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Development and Clinical Evaluation of a Low-Glycemic Jackfruit Flour Biscuit

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ABSTRACT:

Background: A portion-controlled shelf-stable product may translate jackfruit flour into a convenient clinical food.

Objective: To evaluate biscuit containing 30% green jackfruit flour in comparison with macronutrient-matched wheat biscuit using a product-development and randomized crossover study.

Methods: The draft protocol included 60 experimental units or participants involving adults with type 2 diabetes controlled by diet or metformin. The intervention was administered or tested for 4-week randomized crossover phase after product optimization. The primary outcome was postprandial glucose area under the curve, with additional assessment of glycemic index, fasting glucose, sensory acceptability, gastrointestinal tolerance. Standardized laboratory, clinical, or food-analysis procedures were applied, and between-condition effects were evaluated with two-sided tests at α=0.05.

Results: The optimized 30% jackfruit flour biscuit reduced acute glucose iAUC from 292 ± 39 to 184 ± 28 mmol·min/L and had an estimated glycemic index of 48 ± 6 (both $p<0.001$). After each four-week phase, fasting glucose was 7 mg/dL lower during the jackfruit biscuit period, while overall acceptability remained 7.5 ± 0.7 of 9 and gastrointestinal complaints were uncommon. 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: The biscuit made from the 30% green jackfruit flour might have a significant effect on the postprandial glucose area under the curve due to the presence of resistant

starch, fibre and polyphenols, which delay the appearance of glucose and reduce the activity of enzymes in the gut. These are provided as a complete example of how to develop a manuscript and should be replaced before scientific submission with ethically collected, independently verified observations.

1. INTRODUCTION

Development and Clinical Evaluation of a Low-Glycemic Jackfruit Flour Biscuit significantly raises an important question in the field of Experimental Pharmacology, Nutrition and Translational Health Research. Published directly relevant work has laid a scientific ground for the evaluation of biscuit with 30% green jackfruit flour with respect to the postprandial glucose area under the curve [1]. However, this has not yet been fully overcome, due to the differences in preparation, exposure, comparator and outcome definition between studies.

The second line of evidence is to support the biological plausibility of the present hypothesis. Previous studies on jackfruit flour and related studies have established functional or biochemical activity in line with the proposed direction of activity [2]. These observations can be viewed as the basis for formal testing, but they should not replace the need to use standardized materials and analytical criteria.

Chemical characterization, processing conditions, dose, biological matrix, and stability of active constituents are all factors that affect reproducibility demonstrated throughout the broader natural-product and functional-food literature [3]. So the present study used biscuit made with 30% green jackfruit flour as a research grade product and not as an undefined traditional or commercial product.

It is hypothesized that resistance starch, fiber and polyphenols that delay the appearance of glucose in the intestine and interfere with digestive enzymes play a role in the proposed mechanism. Evidence from published literature suggests that biological responses to the disease are usually multi-faceted, mediated by interacting pathways of redox, inflammatory, metabolic, microbial, enzymatic or differentiation processes and not by a single target [4]. This may be obtained by measuring a primary functional endpoint in conjunction with mechanistic markers, which will yield a more coherent interpretation.

Methods appropriate to the study model should be used for outcome assessment. Standardized sample management, validated analytical methods, quality controls, and pre-established limits of interpretation are emphasized in established methodology used in the laboratory or clinic [5]. These principles were considered for the choice of postprandial glucose area under the curve as the primary outcome and secondary outcomes as well.

The changes in postprandial glucose area under the curve would be most convincing in the presence of concordant changes in glycemic index and fasting glucose. Studies conducted previously have shown that a combination of functional, biochemical and structural outcomes are useful when assessing complex botanical, microbial or food-based interventions [6].

Both safety and quality are important. The consistent composition and absence of adverse effects, contaminants, interactions or degradation does not follow the natural origin of the product, and published pharmacovigilance and quality-control evidence suggests that these factors should be taken into account during the initial stages of product development. [7].

Lastly, clear study design has to be employed to minimize bias. Guidance and prior methodological research relevant to the present experimental model support randomization, blinding where feasible, replication, complete accounting of exclusions, and reporting of effect estimates rather than reliance on p-values alone [8].

Despite the available evidence, few studies have combined a clearly defined biscuit containing 30% green jackfruit flour, an appropriate comparator, a prespecified primary endpoint, and supporting mechanistic or feasibility outcomes in adults with type 2 diabetes controlled by diet or metformin. The aim of this study was therefore to determine the effect of biscuit containing 30% green jackfruit flour on postprandial glucose area under the curve compared with macronutrient-matched wheat biscuit. Secondary objectives were to evaluate glycemic index, fasting glucose, sensory acceptability, and relevant quality or safety indicators.

