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# APPENDIX

## **Clinical Application of the Food Insulin Index to Diabetes Mellitus**

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*Submitted in total fulfillment of the requirements of the  
degree of Doctor of Philosophy*

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THE UNIVERSITY OF  
**SYDNEY**

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# **Appendix 1**

Published Journal Article

*“The efficacy of carbohydrate counting  
in type 1 diabetes: a systematic review  
& meta-analysis”*



# Efficacy of carbohydrate counting in type 1 diabetes: a systematic review and meta-analysis

Kirstine J Bell, Alan W Barclay, Peter Petocz, Stephen Colagiuri, Jennie C Brand-Miller

## Summary

**Background** Although carbohydrate counting is the recommended dietary strategy for achieving glycaemic control in people with type 1 diabetes, the advice is based on narrative review and grading of the available evidence. We aimed to assess by systematic review and meta-analysis the efficacy of carbohydrate counting on glycaemic control in adults and children with type 1 diabetes.

**Methods** We screened and assessed randomised controlled trials of interventions longer than 3 months that compared carbohydrate counting with general or alternate dietary advice in adults and children with type 1 diabetes. Change in glycated haemoglobin (HbA<sub>1c</sub>) concentration was the primary outcome. The results of clinically and statistically homogenous studies were pooled and meta-analysed using the random-effects model to provide estimates of the efficacy of carbohydrate counting.

**Findings** We identified seven eligible trials, of 311 potentially relevant studies, comprising 599 adults and 104 children with type 1 diabetes. Study quality score averaged 7.6 out of 13. Overall there was no significant improvement in HbA<sub>1c</sub> concentration with carbohydrate counting versus the control or usual care ( $-0.35\%$  [ $-3.9$  mmol/mol], 95% CI  $-0.75$  to  $0.06$ ;  $p=0.096$ ). We identified significant heterogeneity between studies, which was potentially related to differences in study design. In the five studies in adults with a parallel design, there was a  $0.64\%$  point ( $7.0$  mmol/mol) reduction in HbA<sub>1c</sub> with carbohydrate counting versus control (95% CI  $-0.91$  to  $-0.37$ ;  $p<0.0001$ ).

**Interpretation** There is some evidence to support the recommendation of carbohydrate counting over alternate advice or usual care in adults with type 1 diabetes. Additional studies are needed to support promotion of carbohydrate counting over other methods of matching insulin dose to food intake.

**Funding** None.

## Introduction

Type 1 diabetes is an autoimmune disorder characterised by chronic hyperglycaemia, which results from an absolute endogenous insulin deficiency. Present medical management revolves around exogenous insulin therapy to restore blood glucose levels to within an optimum range. At present there is no cure for type 1 diabetes; therefore, effective strategies to assist in the achievement and maintenance of normoglycaemia are needed to promote the acute and long-term health and wellbeing of individuals with type 1 diabetes.

Carbohydrate counting has long been thought of as the cornerstone of intensive insulin therapy, with bolus insulin doses matched to the total carbohydrate content of the meal.<sup>1</sup> This practice is based on the premise that carbohydrate is the predominant macronutrient contributing to the rise in postprandial glycaemia. Carbohydrate counting ranges from an awareness of foods that contain carbohydrate and their effect on blood glucose levels, through to counting the number of 15 g carbohydrate exchanges, 10 g portions, or grams of carbohydrate eaten. An insulin to carbohydrate ratio is used to calculate the bolus insulin dose needed.<sup>2</sup>

30 years ago, Slama and colleagues<sup>3</sup> showed a significant correlation between the amount of carbohydrate consumed and the dose of insulin needed

to restore blood glucose levels using an artificial pancreas. Further work confirmed the linear relation between carbohydrate intake and insulin need.<sup>4</sup> However, the underlying theoretical basis and its practical use have since been questioned.<sup>5-9</sup> Bao and colleagues,<sup>10</sup> for example, showed that available carbohydrate (ie, carbohydrates that are able to be digested and absorbed) could explain much of the variance in glucose response to isocaloric portions of single foods, but was not a significant predictor of the response to mixed meals containing variable amounts of carbohydrate, fat, and protein. Moreover, the same amount of available carbohydrate from different food sources is known to produce significantly varying blood glucose responses in both healthy individuals and those with diabetes.<sup>5,11,12</sup> Indeed, the predictable difference in responses to different carbohydrate-containing foods is the basis of the glycaemic index (GI).

Surprisingly, the efficacy of carbohydrate counting has not been assessed as a benchmark for other dietary strategies. Present international recommendations<sup>1,8,13</sup> supporting the use of carbohydrate counting in practice are based simply on narrative review and grading of the limited available evidence. Hence, our objective was to do a systematic review and meta-analysis of randomised controlled trials, comparing carbohydrate counting

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interventions with general or alternate dietary advice in adults and children with type 1 diabetes. Glycaemic control, as judged by glycated haemoglobin (HbA<sub>1c</sub>) concentration, was the primary outcome measure.

## Methods

### Search strategy and selection criteria

We searched all relevant biomedical databases, including Medline, Embase, the Cumulative Index to Nursing and Allied Health Literature, Web of Knowledge, and the Cochrane Central Register of Controlled Trials. In consultation with a medical librarian, we developed a search strategy based on an analysis of medical subject headings, terms, and key text words from January, 1980, to August, 2013. A start date of January, 1980, was intentionally chosen because HbA<sub>1c</sub> assays were becoming routinely available in the early 1980s.<sup>14</sup> We combined terms for “randomised controlled trials”, “type 1 diabetes”, “glycaemic control”, and “carbohydrate counting”. Reference lists from relevant meta-analyses, systematic reviews, and clinical guidelines were also assessed. The panel shows the search and selection process. No protocol for this review has been published.

Two review authors (KJB and AWB) independently screened all study titles and abstracts identified through the search strategies against predetermined selection criteria to identify potentially relevant studies. Duplicate records were removed and multiple reports on the same study were collated as one. Full-text copies of potentially relevant studies were sourced and independently assessed

by the reviewers for compliance with the selection criteria. To be included, studies had to be written in English and published between January, 1980, and August, 2013. All published randomised and quasirandomised controlled clinical trials of interventions that compared the management of type 1 diabetes with and without carbohydrate counting in either children or adults with type 1 diabetes for at least 3 months were included. Trials in pregnant women were acceptable. For this analysis, carbohydrate counting was defined as all methods of quantifying the amount of carbohydrate consumed for the purpose of establishing prandial insulin dose, in accordance with the definition of the American Diabetes Association.<sup>1</sup> This definition included counting in grams, using carbohydrate exchanges or portions, and both flexible and fixed insulin therapy. Interventions where insulin therapy or diabetes education was simultaneously intensified were accepted for inclusion because carbohydrate counting is intricately linked with insulin therapy. This factor was noted as a potential confounder.

### Data extraction and quality assessment

The data from included studies were independently extracted using a predetermined form by two authors (KJB and AWB) and compared for accuracy. Any differences between reviewers' data extraction results were resolved through discussion. Where there was uncertainty, authors were contacted for clarification.

The primary outcome measure was HbA<sub>1c</sub> concentration. Secondary measures were number overall and severity of hypoglycaemic episodes, fasting plasma glucose, insulin dose needed to maintain glycaemic control, bodyweight change, and quality of life (measured by a validated instrument).

The quality of each study was independently assessed by two authors (KJB and AWB) on the basis of several factors, and was scored according to the corresponding criteria. Quality assessment items were random sequence generation, allocation concealment, masking intervention for outcome assessment, subject attrition rate or lost-to-follow-up rate, incomplete outcome data, protocol deviation, selective reporting, and use of an attention placebo in the control group.

Table 1 shows the complete list and scoring criteria.

### Statistical analysis

The software Comprehensive Meta-Analysis was used to analyse the data. Since all data collected were continuous, the results were expressed as the difference in means calculated from end of treatment values, with 95% CIs. Crossover studies were included, and were analysed using the mean and SD of the change from baseline to the endpoint of each intervention period. Heterogeneity between studies was assessed using the  $\chi^2$  test, with a significance level of 0.05 judged to be evidence of heterogeneity. Funnel plots were used in exploratory data analyses to assess for the potential existence of publication

#### Panel: Medline search strategy

##### “Type 1 diabetes mellitus”

1 Exp diabetes mellitus, insulin dependent/

##### “Carbohydrate counting”

- 2 Exp dietary carbohydrates/
- 3 Exp nutrition therapy/
- 4 Carbohydrate counting.tw
- 5 Carbohydrate exchange?.mp.
- 6 Carbohydrate portion?.mp
- 7 Insulin to carbohydrate ratio\$.mp.
- 8 Or/2-7

##### “Glycemic control”

- 9 Exp blood glucose
- 10 Exp hemoglobin A, glycosylated
- 11 Or/9-10

##### “Type 1 diabetes” AND “carbohydrate counting” AND “glycemic control”

- 12 1 and 8 and 11
- 13 Limit to “randomized controlled trials”
- 14 Limit to publications between 1980 and present

Unless otherwise stated, search terms were free text terms. Exp=exploded MeSH (medical subject heading; Medline medical index term). \$=any character(s). ?=substitute for one or no characters. tw=text word. mp=multipurpose.

Criteria	
<b>Selection bias</b>	
Random sequence generation	0=unclear/not randomised; 1=pseudorandomised; 2=appropriately randomised
Allocation concealment	0=not concealed/unclear; 1=concealed
<b>Detection bias</b>	
Masking of outcome assessment	0=unclear/not masked; 1=outcome masked from assessor
<b>Attrition bias</b>	
Participant attrition rate or lost-to-follow-up rate	0=25·0% or greater; 1=15·0–24·9%; 2=5·0–14·9%; 3=0–4·9%
Incomplete outcome data	0=not discussed; 1=used one method of dealing with missing data and discussed potential effect; 2=compared multiple strategies for dealing with missing data and discussed effect on results/conclusions
Protocol deviation	0=unclear/significant deviation/effect of deviation not discussed when interpreting results; 1=some protocol deviation but effect discussed when interpreting results; 2=no protocol deviation
<b>Reporting bias</b>	
Selective reporting	0=outcome measures not reported with no explanation; 1=outcome measures not reported with explanation/discussion of effect; 2=no outcome measures omitted
<b>Other bias</b>	
Attention placebo	0=no attention placebo; 1=attention placebo

Table 1: Assessment of risk of bias

bias. The results of clinically and statistically homogeneous studies were pooled and meta-analysed using the random-effects model to provide estimates of the efficacy of carbohydrate counting. Statistical significance was set at a p value of less than 0·05 for all outcome measures.

Several subgroup analyses were done: carbohydrate counting method (grams vs 10 g portions vs 15 g exchanges), adults versus children, and pregnant versus not pregnant.

Sensitivity analyses were done with the one-study-removed sensitivity analysis and by excluding studies identified as having a high risk of bias.

### Role of the funding source

There was no funding source for this study. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

### Results

From the 311 studies identified through the literature search and additional hand-searching, 18 papers were identified as potentially relevant (figure 1)<sup>15–32</sup> Of those 18 studies, eight were excluded because there was no control group (or no control group without carbohydrate counting),<sup>15–22</sup> one was not an original article,<sup>23</sup> one was in patients with type 2 diabetes,<sup>24</sup> and one did not report HbA<sub>1c</sub> concentrations.<sup>25</sup> The remaining seven studies,<sup>26–32</sup> totalling 703 participants (599 adults and 104 children), met the inclusion criteria. Table 2 presents the characteristics of the participants and outcomes of these studies, including the number and mean age of the participants, study design, intervention duration, and study quality score. Six studies were done in parallel<sup>26,27,29,30,32</sup> and one was a cross-over with three interventions.<sup>28</sup> Six of the seven studies were done in

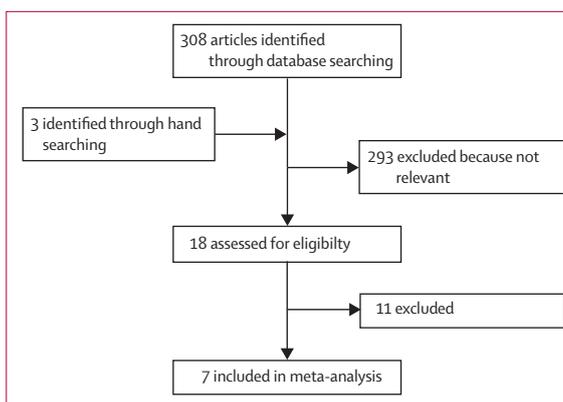


Figure 1: Study selection

adults<sup>26,28–32</sup> and one recruited children aged 8–13 years.<sup>27</sup> All studies were done in an outpatient clinical setting, with individual appointments provided in three studies<sup>27–29</sup> and group education sessions done in four studies.<sup>26,30,32</sup> Study duration averaged 11 months (range 3·5–30). In each study, patients used carbohydrate intake to determine insulin dose, although various methods of quantifying carbohydrate counting were taught. Two studies instructed participants to count grams of carbohydrate per meal<sup>28,29</sup> one study used 10 g carbohydrate portions,<sup>26</sup> another used 15 g carbohydrate exchanges,<sup>27</sup> and three studies<sup>30–32</sup> did not specify how carbohydrate was quantified and the authors could not be contacted. In six of the seven studies, participants in the control groups received what was described as usual care and general nutrition education.<sup>26,28–32</sup> One study compared carbohydrate counting with a flexible (non-measured) low glycaemic index diet.<sup>27</sup>

Assessment of the quality of the studies showed an average score of 7·6 out of a possible 13 points (range 5–10). All studies used appropriate randomisation

