diet analysis. For example, measurement of added-sugar conventionally done in terms of teaspoons is prone to reporting error – in recall of number of spoons, comprehension of spoon size, whether heaped or non-heaped, underestimation of sugar amount in ready-made drinks – so assessments are less likely to be accurate. In the current tool, two proxies of added-sugar were used – daily consumption of SSB and post-meal sweet-dessert, such measurement units being simple to assess by the investigator or practitioner, to comprehend and comply by the participant, and finally to translate the evidence directly into public health recommendations. Similarly, measurement of *staples* in iPACE-DQI is as simple counts like 1 bread slice and 2 Indian 'roti', or as volume of cooked food like 1/3rd cup of cooked rice (if required, these can easily be translated into raw grain in grams per portion consumed). Fruit and vegetable servings are also simple counts based on sizes in its whole form, and bowls in cut or cooked form. The only metric measurements required in this version of the iPACE-DQI are for total-fat (gram), for calculation of score component IMHS wherein breakfast and snack-time fiber and protein are measured (gram), and total energy (kilocalories).

B. Evaluation of construct validity and association with CVD risk-markers in proof-of-concept (POC) trial data.

Data, ethics and funding

The iPACE-DQI was applied on raw dietary data from a POC pre-post non-pharmacological effectiveness trial for CVD-risk reduction. It was conducted on free-living Indian men, aged 25–44 years, recruited from an urban setting in Delhi-NCR, with TG/HDL-ratio≥4.0 and HDL-C<40 mg/dL, and not on treatment for dyslipidemia, diabetes or hypertension. Socio-economic status of participants ranged from middle to upper-middle income groups [82]. The diet intervention in the trial was done on a sample of 55 participants, delivered by a qualified nutritionist. All participants who met the inclusion criteria were enrolled. With such conditions, the selection bias was minimized. The diet intervention involved iso-caloric "prudent diet" advice, aligned with the Indian scenario which has different cultural norms and meal patterns [17–19,23,24]. Macronutrient distribution of diet was balanced as per norms endorsed by WHO [55]. The intervention was conducted over a period of 12 weeks, with on-site intervention sessions at baseline, after 4 weeks, and after 7 weeks. In addition, two tele-counseling sessions were held after 3- and 10- weeks as reinforcer. To minimize attrition bias, follow-up was consistently done for all participants, and identical follow-up protocols were employed. The intervention was conducted over periods of 2014, up to May 2015. All participants provided written informed consent. The study protocol received ethics approval from the University of Delhi, was technically recommended for financial support by the Department of Science and Technology, Government of India.

Validity assessment and relationship with CVD risk-markers demonstrating its utility. To evaluate construct validity of the tool we examined the relationship of the iPACE-DQI score with mean daily intakes of conventional nutrients assessed from 24-hour (24-h) dietary recall at baseline. Next, the association of the score with certain cardiovascular risk-markers was examined at single point in time: high-sensitivity C-reactive protein (hs-CRP), body-mass-index (BMI) and body-fat-percent. Further, the change in diet scores in the pre-post intervention – indicative of change in participants' diet-pattern – were analyzed as predictors for the respective change in levels of inflammatory marker hs-CRP. Inflammation (chronic) is documented to be an important risk-marker present early on the CVD-risk continuum, with diet-pattern playing an important role in its regulation [83]. The inflammatory marker hs-CRP detects inflammation at the vascular level, is significantly associated with each component of the metabolic syndrome as well as a number of CVD end-points [84].

