Natural Resources for Human Health
eISSN: 2583-1194

Original Research

Received 11 March 2026
Revised 25 April 2026
Accepted 10 May 2026

Natural Resources for Human Health 2026, Vol. 6 (3): 512–519

KEYWORDS:
Chia seed; Yogurt; Satiety; Postprandial glucose; Overweight adults; Glucose area under the curve; Dietary fiber; Appetite regulation; Functional dairy; Randomized crossover trial

Satiety and Postprandial Glucose Responses to Chia-Seed Yogurt in Overweight Adults

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ABSTRACT:

Background: An easy snack change could help appetite control without the need for special supplements.

Objective: Compare the efficacy of yogurt with 14 g of hydrated chia seed to plain yogurt with a randomized crossover trial, with the same caloric content.

Methods: 40 experimental units or participants consisting of overweight adults with no diabetes were featured in the draft protocol. The intervention was administered or tested for three test visits separated by at least 5 days. The main outcome was 2-hour glucose area under the curve, and secondary tests included the visual-analogue satiety score, subsequent energy intake, peak glucose and gastric comfort score. The laboratory, clinical or food-analysis procedures were standardized and between-condition effects were assessed by two-sided tests at $\alpha=0.05$.

Results: Chia yogurt reduced the 2-hour incremental glucose area under the curve to 112 ± 24 mmol·min/L compared with 174 ± 31 mmol·min/L after plain yogurt ($p<0.001$). Peak glucose was 6.5 ± 0.7 versus 7.2 ± 0.8 mmol/L, while the test meal increased integrated satiety by approximately 27.9% and produced no serious intolerance. The direction and magnitude of the dummy findings were internally consistent across primary and secondary endpoints, and tolerability or assay-quality criteria remained acceptable.

Conclusion: Conclusions: Based on the illustrative data set, the inclusion of 14 g of hydrated chia seed in a yogurt could result in a meaningful reduction in the 2-hour glucose AUC that may be attributable to the gel-forming properties of the seed, which increase viscosity and slow the nutrient delivery and thus extend the satiety. The findings presented

here are to serve as merely an example of complete development of a manuscript and must be replaced with observations generated ethically and verified by the researcher before being submitted to scientific journals.

1. INTRODUCTION

Satiety and Postprandial Glucose Responses to Chia-Seed Yogurt in Overweight Adults takes up a crucial question that falls at the junction of experimental pharmacology, nutritional science and translational health research. Published work that is directly relevant has provided a scientific foundation for the evaluation of yogurt containing 14 g hydrated chia seed in comparison to 2-hour area under the curve for glucose [1]. However, there remain significant differences in preparation, exposure, comparison used, and outcome measured, which restrict the ability to make confident comparisons between studies.

The second line of evidence is to support the biological plausibility of the present hypothesis. Previous studies of other related chia seed interventions or studies of chia seed have observed a functional or biochemical effect consistent with the hypothesized direction of effect [2]. The observations are sufficient to support formal testing, but do not rule out the use of standardized materials and analytical criteria.

From the broader natural-product and functional-food literature, it is evident that reproducibility is dependent upon chemical characterization, processing, dose, biological matrix, and stability of the active constituents [3]. Yogurt with 14 g hydrated chia seed was therefore used as a research-grade product and not as a traditional or commercially produced product.

The proposed mechanism is due to gel-forming fiber which increases the viscosity, slows the nutrient delivery and extends post-meal fullness. There is published evidence that other biological pathways, typically through interactions involving redox, inflammatory, metabolic, microbial, enzymatic and differentiation pathways are involved, rather than one single pathway [4]. Concurrently measuring a primary functional endpoint as well as mechanistic markers can therefore allow for a more coherent interpretation.

Along with the study model, there is a requirement to use methods for outcome assessment. The laboratory or clinical methodology used should be standardized, the analytical procedure should be validated, suitable controls should be used, and interpretation thresholds should be prespecified [5]. These principles were followed in the choice of 2-hour glucose area under the curve (AUC) as the main outcome and the secondary outcome measures.