	Length of study	Number of participants*	Population†	Intervention‡	Control§	HbA <sub>1c</sub> (%)¶	Secondary outcomes¶	Intention-to-treat analysis?	Quality score (maximum 13)
DAFNE <sup>26</sup>	12 months	169 (intervention 68/84, 19%; control 72/85, 15%)	Type 1 diabetes, 44% male, mean age 40 years (SD 9), England	5 day course run by diabetes educator in matching insulin to carbohydrate intake, group education, 10 g carbohydrate exchanges	Usual care	9.4 (1.2) to 8.4 (1.2; intervention); 9.3 (1.1) to 9.4 (1.1; control); p<0.0001	Weight: 80.5 kg (16.7) to 81.5 (16.9; intervention); 77.4 (13.4) to 77.3 (13.4; control); p=0.11; Hypo (proportion of participants experiencing severe hypo in past 6 months, coma, or needing third-party assistance): 22–18% (intervention), 11–15% (control); p=0.67; Insulin dose: 0.71 to 0.74 U/kg, p=0.017 (intervention); 0.71 to 0.70, p=0.47 (control); QoL (ADDQoL): -2.0 (1.6) to -1.6 (1.6; intervention), -1.9 (1.3) to -1.9 (1.4; control); p<0.01	No	9
Gilbertson et al <sup>27</sup>	12 months	104 (intervention 38/49, 22%; control 51/55, 7%)	Type 1 diabetes, 51% male, mean age 10 years (SD 2; intervention) and 11 years (SD 2; control), Australia	Meal plan with set number of carbohydrate exchanges per meal/snack, individual education (one session with dietitian), 15 g carbohydrate exchanges	Low glycaemic index diet with no portion prescription but general guide, individual education (one individual session with dietitian)	8.6 (1.4) to 8.6 (1.4; intervention); 8.3 (1.3) to 8.0 (1.0; control); p=0.05	Hypo (mean number of episodes per month; <3.5 mmol/L): 7.3 (5.7) to 5.8 (5.5; intervention), 6.9 (6.2) to 6.9 (6.8; control); p=0.37; Insulin dose: 0.9 U/kg (0.3) to 1.00 (0.3; intervention), 1.0 (0.3) to 1.1 (0.3; control); p=0.87	Yes	8
Kalergis et al <sup>28</sup>	3.5 months	21 (intervention 15/21, 29%; control 15/21, 29%)	Type 1 diabetes, 40% male, mean age 38 years, Canada	Meal plan with insulin adjusted using 1 unit to 10 g ratio, individual education (monthly clinic visits and then weekly telephone review), 1 g increments	Meal plan using food group exchange system and no insulin adjustments, individual education (monthly clinic visits and then weekly telephone review)	7.6 (1.3) to 7.2 (0.9), -0.21 (0.18; intervention); 7.7 (1.24) to 7.9 (1.4; control); -0.24 (0.22), not significant	Weight: 67.7 kg (3.0) to 67.4 (3.2; intervention), 67.7 (3.0) to 68.2 (2.9; control); Hypo (episodes per 100 patient years at endpoint; <4 mmol/L): 53 (intervention), 48 (control); not significant; QoL (DQOL): 2.0 (0.10) to 1.8 (0.11; intervention), 2.0 (0.10) to 2.0 (0.13; control); not significant	No	7
Laurenzi et al <sup>29</sup>	24 weeks	61 (intervention 28/30, 7%; control 28/31, 10%)	Type 1 diabetes, 54% male, mean age 41 years (SD 10; intervention) and 40 years (SD 10; control), Italy	Education programme including estimating grams of carbohydrate and matching with insulin, individual education (four to five visits with dietitian in 12 weeks), 1 g increments	Usual care	7.9 (0.9, baseline), -0.4 (mean change; intervention); 8.10 (1.5; baseline), -0.05 (mean change; control); p=0.05	Insulin dose: 36 U/day (median; intervention), 33 (median; control); p=0.282	No	7
Scavone et al <sup>30</sup>	9 months	256 (intervention 73/100, 27%; control 156/156, 0%)	Type 1 diabetes, 49% male, mean age 39 years (SD 11), Italy	Nutrition education programme including estimating carbohydrate content and matching insulin to carbohydrate, group education (one session per week for 4 weeks then 3 monthly reviews to 9 months), not stated	Usual care	7.8 (1.3) to 7.4 (0.9; intervention); 7.5 (0.8) to 7.5 (1.1; control); p<0.01	Hypo (number of hypo events; <3.9 mmol/L): 4 (intervention), 7 (control); p<0.05; Insulin dose: 23.5 U/24 h (10.9; intervention), 27.7 (17.1; control); p=0.03	Not stated	5
Schmidt et al <sup>31</sup>	16 weeks	36 (intervention 21/27, 22%; control 8/9, 11%)	Type 1 diabetes, 52% male (intervention) and 75% male (control), mean age 41 years (SD 10; intervention) and 46 years (SD 9; control), Denmark	Diabetes education programme plus carbohydrate counting using individualised insulin to carbohydrate ratio, group education (one 3 h session, one individual review, two 15 min telephone reviews), not stated	Diabetes education programme including empirical mealtime insulin adjustment based on prescribed doses	9.2 (0.6) to 8.4 (0.9), -0.8 (intervention); 9.1 (0.7) to 8.9 (1.1), -0.1 (control); p=0.175	Hypo (perceived frequency: scored 0–6; higher scores indicate higher perceived frequency): 2.3 (1.4) to 2.2 (1.1), -0.1; not significant (intervention); 2.4 (1.3) to 1.8 (1.4), -0.6; not significant (control); not significant between groups; total reported episodes needing third-party assistance: 2 (intervention), 1 (control); Insulin dose: 0.7 U/kg per 24 h (0.17; baseline), -0.03 (0.11; change mean; intervention); 0.7 (0.2; baseline), -0.01 (0.07; change mean; control); QoL (ADDQoL): -2.0 (1.7) to -1.8 (1.6); not significant (intervention); -2.0 (1.7) to -1.4 (0.9); not significant (intervention); not significant between groups	Yes	7

(Continues on next page)

	Length of study	Number of participants*	Population†	Intervention‡	Control§	HbA <sub>1c</sub> (%)¶	Secondary outcomes¶¶	Intention-to-treat analysis?	Quality score (maximum 13)
(Continued from previous page)									
Trento et al <sup>32</sup>	30 months	56 (intervention 27/27, 0%; control 29/29, 0%)	Type 1 diabetes, 67% male; mean age 37 years (SD 13; intervention) and 37 years (SD 8; control), Italy	Carbohydrate counting programme including matching insulin to carbohydrate embedded into usual group care programme, group education (at least eight education sessions), not stated	Usual diabetes care programme, group education (at least eight education sessions)	7.6 (1.3) to 7.2 (0.9); -0.21 (0.18); not significant (intervention); 7.7 (1.24) to 7.9 (1.4); -0.24 (0.22); not significant within group (control); p<0.05 between groups	Weight: 71.9 kg (10.0) to 71.9 (9.3), 0.65 (0.91); not significant (intervention); 66.9 (10.7) to 67.1 (10.2), -0.17 (0.87); not significant (control); Hypo (absolute number of severe hypo for group; needing third-party assistance) 5 (intervention), 6 (control); Insulin dose: 47.9 U/kg (10.6) to 46.1 (12.7), 0.82 (1.57), not significant (intervention); 45.7 (12.6) to 49.3 (17.2), -4.4 (2.48; control); not significant between groups; QoL (DQoL): 88.7 (9.2) to 78.0 (9.9), 10.7 (1.3); p<0.0001 (intervention); 88.7 (12.5) to 80.4 (11.7), 8.3 (1.47); p<0.0001 within group (control); not significant between groups	Yes	10
All studies were randomised controlled trials except for Kalergis et al, which used a randomised controlled crossover design. QoL=quality of life. ADDQoL=audit of diabetes-dependent quality of life. DQoL=diabetes quality of life. *Number completing study/number allocated, attrition rate. †Diabetes type, sex, age, country. ‡Description, education mode, carbohydrate counting method. §Description, education mode, carbohydrate counting method. ¶Baseline mean (SD) to endpoint mean (SD), change mean (SD); p value between groups.									
<b>Table 2: Summary of included studies</b>									

strategies; however, none of the studies had adequate intervention allocation concealment and none masked the intervention from the outcome assessor. The highest scoring studies had the lowest attrition rates and showed the least risk of bias. Four of the six studies had concurrent intensification of the insulin regimen,<sup>26,28,29,32</sup> and only four provided an attention placebo—ie, participants in the control group had equivalent amounts of contact time as those in the carbohydrate counting group.<sup>27,28,31,32</sup>

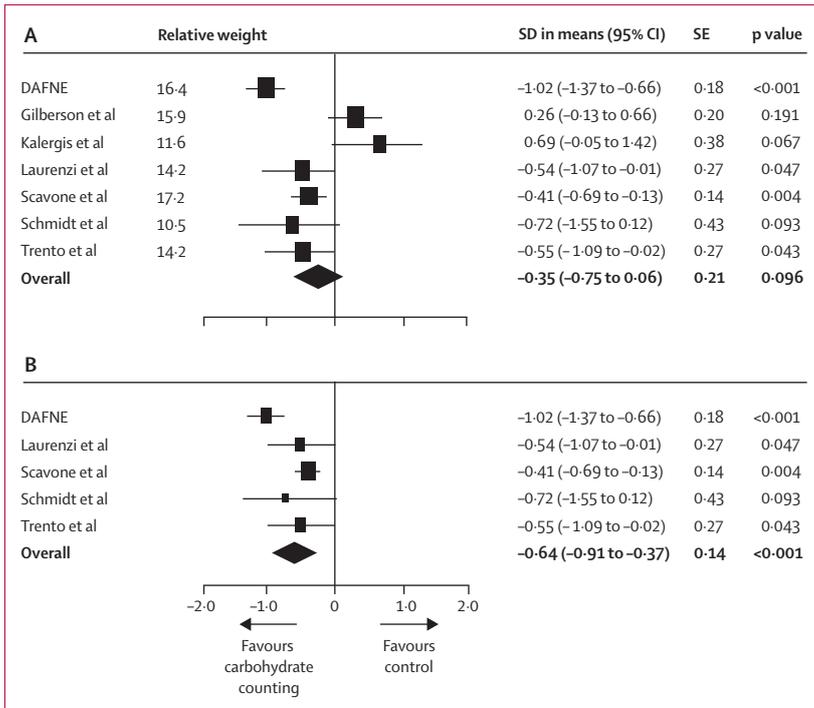
Meta-analysis of changes in HbA<sub>1c</sub> concentrations showed heterogeneous findings. Five studies favoured carbohydrate counting,<sup>26,29,30,32</sup> whereas two favoured the control group.<sup>27,28</sup> The change in HbA<sub>1c</sub> concentration between baseline and end of treatment ranged from a reduction of 1.0% points to an increase of 0.14% points (-11 to 15 mmol/mol) in the carbohydrate counting groups, and a reduction of 0.3% points to an increase of 0.24% points (-3.3 to 2.6 mmol/mol) in the control groups. There was no significant improvement in HbA<sub>1c</sub> concentration with carbohydrate counting versus control or usual care using the random effects model (-0.35%; 95% CI -0.75 to 0.06; p=0.096; figure 2). Assessment of the funnel plot did not suggest asymmetry and thus there is no evidence of publication bias. Heterogeneity ( $\chi^2$ ) between the studies was significant (32%, p<0.0001), potentially related to study design. In the five studies that used a parallel design, comparing carbohydrate counting with alternative advice or usual care, the difference in HbA<sub>1c</sub> concentration between baseline and the end of the intervention was an additional reduction of 0.64% points in the carbohydrate counting groups (95% CI -0.91 to -0.37; p<0.0001; figure 2).

Certain assumptions were made to facilitate the meta-analysis. The SD for the change in HbA<sub>1c</sub> concentration

from baseline to the end of the intervention is needed to assess the significance of the change; however, the report by Trento and colleagues<sup>32</sup> was the only one reporting this information. In the report by Laurenzi and colleagues,<sup>29</sup> the SD of the change was based on the reported p value for the difference between the intervention and control groups. The calculated SD was 0.45 for carbohydrate counting and 0.8 for the control group. Kalergis and colleagues<sup>28</sup> reported the SE of the change, although the values seemed too large; we established that these values were probably the SD of the change and treated them accordingly. Finally, for the remaining studies that did not report the SD of the change,<sup>26,27,30,31</sup> a correlation of 0.5 between baseline and endpoint in the control data, and 0.6 in the intervention data was assumed, on the basis of values published in the report by Trento and colleagues.<sup>32</sup>

As part of the sensitivity analysis, and to verify the effects of these assumptions, a one-study-removed analysis was done. All results remained consistent when either the studies by Gilbertson and colleagues<sup>27</sup> or Kalergis and colleagues<sup>28</sup> were removed from the analysis, making the result significant (p=0.016 and 0.015, respectively).

There was inconsistency in the way hypoglycaemia was defined and reported. Four studies defined hypoglycaemia as an objective blood glucose value but the cutoff value varied from less than 4 mmol/L to less than 2.8 mmol/L.<sup>27-30</sup> Three studies only reported what they described as severe hypoglycaemia, which was defined as whether third-party assistance was needed.<sup>26,31,32</sup> Schmidt and colleagues<sup>31</sup> measured perceived hypoglycaemia with a questionnaire. Six studies reported hypoglycaemic events at the conclusion of the intervention, yet only three reported events at baseline.<sup>26,27,31</sup> Two studies reported significantly less self-reported hypoglycaemia in the



**Figure 2: Meta-analysis of changes in HbA<sub>1c</sub> after carbohydrate counting versus alternate advice or usual care in type 1 diabetes**  
 All seven studies (A) and the five studies in adults using a parallel design (B). The studies included are described in table 2.

carbohydrate counting group than in the control group, but did not report the level of significance.<sup>30,31</sup> In one study, there were two episodes of severe hypoglycaemia in the carbohydrate counting group compared with one in the control group.<sup>31</sup> Overall, six studies reported a non-significant decrease in the frequency of hypoglycaemic events in the carbohydrate counting group.<sup>26-31</sup>

Five studies measured quality of life using a validated instrument;<sup>26,28,29,31,32</sup> however, only two studies used the same questionnaire and, thus, a meta-analysis was not possible. All five studies showed a non-significant preference towards improved quality of life with carbohydrate counting, but only the Dose Adjustment for Normal Eating (DAFNE) study group<sup>26</sup> showed a significant difference between groups. Laurenzi and colleagues<sup>29</sup> reported a significant improvement in scores relating to dietary restrictions (p=0.008), but no other significant results. They did not report the overall scores and associated p value.

