Study Protocol

of

Incorporating acacia gum into a commonly consumed food improves postprandial glucose regulation in healthy adults

1. INTRODUCTION

Abnormal postprandial blood glucose (PPG) is considered as a strong predictor in developing certain metabolic diseases as type 2 diabetes (T2D) (O'Keefe & Bell, 2007). Prolonged high blood glucose is a well-known aetiology of T2D and it is diagnostically defined by abnormal glucose homeostasis (WHO, 2006). PPG response is determined by carbohydrate-rich foods consumption (Wolever & Bolognesi, 1996). These foods are ranked according to their effect on PPG by the glycaemic index (Jenkins et al., 1981). Low-glycaemic-index diet was evidenced to be beneficial on controlling glycaemia in T2D on the long run (Greenwood et al., 2013; Jenkins et al., 2002, 2008). Many factors cause a carbohydrate-based food to affect PPG, including the physical structure of that food, the type of carbohydrate it is made up from, and the hormonal and neural responses its consumption induces. different PPG and insulin responses can result from consuming the same food due to the effect of processing, as evidenced in the cases of retrograded and native starch (Wang & Copeland, 2013).

There is systematic evidence that dietary soluble fiber, of which guar gum belongs to, have a long-term remarkable effect on controlling glycaemia. One of the proposed mechanisms of action of dietary fibre is that it expands in the presence of water upon ingestion to work as a bulk laxative to normalizes bowel movement. Like other fibers, it decreases blood glucose by absorbing lipids and glucose in the gastrointestinal (GI) tract, and thus reducing carbohydrate delivery from the upper GI to the portal vein, and hence the liver. Indeed, daily consumption of 15g of guar gum for 48 weeks was evidenced to enhance PPG tolerance and glycemic control in humans (Chuang et al., 1992; Groop et al., 1993). Moreover, consuming 5g of guar gum four times daily for 6 weeks prior to meals was reported to decrease PPG and fasting blood glucose, insulin requirements, and hemoglobin A1c (HbA1c) in patients with insulin-dependent diabetes (Ebeling et al., 1988; Vuorinen-Markkola et al., 1992). These promising results are encouraging approach to be used for long-term prevention of hyperglycemia, at a population level through lifestyle interventions.

Limited studies in the literature have shown similar beneficial metabolic results with Acacia gum (Arabic gum) consumption. Acacia gum is readily available in our area of the world, and is comparatively cheap. A recent study has shown a positive effects of acute 40 g acacia gum consumption on satiety and appetite, however, no significant difference was shown on glycemic response (Larson et al., 2021). This might be due to the confounding effect of other meal composition. Another study indicated significant decrease in both lipid profile and fasting blood glucose in patients with T2D (Babiker et al., 2017). However, additional studies are required to explore the effect of Acacia gum ingestion on PPG in healthy humans.

The intention of the present protocol is to study the impact of consuming acacia gum incorporated food product on PPG. As the physical state of food can be a significant determinant of postprandial glycaemic response, using Acacia gum enriched flour allows the study of this phenomenon in some depth.

2. **Study:** ***The role of incorporating Acacia gum in foods on glucose homeostasis in healthy humans: a pilot study***

Study methodology: A randomised, control, paralleled study.

Participants: 12 normal and overweight healthy male and female volunteers aged between 18 and 40 years with body mass index (BMI) of 18.5-30 kg/m^2.

Support of number of volunteers: As this was a pilot study, a formal sample size calculation was not appropriate. A sample size of 12 participants was justified a priori based on the study objectives. This sample size was based on published recommendations of a minimum sample size of 12 participants for pilot studies (Moore et al., 2011)

Health Screening

Participants will attend the 'Food, Nutrition and Lifestyle Research Unit'- King Fahad Medical Research at King Abdulaziz University where their eligibility will be assessed. They will have a blood test (fasting blood glucose) and height and weight measurements will also be taken. All women of child bearing age should confirm a self-reported non-pregnancy status.

Participants will be told not to start any other new diets or intensive exercise regimes during the study period as this may give us conflicting results.

Study Days visits 1 and 2:

The day prior to the study visit, participants will be requested to refrain from strenuous exercise and caffeine intake. Participants will then be requested to fast overnight (they are allowed to drink water) and will come to the 'Food, Nutrition and Lifestyle Research Unit'- King Fahad Medical Research at King Abdulaziz University the following morning.
Participants will then receive a small meal (0 min) with the assigned food product (control or test food) that will contain either biscuit made of white flour (control) or 20% of Acacia gum incorporated to white flour (test food) on each study visit. Two ml of postprandial blood samples will be taken at 15, 30, 45, 60, 90, 120, and 180 min to measure glucose and insulin.

Appetite and satiety will be assessed by visual analogue scale every 60 min.

PARTICIPANT ENTRY

INCLUSION CRITERIA

- Male and female self-reported healthy volunteers (aged 18 to 40 years)
- Normal to overweight individuals (body mass index (BMI) 18.5-30 kg/m^2)

EXCLUSION CRITERIA

- Substance abuse
- Excess alcohol intake

- Pregnancy
- Diabetes
- Cardiovascular disease
- Cancer
- Gastrointestinal disease e.g. inflammatory bowel disease or irritable bowel syndrome
- Kidney disease
- Liver disease
- Pancreatitis
- Use of medications likely to interfere with energy metabolism, appetite regulation and hormonal balance, including: anti-inflammatory drugs or steroids, antibiotics, androgens, phenytoin, erythromycin or thyroid hormones.

Any participants with the above conditions would already have an altered pattern of hormones and inflammatory molecules because of their disease process and would therefore give us confounding or misleading results.

WITHDRAWAL CRITERIA

The safety of the study participants takes priority. Any significant adverse event (as assessed by the researchers) will halt the study and the ethics committee and sponsor will be informed as per standard protocol. All adverse events will be recorded and investigators will review each adverse event as it arises. In addition, participants will be free to withdraw at any time and are not required to give a reason.

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