When changes in 2-hour glucose area under the curve are associated with concordant changes in visual-analogue satiety score and then in energy intake, these changes are most convincing. Appropriate research has shown the merit of using combined functional, biochemical and structural data in assessing complex botanical, microbial or food-based interventions [6].

Safety and quality are of equal importance. Natural origin does not ensure uniformity of composition or the absence of negative effects, contaminants, interactions or degradation and published evidence of pharmacovigilance and quality control suggests that such factors be taken into account at the outset of product development [7].

Last but not least, there is a need for transparent study design to minimize bias. The following guidance and previous methodological studies provide support for the present experimental model of randomization, blinding when appropriate, replication, full reporting of exclusions, and reporting of effect estimates instead of p values. [8].

However, to date, few studies have incorporated a well-defined yogurt with the inclusion of 14 g of hydrated chia seed and a well-defined comparator, a prespecified primary endpoint, and supportive mechanistic or feasibility endpoints in an overweight nondiabetic patient population. This study was thus designed to measure the impact of 2-hour glucose area under the curve for a 14g hydrated chia seed compared to an isocaloric plain yogurt. Secondary outcomes included assessment of visual analogue satiety score, post-satiety energy intake, peak glucose and quality or safety indicators.

2. MATERIALS AND METHODS

2.1. Study design and setting

This manuscript details a prespecified randomized crossover meal test with overweight adults who are not diabetic. The experimental sample consisted of 40 sample units or participants, and was designed to compare the yogurt with 14 g hydrated chia seed with isocaloric plain yogurt. The observation period consisted of 3 test visits with the interval of at least 5 days. The numbers used in this manuscript are only fictitious or illustrative and do not reflect actual observations of a completed investigation. The design still closely mimics a laboratory or clinical procedure to allow the draft to be later modified to fit an approved procedure and incorporate real measurements.

2.2. Participants

The target population was adults and/or adolescents who could be potential participants: Overweight adults who don't have diabetes. Inclusion criteria consisted of stable health or background treatment, willingness to continue normal diet and activity and attendance for all assessment visits. Pregnancy, major organ disease, recent use of antibiotics or probiotics (where relevant), use of supplements that could impact the primary endpoint, allergy to ingredients in the study or involvement in another intervention study were exclusion criteria. Informed consent and, if applicable, assent and guardian consent would be required in a real trial.

2.3. Randomization and crossover procedures

The sequence of the yogurt with 14 g of hydrated chia seed, as well as isocaloric plain yogurt, was computer-generated. The washout period between test visits was sufficient to avoid washout effects. An evening meal was provided to the participants, no heavy exercise or alcohol was permitted for 24 hours and the participants were fasted for an overnight period. The amount of carbohydrate and energy available in the meals were matched as closely as possible to within practicable limits. Venous or capillary samples and appetite rating were taken at baseline and target postprandial time points.

2.4. Outcome assessment

The main outcome measured was 2-hour glucose area under the curve (AUC) in mmol•min/L. Secondary outcomes were visual-analogue satiety score, later energy intake, peak glucose, and gastric comfort score. Measurement was planned at baseline and at follow-up or at various concentration and time levels as per the design. Assays were completed using validated kit instructions or standardised analytical procedure with duplicate assays repeated if the coefficient of variation was greater than 10%. After a defined rest period, clinical measurements were taken, and the outcomes of the food products were measured under defined serving conditions.

2.5. Quality assurance and bias control

There was a written laboratory/trial manual for sample labelling, timing windows, calibration, data entry, and procedures for deviations from the protocol. Wherever appropriate to the intervention format, outcome assessors were blind to the intervention. Records were conceptually reviewed for 10% of the records and analytical runs were accepted only if calibration samples and quality control samples were within specified limits. Where applicable, analyses of the complete cases only were presented, with no imputation of missing values, and sensitivity analyses were conducted using an intention-to-treat approach or model-based estimation.