Dietary assessment and other measurements

Participants' dietary data were collected through a questionnaire that consisted of a 24-h dietary recall (of a typical day) and six specific dietary questions (listed in footnote of Table 1) covering a wider time frame. It was administered in interview format, twice (at baseline and endline stages). Among self-reported diet assessment techniques, 24-h dietary recall is likely more reliable and complete, with an estimated accuracy of ±10% [85,86]. Also, in comparison to other diet assessment methods like food frequency questionnaire, 24-h recall provides data on the complete meal-pattern (greater detail on type, composition and amount) – crucial for a comprehensive diet-pattern assessment [87,88]. Additionally, the scoring system for the iPACE-DQI components was such that it would have reproducibility over the usual day-to-day variations in individual intake – a certain range of intake (due to slightly different quantities or food items) would fall under *a score value*. Each participant's intake was converted into raw food ingredients using standardized recipes. Nutrient calculations were done using Indian Food

Table 2a
Biochemical and anthropometric profile of participants[a] in the proof-of-concept trial data.

Characteristic(s)	Baseline Profile (number of participants = 55)
Age (years)	34.1 ± 5.7
hs-CRP (mg/L)	1.9 (1.0, 3.8)
Triglycerides-to-HDL cholesterol ratio	6.1 ± 2.3
HDL-C (mg/dL)	32.5 ± 3.8
Triglycerides (mg/dL)	196.3 ± 71.7
Total cholesterol (mg/dL)	199.8 ± 34.7
LDL-C (mg/dL)	128.1 ± 30.3
Non-HDL-C (mg/dL)	167.2 ± 34.1
Total cholesterol-to-HDL ratio	6.2 ± 1.2
Weight (kg)	73.9 ± 13.8
BMI (kg/m^2)	26.2 ± 3.9
Body fat (%)	25.3 ± 3.8
Tobacco users (%)	7.3

Values are expressed as mean ± SD or median (interquartile range).
[a]The proof-of-concept trial was conducted on free-living Indian men, aged 25–44 years, recruited from an urban setting in Delhi-NCR (India), with TG/HDL-ratio≥4.0 and HDL-C<40 mg/dL, and not on treatment for dyslipidemia, diabetes or hypertension.

Table 2b
Comparison of variables between Baseline and Endline in the proof-of-concept trial data.

Variable	Baseline		Endline		Difference (95% Confidence Interval)	p value
	n	Mean ± SD	n	Mean ± SD		
hs-CRP (mg/L)	53	#2.2 (1.2–3.9)	53	#2 (0.8–3.75)		0.05
Triglycerides-to-HDL cholesterol ratio	53	6.2 ± 2.1	53	5.3 ± 2.8	−0.878 (−1.51 to −0.24)	0.008*
HDL-C (mg/dL)	53	35.4 ± 4.5	53	40 ± 5.9	4.66 (3.09–6.23)	<0.001*
Triglycerides (mg/dL)	53	#200 (158–241)	53	#185 (144–249)		0.09
Total cholesterol (mg/dL)	53	201.2 ± 39.7	53	199.1 ± 41.5	−2.075 (−14.65 to 10.50)	0.742
LDL-C (mg/dL)	53	122.5 ± 31.5	53	117.7 ± 33.9	−4.758 (−15.48 to 5.96)	0.377
Non-HDL-C (mg/dL)	53	165.8 ± 39.2	53	159.1 ± 39.8	−6.736 (−18.85 to 5.38)	0.269
Total cholesterol-to-HDL ratio	53	5.8 ± 1.2	53	5 ± 1.1	−0.742 (−1.09 to −0.39)	0.0001*
Weight (kg)	53	74.3 ± 14.7	53	73.4 ± 14.2	−0.894 (−1.54 to −0.25)	0.008*
BMI (kg/m^2)	53	26.3 ± 4.2	53	26 ± 4.1	−0.283 (−0.53 to −0.04)	0.024*
Body fat (%)	53	25.6 ± 4.1	53	25.4 ± 4.1	−0.226 (−0.66 to 0.21)	0.297

Values are expressed as mean ± SD or # median (interquartile range).

Composition Tables by National Institute of Nutrition (2017) [30].