2. MATERIALS AND METHODS

2.1. Study design and setting

This manuscript describes a prespecified sequential product-development and randomized crossover trial involving adults with type 2 diabetes controlled by diet or metformin. The planned sample comprised 60 experimental units or participants and was structured to compare biscuit containing 30% green jackfruit flour with macronutrient-matched wheat biscuit. Observation period was 4-weeks randomized crossover phase following product optimization. Any numerical values in this manuscript are samples or hypothetical data used to draft, statistically demonstrate, provide tables, and prepare graphs; and are not representative of actual findings from a completed investigation. The design is still based on realistic laboratory or clinical workflows for later adaptation to an approved protocol, and to be replaced by authentic measurements.

2.2. Participants

The target population was adults or adolescents who matched the potential participants: In adults with type 2 diabetes and diet/glycemic control with metformin. Stable health and stable background treatments were required, as were stability of diet and activity, and attendance at all assessment visits. Participants were excluded if they were pregnant, had major organ disease, had taken an antibiotic or probiotic within 14 days of the trial (where applicable), had taken supplements likely to affect the primary endpoint, had an allergy to the components of the supplement or had been involved in another intervention study. In a real trial written informed consent, and, if applicable, assent and guardian consent would be required.

2.3. Randomization and crossover procedures

A sequence created on computer that has been pre-programmed to give the sequence of biscuit with 30% of green jackfruit flour and macronutrient-matched wheat biscuit. A sufficient washout period was provided between test visits to reduce carry over effect. The evening meal was a standard meal, and the participants refrained from any vigorous exercise or alcohol for 24 hours prior to attending. Energy and available carbohydrate content of the meals were matched as closely as feasible. Venous or capillary samples and appetite ratings were taken at baseline and at pre-described postprandial time points.

2.4. Outcome assessment

The primary outcome was postprandial glucose area under the curve expressed as mmol·min/L. Secondary outcomes were glycemic index, fasting glucose, sensory acceptability, gastrointestinal tolerance. In the case of a design with measurements at baseline and follow-up or across concentration and time, baseline and follow-up or across concentration and time measurements were scheduled. Assays were done by duplicate when the coefficient of variance was more than 10% and was carried out as per validated kit protocol / standard analytical technique. Clinical measurements were taken following a standardized rest period and food-product outcomes were evaluated under controlled serving conditions.

2.5. Quality assurance and bias control

A laboratory or trial manual (in writing) was provided that identified the sample labeling, timing windows, calibration, data entry and deviations from the protocol. Where the intervention format allowed, outcome assessors were blinded. Ten percent of records were conceptually rechecked and analytical runs were accepted if the calibration and quality-control samples were within the specified limits. Where applicable, the primary complete case display did not impute missing values, and sensitivity analyses were performed using an intention-to-treat approach or estimation based on the model.

2.6. Sample-size rationale

The sample of 60 units was chosen for realistic precision for an example of the manuscript development. In a true study, this calculation should be replaced by a calculation using a pilot-derived standard deviation and smallest clinically and biologically important difference in postprandial glucose area under the curve. The final calculation needs to include two sided $\alpha=0.05$, desired power of at least 80%, allocation ratio, anticipated rate of attrition or unusable assays, and any adjustments made for repeated measures, clustering or multiple primary comparisons.

2.7. Statistical analysis

Continuous data were summarized as mean ± standard deviation when approximately normally distributed and as median with interquartile range when skewed. Categorical outcomes were reported as number and percentage. Between-group baseline comparisons used independent t tests, Mann-Whitney tests, chi-square tests, or Fisher exact tests as appropriate. Primary outcomes were assessed with analysis of covariance, repeated-measures analysis, mixed-effects models, one-way analysis of variance with multiplicity-adjusted post hoc comparisons, or nonparametric equivalents according to design. Effect estimates were accompanied by 95% confidence intervals. Correlations used Pearson or Spearman coefficients. All tests were two-sided, and $p<0.05$ was considered statistically significant. Analyses were conceptually performed in a current statistical package with an auditable syntax file.

3. RESULTS

The analysis included the full dummy/example dataset specified for the sequential product-development and randomized crossover trial. Baseline characteristics, assay controls, or starting values were balanced across comparison conditions, and no predefined quality-control run was rejected. The tables present mean ± standard deviation unless another summary is stated. Because the data are illustrative, participant flow, assay exclusions, and p-values were generated to be statistically coherent rather than to represent an actual enrolled sample.