All studies reported the insulin dose as units of insulin per day or units of insulin/kg per day. Four of the five studies that assessed changes in insulin dose reported a non-significant difference between groups with no consistent pattern.<sup>26,27,31,32</sup> Only Scavone and colleagues<sup>30</sup> reported a significant difference between endpoint insulin doses (23 vs 28 units of insulin per 24 h in the intervention vs control group, respectively; p=0.03) but did not report baseline or change values.

Four studies measured weight at baseline and at the end of the intervention.<sup>26,28,31,32</sup> All reported a non-significant difference between groups.

Only one study reported the change in fasting plasma glucose between baseline and the end of the 30 month study.<sup>32</sup> Fasting plasma glucose levels dropped non-significantly by 0.27 mmol/L (SD 1.50) in the group using carbohydrate counting.

Adults might be more accurate than children in estimating carbohydrate content of meals. In the six studies comprising 599 adults,<sup>26,28-32</sup> there was a -0.4% difference in HbA<sub>1c</sub> concentration favouring carbohydrate counting (marginally significant p=0.048). Only one study involved children<sup>27</sup> and, therefore, a comparison of adults versus children was not appropriate. There were too few studies to allow meta-analysis of different strategies used for quantifying carbohydrate (eg, counting in grams vs 10 g or 15 g exchanges), and there were no studies in pregnancy that fit the inclusion criteria.

## Discussion

Our systematic review identified seven eligible trials comparing the efficacy of carbohydrate counting on glycaemic control as established by changes in HbA<sub>1c</sub> concentration in adults and children with type 1 diabetes.<sup>26-32</sup> The results were heterogeneous, with five studies supporting carbohydrate counting and two trials (one crossover study, one in children) suggesting less quantitative methods were superior or equally effective. Overall, the difference in HbA<sub>1c</sub> concentrations between participants using carbohydrate counting and those receiving usual care was not statistically significant. However, in the five studies that were confined to adults, the difference in HbA<sub>1c</sub> concentration favoured carbohydrate counting (-0.6% reduction), a result that was both clinically and statistically significant (p<0.0001).

This systematic review and meta-analysis has several strengths. Although several reviews of carbohydrate counting have been published, to our knowledge this paper is the first meta-analysis. Meta-analysis provides the opportunity to quantify the improvement in HbA<sub>1c</sub> that can be expected with the introduction of carbohydrate counting education. It also allows carbohydrate counting to be compared with other available glycaemic control strategies and offers a benchmark for future interventions. Our inclusion criteria ensured that only studies of sufficient quality were eligible. We accepted only randomised controlled trials of greater than 3 months duration and independently assessed the risk of bias for each study, taking this score into account when analysing and interpreting the findings. No study was identified as having a high risk of bias and, therefore, no studies were excluded for this reason. Additionally, our one-study-removed sensitivity analysis, allowed us to assess whether lower quality scoring studies affected the final result; however, excluding the lowest scoring study did not alter the final result.

There are several limitations. Because so few studies met the inclusion criteria, caution must be applied in interpreting the results of this meta-analysis. Several studies from the Diabetes Teaching and Treatment Program and DAFNE programme have shown improvements in HbA<sub>1c</sub> using carbohydrate counting,<sup>33–35</sup> but these studies were not designed as trials and they lacked control groups. The limited number of included studies meant that most planned subgroup analyses could not be done, including studies in children versus adults. The one study in children showed a significant difference between interventions, favouring the alternative approach (a low glycaemic index diet) over carbohydrate counting. Conversely, the noted pattern of improved glycaemic control among adults should also be interpreted with care, because most of the studies had a concurrent intensification of the insulin regimen in the intervention group, which might have reduced HbA<sub>1c</sub> concentration independently of dietary advice. Similarly, four of the seven studies did not provide an attention placebo for the control group.<sup>26,29,30,31</sup> Since it is possible for glycaemic control to improve due to increased contact time with health-care professionals, this might be an additional source of bias and should be taken into account when interpreting the results.

An additional limitation is that the included studies have not measured or reported compliance with the intervention, nor the effectiveness of the education provided. The effectiveness of carbohydrate counting might ultimately be restricted by both compliance and the ability of adults and children to accurately estimate carbohydrate content. Mehta and colleagues<sup>22</sup> showed that greater accuracy and precision in a parent's ability to count carbohydrates was associated with a lower HbA<sub>1c</sub> concentration in their child; however, only precision was a significant predictor of HbA<sub>1c</sub> ( $p=0.9$  and  $p=0.02$ , respectively). HbA<sub>1c</sub> concentration was 0.8% lower for parents who were greater than the 75th percentile for precision. The scientific literature shows a wide variation in this ability, with some studies showing that most participants are able to accurately estimate carbohydrate to within 10–15 g<sup>36,37</sup> or within 15–20% of the true value.<sup>6,22</sup> Whereas, other reports revealed that only half could accurately estimate carbohydrate content,<sup>38</sup> or had large variations in estimations.<sup>39</sup> Unfortunately, in the present study, the planned subgroup analysis comparing methods of quantifying carbohydrate could not be done because of the small number of eligible trials. Future studies should therefore assess the role of precision, and the effectiveness of one strategy over another.

Furthermore, the lack of consistency in the way in which hypoglycaemia was measured and reported prevented the results from being meta-analysed. The data suggests that there might be a decreased risk of hypoglycaemia with carbohydrate counting, which further suggests the reductions in HbA<sub>1c</sub> concentration are a result of stabilised glycaemic control rather than just an overall lowering of

blood glucose levels. It should be noted that reports of hypoglycaemic episodes based on blood glucose meter readings might not be a true representation of the incidence of hypoglycaemia, because some meters are not accurate below the normal range.

A prescribed meal plan might lower HbA<sub>1c</sub> concentration irrespective of whether it includes carbohydrate counting. For example, Mehta and colleagues<sup>40</sup> showed that HbA<sub>1c</sub> correlated with dietary adherence in youths aged 9–14 years, with those in the lowest tertile for dietary adherence having HbA<sub>1c</sub> 0.6–0.9% greater than those in the higher tertiles. In the Diabetes Control and Complications Trial, HbA<sub>1c</sub> was 0.9% lower in those participants who followed a prescribed diet “most of the time” compared with those following a plan “less than half of the time”.<sup>41</sup> However, carbohydrate counting with flexible insulin therapy might be advantageous to quality of life because it allows more dietary flexibility.

In practice, many people with type 1 diabetes have difficulty managing their postprandial blood glucose levels. Ahola and colleagues<sup>39</sup> reported that only a third could maintain postprandial normoglycaemia and, even in those with apparently good metabolic control, about 40% experienced frequent hyperglycaemia. In view of the weaknesses in the theoretical basis for carbohydrate counting, alternate methods of establishing prandial insulin dose should be explored. With developments in medical technology and a shift towards patient-centred care, insulin therapy, and concomitantly medical nutrition therapy, has become more flexible. Carbohydrate counting is recommended to match insulin doses to food choices, yet alternate methods other than carbohydrate counting have rarely been studied. It is possible that other methods of matching insulin with food are not being studied because of the belief that carbohydrate counting is a well founded, evidence-based therapy. Indeed, this meta-analysis shows the scarcity of high-level evidence. Five studies suggest carbohydrate counting is better than usual care, but there are too few studies comparing carbohydrate counting with similarly intensive but different methods of matching insulin to food.

#### Contributors

All authors designed the research, KJB and AWB did the research, and PP did the statistical analysis. KJB wrote the first draft and all authors contributed to the writing of the final report. JCB-M had primary responsibility for final content.

#### Conflicts of interest

JCB-M, SC, and AWB are coauthors of lay books about the glycaemic index of foods. JCB-M and AWB are directors of the Glycemic Index Foundation, a not-for-profit company that administers a food endorsement programme based on the glycaemic index of foods. All other authors declare that they have no conflicts of interest.

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# **Appendix 2**

## Systematic Review Search Strategy

## **Systematic Review & Meta-Analysis: Search Strategy (MEDLINE Example)**

Unless otherwise stated, search terms were free text terms; exp = exploded MeSH: Medical subject heading (Medline medical index term); the dollar sign (\$) stands for any character(s); the question mark (?) = to substitute for one or no characters; tw = text word.

### Type 1 Diabetes Mellitus

1. exp diabetes mellitus, insulin dependent/

### Carbohydrate Counting

2. exp Dietary Carbohydrates/
3. exp Nutrition Therapy/
4. carbohydrate counting.tw
5. carbohydrate exchange?.mp.
6. carbohydrate portion?.mp
7. insulin to carbohydrate ratio\$.mp.
8. or/2-7

### Glycemic Control

9. exp Blood Glucose
10. exp Hemoglobin A, glycosylated
11. or/9-10

### Type 1 Diabetes AND Carbohydrate Counting AND Glycemic Control

12. 1 and 8 and 11
13. Limit to 'Randomized Controlled Trials'
14. Limit to Publications between 1980 – Present

# **Appendix 3**

FII Database

**Table A:** Macronutrient composition, Glycaemic Index (GI), Glycaemic Load (GL), Glucose Score (GS), and Food Insulin Index (FII) for 1000-kJ portions of the reference food and test foods

<b>Food</b>	<b>Test Date</b>	<b>Weight (g/MJ)</b>	<b>Protein (g/MJ)</b>	<b>Fat (g/MJ)</b>	<b>AvCHO (g/MJ)</b>	<b>Sugar (g/MJ)</b>	<b>Fibre (g/MJ)</b>	<b>GI (%)</b>	<b>GL (g/MJ)</b>	<b>GS (%)</b>	<b>FII (%)</b>
Glucose (Glucodin Energy Powder)	2005	59	0	0	59	59	0	100	59	100	100
<b>Dairy Products</b>											
Cream cheese (Coles)	2003	68	6	24	3	2	0	0	0	4	18
93% Fat-free cheddar cheese (Dairy Farmers)	2003	119	41	8	1	1	0	0	0	6	20
Full cream milk (Dairy Farmers)	1999	368	11	14	17	17	0	31	5	12	24
Cheddar cheese (Coles)		59	15	21	0	0	0	0	0	39	33
1% Fat milk (Dairy Farmers)	2005	558	20	6	27	27	0	29	8	16	34
Reduced-fat cottage cheese (Dairy Farmers)	2006	234	29	10	7	7	0	10	1	9	40
Low-fat processed cheese slice (Kraft Foods Ltd)	2003	154	36	4	15	15	0	10	2	14	42
Low-fat cottage cheese (Bulla Dairy Foods)	2007	264	30	6	16	14	0	10	2	4	52
Skim milk (Dairy Farmers)	2001	690	25	1	33	33	0	29	9	25	60
Peach-mango frozen yoghurt (Streets)	2004	181	9	5	38	36	0	51	19	41	64

<b>Food</b>	<b>Test Date</b>	<b>Weight (g/MJ)</b>	<b>Protein (g/MJ)</b>	<b>Fat (g/MJ)</b>	<b>AvCHO (g/MJ)</b>	<b>Sugar (g/MJ)</b>	<b>Fibre (g/MJ)</b>	<b>GI (%)</b>	<b>GL (g/MJ)</b>	<b>GS (%)</b>	<b>FII (%)</b>
Blue Ribbon)											
Vanilla ice-cream (Dairy Bell)	1997	120	5	13	26	26	0	50	13	49	65
Low-fat vanilla ice-cream (Coles)	2004	185	6	7	44	37	0	43	19	50	69
Low-fat strawberry yoghurt (Dairy Farmers)	1997	260	12	5	38	38	1	31	12	43	84
<b>Breads, Cereals, Grains, Rice &amp; Pasta</b>											
All-Bran Original (Kellogg's Foods Inc, Australia)	1997	74	12	3	43	14	14	30	13	28	23
Porridge (Uncle Toby's Inc, Australia)	1997	60	11	5	37	8	5	57	21	30	29
White pasta, spirals, boiled (San Remo)	1997	201	8	1	49	2	4	46	23	32	29
Wholemeal pasta, boiled (San Remo)	1997	218	11	2	49	1	11	42	20	48	29
Tortilla, white, corn (San Diego Tortilla Factory, Australia)	2007	104	6	2	47	1	4	49	23	43	36
100% Natural Granola Oats, Honey & Raisins (Quaker Oats Inc, USA)	2004	55	6	9	35	16	3	44	15	35	41
Grain bread (Tiptop Bakeries Inc)	1997	108	9	5	40	2	7	50	20	42	41
Lentils in tomato sauce (Australia)	1997	253	19	5	29	4	11	37	11	43	42
Brown rice, boiled (Ricegrowers Inc)	1997	148	5	2	53	1	1	72	38	73	45
Special K (Kellogg's Foods Inc,	1997	63	15	2	41	14	1	54	22	49	48

<b>Food</b>	<b>Test Date</b>	<b>Weight (g/MJ)</b>	<b>Protein (g/MJ)</b>	<b>Fat (g/MJ)</b>	<b>AvCHO (g/MJ)</b>	<b>Sugar (g/MJ)</b>	<b>Fibre (g/MJ)</b>	<b>GI (%)</b>	<b>GL (g/MJ)</b>	<b>GS (%)</b>	<b>FII (%)</b>
Australia)											
Cracklin' Oat Bran (Kellogg Foods Inc, USA)	2004	58	5	8	36	21	6	55	20	46	48
Honeysmacks (Kellogg Foods Inc, Australia)	1997	63	9	2	48	31	3	71	34	42	49
Soy-Lin grain bread (Burgen)	2006	99	15	7	29	2	5	36	11	34	52
Sustain (Kellogg Foods Inc, Australia)	1997	62	10	3	43	14	4	55	24	46	52
Cornflakes (Kellogg Foods Inc, Australia)	1997	64	5	0	53	10	2	77	41	53	55
All-Bran Complete Wheat Flakes (Kellogg's Foods Inc, USA)	2007	76	7	2	47	11	9	60	28	60	55
Great Grains (Kraft Foods Inc, USA)	2008	59	6	7	39	10	5	74	29	54	57
7 Wholegrain Puffs (Kashi)	2007	63	7	2	51	0	3	65	33	64	59
Honey Bunches of Oats (Post Foods Inc, USA)	2008	61	6	5	42	11	4	63	26	63	61
Cheerios (General Mills Inc)	2004	65	7	4	43	3	7	74	32	62	63
Lucky Charms (General Mills Inc)	2004	59	4	2	48	26	2	69	33	85	69
Raisin Bran (Kellogg's Foods Inc, USA)	1999	74	6	2	49	22	8	61	30	58	69
Wholemeal bread (Riga Bakeries,	1997	101	8	3	45	2	7	74	34	68	70