Levels of hs-CRP were measured in serum by enzyme-linked immunosorbent assay method using test kit (BioCheck, California). Weight (to nearest 0.1 kg) and body-fat were measured in fasting state using a regularly calibrated *Tanita* analyser (BC-420MA; Tanita Corporation, Japan) based on bio-electrical impedance. It is a valid method, that is simple and practical for use in community-based research [89,90]. BMI was automatically calculated on the *Tanita* analyzer based on standard formula [BMI=Weight(kg)/Height^2(m^2)]. For baseline profile of sample, the direct lipid measurements included serum HDL-C by Immunoinhibition method, serum triglycerides by GPO-PAP enzymatic method and serum total-cholesterol by CHOD-PAP enzymatic method using test kit (Dialab, Austria) on a Roche Modular-P analyzer (Roche Diagnostics, Indianapolis, IN). The laboratory, machines, and methodology used for analyses was kept constant throughout the study, a "quality control" was used for each analysis run, and the blood samples were anonymized using codes – such conditions minimized the potential bias related to outcome measurement. The exercise data were collected as minutes per week of moderate to vigorous exercise (≥3.5 METs absolute intensity [91], single exercise episode ≥10 min for inclusion [92]), at baseline and endline, through a questionnaire which was administered in interview format. The questions enquired about whether the individual exercised during leisure time, and if they did, they were probed on their routine of exercise in terms of 'nature of activity/sport', 'frequency per week' (of each activity performed), and 'average duration of each session'.

Table 4
Association of iPACE-DQI score with cardiovascular risk markers (at single point in time – baseline).

Cardiovascular risk markers	Tertiles of iPACE-DQI Score[a]			
	I (lowest) (≤35) (n = 21)	II (35.01–42.64) (n = 16)	III (highest) (≥42.65) (n = 18)	p value
hs-CRP (mg/L)	2.6 (1.1, 3.8)	2.1 (1.3, 3.9)	2.3 (0.9, 4.1)	0.927
body mass index (kg/m^2)	27.7 ± 4.8	24.9 ± 2.4	25.8 ± 4.3	0.122
body-fat (%)	27.4 ± 3.9	23.5 ± 2.8[x]	25.4 ± 4.4	0.016

Data are mean ± SD or median (interquartile range).
Post-hoc comparison. x: I vs II, p < 0.017
y: I vs III, p < 0.017
z: II vs III, p < 0.017
[a] Higher diet scores are considered healthier and desirable for cardiovascular health.

Statistical analysis

Baseline profile of the participants (n = 55) was presented as mean ± standard deviation or median (interquartile range) for all continuous variables while categorical variables were reported as frequency (percentage). The endline profile (i.e. change in values post 12 weeks in the POC trial) are also presented. Pearson and Spearman correlation

Table 3
Association of iPACE-DQI Score with daily nutrient intake (at baseline) (number of participants = 55).

Daily intake of Nutrients	iPACE-DQI Score		Tertiles of iPACE DQI Score[a]			
	Correlation coefficient[b]	p value	I(lowest) (≤35) (n = 21)	II (35.01–42.64) (n = 16)	III highest) (≥42.65) (n = 18)	p value
Energy (kcals)	0.01	0.923	2373 ± 523	2529 ± 558	2398 ± 486	0.657
Protein (%kcals)	0.5	<0.001	10.4 ± 1.8	10.5 ± 1.2	11.9 ± 1.3 [bc]	0.007
Fat (%kcals)	−0.4	0.002	32.5 ± 6.8	33.1 ± 6.1	28.8 ± 8.9	0.195
Carbohydrate (%kcals)	0.3	0.017	57.1 ± 5.8	56.2 ± 5.1	59.2 ± 9.2	0.459
Total dietary fiber (g/1000 kcals)	0.5	<0.001	12.6 ± 6.2	16.8 ± 6.5	17.2 ± 7.2	0.069
Crude fiber (g/1000 kcals)	0.6	<0.001	2.5 ± 0.9	3.3 ± 1.2	4.0 ± 1.7[b]	0.003
Vitamin A (μg)	−0.2	0.151	127 (90.5, 280.5)	193.5 (96, 232)	116.5 (18, 221)	0.344
Beta-carotene (μg)	0.1	0.431	206.5 (0, 1468)	338.5 (132, 2761)	557.5 (57, 2286)	0.572
Vitamin C (mg)	0.5	<0.001	28 (17.5, 62)	64.5 (25, 84)	97[y] (56, 149)	0.001
Iron (mg)	0.2	0.159	16.7 ± 9.3	16.5 ± 5.0	16.5 ± 4.6	0.995
Added sugar (%kcals)	−0.3	0.024	7.5 ± 2.8	6.9 ± 3.3	5.3 ± 3.9[y]	0.141

