Sub analyses – Supplementary document

To investigate our findings, we further undertook *a posteriori* analyses to guide the design of future studies. Due to the dynamic nature of glucose metabolism after kidney transplant, and broad eligibility criteria of 3-24 months post-transplant, we restricted our analysis to participants under 12-months post-transplant at time of study commencement (n=82). Active versus passive lifestyle intervention demonstrated no change in insulin secretion (mean difference -646 [95% CI -4,922 to +3,629], p=0.764) or disposition index (mean difference -40.4 [95% CI -5,935 to +5,855], p=0.989), but a trend towards significant improvement in insulin sensitivity (mean difference -1.0 [95% CI -2.1 to +0.1], p=0.069) and significant change in weight (mean difference -2.1 [95% CI -3.9 to -0.3], p=0.020). PTDM rates between active versus passive intervention was 9.8% versus 18.4% respectively (p=0.216).

Next, we analysed participants with a BMI of 25 mg/m^2 or higher (n=73). Active versus passive lifestyle intervention demonstrated no change in insulin secretion (mean difference -2,089 [95% CI -6,542 to +2,363], p=0.353), insulin sensitivity (mean difference -0.5 [95% CI -1.6 to +0.6], p=0.334) or disposition index (mean difference -3,372 [95% CI -9,147 to +2,401], p=0.248), but a significant change in weight (mean difference -2.9 [95% CI -5.0 to -0.8], p=0.008). PTDM rates between active versus passive intervention was 11.1% versus 24.2% respectively (p=0.131).

Restricting analyses to participants who are within 12-months post-transplant and have a BMI of 25 mg/m^2 or higher (n=55), there was no significant difference in insulin secretion, insulin sensitivity or disposition index but significant change in weight (mean difference -2.5 [95% CI

-4.9 to -0.1], p=0.042). PTDM rates between active versus passive intervention was 10.7% versus 25.9% respectively (p=0.133).

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5-6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	6-7
	4b	Settings and locations where the data were collected	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-10
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	12
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	n/a
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	12-13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	12-13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	13-14 and Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	13
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Tables 1-4
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Tables 2-4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	14-16
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	15 and Table 4
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17-18, 20-21
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19-20
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	17-21
Other information			
Registration	23	Registration number and name of trial registry	4, 7
Protocol	24	Where the full trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	4, 13

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Queen Elizabeth Hospital Birmingham
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A guide to diet after kidney transplantation – patient information

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Nutrition and transplantation

Following your kidney transplant, many of the dietary restrictions you previously followed may no longer be necessary. You may be unsure of what to eat, the aim of this diet sheet is to answer your questions.

If your new kidney is slow to start functioning, you may need to remain on a restricted diet for a short while. However, as your kidney function improves, you may be able to have more variety in your diet. Your dietitian will advise you on this.

What kind of diet should I be following?

To get the most out of your new kidney, the emphasis will now be on healthy eating and food safety. Additionally you may need to stop eating certain foods as they can interfere with some of the medication you now need to take.

Healthy eating after kidney transplantation

One of the benefits of a successful kidney transplant is that you can enjoy a more varied diet. Usually your potassium restriction is lifted enabling you to eat foods you may previously had to limit.

With fewer diet restrictions, the effect of steroids and an improvement in appetite, you may put on weight. It is a common problem for post–transplant patients to rapidly gain weight. Healthy eating will help you to control your weight and keep your blood levels of cholesterol and other blood fats as near normal as possible. Controlling your weight and cholesterol will help to reduce your risk of heart disease and stroke. Including calcium is also important to keep your bones healthy and reduce your risk of osteoporosis (suffering from brittle or fragile bones).

Healthy eating

Enjoying a healthy diet is all about getting the balance right.

You should select a variety of foods from each of the five food groups in the proportions shown on page 3.

Eatwell Guide

Use the Eatwell Guide to help you get a balance of healthier and more sustainable food. It shows how much of what you eat overall should come from each food group.

Check the label on packaged foods

Each serving (150g) contains

Energy	Fat	Saturates	Sugars	Salt
1046kJ 250kcal	3.0g	1.3g	34g	0.9g
	LOW	LOW	HIGH	MED
13%	4%	7%	38%	15%

of an adult's reference intake
Typical values (as sold) per 100g: 697kJ/ 167kcal

Choose foods lower in fat, salt and sugars

Fruit and vegetables

Eat at least 5 portions of a variety of fruit and vegetables every day

Raisins
Chopped tomatoes
Frozen peas

Potatoes, bread, rice, pasta and other starchy carbohydrates

Choose wholegrain or higher fibre versions with less added fat, salt and sugar

Potatoes
Whole grain cereal
Cous Cous
Porridge
Bagels
Whole wheat pasta
Rice
Spaghetti

Beans, pulses, fish, eggs, meat and other proteins

Eat more beans and pulses, 2 portions of sustainably sourced fish per week, one of which is oily. Eat less red and processed meat

Lentils
Beans lower salt and sugar
Tuna
Lean mince
Plain nuts
Chick peas

Dairy and alternatives

Choose lower fat and lower sugar options

Low fat soft cheese
Semi skimmed milk
Soya drink
Plain Low fat Yoghurt

Oil & spreads

Choose unsaturated oils and use in small amounts

Veg oil
Lower fat spread

Eat less often and in small amounts

Sauce
Crisps

6-8 a day

Water, lower fat milk, sugar-free drinks including tea and coffee all count.