<b>Food</b>	<b>Test Date</b>	<b>Weight (g/MJ)</b>	<b>Protein (g/MJ)</b>	<b>Fat (g/MJ)</b>	<b>AvCHO (g/MJ)</b>	<b>Sugar (g/MJ)</b>	<b>Fibre (g/MJ)</b>	<b>GI (%)</b>	<b>GL (g/MJ)</b>	<b>GS (%)</b>	<b>FII (%)</b>
Australia)											
Frosted Flakes (Kellogg Foods Inc, USA)	2002	62	2	0	54	24	2	55	30	70	72
White bread (Sunblest, Tiptop Pty Ltd)	2005	97	9	2	44	3	3	70	31	70	73
Wheaties (General Mills Inc)	2008	67	7	1	46	10	7	75	35	78	78
Cornflakes (Kellogg Foods Inc, USA)	2004	67	5	0	55	4	2	81	45	100	82
Special K (Kellogg's Foods Inc, USA)	1999	63	13	1	44	8	2	69	30	69	86
Original Shredded Wheat (Post Foods Inc, USA)	2004	68	7	2	45	0	9	75	34	92	91
Rice Bubbles (Kellogg Foods Inc, Australia)	2007	62	4	0	54	6	1	88	48	99	94
Grapenuts (Post Foods Inc, USA)	1999	69	9	1	48	8	6	75	36	79	110
<b>Fruit &amp; Fruit Juice</b>											
Avocado, raw, peeled (USA)	2002	112	2	25	0	0	2	0	0	1	4
Seedless raisins (Sunbeam Food Inc, Australia)	2006	72	2	1	56	55	4	64	36	54	31
Red Delicious apple, raw (Australia)	1997	435	1	0	58	57	9	36	21	35	43
Orange, raw, peeled (Australia)	1997	625	7	1	51	51	13	42	21	27	44
Apple juice (Berrivale, Australia)	1999	588	0	0	59	59	0	39	23	53	47
Peaches canned in juice (SPC Ardmona,	2007	485	2	1	55	42	6	40	22	50	54

<b>Food</b>	<b>Test Date</b>	<b>Weight (g/MJ)</b>	<b>Protein (g/MJ)</b>	<b>Fat (g/MJ)</b>	<b>AvCHO (g/MJ)</b>	<b>Sugar (g/MJ)</b>	<b>Fibre (g/MJ)</b>	<b>GI (%)</b>	<b>GL (g/MJ)</b>	<b>GS (%)</b>	<b>FII (%)</b>
Australia)											
Orange juice (Mr Juicy, Australia)	2007	625	3	0	53	53	1	53	28	53	55
Banana, raw, peeled (Australia)	1997	279	3	0	56	47	6	52	29	55	59
Black grapes, raw (Australia)	1997	395	1	0	57	57	4	50	28	52	60
Peaches canned in syrup (SPC Ardmona, Australia)	2007	346	1	2	56	53	4	58	32	67	65
Honeydew melon, raw (Australia)	2006	714	5	2	46	46	1	62	29	62	93
<b>Vegetables &amp; Legumes</b>											
Coleslaw (Coles)	2002	252	5	10	34	33	7	39	13	20	20
Canned navy beans (Eden Organic, USA)	2005	281	19	5	28	0	24	31	9	20	23
Frozen corn (McCain Foods Pty Ltd)	2006	222	6	3	43	10	7	47	20	36	39
Carrot juice, fresh (Australia)	2006	762	6	1	41	41	24	43	18	44	41
Tomato pasta Sauce (Paul Newman)	2006	445	6	8	38	34	0	31	12	34	41
Baked Beans (Franklins)	1997	351	16	2	39	16	17	44	17	80	88
Potato, russet, peeled and boiled (Australia)	1997	368	10	1	49	3	9	78	38	99	88
<b>Meat &amp; Protein Alternatives</b>											
Walnuts (Lucky California)	2003	35	6	23	1	1	3	0	0	4	5
Short-cut bacon (Primo Smallgoods)	2007	106	16	19	1	1	0	0	0	3	9

<b>Food</b>	<b>Test Date</b>	<b>Weight (g/MJ)</b>	<b>Protein (g/MJ)</b>	<b>Fat (g/MJ)</b>	<b>AvCHO (g/MJ)</b>	<b>Sugar (g/MJ)</b>	<b>Fibre (g/MJ)</b>	<b>GI (%)</b>	<b>GL (g/MJ)</b>	<b>GS (%)</b>	<b>FII (%)</b>
Bologna (Australia)	2001	111	24	9	13	3	3	0	0	6	11
Peanut butter (Kraft Foods Inc, Australia)	2001	41	9	20	7	2	5	14	1	6	11
Peanuts, salted and roasted (Grocery Wholesalers Inc, Australia)	1997	38	10	20	5	2	2	14	1	8	15
Frankfurter/hot dog (Australia)	2001	95	14	19	3	0	2	28	1	8	16
Tuna in oil, drained (Coles)	2003	135	24	15	2	1	0	0	0	4	16
Roast chicken, without skin (Woolworth Inc)	2005	113	31	13	0	0	0	0	0	1	17
Chicken, panfried with skin (Australia)	2005	94	23	17	0	0	0	0	0	5	19
Prawns, boiled and peeled (Findus Seafood Deli)	2003	235	48	4	2	1	0	0	0	5	21
Tofu (Soyco)	2003	227	27	11	7	1	3	15	1	5	21
Eggs, poached (Australia)	1997	160	21	18	1	1	0	0	0	29	23
Beef taco (Bruce Foods Corporation, USA)	2004	138	20	13	9	1	2	39	4	11	24
Tuna in water, drained (Coles)	2001	239	48	5	0	0	0	0	0	8	26
Beef steak, grilled (Australia)	1997	158	42	8	0	0	0	0	0	15	37
White fish (Ling) fillet (Australia)	1997	333	56	1	0	0	0	0	0	20	43
Battered fish fillet (Coles)	2002	110	13	15	14	0	1	38	5	29	54

<b>Food</b>	<b>Test Date</b>	<b>Weight (g/MJ)</b>	<b>Protein (g/MJ)</b>	<b>Fat (g/MJ)</b>	<b>AvCHO (g/MJ)</b>	<b>Sugar (g/MJ)</b>	<b>Fibre (g/MJ)</b>	<b>GI (%)</b>	<b>GL (g/MJ)</b>	<b>GS (%)</b>	<b>FII (%)</b>
<b>Fats &amp; Oils</b>											
Butter (Western Star Original)	2007	33	0	27	0	0	0	0	0	2	2
Olive oil (Australia)	2005	27	0	27	0	0	0	0	0	1	3
<b>Beverages</b>											
Gin, 40% alcohol (Australia)	2001	111	0	0	0	0	0	0	0	7	1
White wine, 11% alcohol (Australia)	2001	362	1	0	1	0	0	0	0	5	3
Beer, 4.9% alcohol (Budweiser, Australia)	2001	671	2	0	13	0	0	66	9	41	20
Coca-Cola (Coca-Cola Amatil Inc)	1999	595	0	0	59	59	0	53	31	50	44
Ice tea (Narkena Ltd)	2006	622	0	0	59	59	0	59	35	59	69
Orange-mango fruit drink (Frosts Food & Beverage, Singapore)	2007	833	1	0	58	58	0	67	39	67	76
<b>Confectionery</b>											
Milk chocolate (Hershey Foods Inc, USA)	2004	45	3	14	25	23	1	43	11	27	34
Snickers bar (Masterfoods, USA)	2004	50	3	12	29	25	1	42	12	27	37
Sherbet (Nestle Pty Ltd, Australia)	2007	217	3	3	50	48	0	59	30	61	76
Mars bar (Mars Confectionary Inc, Australia)	1997	54	3	9	38	37	2	62	23	55	89

<b>Food</b>	<b>Test Date</b>	<b>Weight (g/MJ)</b>	<b>Protein (g/MJ)</b>	<b>Fat (g/MJ)</b>	<b>AvCHO (g/MJ)</b>	<b>Sugar (g/MJ)</b>	<b>Fibre (g/MJ)</b>	<b>GI (%)</b>	<b>GL (g/MJ)</b>	<b>GS (%)</b>	<b>FII (%)</b>
Jellybeans (Grocery Wholesalers Inc, Australia)	1997	88	3	0	56	45	0	78	44	83	117
<b>Snacks Foods</b>											
Chocolate chip cookie (Chips Ahoy)	2004	49	3	12	30	15	2	50	15	21	33
Muesli bar (Uncle Toby's Inc)	1997	63	11	5	37	17	7	56	21	30	34
Honey-raisin bran muffin (Sun Maid, USA)	2004	64	3	8	38	23	3	56	21	32	37
Popcorn (Uncle Toby's Inc)	1997	52	5	13	27	2	6	66	18	43	39
Cinnamon swirl pastry (Bimbo Bakeries, USA)	2004	63	4	10	31	14	2	40	12	39	42
Corn chips (The Smith's Snackfood Company)	1999	46	3	13	24	1	5	42	10	32	45
Jatz cracker (Arnotts, Australia)	2007	51	4	9	34	2	2	55	18	37	45
Potato chips (The Smith's Snackfood Company)	1997	44	3	16	22	0	2	60	13	36	45
Apple pie (Sara Lee)	2002	85	3	11	32	16	1	41	13	39	47
Reduced-fat chocolate chip cookie (Chips Ahoy, USA)	2004	53	3	9	36	15	2	50	18	47	49
40% Reduced-fat potato chips (Cape Cod	2004	51	4	11	31	2	2	60	19	40	51

<b>Food</b>	<b>Test Date</b>	<b>Weight (g/MJ)</b>	<b>Protein (g/MJ)</b>	<b>Fat (g/MJ)</b>	<b>AvCHO (g/MJ)</b>	<b>Sugar (g/MJ)</b>	<b>Fibre (g/MJ)</b>	<b>GI (%)</b>	<b>GL (g/MJ)</b>	<b>GS (%)</b>	<b>FII (%)</b>
Potato Chip Company)											
Super moist yellow cake with chocolate frosting (Betty Crocker, USA)	2004	73	2	11	32	21	1	42	13	33	53
Donut with cinnamon sugar (Woolworths)	1997	65	4	13	26	9	1	76	20	44	54
Fat-free oatmeal raisin cookie (Archway Cookies Inc)	2004	67	2	0	53	30	2	54	29	50	54
Croissant (Woolworths)	1997	66	6	12	29	3	2	67	19	52	58
Panjacks (White Wings Pty Ltd)	2004	121	5	3	48	17	2	67	32	67	58
Chocolate brownie with frosting (White Wings Pty Ltd, Australia)	1997	64	4	12	30	20	1	38	11	39	60
Raspberry jam (Cottees)	2005	88	0	0	59	59	1	51	30	58	62
Water crackers (Grocery Wholesalers Ltd)	1997	58	6	5	42	1	2	78	33	83	64
Chocolate chip cookies (Arnotts Biscuits Ltd, Australia)	1997	51	2	11	35	19	1	62	22	52	67
Blueberry streusel muffin (Pinnacle Foods Group LLC, USA)	2004	79	4	7	41	22	1	55	22	62	69
Fat-free blueberry muffin (Continental	2004	101	3	1	51	28	3	71	36	67	69

<b>Food</b>	<b>Test Date</b>	<b>Weight (g/MJ)</b>	<b>Protein (g/MJ)</b>	<b>Fat (g/MJ)</b>	<b>AvCHO (g/MJ)</b>	<b>Sugar (g/MJ)</b>	<b>Fibre (g/MJ)</b>	<b>GI (%)</b>	<b>GL (g/MJ)</b>	<b>GS (%)</b>	<b>FII (%)</b>
Mills Pty Ltd)											
97% Fat-free pretzels (Parkers)	2004	63	6	2	50	2	3	84	42	85	74
Original Pancake & Waffle Mix (Quaker Oats Inc, USA)	2004	132	6	1	51	9	1	67	34	71	110
<b>Mixed Meals &amp; Take-Away Foods</b>											
Beef lasagne (Sara Lee Bakery Pty Ltd)	2002	164	12	10	25	3	1	38	10	15	34
Cheese pizza (McCains, Australia)	1999	90	12	8	30	2	0	60	18	41	47
French fries (McCain's Foods Inc)	1997	93	4	9	37	2	4	70	26	50	54
French fries (McDonald's Inc)	2002	76	3	13	26	1	3	70	18	39	57

# **Appendix 4**

FII Testing

Participant Information Sheet

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**Prof. Jennie C Brand-Miller**  
BSc, PhD, FAIFST, FNSA

Room 472, Building G08  
Telephone: +61 2 9351 3759  
Email: jennie.brandmiller@sydney.edu.au

## **TESTING OF FOODS FOR THEIR GLYCEMIC INDEX AND OTHER METABOLIC VARIABLES**

### *Student Research*

### **PARTICIPANT INFORMATION SHEET**

We are seeking healthy individuals aged between 18 and 65 years with no known food allergies, to participate in a study measuring the effects of foods, food ingredients and beverages on blood glucose and insulin levels. This research is being undertaken by a student, Kirstine Bell, under the supervision of Professor Jennie Brand-Miller.

Your blood glucose and biochemical responses will be used to calculate the glycemic index (GI) of the foods and other parameters relevant to health and disease prevention (insulin responses, hunger, fullness).

Before you begin your first study session, you will be required to complete a short 1-page screening questionnaire to ensure you are eligible to participate. For your own safety, it's important that you do **not** participate if you have any type of food allergy/intolerance (eg to wheat, cow's milk, lactose, eggs, peanuts).

If you decide to participate, you will be required to visit the Human Nutrition Unit's metabolic kitchen room (room 406) on the top floor of the Old Teachers' College on 9 separate mornings over the next 6 weeks.