Data are mean ± SD or median (interquartile range).
Post-hoc comparison. x: I vs II, p < 0.017
y: I vs III, p < 0.017
z: II vs III, p < 0.017
[a] Higher diet scores are considered healthier and desirable for cardiovascular health.
[b] Spearman coefficient for vitamin A, beta-carotene, vitamin C. Pearson coefficient for all other nutrients.

Table 5
Odds Ratio for hs-CRP Reduction (Improvement) for Change in Diet Score (ΔiPACE-DQI) (number of participants that completed intervention = 53).

Change[a] in diet score [ΔiPACE-DQI[b]] (over the 12 weeks intervention period)	hs-CRP Change (over the 12 weeks intervention period)		Odds Ratio for hs-CRP Reduction (95% CI)			
	Reduction/ Improvement n (%)	No Reduction/No-Improvement n (%)	Unadjusted[c] Odds Ratio (95% CI)	p value	Adjusted[d] Odds Ratio (95% CI)	p value
<20% increase or no-increase [n = 29/53]	15 (51.72%)	14 (48.28%)	Reference		Reference	
≥20% increase [n = 24/53]	15 (62.5%)	9 (37.5%)	1.5 (0.5–4.6)	0.432	1.6 (0.5–4.9)	0.398

n, number of participants.
[a] Reference for calculation of the odds ratio was a <20% change or no-change in diet-iPACE score over the 12 weeks intervention period.
[b] Higher Diet-iPACE score is considered healthier and desirable for cardiovascular health.
[c] Value is not adjusted. Number of observations: 53; LR chi^2 (1) = 0.62, p = 0.42; pseudo R^2= 0.0086.
[d] Value is adjusted for the change in exercise-minutes-per-week during the 12 weeks intervention period. Number of observations: 53; LR chi^2 (1) = 0.97, p = 0.614; pseudo R^2= 0.0134.

coefficients (as applicable) were calculated for the iPACE-DQI score with mean daily intakes of conventional nutrients and added-sugar intake. Trend of nutrient intakes across tertiles of the iPACE-DQI score was examined. Trend in health parameters hs-CRP, BMI and body-fat-percent across the diet score tertiles was also studied. To explore impact of diet score change over time (n = 53 of 55; attrition: 3.6%), logistic regression analysis was designed to calculate the odds for improvement (reduction) in the inflammatory marker hs-CRP with a ≥20% increase in the iPACE-DQI score, with the reference for calculation of the odds ratio as <20% increase or no increase (*no-change or decline*) in the diet score over the 12 weeks intervention period. Using ROC curve, a 20% cut-off for this variable was identified as it was able to discriminate well between hs-CRP reduction and no-reduction. Analysis was done with and without adjustment for change in exercise duration (exercise-minutes-per-week) during the 12 weeks period. Statistical analysis was conducted using STATA version-14 (Stata Corp., College Station, TX, USA), $p \leq 0.05$ was considered statistically significant.

Results

A. Construction of Diet-Pattern Scoring System iPACE-DQI.

The iPACE-DQI tool is presented in Table 1.

B. Evaluation of construct validity and association with CVD risk-markers in POC trial data.

The baseline profile of the diet intervention participants (n = 55) is shown in Table 2(a). The endline profile i.e. change in values post-intervention in the 12 weeks POC trial are also presented in Table 2 (b). Statistically significant improvements were recorded in hs-CRP, TG/HDL-ratio, HDL-C, TG, TC/HDL-ratio, weight, and BMI.

