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# **Formative Development of a Framework to Inform Recruitment, Enrollment, and Retention of Participants in BRAVE**

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# Study Purpose and Objectives

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## Purpose

- To formatively develop, using applied qualitative health research methods, a framework to inform recruitment, enrollment, and retention strategies in the BRAVE trial

## Objectives

- 1.To identify individual, relational, organizational and social factors that influence an individual's decision to enroll and maintain participation in an RCT evaluating medical vs surgical interventions for weight reduction.
- 2.To identify recommendations, grounded in the experiences of individuals with BMI  $>35\text{kg/m}^2$  and CVD, on how research teams can improve rates of recruitment, enrollment, and retention in the RCT.

# Methods: Applied Qualitative Health Research

Design	Qualitative description (Bradshaw, Atkinson, & Doody, 2017)
Context	One or Two Centres: Hamilton + ? one in Quebec
Sampling	<p>Triangulation of two data sources: 1) patients; and 2) center/research staff</p> <p>A purposeful sample of 3 groups of patients (who meet BRAVE trial inclusion criteria) will be invited to participate.:</p> <ol style="list-style-type: none"><li>1. Individuals who originally declined screening</li><li>1. Individuals who consented to screening but not to randomization</li><li>2. Individuals who consented, and randomized</li></ol> <p>Snowball sampling to identify 1-2 research staff/investigators at each of the two sites who can speak to local logistical, project, and organizational factors.</p>
Sample Size	<p>Patients = 12 from each site</p> <p>Research staff/investigators = 2-4</p>

# Methods: Applied Qualitative Health Research

Comp	Description
Data collection	<p><i>Patients &amp; Staff</i></p> <p>Semi-structured interview conducted either face-to-face, Zoom, or phone Interview length: 30-60 minutes conducted by research coordinator/nurse researcher</p>
Data analysis	<p><i>Team-Based Rapid Qualitative Analysis</i></p> <ul style="list-style-type: none"><li>• Verbatim transcription of each interview (de-identified)</li><li>• Data summary template (domains developed from interview questions)</li><li>• Pilot &amp; finalize data summary template with 2 transcripts (2 researchers)</li><li>• 2.5 day, in-person analysis session (8 analysts) – each analyst, extracts data from transcript (including 1-2 “power quotes”), summarizes it by domain within template; data per domain merged. Kanban project management tool used to manage workflow.</li><li>• Each domain is assigned to an analyst to “synthesize” findings</li><li>• Each domain report used to construct report of findings</li></ul>

# Interview Guide: Questions for Consideration (1)

## Introduction:

- Review goals of BRAVE trial; describe steps/process for recruitment and enrollment

## Draft Questions:

- How did you learn about the BRAVE trial? What were your initial perceptions of the trial goals?
- At what point in the recruitment or screening process did you make your decision with respect to participating in the trial?
- What factors influenced your decision?
  - Prompt for factors across multiple levels: individual, relational, project-related, organizational, social
  - Individuals are randomized to either BS or MM – if you were randomized to receive BS – how would that influence your decision to continue in the study? To receive MM – how would that influence your decision to continue in the study?

# Interview Guide: Questions for Consideration(2)

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## Draft Questions:

- What recommendations would you have for teams conducting this type of research to:
  - Create awareness about study (explore advertising strategies)
  - To recruit/invite individuals to participate (what information is needed, from who, compensation)
  - Navigate the screening and consent process
  - To increase rates of participation and retention

# Budget Considerations

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Resource	Considerations
Human resources	<ul style="list-style-type: none"><li>• Staff to review database for eligible participants, contact, recruit and consent into study</li><li>• Skilled qualitative interviewer to conduct interviews</li><li>• Transcription of recorded interviews</li></ul>
Honorarium	<ul style="list-style-type: none"><li>• Honorarium for each study participant</li></ul>
Analysis	<ul style="list-style-type: none"><li>• In-person analysis session, typical 2 full days @ hotel with conference room; project to cover 1-2 night accommodation (1 night if feasible for all analysts to arrive by 8:30 AM on Day 1), meals for 8 analysts and 1 meeting coordinator/admin (to track workflow, take minutes, manage local logistics), mileage</li></ul>

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