### **ON THE DAY BEFORE EACH TEST SESSION, YOU ARE REQUIRED TO:**

- Avoid alcohol.
- Avoid over or under-eating.
- Avoid over-exercising (ie more physical activity than is usual)
- Ensure you eat an evening meal. It should include a serving of carbohydrate-rich foods, such as potatoes, rice, bread, pasta, noodles, couscous, or corn.
- Avoid legumes (lentils, chickpeas, baked beans, etc) for the evening meal.
- FAST for at least 10 hours (overnight) before attending your test session. For example, if your test session is scheduled to begin at 7 am Tuesday morning, you will need to cease eating by 9 pm on Monday night. During this time you are permitted to drink only water.
- NOT eat breakfast on the morning of the test and report to the test rooms in a fasting condition.
- Reschedule your appointment if you don't feel well or need to take new medication.

### **DURING EACH TEST SESSION...**

- You will be required to consume a fixed portion of the test food with a glass of water or the reference food (glucose dissolved in water) within 15 minutes.

- A blood sample [**about 20 drops**] will be taken from a finger tip using a small automatic lancet device twice before you start eating and then at 15, 30, 45, 60, 90 and 120 minutes after eating commenced (8 finger-prick blood samples (each < 1 mL) per test session).
- Complete a food, activity and wellness questionnaire and assess your feeling of fullness just after each blood sample is taken.
- You are required to remain seated in the test room and to refrain from any further eating.
- You may study, read or chat with the other study participants.
- After the last blood sample has been taken, you may help yourself to breakfast.
- You will need to allow a little more than 2 hours for each test session.

*Continued over leaf*

## **TESTING OF FOODS FOR THEIR GLYCEMIC INDEX AND OTHER METABOLIC VARIABLES**

### **ARE THERE ANY ADVERSE EFFECTS OR RISKS?**

Although your fingers will be pricked with very small lancets, you may experience **minor discomfort** during blood taking procedures, particularly during your first test session, and your fingertips may feel slightly tender for the rest of the day. However, many people do not feel any discomfort at all, and the investigators try to make the procedures as quick and as painless as possible.

**Blood is a source of infectious disease** and during any blood sampling procedure there is a risk of cross infection between study participants and investigators. However, in this study, the risk is minimal because the investigator taking the blood samples will wear clean disposable gloves when taking blood samples and will maintain the blood sampling area in a hygienic condition. Blood samples will be taken from warmed hands and fingertips will be sterilised before and after each blood sample is taken. A new sterile lancet will be used for each blood sample and the lancets cannot be re-used.

Participation in this study is entirely voluntary: you are not obliged to participate and if you choose to participate you can withdraw at any time without repercussions. Whatever your decision, it will not affect your relationship with the investigators. If you are a University of Sydney student, participation in, or withdrawal from the study will not influence your academic progress in any way.

**You are free to withdraw from the study at any time without affecting your relationship with the researchers or the University of Sydney now or in the future.**

All personal information and results arising from the study will be used for research purposes only and will remain strictly confidential. You will not be personally identified in any publications or presentations arising from this research study. While we intend that this research study furthers medical knowledge and may improve treatment or management of certain diseases (eg. diabetes) in the future, it may not be of direct benefit to you.

**On some occasions, filming may take place but you have the option of not participating at those times.**

### **PAYMENT FOR PARTICIPATION**

You will receive **\$30** for each test session to compensate you for your time. The payment will be made in full at the completion of the study ie all 9 test sessions within 6 weeks. If you decide to withdraw, you will be paid for the sessions you have already completed.

While participating in this study, it is important that you maintain your usual diet and lifestyle and do not attempt to gain or lose weight. Please do not schedule any of your test sessions the day after a party or late night social event as this can affect your test results.

### CONTACT INFORMATION

If you would like further information or need to change a test session, please contact Kirstine Bell on: Ph: 9351 4672 (work hours) or 9351 6276 (test room) or 0400 167 043, email: [kbel8134@uni.sydney.edu.au](mailto:kbel8134@uni.sydney.edu.au).

**ANY PERSON WITH CONCERNS OR COMPLAINTS ABOUT THE CONDUCT OF A RESEARCH STUDY CAN CONTACT THE DEPUTY MANAGER, HUMAN ETHICS ADMINISTRATION, UNIVERSITY OF SYDNEY ON +61 2 8627 8176 (TELEPHONE); +61 2 8627 8177 (FACSIMILE) OR RO.HUMANETHICS@SYDNEY.EDU.AU (EMAIL).**

# **Appendix 5**

FII Testing  
Consent Form



ABN 15 211 513 464

**The University of Sydney  
NSW 2006 AUSTRALIA**

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**Prof. Jennie C Brand-Miller**  
BSc, PhD, FAIFST, FNSA

Room 472, Building G08  
Telephone: +61 2 9351 3759  
Email: jennie.brandmiller@sydney.edu.au

## **TESTING OF FOODS FOR THEIR GLYCEMIC INDEX AND OTHER METABOLIC VARIABLES**

*Student Research*

### **PARTICIPANT CONSENT FORM**

I \_\_\_\_\_, voluntarily consent to take part in this study to determine the glycemic (blood glucose) and insulin responses to six foods.

I confirm that the investigator has explained to me the nature, purpose, procedures and possible risks of the study referenced above. I confirm that I have read and understood the participant information sheet and have freely agreed to follow all of the study's requirements. I realise that this study will involve me physically and mentally in the manner described in the information sheet. I recognise that this research intends to develop a better understanding of the biochemical effects of certain foods, and that I may not personally benefit from the results.

I confirm that the personal details I have given the investigators are true and that I do not suffer from any food allergies or food intolerances and that I find the test foods suitable for consumption. I understand that the foods will be prepared and served in a hygienic manner. I am personally responsible for consuming all foods and drinks in a safe manner and agree to consume all of the test foods at my own risk.

Occasionally, filming may take place at the testing centre but you may choose not to participate at those times if you wish. I am willing to participate in testing on days when filming is occurring: YES  NO

I understand that my personal details and study results will be used for research purposes only and will only be seen by the study investigators. Any publications or presentations associated with this research will not identify me personally. I understand that my participation is entirely voluntary and that I am free to withdraw from the study at any time without repercussions. I understand that I will be paid \$30 per test session, and that I will only receive this payment after completing the study. If I decide to withdraw from the study, I will be paid for the sessions I have already completed.

**Signature of Subject :**

**Date:**

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# **Appendix 6**

## FII Testing Screening Questionnaire



**The University of Sydney**

NSW 2006 Australia

HUMAN NUTRITION UNIT

**THE HUMAN NUTRITION UNIT**

School of Molecular & Microbial Biosciences G08

University of Sydney NSW 2006 Australia

Phone: (61-2) 9351 3759

Fax: (61-2) 9351 6022

j.brandmiller@mmb.usyd.edu.au

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**Prof. Janette C Brand-Miller** *BSc, PhD, FAIFST, FNSA*

**TESTING OF FOODS FOR THEIR GLYCEMIC INDEX AND OTHER METABOLIC VARIABLES**

**SCREENING QUESTIONNAIRE**

**NAME:** \_\_\_\_\_

**ADDRESS:** \_\_\_\_\_

**SUBURB:** \_\_\_\_\_

**POST CODE:**

\_\_\_\_\_

**PHONE NO. Home:** \_\_\_\_\_

**Mob:**

\_\_\_\_\_

**EMAIL:** \_\_\_\_\_ **Student ID No.** \_\_\_\_\_

**GENDER (CIRCLE ONE)**

**MALE**

**FEMALE**

**DATE OF BIRTH:** \_\_\_\_\_ **AGE:** \_\_\_\_\_ years

**PLACE OF BIRTH (town and country)**

\_\_\_\_\_

**Which ethnic group do you belong to?**

\_\_\_\_\_

(eg. Caucasian, Chinese, Indonesian)

**Height and weight measured by the investigators:**

**WEIGHT without shoes** \_\_\_\_\_ kg

**HEIGHT without shoes** \_\_\_\_\_ m

**PLEASE ANSWER ALL OF THE FOLLOWING QUESTIONS:**

**1. Do you smoke?**

**YES / NO**

If NO, have you ever smoked and if so, when did you stop?

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**2. Do you follow any type of special diet ?**

**YES / NO**

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**3. Do you suffer from any food allergies or intolerances ?**

**YES / NO**

If YES, please describe the allergy/intolerance and when it started

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---

**4. Do you have regular physical activity habits?**

**YES / NO**

If YES, please describe your average weekly physical activity routine (list the type and duration of each activity, including extended periods of walking)

---

---

**5. Do you have a family history of diabetes?**

**YES / NO**

If YES, please state which relatives and which type of diabetes:

---

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**6. Have you ever had a major illness?**

**YES / NO**

If YES, please describe the illness, and when it started and ended

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---

**7. Are you currently suffering from any health problems**

**YES / NO**

If YES, please describe each problem and when it started

---

---

**8. Do you take any prescription medication?**

**YES / NO**

If YES, please list the name of each medicine (tablet dose + number of tablets per day)

---

---

**9. Do you take any over-the-counter medications on a regular basis?**

**YES / NO**

If YES, please list the name and dose of each medication:

---

---

**10. On average how many hours of sleep do you get per night? \_\_\_\_\_**

# **Appendix 7**

FII Testing

Session Questionnaire



**Prof. Jennie C Brand-Miller**  
BSc, PhD, FAIFST, FNSA

Room 472  
Building G08  
Telephone: +61 2 9351 3759  
Facsimile: +61 2 9351 6022  
Email: jennie.brandmiller@sydney.edu.au

### Test Session Questionnaire

Participant Number \_\_\_\_\_

Day & Date \_\_\_\_\_

Food \_\_\_\_\_

Test No. \_\_\_\_\_

BEFORE you start to consume your test food, please answer the following questions:

1. Please list the time you arrived here this morning: \_\_\_\_\_ AM

2. Have you been well since your last test session? Circle one: YES / NO

If NO, please state why.

\_\_\_\_\_

3. Have you taken any medications since your last test session? YES / NO

If YES, please state why and give specific details about the type of medication you took (name of medication, dose, and amount).

\_\_\_\_\_

4. What time was your last meal? \_\_\_\_\_

5. What did you eat at your last meal? Please describe.

\_\_\_\_\_

\_\_\_\_\_

6. Did you consume any alcohol or legumes yesterday? YES / NO

If YES, please state how much and what time.

\_\_\_\_\_

7. Did you do any physical activity yesterday? YES / NO

If YES, please describe the type and duration.

\_\_\_\_\_

\_\_\_\_\_

8. What is your body weight this morning? \_\_\_\_\_ kg

Please ask the investigator to weigh you on the digital scales without your shoes

## **Before eating the test food (0 min)**

Mark a line through the scale below at the point that best indicates how you are feeling now. Please rate your actual physical sensation of hunger or fullness, rather than simply your desire to eat something.

How hungry or full do you feel now?

extremely hungry      hungry      slightly hungry      no particular feeling      slightly full      full      extremely full

---

## **EATING INSTRUCTIONS**

1. List the time that appears on your watch or the general clock before you begin eating
  - a. What time is it now? \_\_\_\_\_ AM
2. Start your stopwatch as soon as you start eating.
3. Eat and drink at a comfortable pace, but please finish everything within 12 minutes.
4. As soon as you finish eating, check the time on your stopwatch (but don't stop it).

Time you finished eating as recorded by your stopwatch: \_\_\_\_\_

Did you completely consume all the food/drink served to you?                      YES / NO

Describe the food you consumed today:

---

5. Keep your stopwatch running and answer the following 3 questions.

How much did you like this food?

dislike very much      dislike moderately      dislike slightly      neither like nor dislike      like slightly      like moderately      like very much

---

How difficult was this food to eat?

Not at all difficult \_\_\_\_\_ Extremely difficult

How much more of this food would you need to eat in order to feel completely satisfied?

Nothing at all \_\_\_\_\_ A very large amount

### **15 minutes**

How hungry or full do you feel now?

extremely hungry	hungry	slightly hungry	no particular feeling	slightly full	full	extremely full
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### **30 minutes**

How hungry or full do you feel now?

extremely hungry	hungry	slightly hungry	no particular feeling	slightly full	full	extremely full
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### **45 minutes**

How hungry or full do you feel now?

extremely hungry	hungry	slightly hungry	no particular feeling	slightly full	full	extremely full
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---

### **60 minutes**

How hungry or full do you feel now?

extremely hungry	hungry	slightly hungry	no particular feeling	slightly full	full	extremely full
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### **90 minutes**

How hungry or full do you feel now?

extremely hungry	hungry	slightly hungry	no particular feeling	slightly full	full	extremely full
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### **120 minutes**

How hungry or full do you feel now?

extremely hungry	hungry	slightly hungry	no particular feeling	slightly full	full	extremely full
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How much food would you need to eat NOW in order to completely satisfy your hunger?

Nothing at all \_\_\_\_\_ A very large amount

# **Appendix 8**

FII for Protein Foods Study (NIDDA 2)

Participant Information Sheet



ABN 15 211 513 464

**Jennie Brand-Miller** BSc. PhD(NSW) FAIFST, AM  
Professor of Human Nutrition  
Boden Institute of Obesity, Nutrition & Exercise

Telephone: +61 2 9351 3759  
Facsimile: +61 2 9351 6022  
Email: [jennie.brandmiller@sydney.edu.au](mailto:jennie.brandmiller@sydney.edu.au)

## **RESEARCH STUDY INTO NORMAL INSULIN DEMAND FOR DOSE ADJUSTMENT 2: THE NIDDA 2 STUDY**

### **PARTICIPANT INFORMATION STATEMENT**

You are invited to take part in a research study called “Normal Insulin Demand for Dose Adjustment 2 (NIDDA 2) The aim is to compare the Food Insulin Index (FII) formula with carbohydrate counting to estimate mealtime insulin dose on your blood sugar levels after consuming six different foods. All participants are adults with type 1 diabetes using insulin pump therapy. The study is being conducted by *Kirstine Bell (PhD student)* and will form the basis for the degree of Doctor of Philosophy at the University of Sydney under the supervision of Professor Jennie Brand-Miller and Dr. Gabrielle Howard.