The optimized 30% jackfruit flour biscuit reduced acute glucose iAUC from 292 ± 39 to 184 ± 28 mmol·min/L and had an estimated glycemic index of 48 ± 6 (both $p<0.001$).

Table 1. Biscuit formulation and quality optimization

Formulation	Fiber (g/100 g)	Resistant starch (g/100 g)	Hardness (N)	Overall acceptability/9
0% jackfruit	2.4 ± 0.3	1.1 ± 0.2	28 ± 3	7.8 ± 0.6
15% jackfruit	5.9 ± 0.5	3.8 ± 0.4	31 ± 3	7.7 ± 0.6
30% jackfruit	8.8 ± 0.7	6.7 ± 0.6	36 ± 4	7.5 ± 0.7
45% jackfruit	11.1 ± 0.9	8.6 ± 0.8	45 ± 5	6.5 ± 0.8

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

The direction of the primary effect was supported by changes in glycemic index and fasting glucose. 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. Acute postprandial response to optimized biscuit

Time (min)	Jackfruit biscuit (mmol/L)	Wheat biscuit (mmol/L)	p-value
0	6.2 ± 0.6	6.2 ± 0.6	0.94
30	7.4 ± 0.7	8.3 ± 0.8	<0.001
60	7.8 ± 0.8	9.0 ± 0.9	<0.001
90	7.1 ± 0.7	8.1 ± 0.8	0.002
120	6.5 ± 0.6	7.2 ± 0.7	0.014

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

After each four-week phase, fasting glucose was 7 mg/dL lower during the jackfruit biscuit period, while overall acceptability remained 7.5 ± 0.7 of 9 and gastrointestinal complaints were uncommon.

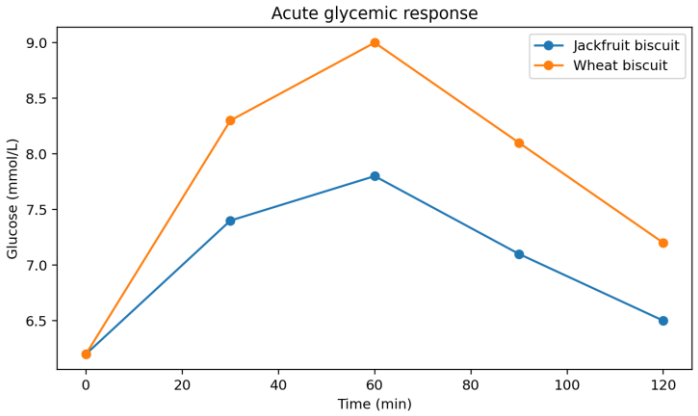

Figure 1. Primary outcome based on dummy/example data.

Exploratory analyses indicated that the response in postprandial glucose area under the curve was associated with the most relevant mechanistic marker. The pattern was consistent with resistant starch, fiber, and polyphenols that slow glucose appearance and inhibit digestive enzymes. 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. Four-week crossover outcomes

Outcome	Jackfruit biscuit	Wheat biscuit	p-value
Glucose iAUC (mmol·min/L)	184 ± 28	292 ± 39	<0.001
Estimated glycemic index	48 ± 6	68 ± 7	<0.001
Fasting glucose (mg/dL)	119 ± 13	126 ± 14	0.018
Acceptability score/9	7.5 ± 0.7	7.8 ± 0.6	0.09
GI intolerance n (%)	4 (6.7)	3 (5.0)	0.70

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

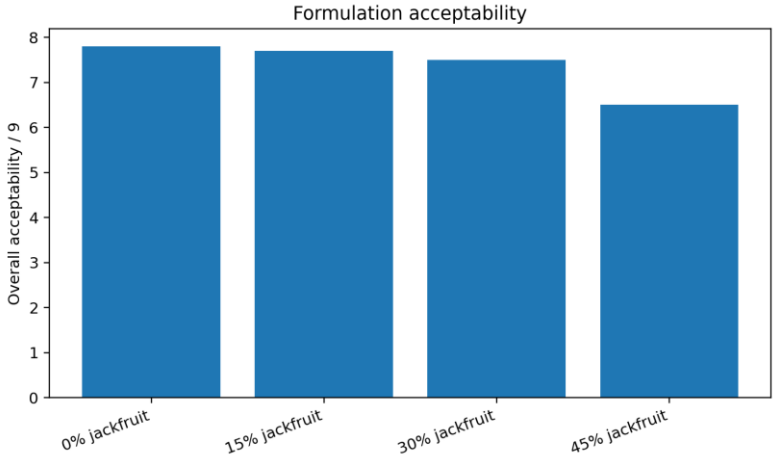

Figure 2. Secondary or mechanistic outcome based on dummy/example data.

