Appendix 1.

Focus groups in the PEARs study

We conducted two focus groups at the introductory phase of the study. These were performed by MAK after appropriate training over 2 sessions from 10 randomly selected women with BMI 25-40 approached at the antenatal clinics. The objectives were to:

- Ascertain women's information needs in pregnancy with respect to diet and exercise
- Ascertain their current sources of information and how these assist or not with their understanding of pregnancy or general health issues
- Learn what they would like to see in an app design and what would encourage them to use an app particularly designed for pregnancy
- Ascertain how they perceive their current lifestyle to be i.e. diet and exercise habits
- Ascertain the participants' level of current knowledge on appropriate nutrition and physical activity in pregnancy
- Find out what motivates women to eat well/exercise
- Find out what obstacles there are to leading a healthy lifestyle for women both outside pregnancy and whilst pregnant

How the focus group was structured

Part 1

- Introduction/icebreakers
- Purpose of the focus group was explained

Part 2

- Ascertained general knowledge of appropriate nutrition, physical activity and weight gain in pregnancy
- Explored current lifestyle habits
- Discussed motivations and obstacles to leading a healthy lifestyle

Part 3

- Explored what nutritional and exercise information they would like to see in an app
- What would deter or stop them from using an app
- What would motivate them to engage with an app

Kennelly MA, Ainschough K, Lindsay KL, O'Sullivan E, Gibney ER, McCarthy M, et al. Pregnancy exercise and nutrition with smartphone application support: a randomized controlled trial. Obstet Gynecol 2018; 131.
The authors provided this information as a supplement to their article.

Format of education session for the intervention group after randomization:

- Introductions- participant is introduced to members of the research team (research registrar (MAK) and research nutritionist (KMA))
- Questionnaire packs given at recruitment are retrieved and checked for completeness.
- Explore the participants' general knowledge on healthy eating and physical activity in pregnancy
- Explore the participants' feelings and attitudes with respect to healthy nutrition and physical activity participation
- Smart phone app is downloaded (or the link to access on android is sent) and the participant is shown how to navigate their way through the different components.

Gestational Weight Gain:

- Explain the importance of a healthy gestational weight gain during pregnancy and the IOM recommendations [1] developed based on this.
- Discussion of appropriate IOM weight gain ranges based on participant's early-pregnancy BMI.
- Calculation of ideal weight gain based on early pregnancy weight and upper limit for recommended weight gain range.
- Advise participant to check weight recorded at outpatient visits to hospital as well as at both brief follow-up visits with research team.

Nutrition

- Discuss "Healthy Eating for Pregnancy' guidelines (including the food pyramid)
- Explore participant current knowledge of glycemic index (GI) and low-GI diets.
- Explain GI – the effect of different carbohydrates on blood glucose and the use of low-GI diets as a way of managing gestational diabetes.

- Discuss rationale for the study; potential maternal and fetal consequences of consuming high-GI carbohydrates during pregnancy, and potential benefits known of consuming low-GI carbohydrates during pregnancy.
- Explain caloric energy recommendations during pregnancy, addressing the 'eating for two' myth and explain that a low-GI diet fits those energy recommendations.
- Discuss three key ways in which participants can adopt a low-GI diet: (1) eat low-GI types of carbohydrates, (2) eat an adequate portion size of low-GI carbohydrates, and (3) combine low-GI carbohydrates with good sources of protein and fat to lower the glycemic load of the meal.
- Explore current dietary habits with respect to the GI of foods by examining food diaries and discussion with participant.
- Discuss "Healthy Eating for Pregnancy' guidelines (including the food pyramid) with emphasis on a low-GI diet .
- Give examples of 'food swapping' i.e. substituting high-GI foods for low-GI foods using examples from current diet. Discuss a wide range of low-GI food swaps for different sources of carbohydrates.
- Discuss food safety and brief overview of nutrition myths in pregnancy.
- Explore recipes from the app – examples of low-GI meals and snacks to eat throughout the day.
- Discuss barriers or challenges to adopting dietary changes with women – help them to identify ways to overcome challenges or alternatives. Give examples of previous patient success as examples where relevant.
- Set SMART goals to reduce GI and GL based on participant's current dietary practices.

Physical activity

- Explain the benefits of physical activity in pregnancy
- Explain current guidelines for physical activity in pregnancy: As per ACOG guidelines i.e. 30 minutes per day of moderate intensity physical activity (moderate

intensity described to participants as a level where there is some sweating, some shortness of breath but it is still possible to hold a conversation) [2].

- Explore current physical activity participation by examining physical activity questionnaire responses and discussion with participant.
- Explore any challenges or difficulties perceived by the participant with respect to taking part in physical activity. Help them to identify ways to overcome any difficulties. Discuss any previous attempts at increasing physical activity where necessary. Give examples of previous patient success.
- Set physical activity SMART goals to achieve ACOG recommendations based on the participant's current level of activity; types of exercise they would like to try or continue with, different ways to achieve the 30 minutes per day (e.g. one solid 30-minute session, two 15-minute sessions, 3 10-minute sessions).
- Answer any participant concerns or queries regarding physical activity.
- Inform the participant about the physical activity section of the app and the 'exercise of the day' on the homepage of the app.