If you agree to participate in this study, you will be required to visit Dr. Gabrielle Howard’s room (Level 2, 27 Belgrave Street, Manly NSW 2095) on twelve separate evenings (between 5-6pm). The visits will take a little more than 3 hours of your time.

In the 2 weeks prior to the study, you will be asked to attend a group workshop to review your insulin delivery settings and carbohydrate counting skills. The workshop will take about one hour and it will be facilitated by Robyn Gray (a credentialed diabetes educator) and Diane Munns (an accredited practising dietitian). This group workshop is a normal part of attending the Insulin Pump Clinic.

**On the day before the test commencement:**

- You must avoid alcohol, over or under-eating and avoid over-exercising

**On the day of the test:**

- If you are unwell, please call to reschedule your test session.
- You must eat the same breakfast and lunch meals each testing day. These are of your choosing but must be a consistent type and amount of food. You need to forego any other food and drinks for the day, however you may drink water as desired.
- If hypoglycaemia occurs, you should take glucose tablets instantly and report this event when you come for the testing.
- If hyperglycaemia occurs, you may use your insulin pump to apply a correction dose at 3pm, running for no longer than 2 hours (i.e correction dose has finished by 5pm).
- You will need to arrive at Sydney Insulin Pump Clinic (Level 2, 27 Belgrave Street, Manly NSW 2095) between 5-6pm.
- Your blood glucose level will be checked on arrival with a blood glucose monitor.
- You will be asked to consume one of the six different foods comprising of steak OR battered fish OR baked beans OR yoghurt OR peanuts OR eggs.
- Mrs Robyn Gray (Credentialled Diabetes Educator, CDE) will advise the bolus insulin dose to be given to you.
- You will be required to remain sedentary in the test room for 3 hours after eating the meal and to refrain from any further eating.
- We will take a finger-prick blood sample (one drop) every 30 minutes for 3 hours after starting eating the meal to check the blood glucose readings with a blood glucose monitor.
- You will be in a group and you can watch TV, read, use your computer (wireless internet will be available) or chat with other participants during the 3-hour test session.
- We will provide foods to consume at the end of the test if you are hungry.

Although it is not expected, you may experience mild hyperglycaemia hypoglycaemia during the 3-hour session. This risk will be no greater than during your routine day-to-day management of diabetes. You will be monitored by Robyn Gray (CDE), however you will not be aware of your blood glucose results, unless hypoglycaemia occurs. In

this instance you will be informed, your testing session terminated and your hypoglycaemia treated appropriately.

All aspects of the study, including results, will be strictly confidential and only the investigators involved in this project will have access to information on participants, except as required by law. A report of the study may be submitted for publication, but individual participants will not be identifiable. The data will be kept in the password-protected computer files. The hard copies will also be stored in a separate location under lock and key for 15 years after which the data will be disposed of.

While we intend that this research study furthers medical knowledge and may improve treatment of type 1 diabetes in the future, the result may not be of direct benefit to you. However in return for your time, effort and travel expenses, you will be paid \$600 (\$50 X 12 test sessions) for taking part in this study. The payment will be made in full at the completion of the study. If you decide to withdraw, you will be paid for the sessions you have already completed.

**PLEASE NOTE: Participation in this study is entirely voluntary. You are not obliged to participate and - if you do participate - you can withdraw at any time. Any information you may have given to the researchers up to that point will be destroyed upon your request. Whatever your decision, it will not affect your medical treatment or your relationship with medical staff.**

When you have read this information, Mrs Robyn Gray or Ms Kirstine Bell will discuss it with you further and answer any questions you may have. If you would like more information at any stage, please feel free to contact Kirstine Bell by email: [kbel8134@uni.sydney.edu.au](mailto:kbel8134@uni.sydney.edu.au), Dr. Gabrielle Howard, Endocrinologist, on 02 9976 6010 or email: [drhoward@ozemail.com.au](mailto:drhoward@ozemail.com.au) or Mrs Robyn Gray, Credentialed Diabetes Educator, on 02 9976 6010.

**Any person with concerns or complaints about the conduct of a research study can contact the Manager, Ethics Administration, University of Sydney on (02) 8627 8176; (02) or [ro.humanthics@sydney.edu.au](mailto:ro.humanthics@sydney.edu.au) (Email).**

*This information sheet is for you to keep.*

# **Appendix 9**

FII for Protein Foods Study (NIDDA 2)

Consent Form



ABN 15 211 513 464

Jennie Brand-Miller BSc. PhD(NSW) FAIFST, AM
Professor of Human Nutrition
Boden Institute of Obesity, Nutrition & Exercise

Telephone: +61 2 9351 3759
Facsimile: +61 2 9351 6022
Email:
jennie.brandmiller@sydney.edu.au

PARTICIPANT CONSENT FORM

I, .....[PRINT NAME], give consent to my participation in the research project

TITLE: NORMAL INSULIN DEMAND FOR DOSE-ADJUSTMENT 2 (THE NIDDA 2 STUDY)

In giving my consent I acknowledge that:

- 1. The procedures required for the project and the time involved (including any inconvenience, risk, discomfort or side effect, and of their implications) have been explained to me, and any questions I have about the project have been answered to my satisfaction.
2. I have read the "Participant Information Statement" and have been given the opportunity to discuss the information and my involvement in the project with the researchers.
3. I understand that I can withdraw from the study at any time, without affecting my relationship with the researcher(s) or the University of Sydney and my routine clinical care as a patient in Sydney Insulin Pump Clinic now or in the future.
4. I understand that my involvement is strictly confidential and no information about me will be used in any way that reveals my identity.
5. I understand that being in this study is completely voluntary - I am not under any obligation to consent.

Participant:

Signed :.....

Name (print) : ..... Date: .....

Witness: (If the interpreter or the relative speaking English involved)

Signed: .....

Name (print) :..... Date: .....

# **Appendix 10**

FII for Protein Foods Study (NIDDA 2)

Study Advertisement

# INTERESTED IN A NEW WAY TO MATCH YOUR INSULIN TO WHAT YOU EAT?

You could be part of our next study...



 If you are aged between 18-85 years old with well-controlled type 1 diabetes (HbA1c 6-8.5%), you could be eligible to participate in our new study.

We are looking to see if a new food insulin index can better predict your mealtime insulin bolus, helping you keep your diabetes under control.

If you would like more information please call Gabrielle Howard or Robyn Gray at Sydney Insulin Pump Clinic on Ph. 9976 6010

# **Appendix 11**

FII for Protein Foods Study (NIDDA 2)

Screening Questionnaire



ABN 15 211 513 464

**Jennie Brand-Miller** BSc. PhD(NSW) FAIFST, AM  
Professor of Human Nutrition  
Boden Institute of Obesity, Nutrition & Exercise

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Facsimile: +61 2 9351 6022  
Email:  
[jennie.brandmiller@sydney.edu.au](mailto:jennie.brandmiller@sydney.edu.au)

## **NORMAL INSULIN DEMAND FOR DOSE-ADJUSTMENT 2: NIDDA 2**

### **PARTICIPANT DETAILS**

**NAME:** \_\_\_\_\_

**ADDRESS:** \_\_\_\_\_

**SUBURB:** \_\_\_\_\_ **POST CODE:** \_\_\_\_\_

**PHONE NO: HOME:** \_\_\_\_\_

**MOBILE:** \_\_\_\_\_

**WORK:** \_\_\_\_\_

**EMAIL:** \_\_\_\_\_

**PREFERRED CONTACT (Please Circle):** HOME / MOBILE / WORK / EMAIL

**GENDER (Please Circle):**            **MALE**                    **FEMALE**

**DATE OF BIRTH:** \_\_\_\_\_ **AGE:** \_\_\_\_\_ years

**PLACE OF BIRTH (Town & Country):** \_\_\_\_\_

**ETHNIC GROUP (eg. caucasian, chinese, indian etc):** \_\_\_\_\_

**HEIGHT (without shoes):** \_\_\_\_\_ m      **WEIGHT (without shoes):** \_\_\_\_\_ kg

**PLEASE ANSWER ALL OF THE FOLLOWING QUESTIONS**

**1. Do you smoke?**

**YES / NO**

If NO, have you ever smoked and if so when did you stop?

---

---

**2. Do you follow any special diet?**

**YES / NO**

---

---

**3. Do you have any food allergies or intolerances?**

**YES / NO**

If YES, please describe the allergy/intolerance (food and symptoms) and when it started.

---

---

**4. Do you have regular physical activity habits**

**YES / NO**

If YES, please describe your weekly physical activity routine (type and duration of each activity including extended periods of walking).

---

---

**5. Do you have type 1 diabetes?**

**YES / NO**

If YES, please state when you were diagnosed.

---

**6. Do you currently take any medications on a regular basis?**

**YES / NO**

This includes prescription and over-the-counter medications. Please specify the name, dose and how often you take each medication.

---

---

**7. Do you have a family history of diabetes?**

**YES / NO**

If YES, please state which relatives and which type of diabetes they have.

---

---

**8. Do you currently have any other health issues?**

**YES / NO**

If YES, please describe each issue and when it started

---

---

**9. On average, how many hours of sleep do you get per night? \_\_\_\_\_**

# **Appendix 12**

FII for Protein Foods Study (NIDDA 2)

Test Session Questionnaire



**RESEARCH STUDY INTO NORMAL INSULIN DEMAND FOR  
DOSE-ADJUSTMENT 2 (NIDDA 2)**

**SESSION QUESTIONNAIRE**

**Name:** \_\_\_\_\_

**Date:** \_\_\_\_\_

1. What did you have for breakfast this morning?
  
2. What did you have for lunch today? What time?
  
3. Have you had anything else to eat or drink today? If yes, what did you have and what time?
  
4. Have you had any alcohol to drink in the past 24 hours? If yes, how much?
  
6. What physical activity/exercise have you done today? (Activity, duration, intensity)
  
7. How would you rate your stress levels today?

1  
Not stressed  
at all

2

3  
Somewhat  
Stressed

4

5  
Very  
Stressed

8. Have you experience any hypoglycemia (BGL < 3.9mmol/L) today?

If yes, what time?

# **Appendix 13**

FOODII Study

Participant Information Sheet

**Human Nutrition Unit**  
**School of Molecular Bioscience**  
**Faculty of Science**  
Room 472  
Biochemistry building, G08  
University of Sydney NSW 2006  
AUSTRALIA

ABN 15 211 513 464

**Jennie Brand-Miller** BSc. PhD(NSW) FAIFST, AM  
Professor of Human Nutrition  
Boden Institute of Obesity, Nutrition & Exercise

Telephone: +61 2 9351 3759  
Facsimile: +61 2 9351 6022  
Email: [jennie.brandmiller@sydney.edu.au](mailto:jennie.brandmiller@sydney.edu.au)

## **FOOD INSULIN INDEX (FII) VERSUS TRADITIONAL CARBOHYDRATE COUNTING FOR GLYCEMIC CONTROL IN ADULTS WITH TYPE 1 DIABETES: THE FOODII STUDY**

### **PARTICIPANT INFORMATION STATEMENT**

You are invited to participate in a study called 'The Food Insulin Index (FII) versus traditional carbohydrate counting for glycemic control in adults with type 1 diabetes: The FOODII Study. The aim is to compare a novel Food Insulin Index (FII) formula with carbohydrate counting to estimate mealtime insulin dose on your glycated hemoglobin level (also called HbA1c level) after 3 months use. All participants are adults with type 1 diabetes using insulin pump therapy.

#### **Who is carrying out the study?**

The study is being conducted by *Kirstine Bell (PhD student)* and will form the basis for the degree of Doctor of Philosophy at the University of Sydney under the supervision of Professor Jennie Brand-Miller and Dr. Gabrielle Howard. A diabetes educator (Robyn Gray) and dietitian (Diane Munns) are also involved.

#### **What does the study involve?**

If you agree to participate in this study, you will be randomly allocated to either the Food Insulin Index or carbohydrate counting group. In the two weeks prior to the study, your blood glucose levels will be recorded by a continuous glucose monitoring system (CGMS) for 6 days and your glycated haemoglobin level (HbA1c, a measure of long term glycaemic control) measured through a blood test. You will be required to attend two appointments with the dietitian: one group education session (3 hours) and one individual appointment (60 mins), to receive information and advice based on your allocated study group. You will receive written information and resources, and if you own an iPhone, you can opt to have an iPhone application uploaded onto your device, to assist you. Over the following ~120 days (3 months), you will need to

estimate your mealtime insulin dose using either the Food Insulin Index or carbohydrate counting depending on the education provided to you. At the end of the 3 months, your blood glucose levels will be recorded by CGMS over 6 days and your glycated haemoglobin level re-measured through a second blood test.

Although it is not expected, you may experience episodes of hyperglycaemia or hypoglycaemia during the study. This risk will be no greater than during your routine day-to-day management of diabetes. You may also experience mild discomfort during the blood test to measure your HbA1c and during the insertion of the sensor for the continuous glucose monitoring. Care will be taken to minimise any potential discomfort. The discomfort will be no greater than the discomfort experienced during your routine HbA1c blood tests and, if you use continuous glucose monitoring, the insertion of your sensors.

### **How much time will the study take?**

At the beginning of the study, you will need to attend a 3 hour group education workshop and a 1 hour individual appointment with the dietitian. Additionally at both the beginning and end of the study, you will need to visit your local pathology laboratory to have a blood test and have a CGMS sensor inserted that you will wear for 6 consecutive days while undergoing your usual daily activities. During your 3 month involvement in the study, you need to estimate your mealtime insulin dose using either the Food Insulin Index or carbohydrate counting depending your allocated study group but are otherwise free to undergo your usual daily activities.

### **Can I withdraw from the study?**

Being in this study is completely voluntary - you are not under any obligation to consent and - if you do consent - you can withdraw at any time without affecting your relationship with The University of Sydney, Dr Gabrielle Howard or Dr Stephen Thornley.

### **Will anyone else know the results?**

All aspects of the study, including results, will be strictly confidential and only the investigators involved in this project will have access to information on participants. A report of the study may be submitted for publication, but individual participants will not be identifiable. The data will be kept in the password-protected computer files. The hard copies will also be stored in a separate location under lock and key for 15 years after which the data will be disposed of.

