

Bariatric surgery for the Reduction of Cardiovascular Events: Canadian Recruitment



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Canadian centres



- Total of 14 Canadian sites
 - Recruiting from 6 sites
 - 4 sites soon to come online (Unity health, Joliette, U. de Montreal and Kingston)
 - Active discussions with Humber river, H. Pierre-Boucher, McGill and Moncton



Recruitment

as of January 15, 2023

SITES		Start Date	Totals Prior to Last 3 Months		Monthly Progress last 3 months						Totals to Date		
					November 2022		December 2022		January 2023*				
			Consent	Rand	Consent	Rand	Consent	Rand	Consent	Rand	Screening Consent	Ready to Rand	Rand
0001	Hamilton	2020-10-30	85	38	4	0	1	4	2	2	92	0	44
0002	London	2021-08-27	7	2	0	0	1	0	2	0	10	1	2
0004	Ottawa	2022-10-24	-	-	-	-	0	0	0	0	-	-	-
0005	Laval	2022-06-24	2	1	1	0	2	2	0	1	5	0	4
0009	UHN	2022-08-30	3	0	1	0	1	1	0	0	5	2	1
0011	Winnipeg	2022-09-20	-	-	-	-	1	0	0	0	1	0	0
TOTALS			97	41	6	0	6	7	4	3	113	4	51

Canadian Sites Screening

As of January 27, 2023



	HGH/ SJHH	London	Laval	UHN	Ottawa	Winnipeg	TOTAL
Individuals Approached (Screened)	344	15	51	8	3	1	422
Individual declined to proceed	139	2	4	1	1	0	147 (34.8%)
Ineligible	38	3	13	0	0	0	54 (12.8%)
Ongoing assessment / discussion	75	3	29	1	2	0	110 (26.1%)
Ref Bariatric work-up	92	7	5	6	0	1	111 (26.3%)

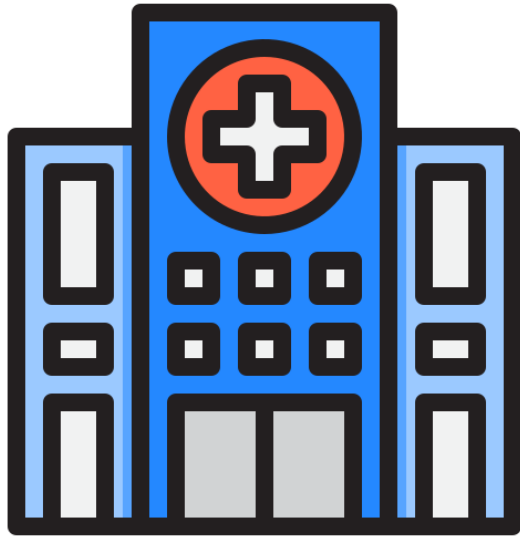
Canadian Sites Recruitment

As of January 27, 2023



	HGH/ SJHH	London	Laval	UHN	Ottawa	Winnipeg	TOTAL
Referrals	92	10	5	5	0	1	113
Ppt declined to proceed	36	3	0	0	0	0	39
Bariatric workup	12	4	1	2	0	1	20
Pending randomization	1	1	1	2	0	0	3
<i>Potential Rands</i>	<i>13</i>	<i>5</i>	<i>2</i>	<i>4</i>	<i>0</i>	<i>1</i>	<i>23</i>
Randomized	43	2	3	1	0	0	51
MWM arm	22	1	2	0	0	0	26
Surgery arm	21	1	1	1	0	0	25
Surgeries completed	18	1	1	0	0	0	20

Barriers and hidden challenges



Challenges we faced and their solutions

- Clear obstacles and hidden challenges to recruitment:
 - Patients with CVD are not common at bariatric clinics
 - Patients on surgical waitlists already committed
 - Lack of awareness / familiarity with the study
- Solutions:
 - Consider solutions to obstacles and barriers: at organizational, staff and patient levels
 - Develop strong ties with cardiology → need a reliable cardiology pipeline
 - Need champion(s) (Cardiology, Surgery, Anesthesia)
 - Recruitment in cardiology clinics & screening of HF, arrhythmia, prevention, stroke clinic
 - Posters / pocket protocols / rounds presentations
 - Simplify referral process
 - Recruiters should know protocol well & learn to present study importance and equipoise
 - Emphasize all patients will get best available care
 - Hotline for each site

Challenges we faced and their solutions

- Participants:
 - Patients don't think weight is an issue
 - Patients haven't contemplated bariatric 'surgery' before
 - Lack of familiarity with the procedure
 - Fear of having the intervention (risks and side effects)
 - Patients prefer to lose weight on their own (but do not realize people fail at this)
- Solutions:
 - Educate patients about the bariatric observational data
 - BRAVE may provide a frame-work for patients to lose weight
 - No interest today does not mean no interest tomorrow
 - Multiple discussions may be needed
 - Involve family in the discussion
 - Offer the opportunity to speak to patients who have had surgery

RECRUITMENT STRATEGY

Call #1:

- Follow a script to give a brief overview (don't overwhelm with information)
- Mention the team
- Provide additional information by email/mail

Call #2/Follow-up calls:

- Randomization process, costs
- Timeline - assessment period & pace
- Provide more details about the medical program, post-surgery recovery
- Benefits of being in BRAVE versus seeking other opportunities
- Offer follow-up calls – give time & space if needed



COMMON QUESTIONS

Do I need to decide/participate now?

Can I withdraw if I don't get my choice?

How do I know if the surgery is safe for me?

I've heard some bad stories about bariatric surgery!

How much time do I need to take off for the study?

Reasons why patients decline to participate

Reason	N (%)
Nervous / fear of surgery	32 (22.2%)
Not interested in research	34 (23.6%)
Not comfortable with randomization	5 (3.5%)
Wants to try weight loss on own	16 (11.1%)
Personal stressors- other health issues, financial concerns, work constraints, family issues	11 (7.6%)
Other- language barrier, distance, fear of not being able to change diet habits	11 (7.6%)
No reason given	35 (24.3%)

Proposed Strategy

Recruitment process complex and involves multiple interfaces

- Qualitative assessment
- Build stronger ties with referral groups
- Active screening
- Multisite training