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Official Title: Feasibility Trial of a Lifestyle Intervention for Pregnant People with Gestational Diabetes

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Statistical Analysis Plan

We will conduct data management and descriptive analyses using SAS 9.4 (SAS Institute, Inc., Cary, NC). We summarized participant characteristics and feasibility and acceptability outcomes, overall and by treatment condition. We will report recruitment and retention using a CONSORT diagram specific to feasibility pilot trials. We will export transcripts auto-generated by Webex to Excel. One member of the research team will listen to the recording and correct the transcript, and a second team member will listen to the recording to confirm the corrections. We will conduct a rapid qualitative analysis of participant feedback to inform continued development of the Meals4Moms program.

Feasibility Outcomes

Below we detail our feasibility outcomes, how they will be measured, benchmarks for assessing feasibility, and how we will use resulting information to inform the design of the efficacy trial. This table is also included in the study protocol (document dated 1/31/24).

Feasibility outcome	**How measured**	**Benchmark**	**How information will inform design of efficacy trial**
Recruitment	Recruitment rates will be calculated from the number of patients approached and reasons for ineligibility and non-participation.	At least 75% of the patients screened as eligible should be recruited but the trial will not be feasible if recruitment uptake is 50% or less; we anticipate recruiting 4-5 participants per month	We will compare yield from different recruitment approaches and finalize our approach for the efficacy trial based on the most effective and efficient approaches. We will examine whether any eligibility criteria are excluding an inordinate proportion of otherwise eligible women, and if so, reassess scientific and practical necessity of each eligibility criterion. If recruitment rates are lower than expected, we will adjust recruitment timelines or modify our recruitment strategy or consider a second clinical site.
Retention	Proportion of participants who complete any aspect of the follow-up assessment	≥80% retention in each arm with 65% or less retention indicating that the main trial is not feasible	If retention is lower than expected, we will explore reasons for drop-out and modify the protocol to address these challenges.
Receipt of intervention	Records of # meals ordered per week; Records of # of	≥80% ordered meals based on 21 meals per week	If compliance with meal ordering does not meet our targets, we will explore alternative strategies for increasing compliance with the interventions and modify the protocol to address these

	exercise sessions		challenges. We will also describe engagement with other aspects of the intervention website using back-end data from the intervention website and qualitative feedback from post-intervention interviews with participants randomized to the M4M condition.
Intervention acceptability	Participants in both conditions will be asked if they would participate again if they had GDM in the future and if they would recommend the program to a friend with GDM (5-item Likert scales of likelihood)	≥80% of participants indicate "likely" or "very likely" on both measures of acceptability	We will interview participants in the M4M condition who have completed the trial (after delivery) to understand feasibility and acceptability issues and use their feedback to modify study procedures or intervention materials before moving to a full-scale efficacy trial. We will also examine responses to addition questions assessing frequency of use of and ratings of helpfulness and relevance of other aspects of the M4M intervention.