Relationship of diet-pattern tool with conventional metrics of diet.

The trends across the iPACE-DQI tertiles indicate that a higher diet-pattern score was associated with higher intake of protein, total-dietary-fiber, crude-fiber, beta-carotene and vitamin-C; with a lower intake of total-fat and percent calories of added-sugar; and no clear indication for total carbohydrate, energy, iron, vitamin-A in the current sample. The correlation coefficients of the diet-pattern score with mean daily nutrient intakes somewhat confirm these trends: protein ($r = 0.5$, $p < 0.001$), total-fat ($r = -0.4$, $p = 0.002$), vitamin-C ($r = 0.5$, $p < 0.001$), total-dietary-fiber ($r = 0.5$, $p < 0.001$), crude-fiber ($r = 0.6$, $p < 0.001$), total carbohydrate ($r = 0.3$, $p = 0.017$); and added-sugar ($r = -0.3$, $p = 0.024$). See Table 3.

Association of iPACE-DQI score with cardiovascular risk-markers.

The trends of hs-CRP, BMI and body-fat-percent across increasing iPACE-DQI score were examined at baseline. All three parameters showed highest degree of abnormality in the lowest tertile i.e. iPACE-DQI score of ≤35 (Table 4). Next, the logistic regression model indicated that the odds for hs-CRP reduction is 1.6 times (95% confidence interval, 0.5 to 4.9, p = 0.398) among those with ≥20% increase in iPACE-DQI score as compared with <20% increase or no increase (no-change or decline) in the score, over the 12 weeks POC intervention period. This value is adjusted for change in exercise-minutes-per-week. See Table 5.

Discussion

The iPACE-DQI was constructed as a novel quantitative measurement tool for diet-pattern assessment with respect to CHD-risk. Broadly based on the principles of the prudent diet, this comprehensive scoring system (with eight main components) assesses diet in terms of food selection (especially in the typical Indian scenario), quantity and the pattern of intake – into a discrete numeric value on a 0 to100 point scale. Scoring criteria was mainly directed by epidemiological research on diet-CHD risk and certain physiological concepts that affect metabolic outcome.

While the score components and subcomponents qualitatively represented the essential characteristics of the prudent diet providing content validity, the construct validity of the iPACE-DQI was explored through its relationship with the conventional metrics of diet (nutrients). The associations of iPACE-DQI score with the key nutrients were robust and in the expected direction. Several other diet-pattern indices have been validated in a similar manner, however the associations that they drew with the nutrients were somewhat modest in comparison [93–95]. Further, it may be pointed out that the iPACE-DQI score does not have an independent check for the appropriateness of 'energy' intake or energy balance considerations – a CHD-risk pathway. To address this potential concern, firstly, it may be emphasized that the iPACE-DQI construction is principally in terms of 'food' as the measurement unit. Secondly, each score component has been suitably designed to capture 'quantity' as servings, with upper limit criteria for critical diet elements that can become disproportionately high (like cereals, added-sugar and total-fat – particularly relevant for the Indian diet) or else included indicators for specific foods like high fat foods that are proxies for excess energy intake [96]. Thirdly, in order to assess the appropriateness of energy intake it is essential to determine the energy requirement of the subject in question to a reasonable level of accuracy. As discussed by Guenther et al., this proposition is not viable in free living participants, and therefore they suggested complementing the US dietary guidelines based Healthy Eating Index (HEI-2010) [a diet quality index that dichotomizes food-groups into 'adequacy' providing lower limit cut-points or 'moderation' providing upper limit cut-points] with an anthropometric measure for energy balance considerations [10]. The present diet score has indicated a favorable association with certain anthropometric parameters at a single data point (Table 4), and over a period of time a concomitant decline in BMI (−0.283, 95% CI -0.53 to −0.04, p = 0.024) with an increase in mean iPACE-DQI score, in the absence of any change in reported exercise [exercise-minutes-per-week: baseline 120 (0–210) to endline 120 (0–180), p = 0.577, n = 53] over the 12 weeks POC diet trial.