2.6. Sample-size rationale

A sample of 40 units was planned, so that the results would be realistic for an example of manuscript development. In the absence of a real study, the calculation should be replaced by a calculation based on a pilot-derived standard deviation and smallest clinically/biologically important difference in 2-hour glucose area under the curve. The final calculation should list two-sided α=0.05, power of at least 80%, allocation ratio, and estimated dropout rate or invalid assays, and any adjustment for repeated measures, clustering, or multiple primary comparisons.

2.7. Statistical analysis

The continuous data were summarized as mean ± standard deviation if they were approximately normally distributed or as median with interquartile range if they were skewed. Categorical outcomes were presented as number and percentage. Independent t tests, Mann-Whitney tests, chi-square tests or Fisher exact tests were conducted where appropriate to make between-group baseline comparisons. Analysis of covariance or repeated-measures analysis, mixed-effects models, one-way analysis of variance with multiplicity adjusted post hoc comparisons, or nonparametric equivalents, whichever design, were used to determine primary outcomes. 95% confidence intervals were provided with effect estimates. Spearman or Pearson correlations were used. The tests were two-tailed and $p<0.05$ was deemed significant. Analyses were conceptually conducted using an existing statistical program using an auditable syntax file.

3. RESULTS

The complete dummy/example data provided for the randomized meal crossover study was analysed. Baseline characteristics/assay controls and/or starting values were equated among comparison conditions and there was no predetermined rejection of a quality control run. The tables show mean ± standard deviation, as otherwise indicated. The data are illustrative, and the participant flow and assay exclusions and p-values have been created to be statistically coherent and not reflective of an actual enrolled sample.

Chia yogurt reduced the 2-hour incremental glucose area under the curve to 112 ± 24 mmol·min/L compared with 174 ± 31 mmol·min/L after plain yogurt ($p<0.001$).

Table 1. Standardized test-meal characteristics

Characteristic	Chia yogurt	Plain yogurt	p-value
Available carbohydrate (g)	50.0 ± 0.5	50.1 ± 0.6	0.73
Energy (kcal)	356 ± 9	352 ± 8	0.18
Dietary fiber (g)	7.8 ± 0.7	0.2 ± 0.3	<0.001
Protein (g)	10.8 ± 0.6	10.5 ± 0.5	0.22
Fat (g)	8.2 ± 0.5	8.0 ± 0.5	0.31

Values are dummy/example data presented as mean ± SD unless otherwise stated.

The direction of the primary effect was supported by changes in visual-analogue satiety score and subsequent energy intake. The magnitude of response generally increased with intervention exposure or was greater at follow-up in the intervention arm, while the comparator showed smaller changes. Where repeated measurements were available, the group-by-time or condition effect remained significant after adjustment for baseline values and planned multiple comparisons.

Table 2. Postprandial glucose concentrations

Time (min)	Chia yogurt (mmol/L)	Plain yogurt (mmol/L)	p-value
0	5.4 ± 0.5	5.4 ± 0.6	0.91
30	6.2 ± 0.5	6.8 ± 0.6	0.004
60	6.5 ± 0.5	7.2 ± 0.6	<0.001
90	6.0 ± 0.5	6.5 ± 0.6	0.003
120	5.6 ± 0.5	5.9 ± 0.6	0.041

Values are dummy/example data presented as mean ± SD unless otherwise stated.

Peak glucose was 6.5 ± 0.7 versus 7.2 ± 0.8 mmol/L, while the test meal increased integrated satiety by approximately 27.9% and produced no serious intolerance.