**Will the study benefit me?**

While we intend that this research study furthers medical knowledge and may improve treatment of type 1 diabetes in the future, the result may not be of direct benefit to you. However in return for your time, effort and travel expenses, you will receive \$200 for taking part in this study. The payment will be made in full at the completion of the study. If you decide to withdraw, you will be paid pro-rata for the duration of your involvement.

**What if I require further information about the study or my involvement in it?**

When you have read this information, Mrs Robyn Gray or Ms Kirstine Bell will discuss it with you further and answer any questions you may have. If you would like more information at any stage, please feel free to contact Kirstine Bell by email:

[kbel8134@uni.sydney.edu.au](mailto:kbel8134@uni.sydney.edu.au), Dr. Gabrielle Howard, Endocrinologist, on 02 9976 6010 or email: [drhoward@ozemail.com.au](mailto:drhoward@ozemail.com.au) or Mrs Robyn Gray, Credentialed Diabetes Educator, on 02 9976 6010.

**What if I have a complaint or any concerns?**

Any person with concerns or complaints about the conduct of a research study can contact The Manager, Human Ethics Administration, University of Sydney on +61 2 8627 8176 (Telephone); +61 2 8627 8177 (Facsimile) or [ro.humanethics@sydney.edu.au](mailto:ro.humanethics@sydney.edu.au) (Email).

*This information sheet is for you to keep*

# **Appendix 14**

FOODII Study

Consent Form



Jennie Brand-Miller BSc. PhD(NSW) FAIFST, AM  
Professor of Human Nutrition  
Boden Institute of Obesity, Nutrition & Exercise

Room 472  
Biochemistry building, G08  
University of Sydney NSW 2006  
AUSTRALIA  
Telephone: +61 2 9351 3759  
Facsimile: +61 2 9351 6022  
Email: jennie.brandmiller@sydney.edu.au  
Web: www.usyd.edu.au/

**PARTICIPANT CONSENT FORM**

I, .....[PRINT NAME], give consent to my participation in the research project

**TITLE: FOOD INSULIN INDEX (FII) VERSUS TRADITIONAL CARBOHYDRATE COUNTING FOR GLYCEMIC CONTROL IN ADULTS WITH TYPE 1 DIABETES: THE FOODII STUDY**

In giving my consent I acknowledge that:

1. The procedures required for the project and the time involved (including any inconvenience, risk, discomfort or side effect, and of their implications) have been explained to me, and any questions I have about the project have been answered to my satisfaction.
2. I have read the Participant Information Statement and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s.
3. I understand that being in this study is completely voluntary – I am not under any obligation to consent.
4. I understand that my involvement is strictly confidential and no information about me will be used in any way that reveals my identity.
5. I understand that I can withdraw from the study at any time, without affecting my relationship with the researcher(s) or the University of Sydney, Sydney Insulin Pump and Endocrine Clinic or Dr Stephen Thornley at Southern Endocrine now or in the future.

**Signed:** .....

**Name:** .....

**Date:** .....

# **Appendix 15**

FOODII Study

Study Advertisement



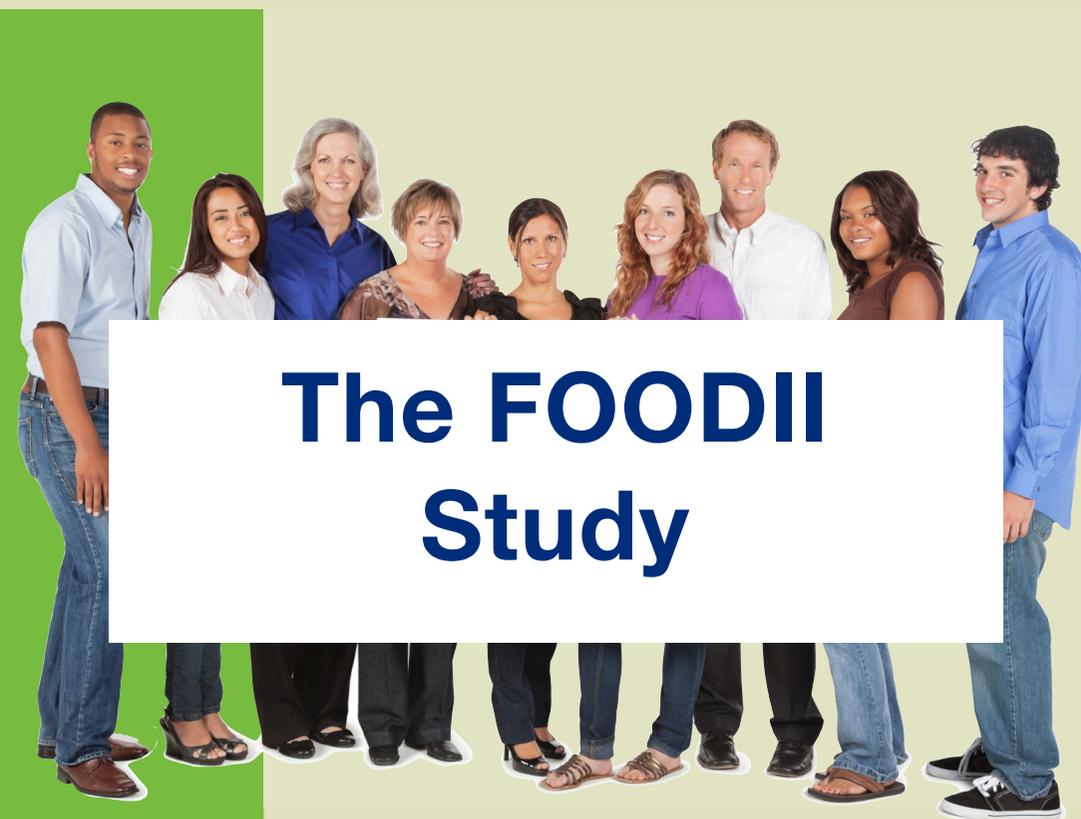
Do you have Type 1  
Diabetes and use  
an Insulin Pump?

**For More Information and to Register  
Your Interest, Please Contact:**

Kirstie Bell, Dietitian, Diabetes Educator and PhD  
Candidate, on 0400 167 043 or email:  
[kbel8134@uni.sydney.edu.au](mailto:kbel8134@uni.sydney.edu.au)

Mrs Robyn Gray, Credentialed Diabetes Educator, on 02  
9976 6010.

YOU'RE INVITED TO JOIN THE....



**The FOODII  
Study**

The Food Insulin Index (FI) is a new way of ranking foods based on the body's natural insulin response to any given food

### **What's the Food Insulin Index Study?**

The Food Insulin Index Study is a new research study looking to see if the new Food Insulin Index (FI) can better help you predict how much insulin you need at mealtimes, helping you better manage your diabetes.

### **Who can be involved?**

Anyone aged 18 years or over, who has type 1 diabetes and is using insulin pump therapy with a HbA1c between 7-9.5%. You need to be regularly testing your blood glucose levels and able to speak and understand English fluently.

### **What does the study involve?**

You will be randomly allocated to either the Food Insulin Index or Carbohydrate Counting group. You will need to attend a 3 hr group education workshop and a 1 hr individual appointment. You will then use your allocated method to estimate your mealtime insulin dose over the next 12 weeks. We will measure your blood glucose levels using a CGMS (Continuous Glucose Monitoring System) and your HbA1c (a measure of long term glycaemic control) through a blood test at the beginning and end of the study.

**You will be reimbursed for your time, travel and effort during the 3 month study**



# **Appendix 16**

FOODII Study

Screening Questionnaire



ABN 15 211 513 464

Jennie Brand-Miller BSc. PhD(NSW) FAIFST, AM  
Professor of Human Nutrition  
Boden Institute of Obesity, Nutrition & Exercise

Telephone: +61 2 9351 3759  
Facsimile: +61 2 9351 6022  
Email:  
[jennie.brandmiller@sydney.edu.au](mailto:jennie.brandmiller@sydney.edu.au)

FOOD INSULIN INDEX (FII) VERSUS TRADITIONAL CARBOHYDRATE COUNTING FOR  
GLYCEMIC CONTROL IN ADULTS WITH TYPE 1 DIABETES: THE FOODII STUDY

SCREENING QUESTIONNAIRE

NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

SUBURB: \_\_\_\_\_ POST CODE: \_\_\_\_\_

PHONE NO. Home: \_\_\_\_\_ Mob: \_\_\_\_\_

EMAIL: \_\_\_\_\_

GENDER (CIRCLE ONE)                      MALE                      FEMALE

DATE OF BIRTH: \_\_\_\_\_ AGE: \_\_\_\_\_ years

PLACE OF BIRTH (town and country) \_\_\_\_\_

Which ethnic group do you belong to? (eg. Caucasian, Chinese, Indonesian)

\_\_\_\_\_

Height and weight:

WEIGHT without shoes \_\_\_\_\_ kg

HEIGHT without shoes \_\_\_\_\_ m

PLEASE ANSWER ALL OF THE FOLLOWING QUESTIONS:

1. Do you have type 1 diabetes? YES / NO

2. What is your current insulin: carbohydrate ratio: \_\_\_\_\_

3. Do you have a family history of diabetes? YES / NO

If YES, please state which relatives and which type of diabetes: \_\_\_\_\_

4. Do you follow any type of special diet ? YES / NO

If YES, please describe: \_\_\_\_\_

5. Do you smoke? YES / NO

If NO, have you ever smoked and if so, when did you stop? \_\_\_\_\_

6. Do you have regular physical activity habits? YES / NO

If YES, please describe your average weekly physical activity routine (list the type and duration of each activity, including extended periods of walking)

\_\_\_\_\_

7. Have you ever had a major illness? YES / NO

If YES, please describe the illness, and when it started and ended

\_\_\_\_\_

8. Are you currently suffering from any other health problems? YES / NO

If YES, please describe each problem and when it started

\_\_\_\_\_

9. Do you take any prescription medication? YES / NO

If YES, please list the name of each medicine (tablet dose + number of tablets per day)

\_\_\_\_\_

10. Do you take any over-the-counter medications on a regular basis? YES / NO

If YES, please list the name and dose of each medication: \_\_\_\_\_

11. On average, how many hours of sleep do you get per night? \_\_\_\_\_

# **Appendix 17**

FOODII Study

Study Completion Questionnaire



THE UNIVERSITY OF  
**SYDNEY**

Human Nutrition Unit  
School of Molecular Bioscience  
Faculty of Science  
Room 472  
Biochemistry building, G08  
University of Sydney NSW 2006  
AUSTRALIA

ABN 15 211 513 464  
Jennie Brand-Miller BSc. PhD(NSW) FAIFST, AM  
Professor of Human Nutrition  
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**FOOD INSULIN INDEX (FII) VERSUS TRADITIONAL  
CARBOHYDRATE COUNTING FOR GLYCEMIC CONTROL IN  
ADULTS WITH TYPE 1 DIABETES: THE FOODII STUDY**

**SATISFACTION SURVEY**

**Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Algorithm:** \_\_\_\_\_

Please place a tick (☐) in the box that best corresponds to your response to the questions about your experiences during this study.

	<b>Strongly Agree</b>	<b>Agree</b>	<b>Neither Agree nor Disagree</b>	<b>Disagree</b>	<b>Strongly Disagree</b>
<b>It was easy to do</b>					
<b>I enjoyed using this system</b>					
<b>I would continue using this system in the future</b>					
<b>I was able to enjoy a variety of foods</b>					
<b>My blood glucose levels were better managed</b>					



ABN 15 211 513 464

Jennie Brand-Miller BSc. PhD(NSW) FAIFST, AM  
Professor of Human Nutrition  
Boden Institute of Obesity, Nutrition & Exercise

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Facsimile: +61 2 9351 6022

Email: [jennie.brandmiller@sydney.edu.au](mailto:jennie.brandmiller@sydney.edu.au)

Please place a tick (☐) in the box that best corresponds to your response to the question.

	All the Time	Most of the Time	Sometimes/ Occasionally	Rarely	Never
How closely did you follow the system?					