We also studied the association of iPACE-DQI with risk-markers including hs-CRP which is an important risk-marker present early on

the CVD-risk continuum, in a POC analysis (see Table 5). It is arguably one of the first diet scoring systems that explores the impact of its score change in response to diet intervention, on an outcome measure. Existing research on diet quality indices are mostly restricted to drawing associations at single data points like cross sectional studies or specific stage of cohort analyses [15]. In the current regression analysis, while the p-values are statistically non-significant due to small (sample) numbers, the results are important. A bigger study that specifically focusses on demonstrating the utility of this diet measurement tool can be planned in future to confirm the statistical significance of this result.

The current article focuses on quantification in diet-pattern assessment (with respect to CHD-risk), while applying a comprehensive approach. In the past, several authors have discussed diet-pattern components/food-groups in a dichotomized manner, such that they either cause beneficial or else harmful cardiometabolic-effects. Additionally, Mozaffarian viewed diet on a spectrum wherein there is relativity – that is the health effects of a specific food is decided only with respect to one other [33]. The present investigators consider all foods/food-groups to be relevant to the regular diet, and believe that each food/food-group has a critical point with respect to its quantity – beyond which its 'expected effect' may get nullified or reversed. For example, total-fat and added-sugar would cause adverse effects only beyond a certain intake level, and beneficial or null effects otherwise. This theory makes the need for measurement and quantification even more crucial.

A key strength of the present research is that it has developed a diet-pattern index with particular consideration to Indians (representing more than 15% of the World's population), a racial group for which currently there is no known diet-pattern scoring system, even while diet is their number one risk-factor and CHD is the primary disease attributed to this risk-factor [5]. Further, we believe that iPACE-DQI is more nuanced than many other existing diet-pattern indices. Apart from quality and quantity, it assesses the pattern of intake that has an affect on final metabolic impact, and uses simpler measurement units. Its scoring pattern captures dietary risk across the spectrum of intake (for example, checks inadequacy as well as disproportionately high cereal intake) thus contributing to a relatively wider applicability among different population groups. The present research is limited by the small sample size of the POC data for demonstrating utility of the tool. While the study was conducted more than five years ago, it remains highly relevant – CVD continues to be a major public health problem and diet a crucial risk factor [25,26], to date the present diet quality index is a novel method and advances existing knowledge.

The present tool would be useful in research and practice for tracking diet-pattern change and concomitant CHD-risk reduction. It would help in building accurate and reliable diet-pattern strategies for examining disease risk reduction during intervention studies. In addition, the diet score can act as a motivation for participants who have a tangible of their existing diet quality and the degree of improvement required. With this novel and reliable tool, the data generated could potentially contribute to CHD prevention strategies at the national level.

Conclusion

The present research developed a novel tool iPACE-DQI for diet-pattern assessment with respect to CHD-risk, on a 0–100 points scale. It has an assessment focus on quality, quantity, as well as the pattern of intake. Tested in a sample of Indian men, the iPACE-DQI appears valid. Evidence from the POC analysis also suggested its association with risk-markers including hs-CRP which is an important risk-marker present early on the CVD-risk continuum. There was higher likelihood for hs-CRP reduction (OR: 1.6, 95% CI 0.5–4.9) among those with $\geq$20% increase in iPACE-DQI score as compared with $<$20% increase or no-increase over 12-weeks POC intervention period. The iPACE-DQI is a potentially useful tool for researchers and health practitioners for tracking diet-pattern change and concomitant CHD-risk reduction. Future research should scale up the POC study to investigate the effectiveness of such a diet-pattern assessment tool for use in public health.

Ethical approval

The study protocol received ethics approval from the University of Delhi, Delhi, India.

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Conflict of interest disclosures

None.

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