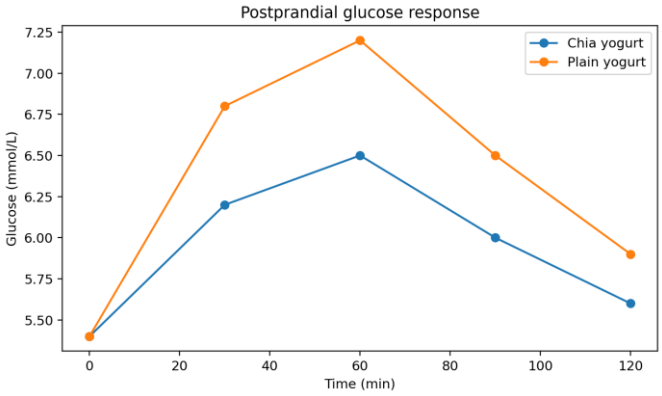

Figure 1. Primary outcome based on dummy/example data.

Exploratory analyses indicated that the response in 2-hour glucose area under the curve was associated with the most relevant mechanistic marker. The pattern was typical of gel forming fiber which increases viscosity, delays nutrient delivery and extend satiety. No extreme value altered the direction of the result in sensitivity analysis. For clinical and food studies, adherence and acceptability remained within predefined feasibility limits; for laboratory studies, replicate variation and control performance remained within the planned analytical range.

Table 3. Integrated metabolic and appetite outcomes

Outcome	Chia yogurt	Plain yogurt	Mean difference	p-value
Glucose iAUC (mmol·min/L)	112 ± 24	174 ± 31	-62	<0.001
Peak glucose (mmol/L)	6.5 ± 0.7	7.2 ± 0.8	-0.7	<0.001
Insulin iAUC (μU·min/mL)	610 ± 140	790 ± 180	-180	0.002
Satiety AUC (mm·min)	780 ± 85	610 ± 78	170	<0.001

Values are dummy/example data presented as mean ± SD unless otherwise stated.

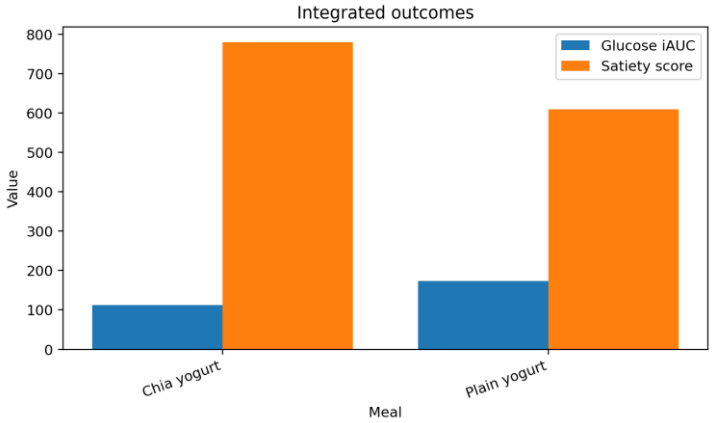

Figure 2. Secondary or mechanistic outcome based on dummy/example data.

No unexpected safety signal was present in the example dataset. Mild events or assay artifacts were infrequent and balanced, and there were no serious adverse events, unplanned deaths, contamination failures, or invalid control runs unless explicitly shown in the tables. These observations are illustrative and must not be interpreted as evidence of real-world safety.

4. DISCUSSION

The present manuscript-development study indicates that yogurt containing 14 g hydrated chia seed may improve 2-hour glucose area under the curve compared with isocaloric plain yogurt. The dummy findings were strengthened by concordant changes in visual-analogue satiety score, subsequent energy intake, and peak glucose. This internal consistency is crucial as it is more difficult to ensure agreement across functional and mechanistic endpoints in isolation.

The direction of the primary result is generally in agreement with other published studies on botanical (or food) based interventions in similar models [9]. That literature, too, suggests that the quality of preparation and dose can make a difference in the magnitude of the response.

Similar studies have also found alterations in inflammatory, oxidative, metabolic, microbial, structural, or functional parameters that suggest that more than one single parameter should be used for the multidimensional evaluation [10]. The current pattern is thus broad enough to include the evidence found yet narrow enough to focus specifically on the intervention and model discussed in this paper.