**Best Aspects:**

---



---



---

**Any Suggestions for Improvement:**

---



---



---

# **Appendix 18**

FOODII Study

Group Education Session Teaching Plans

FOODII Study 2013  
**FID Counting Group Education Session Teaching Plan**

<b>Time</b>	<b>Content</b>	<b>Facilitator Activity</b>	<b>Participant Activity</b>	<b>Resource(s)</b>
10 mins	Introduction	<ul style="list-style-type: none"> <li>• Introduce self</li> <li>• Ask participants to introduce themselves</li> <li>• Introduce session topic and session overview</li> </ul>	<ul style="list-style-type: none"> <li>• Introduce self</li> </ul>	
15 mins	What is FID Counting	<ul style="list-style-type: none"> <li>• What is FID Counting</li> <li>• Why do we use FID Counting</li> <li>• Foods to count</li> <li>• Foods that aren't counted</li> </ul>	<ul style="list-style-type: none"> <li>• Listen</li> <li>• Participate in discussion</li> </ul>	<ul style="list-style-type: none"> <li>• Participant Manual</li> </ul>
20 mins	How to use FID Counting in Practice	<ul style="list-style-type: none"> <li>• How to use FID Counting in Practice</li> <li>• Introduce Apps &amp; Booklets</li> <li>• Demonstrate FID Counting</li> <li>• Lead food diary activity &amp; provide assistance</li> </ul>	<ul style="list-style-type: none"> <li>• Listen</li> <li>• Participate in discussions</li> <li>• Write 1 day food diary (usual food/ example meals)</li> <li>• Determine Meal FID for diary</li> </ul>	<ul style="list-style-type: none"> <li>• Participant Manual</li> <li>• Apps &amp; Booklets</li> <li>• Food Diary Template</li> </ul>
30 mins	Estimating Food Portion Size	<ul style="list-style-type: none"> <li>• Ways to estimate food portion sizes</li> <li>• Lead discussion</li> </ul>	<ul style="list-style-type: none"> <li>• Estimate and then weigh/measure foods</li> <li>• Participate in discussions</li> </ul>	<ul style="list-style-type: none"> <li>• Participant Manual</li> <li>• Foods</li> <li>• Scales, cups and spoons</li> </ul>
15 mins	Summary	<ul style="list-style-type: none"> <li>• Summarise session information</li> <li>• Answer participant questions</li> <li>• Discuss next stage of the study</li> <li>• Schedule individual appointments</li> </ul>	<ul style="list-style-type: none"> <li>• Listen</li> <li>• Participate in discussions</li> <li>• Ask any unanswered questions</li> <li>• Schedule individual appointment</li> </ul>	<ul style="list-style-type: none"> <li>• Individual Appointment Booking Form</li> </ul>

FOODII Study 2013  
**Carb Counting Group Education Session Teaching Plan**

<b>Time</b>	<b>Content</b>	<b>Facilitator Activity</b>	<b>Participant Activity</b>	<b>Resource(s)</b>
10 mins	Introduction	<ul style="list-style-type: none"> <li>• Introduce self</li> <li>• Ask participants to introduce themselves</li> <li>• Introduce session topic and session overview</li> </ul>	<ul style="list-style-type: none"> <li>• Introduce self</li> </ul>	
15 mins	What is Carb Counting	<ul style="list-style-type: none"> <li>• What is Carb Counting</li> <li>• Why do we use Carb Counting</li> <li>• Foods to count</li> <li>• Foods that aren't counted</li> </ul>	<ul style="list-style-type: none"> <li>• Listen</li> <li>• Participate in discussion</li> </ul>	<ul style="list-style-type: none"> <li>• Participant Manual</li> </ul>
20 mins	How to use Carb Counting in Practice	<ul style="list-style-type: none"> <li>• How to use Carb Counting in Practice</li> <li>• Introduce Apps &amp; Booklets</li> <li>• Demonstrate Carb Counting</li> <li>• Lead food diary activity &amp; provide assistance</li> </ul>	<ul style="list-style-type: none"> <li>• Listen</li> <li>• Participate in discussions</li> <li>• Write 1 day food diary (usual food/ example meals)</li> <li>• Determine meal carb content</li> </ul>	<ul style="list-style-type: none"> <li>• Participant Manual</li> <li>• Apps &amp; Booklets</li> <li>• Food Diary Template</li> </ul>
30 mins	Estimating Food Portion Size	<ul style="list-style-type: none"> <li>• Ways to estimate food portion sizes</li> <li>• Lead discussion</li> </ul>	<ul style="list-style-type: none"> <li>• Estimate and then weigh/measure foods</li> <li>• Participate in discussions</li> </ul>	<ul style="list-style-type: none"> <li>• Participant Manual</li> <li>• Foods</li> <li>• Scales, cups and spoons</li> </ul>
15 mins	Summary	<ul style="list-style-type: none"> <li>• Summarise session information</li> <li>• Answer participant questions</li> <li>• Discuss next stage of the study</li> <li>• Schedule individual appointments</li> </ul>	<ul style="list-style-type: none"> <li>• Listen</li> <li>• Participate in discussions</li> <li>• Ask any unanswered questions</li> <li>• Schedule individual appointment</li> </ul>	<ul style="list-style-type: none"> <li>• Individual Appointment Booking Form</li> </ul>

# **Appendix 19**

FII in Type 2 Diabetes Study  
Participant Information Sheet



ABN 15 211 513 464

**Jennie Brand-Miller** BSc. PhD(NSW) FAIFST,  
AM  
Professor of Human Nutrition  
Boden Institute of Obesity, Nutrition & Exercise

Telephone: +61 2 9351 3759  
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Email:  
[jennie.brandmiller@sydney.edu.au](mailto:jennie.brandmiller@sydney.edu.au)

## EFFECT OF DIETS OF VARYING FOOD INSULIN INDEX (FII) ON DAY-LONG GLUCOSE AND INSULIN PROFILES IN ADULTS WITH TYPE 2 DIABETES

### PARTICIPANT INFORMATION STATEMENT

You are invited to take part in a research study called “effect of varying food insulin index (FII) diets on day-long (8 hours) glucose and insulin profiles in adults with type 2 diabetes” The aim is to compare day-long blood glucose and insulin levels after consuming two different diets. Each diet comprises three common meals (breakfast, morning snack and lunch). The study is being conducted by *Kirstie Bell (PhD student)* and will form the basis for the degree of Doctor of Philosophy at the University of Sydney under the supervision of Professor Jennie Brand-Miller.

If you agree to participate in this study, you will be asked to visit the Metabolic Kitchen of the University of Sydney, (Room 406 (Level 4), Old Teachers College, cnr Western Ave and Manning Rd) on **2 separate mornings within 2 weeks** of starting the study. Each visit will take about 8 hours of your time from morning to late afternoon. For your own safety, it's important that you do not participate if you have any type of food allergy or intolerance (eg to wheat, cow's milk, lactose, eggs, peanuts).

#### ON THE DAY BEFORE EACH TEST SESSION:

- You must avoid alcohol, over or under-eating and avoid over-exercising (ie more physical activity than is usual)
- You must eat an evening meal. It should be a low-fat meal based on carbohydrate-rich foods, such as potatoes, rice, bread, pasta, noodles, couscous, or corn.
- You must avoid legumes (lentils, chickpeas, baked beans, etc) for the evening meal.
- You must abstain from food for at least 10 hours (overnight) before attending the test session (e.g. from 10 pm till 8 am). During this time you are permitted to drink only water.
- Reschedule your appointment if you don't feel well or need to take new medication.

#### On the morning of the test:

- You will need to arrive at the Metabolic Kitchen of Human Nutrition Unit in a fasting condition between 7:00 and 8:30 am.
- You will be required to consume three fixed portions of the mixed meals (breakfast, morning snack and lunch) during 8 hours of each test session.
- A fasting finger blood sample **about 20 drops (~0.7 mL)** will be taken 5 minutes before starting eating breakfast. Then blood samples will also be taken at 0, 30, 60, 120 minutes, 180 minutes after starting eating breakfast and lunch and at 0, 30, 60, 90, 120 minutes after morning tea. Totally 13 blood samples (~ 0.7 mL for each) will be taken over 8 hours.
- You are required to remain seated in the test room most of the time and to refrain from any further eating.
- You may study, read or chat with the other study participants.



ABN 15 211 513 464

**Jennie Brand-Miller** BSc. PhD(NSW) FAIFST,  
AM  
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- You will need to allow a little over 8 hours for each test session.

Although your fingers will be pricked with very small lancets, you may experience minor discomfort during blood taking procedures, particularly during your first test session, and your fingertips may feel slightly tender for the rest of the day. However, many people do not feel any discomfort at all, and the investigators try to make the procedures as quick and as painless as possible. Blood is a source of infectious disease and during any blood sampling procedure there is a risk of cross infection between study participants and investigators. However, in this study, the risk is minimal because the investigator taking the blood samples will wear clean disposable plastic gloves when taking blood samples and will maintain the blood sampling area in a hygienic condition. Blood samples will be taken from warmed hands (your hand will be soaked in your own bucket of hot water for 1-2 minutes before each blood collection) and fingertips will be sterilised before and after each blood sample is taken. A new sterile lancet will be used for each blood sample and the lancets cannot be re-used.

All aspects of the study, including results, will be strictly confidential and only the investigators involved in this project will have access to information on participants. A report of the study may be submitted for publication, but individual participants will not be identifiable. The data will be kept in password-protected computer files. The hard copies will also be stored in a separate location under lock and key for 15 years after which the data will be disposed of.

While we intend that this research study furthers medical knowledge and may improve treatment of type 2 diabetes in the future, the result may not be of direct benefit to you. However in return for your time, effort and travel expenses, you will be paid \$100 for each test session (total \$200) for taking part in this study. The payment will be made in full at the completion of the study. If you decide to withdraw, you will be paid for the sessions you have already completed.

**PLEASE NOTE: Participation in this study is entirely voluntary. You are not obliged to participate and - if you do participate - you can withdraw at any time. Any information you may have given to the researchers up to that point will be destroyed upon your request. Whatever your decision, it will not affect your medical treatment or your relationship with medical staff.**

When you have read this information, Ms Kirstie Bell will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Kirstie Bell by email: [kbel8134@uni.sydney.edu.au](mailto:kbel8134@uni.sydney.edu.au) or by telephone on 0400 167 043.

**Any person with concerns or complaints about the conduct of a research study can contact The Manager, Human Ethics Administration, University of Sydney on +61 2 8627 8176 (Telephone); +61 2 8627 8177 (Facsimile) or [ro.humanethics@sydney.edu.au](mailto:ro.humanethics@sydney.edu.au) (Email).**

*This information sheet is for you to keep.*

# **Appendix 20**

FII in Type 2 Diabetes Study

Consent Form



Jennie Brand-Miller BSc. PhD(NSW) FAIFST, AM  
Professor of Human Nutrition  
Boden Institute of Obesity, Nutrition & Exercise

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**PARTICIPANT CONSENT FORM**

I, .....[PRINT NAME], give consent to my participation in the research project

**TITLE: EFFECT OF DIETS OF VARYING FOOD INSULIN INDEX (FII) ON DAY-LONG GLUCOSE AND INSULIN PROFILES IN ADULTS WITH TYPE 2 DIABETES**

In giving my consent I acknowledge that:

1. The procedures required for the project and the time involved (including any inconvenience, risk, discomfort or side effect, and of their implications) have been explained to me, and any questions I have about the project have been answered to my satisfaction.
2. I have read the Participant Information Statement and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s.
3. I understand that I can withdraw from the study at any time, without affecting my relationship with the researcher(s) or the University of Sydney and Australia Diabetes Council now or in the future.
4. I understand that my involvement is strictly confidential and no information about me will be used in any way that reveals my identity.
5. I understand that being in this study is completely voluntary – I am not under any obligation to consent.

**Signed:** .....  
**Name:** .....  
**Date:** .....

# **Appendix 21**

FII in Type 2 Diabetes Study  
Screening Questionnaire



ABN 15 211 513 464

**Jennie Brand-Miller** BSc. PhD(NSW) FAIFST, AM  
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### **NORMAL INSULIN DEMAND FOR DOSE-ADJUSTMENT 3: NIDDA 3**

#### **PARTICIPANT DETAILS**

**NAME:** \_\_\_\_\_

**ADDRESS:** \_\_\_\_\_

**SUBURB:** \_\_\_\_\_ **POST CODE:** \_\_\_\_\_

**PHONE NO: HOME:** \_\_\_\_\_

**MOBILE:** \_\_\_\_\_

**WORK:** \_\_\_\_\_

**EMAIL:** \_\_\_\_\_

**PREFERRED CONTACT (Please Circle):** HOME / MOBILE / WORK / EMAIL

**GENDER (Please Circle):**            **MALE**                    **FEMALE**

**DATE OF BIRTH:** \_\_\_\_\_ **AGE:** \_\_\_\_\_ years

**PLACE OF BIRTH (Town & Country):** \_\_\_\_\_

**ETHNIC GROUP (eg. caucasian, chinese, indian etc):** \_\_\_\_\_

**HEIGHT (without shoes):** \_\_\_\_\_ m      **WEIGHT (without shoes):** \_\_\_\_\_ kg

**PLEASE ANSWER ALL OF THE FOLLOWING QUESTIONS**

**1. Do you smoke?**

**YES / NO**

If NO, have you ever smoked and if so when did you stop?

---

---

**2. Do you follow any special diet?**

**YES / NO**

---

---

**3. Do you have any food allergies or intolerances?**

**YES / NO**

If YES, please describe the allergy/intolerance (food and symptoms) and when it started.

---

---

**4. Do you have regular physical activity habits**

**YES / NO**

If YES, please describe your weekly physical activity routine (type and duration of each activity including extended periods of walking).

---

---

**5. Do you have type 2 diabetes?**

**YES / NO**

If YES, please state when you were diagnosed.

---

**6. Do you currently take any medications on a regular basis?**

**YES / NO**

This includes prescription and over-the-counter medications. Please specify the name, dose and how often you take each medication.

---

---

**7. Do you have a family history of diabetes?**

**YES / NO**

If YES, please state which relatives and which type of diabetes they have.

---

---

**8. Do you currently have any other health issues?**

**YES / NO**

If YES, please describe each issue and when it started

---

---

**9. On average, how many hours of sleep do you get per night? \_\_\_\_\_**

# **Appendix 22**

FII in Type 2 Diabetes Study  
Study Completion Questionnaire



**EFFECT OF DIETS OF VARYING FOOD INSULIN INDEX (FII) ON DAY-LONG  
GLUCOSE AND INSULIN PROFILES IN ADULTS WITH TYPE 2 DIABETES**

**SESSION QUESTIONNAIRE**

Name: \_\_\_\_\_ Date: \_\_\_\_\_ Test ID: \_\_\_\_\_

**BEFORE you start your test session, please answer the following questions:**

**1. What time did you arrive here this morning? \_\_\_\_\_ AM**

**2. Have you been well in the last 24 hours? YES / NO**

If NO, please state why. \_\_\_\_\_

**3. Aside from your regular medications, have you taken any other medications since your last test session? YES / NO**

If YES, please state what medication you took (medication name, dose and frequency) and why you took the medication.

\_\_\_\_\_  
**5. What is your body weight this morning without shoes? \_\_\_\_\_ kg**

**6. What time was your last meal? \_\_\_\_\_**

**7. What did you have to eat? \_\_\_\_\_**

\_\_\_\_\_  
**8. Have you had any alcohol or legumes in the past 24 hours? YES / NO**

If YES, what did you have, how much and when?

\_\_\_\_\_  
**9. Have you done any physical activity today? YES / NO**

If YES, please describe the activity, including type, duration and intensity.

## **EATING INSTRUCTIONS**

1. Record the time on the clock now.

**TIME ON CLOCK NOW:** \_\_\_\_\_ **AM**

2. Start your stopwatch as soon as you start eating.
3. Eat and drink at a comfortable pace, but please finish everything served to you within 12 minutes.
4. As soon as you finish eating please record the time on your stopwatch

**TIME ON STOPWATCH:** \_\_\_\_\_ **minutes**

**Did you completely consume all the food/drink served to you?**

**YES / NO**