Conclusion

- Goal setting (SMART) (refer to previous successful attempts at dietary and exercise lifestyle changes where relevant for the participant)
- Give a brief summary of key points discussed
- Participant Reflection

Behavior-change theories and techniques underpinning the PEARs study

Control Theory was used to deliver the intervention in the following ways, and through the following *behavior-change techniques*:

- enable participants to change diet and physical activity behaviors through *goal setting (behavior)* and to aim for a healthy GWG through calculation of ideal GWG (*goal setting (outcome)*) and to suggest monitoring GWG at subsequent visits (*prompt-self-monitoring of behavioral outcome*).

- Persuade participants to continue with lifestyle changes through brief review of diet and physical activity goals (*prompt review of behavioral goals*) and progress with weight gain and glycemic control (*prompt review of outcome goals, provide feedback on performance*) at follow-up.
- Incentivize participants to continue with lifestyle modifications through provision of generalized messages to encourage healthy progress and the importance of healthy lifestyle via the app, and provision of praise and encouragement via follow-up emails based on any specific feedback from the participant (*prompt reward contingent on effort or progress towards a behavior, prompt reward contingent on successful behavior, stimulate anticipation of future rewards*).
- Social Cognitive Theory was used to deliver the intervention in the following ways, and through the following *behavior-change techniques*:
- educate and incentivize participants about the importance of healthy eating, physical activity and weight gain during pregnancy, and respective health consequences and health benefits of each at the education session, follow-up visits, in follow-up emails and provision of messages via the app (*provide information on consequences of behavior in general*).
- model healthy behavior-change using examples of successes of other participants (*provide normative information about others' behavior*)
- enable participants to feel they can make and persist with diet and physical activity behavior-changes through helping them to identify and/or overcome and challenges they believe to be inhibiting change (*barrier identification/problem solving*) and re-inforce encouragement to pursue changes through generalized messages in email follow-ups and the app (*relapse prevention/coping planning*).
- help participants to think about restructuring their current environment through discussion of how changes to physical activity and diet do not have to be confined to learned situations only and are simple to integrate into most scenarios (*prompting generalization of target behavior*), and describe how it is possible to introduce lifestyle changes with family and friends (*plan social support/social change*).

- persuade participants to persist with healthy behavior-changes via follow-up emails and motivational messages from the app (*teach to use prompts/cues, use of follow up prompts*).

Laboratory analysis

All maternal and cord samples were analyzed for plasma glucose following centrifugation by hospital laboratory staff at the shortest possible interval following sample collection using the AU680 Chemistry analyzer (Beckman Coulter Inc., High Wycomb, UK) and the hexokinase method. Additional sera collected at baseline and post-intervention were centrifuged at 4°C within an hour of collection for 5 minutes. The separated serum was immediately frozen at -20°C, with subsequent transfer to a -80°C freezer. Maternal and cord samples were later analyzed for insulin, c-peptide, triglycerides, total cholesterol, high-density lipoprotein (HDL) and low-density lipoprotein (LDL) cholesterol. Insulin and c-peptide were quantified by automated immune-assay (Roche Cobas 602 ; Roche Diagnostics, Basel, Switzerland) with typical CVs <5%. Total cholesterol, HDL cholesterol, and triglycerides were analyzed on a Roche Cobas 702 analyzer (Roche Diagnostics). LDL cholesterol levels were estimated using the equation of Friedewald *et al* [3]. The HOMA2-IR index was obtained by the program HOMA Calculator v2.2.2 [4]

Statistical analysis

The usual procedure to control the type I error rate in the presence of multiple hypothesis tests, is to attempt to control the "family-wise" error rate in a strong sense. This usually involves a Bonferroni procedure to control for multiple primary endpoints, and/or to control for a number of secondary endpoints. "Family-wise" in the context of a Bonferroni correction means that, of the total number of tests performed we make an adjustment to the p-value for each test so that there is no longer a test-wise 5% type I error rate, but rather a 5% type I error rate over the family of tests. This implies that if one or more of the individual tests gives a false positive result, then the experimental family of tests is deemed to have suffered from a false positive result. This has an interpretative advantage, in that usually when one considers

an experiment or a study with a number of tests, the “positive” (read: statistically significant) test results are taken to be the “findings” of that study, and therefore this is the outcome one should control using a multiplicity adjustment procedure. However, it has the disadvantage that the Bonferroni-corrected p-value imposes a far more stringent false positive rate on individual tests, setting the type I error rate at 2.5% if two tests were performed, at 0.5% if ten tests were performed, and 0.1% if 50 tests were performed. The Bonferroni correction is called “conservative”, in that it reduces the number of type I errors far below 5%. As a result, type II errors are inflated.

Here, we have applied a more liberal correction to control the false discovery rate (FDR) over 47 secondary and exploratory efficacy tests using the Benjamini-Hochberg procedure [5], rather than attempting to maintain the family-wise type I error rate at 5%. We present these adjustments alongside the uncorrected p-values. Briefly, the FDR procedure adjusts the p value so that no more than 5% of statistically significant results are expected to be false, rather than the conservative Bonferroni correction of a global probability of 5% of one or more false positive findings [6].

The procedure ranks the p-values from smallest (1) to largest (m), and calculates the kth adjusted p-value thus:

References

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