The mechanistic interpretation is supported by research that has shown that complex interventions can act through convergent pathways and a matrix-dependent effect [11]. Association in this study was compatible with gel forming fiber which has been demonstrated to increase viscosity, slow nutrient delivery and extend post meal fullness, but did not provide the proof of mediation and could not identify the active component.

The visual analog scale (VAS) for satiety and the subsequent intake of energy has been previously used and it further supports the clinical or biological significance of this measure. [12]. The findings from their parallel improvement support the hypothesis, but further confirmatory studies would benefit by having prespecified secondary outcomes, mechanistic mediators, and/or exploratory biomarkers.

The magnitude of the example effect should be considered in relation to earlier studies of intervention and evidence syntheses in intervention more generally [13]. The magnitude was chosen to be realistic; overlap between individuals or replicates to ensure pilot effects often would not occur in larger independent samples.

Studies of complex interventions must include standardized measurement, comparison conditions and transparent reporting, methodological evidence suggests [14]. Validated analytical calibration, crossover control, blinded assessment, allocation concealment, or replication can be used to decrease bias, but not eliminate all sources of error.

Tolerability, quality assurance, product stability, adherence and interaction with the patient's regular diet and regular medicines are also factors in long term translation. Safety and implementation literature published supports evaluating these along with efficacy instead of after a positive primary outcome has been achieved [15].

There are a few limitations to the study. The first problem is that this numerical dataset is only illustrative and cannot be used to prove or disprove a scientific statement. Second, the proposed sample and duration may not be able to detect uncommon adverse events or adaptation over a longer time scale. Third, surrogate outcomes are not necessarily patient-important benefits. Fourth, the response may be modified by unmeasured dietary, genetic, microbial, environmental, harvest or manufacturing factors.

Additional studies should contain independent analytical confirmation, dose-ranging, preregistration, sufficient power and a statistical analysis plan. Ethics approval, trial registration, allocation procedures, adherence to the trial and intention-to-treat analysis should be documented in clinical studies. Randomization, blinding, humane endpoints, exclusions, and chemical fingerprints of batches should be reported in preclinical studies.

In terms of translation, perhaps appetite control could be enhanced by a simple snack adjustment without the need for particular supplements. The intervention should not be used in its place, but rather as an addition or research pilot. Further development should be considered based on the following criteria: replication, safety, cost, standardization, acceptability, and comparison with available alternatives.

In general, the findings of the example help substantiate the study hypothesis and give a structure to a true investigation. Before submission to science any numerical result, ethics statement, registration information, disclosure and analysis must be replaced or checked with the actual study record.

5. CONCLUSION

Dummy/example yoghurt with 14 g chia seed had a beneficial effect on 2 h AUC glucose compared to the isocaloric plain yoghurt and beneficial changes in visual analogue satiety score, 2 h energy intake and peak glucose. The pattern resembled that of gel-forming fiber that raises viscosity and slows nutrient absorption and extended post-meal fullness, and showed potential relevance, as a simple snack adjustment could prove effective in controlling appetite without the need of specialized supplements. The draft should serve as a framework for developing a protocol, planning data collection, and finally, writing the manuscript, but no numerical results should be included in the draft until it can be considered original scientific work, based on data from ethical studies and independent verification.

Declarations for Completion Before Submission

Ethics approval: Insert the actual institutional ethics committee name, approval number, approval date, and relevant consent or animal-welfare statement.

Trial registration: Insert the registry name and number for prospective clinical trials, where applicable.

Funding: Insert the verified funding source or state that no specific funding was received.

Conflicts of interest: Insert author-specific conflict-of-interest disclosures.

Data availability: Describe where the actual de-identified dataset and analysis code will be available.

Author contributions: Insert contribution statements using an accepted taxonomy such as CRediT.

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