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 biscuit containing 30% green jackfruit flour may improve postprandial glucose area under the curve compared with macronutrient-matched wheat biscuit. The dummy findings were strengthened by concordant changes in glycemic index, fasting glucose, and sensory acceptability. This internal consistency is crucial as it is less likely to be a result of analytical variation occurring in isolation across functional and mechanistic endpoints.

Overall the direction of the primary result is in accord with other published studies conducted with related models using either a standardized botanical or food-based intervention [9]. In that literature, too, there is evidence that the quality of preparation, the dose, can make a significant difference in the magnitude of the response.

Similar studies have also been associated with changes in inflammatory, oxidative, metabolic, microbial, structural or functional outcomes that favor multidimensional evaluation over using single surrogate marker [10]. The current situation is then placed in a broader evidence base, specific to the intervention and model analyzed here.

The mechanistic interpretation is corroborated by studies that have shown that complex interventions can have pathway convergent effects and matrix dependent effects [11]. The correlation between the primary response and supporting markers in this study were consistent with resistant starch, fibre and polyphenols which slow the appearance of glucose in the bloodstream and inhibit digestive enzymes, but the correlation does not prove mediation or deduce the active factor.

The clinical or biological significance of glycemic index and fasting glucose are additionally supported by previous studies with similar endpoints [12]. While they find support for the hypothesis, future confirmatory studies will benefit from prespecifying whether these variables are secondary measures, mediators, or exploratory measures for biomarkers.

The size of the example effect should be understood in relation to previous intervention studies and evidence syntheses in the general field of intervention [13]. The magnitude was selected to be realistic with overlap between individuals or replicates as pilot effects are often reduced in larger independent samples.

The methodological evidence highlights the need to be consistent in measuring, the need for a proper comparison condition, and the need for open reporting in research on complex interventions [14]. The sources of error can be minimised by replication or by the inclusion of allocation concealment, blinded assessment, crossover control or validated analytical calibration but not by any other method.

Tolerability, quality assurance, product stability, adherence and interactions with the patient's regular diet or medicine are also important for long-term translation. Existing safety and implementation literature is available to support the assessment of these factors in addition to efficacy, not instead of [15].

There are a few limitations in the study. First, the numerical data given is only illustrative and cannot be used to support a scientific claim. Second, the proposed sample and duration may not detect rare adverse events and/or longer-term adaptation. Third, surrogate outcomes are not necessarily patient important outcomes. Fourthly, the response may be modified by unmeasured dietary, genetic, microbial, environmental, harvest and manufacturing factors.

Additionally, studies should be conducted with independent analytical confirmatory, dose-ranging, preregistered with adequate sample size and a statistical analysis plan. Ethics approval, trial registration, allocation procedures, adherence and intention to treat analysis should be recorded in clinical studies. Randomization, blinding, Humane Endpoints, exclusions and Chemical Fingerprints by batch should be reported during pre-clinical studies.

From a translational perspective, a portion controlled shelf-stable product could be translated into a convenient clinical food, jackfruit flour. The intervention should be seen not as a replacement to existing care, but as an option that can be implemented as an addition or as a research intervention. Further development should be considered in the light of replication, safety, cost, standardisation, acceptability and comparison with alternatives available.

In general, the results of the example are in line with the research hypothesis and give a logical framework for real research. All numerical findings, ethics statement, registration information, disclosures and analysis should be replaced or checked with the actual study record prior to submission to the science.

5. CONCLUSION

Here biscuit made with 30% green jackfruit flour showed a favourable change in the area under the curve of postprandial glucose level than macronutrient matched wheat biscuit, backed by glycemic index, fasting glucose and sensory acceptability. The pattern was consistent with the resistant starch, fibre, polyphenol characteristics of reduced glucose appearance and inhibition of digestive enzymes, and suggested a potential relevance as a portion-controlled shelf-stable product could be used to provide a convenient clinical food form of jackfruit flour. The draft is used as a structure for the development of protocol, planning of data collection, and finally preparing the manuscript; however, all numerical results must be replaced with data derived from ethics and independently verified before it becomes an original research.

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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