Limit fruit juice and/or smoothies to a total of 150ml a day.

Per day 2000kcal 2500kcal = ALL FOOD + ALL DRINKS

Source: Public Health England in association with the Welsh government, Food Standards Scotland and the Food Standards Agency in Northern Ireland

Tips in following a Healthy Diet

- Eat regular meals and do not miss meals.
- Include starchy foods at each meal. Examples of starchy foods include bread, cereals, rice, pasta and potatoes. Try to choose wholegrain varieties whenever you can.
- Eat foods containing fats sparingly and select lower–fat options where possible. The nutrition labels on food packaging can help you cut down on total fat and saturated fat; low fat is 3g of fat or less per 100g, low in saturated fat is 1.5g of saturated fat or less per 100g. High fat is more than 17.5g of fat per 100g and high in saturated fats is more than 5g of saturates per 100g.
- Limit your intake of added sugar from fizzy drinks, biscuits, cakes, chocolate, desserts etc. You do not need to cut down on sugars found in fruit or dairy products because these foods contain lots of nutrients that are good for us. Nutrition labels tell you how much sugar a food contains. If an item's total sugar content is over 22.5g per 100g, it is high in sugar. Anything under 5g of total sugar per 100g is low.
- Eat more fish, including one portion of oily fish each week. Examples of oily fish include salmon, mackerel, trout, herring, fresh tuna, sardines, pilchards and kippers.
- Aim to eat at least 5 portions of fruit and vegetables a day.
- Eat less salt and salty foods.
- Avoid binge drinking and try not to exceed the recommended alcohol limits of 14 units per week for both men and women. Ensure that you spread your drinking over three days or more if you drink as much as 14 units a week.
- Prednisolone and some of the immunosuppressive medications can cause your bones to lose calcium in the long run, making them more fragile and increasing the risk of fractures. Unless your doctor or dietitian tells you otherwise, you should eat more dairy produce, which is a good source of calcium. Examples include:

- Milk (skimmed or semi–skimmed milk are lower in fat)
- Yoghurts (choose diet or low–fat varieties)
- Cheese (cottage and edam cheeses are lower in fat)
- Tinned fish with edible bones e.g. tinned sardines/salmon
- Dark green vegetables
- Fortified cereals

Food safety following kidney transplantation

The immunosuppressive medications act on the immune system. Due to their impact, you may have a greater chance of picking up a food–borne illness. For this reason you are advised that after a kidney transplant you should follow the food safety guidelines to reduce the likelihood of food poisoning.

General food safety:

- Frequent and thorough hand–washing is vital especially before preparing and eating food.
- Avoid cross–contamination during food preparation and storage, and reheat left–overs thoroughly.
- Be aware of any food that has been left at room temperature such as community picnics or buffets.
- Processed meats like hotdogs should be avoided or cooked very thoroughly.
- Very thoroughly wash or peel vegetables and avoid salad bars at restaurants.
- Travelling to developing countries is risky for transplant recipients and should be discussed with your doctor at least 2 months prior to the trip. If travelling, precautions should be taken, these include:
    - Avoid tap water, ice, beverages made from tap water and fresh fruit juice
    - Select vegetables and fruit that can be peeled
    - Hot foods should be served steaming hot
    - Drink bottle or canned and processed beverages
    - Boil tap water if it is to be used

Some foods may contain harmful bacteria and should be avoided while you are on high doses of immunosuppressive medications (usually for up to six months after your transplant:

- Avoid drinking unpasteurised milk or fruit/vegetable juices/ ciders and eating foods made from unpasteurised milk.
- Avoid unpasteurised soft cheese like feta, bríe and camembert, unless they have been cooked or labelled as pasteurised.
- Avoid raw or undercooked eggs and foods prepared with raw and undercooked eggs such as raw cookie dough or cake batter; and unpasteurised / homemade mayonnaise, hollandaise sauces or caesar salad dressings if made with undercooked eggs.
- Avoid raw or undercooked meat, poultry and fish, including shellfish.

Drug treatment and diet

You will be asked to take a variety of medications to prevent your body from rejecting the new kidney. These medications are known as immunosuppressive medications.

You are advised to avoid the following food and drinks as this would interfere with your immunosuppressive medications:

- Grapefruit juice
- Seville oranges
- Camomile tea
- Guggul tea
- Bergamot oil (commonly contained in Earl Grey tea)
- Red wine
- Star fruit

The following medicinal herbs may also interfere with your immunosuppressive medications and should be avoided:

- St John's Wort
- Echinacea
- Asian ginseng
- Goldenseal
- Alfalfa
- Phellodendron

The most commonly used immunosuppressive medications are tacrolimus (also known as prograf) and mycophenolate mofetil (also known as CellCept or Myfortic). The information provided above is mainly based on these medications. If you are taking other immunosuppressive medications, please check with your local pharmacist to confirm if the above information still applies.

Always buy any medicine or remedies from the pharmacy after showing your medication card to the Pharmacist.

Useful contact

If your have any problems or questions, please contact your dietitian.

Name.....(Renal Dietitian)

The Trust provides free monthly health talks on a variety of medical conditions and treatments. For more information visit www.uhb.nhs.uk/health-talks.htm or call 0121 371 4323.

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