

Brida - Breast Reconstruction Information and Decision Advisor.

Primary Goal: To help women seeking breast reconstruction determine the best option for them.

How will this goal be supported: Through general education about the options available, by providing a way for the participant to clarify which aspects of each option they prefer and which they do not, and by providing relevant patient reported outcome data to each participant.

- **Content Review:**
 - Nick and Jenni first
 - Ed will be last reviewer and will decide final version

- **Enrollment and study particulars:**
 - 80 participants:
 - 40 in usual care arm (electronic brochure)
 - 40 in intervention arm.
 - There will be 2 recruitment windows, each 60 days in duration.
 - The first window will pull participants into the usual care arm.
 - The second will pull participants into the intervention arm.
 - Study staff will be able to set the recruitment mode in the study dashboard so they will have direct control of the recruitment windows.
 - A participant is someone who:
 - Has had or is going to have a mastectomy or lumpectomy.
 - Has contacted the clinic to set up a consultation with a reconstructive surgeon.
 - Has not already had a reconstructive surgery.
 - Potential candidates will be recruited from the clinic appointment roster by staff and forwarded to RA.
 - Enrollment will be by invitation email which will contain:
 - Information about the study
 - A link to the login/consent page
 - An access code to login
 - Study coordinator contact

- **Survey Module:**
 - Newly enrolled participants will be sent to the survey module
 - Participants will enter their email and unique access code to get started.

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- Participants will consent electronically and will then be taken to the baseline survey.
- A reset password option will be available on the login page.
- Will appear separate from intervention.
 - Will be part of Brida system but will not be provide access to or be accessible from the Brida intervention site in any way.
 - Will not make use of the Brida branding.
- **1a (baseline)** - *control* and *intervention* group:
 - Login credentials created at the beginning.
 - Participant will choose how they want to receive notifications and reminders (*email* or *email and text*).
 - Tailoring information gathered.
 - If participant does not finish, a reminder will be sent at 1, 3, and 5 days prompting them to complete survey 1a.
 - At the end of survey 1a, the participant will either be...
 - Shuttled into the Brida decision aid (intervention group) or,
 - Taken to a thank you page with a link to a downloadable PDF version of the *Your Options* brochure (control group).
- **1b (post intervention)**- *intervention* group only:
 - Available after:
 - Participant has interactive with Brida in any way.
 - Participants who finish their report will be taken to survey 1b automatically.
 - If participant does not complete their report or submit a completed survey 1b, a reminder will be sent at 1, 3, and 5 days prompting them to finish both.
 - Survey 1b becomes unavailable if participant has already attended a consultation with their surgeon.
 - Build in the ability for the system to fire a brief survey containing only the tailoring questions if these have not been provided during survey 1a (this is for dissemination).
- **2 (followup)** - *control* and *intervention* group:
 - An invitation to complete is sent:
 - After participant meets with her surgeon and has scheduled reconstruction surgery or...
 - 14 days after consultation date if participant has not:
 - Attended their consult or...
 - Scheduled a surgery date.
 - If participant does not finish, a reminder will be sent at 1, 3, and 5 days prompting them to complete survey 2.
 - RA marks the visit complete in dashboard to trigger the system to send the invitation.

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- **REVIEW MY OPTIONS** (first tab in navigation bar)
 - **Guided Tour:** (builds tiled “Review My Options” view)
 - Accessed the first time participant enters site
 - Also accessible from the Ask Brida menu
 - Introduction
 - Meet Brida, your breast reconstruction information and decision advisor.
 - Clearly state purpose of decision aid: How will the participant’s life be transformed by interacting with this decision aid (aspirational goal/s).
 - Decision point 1:
 - Reconstruct or not?
 - Participant will be given an option to choose which path they would like to explore. The reconstruction path or the non-surgical path.
 - The participant will always be able to navigate to different pathways, for instance, if they choose to review non-surgical options and then decide they want to get more info on reconstruction.
 - Decision Point 2
 - There are two main types of reconstruction options (provide overview information about the following topic areas)
 - Implants
 - Direct implant
 - Expander implant
 - Natural tissue
 - Abdominal Flap
 - Back Flap
 - Other Flaps
 - There are other less common reconstruction options as well:
 - Gap
 - Tug
 - Finally, there are additional Procedures to consider.
 - Show for everyone:
 - Nipple reconstruction & tattooing
 - Fat grafting
 - Show for participants indicating unilateral surgery:
 - Breast enlargement
 - Breast reduction
 - Breast lift
 - **Reconstruction Option Detail Pages:**

- Each reconstruction options tile will link to one of these.
- There will be one of these for each option type:
 - Implant
 - Implant with expander
 - Abdominal Flap
 - Back Flap
 - Alternative Flaps
 - Forms and Prosthesis
 - Going Flat
- Each reconstruction option page will include the following topics:
 - What is it
 - How is it done
 - Timeline (how the surgery is done, how long in the hospital, etc)
 - By the numbers
 - Number of surgeries
 - Stay in hospital
 - Recovery time
 - Pros
 - Cons
 - Risks
 - Patient personalized risk information will be presented here as well.
 - These will be derived from information provided by participants in survey 1a (baseline).
- There will be 2 sidebar information boxes:
 - Sidebar 1 will present a patient vignette, which will be a produced video interview with a patient who has had this procedure done. For example, the direct implant detail page patient video will feature a woman who had the direct implant reconstructive procedure performed.
 - The interview style will be to have the interviewee restate the question stem within the context of their response. The editing style will focus on the patient only (the interviewer will be edited out).
 - The locale will be somewhere inviting, perhaps the Taubman Library. (scout for some locations and take photos).
 - Sidebar 2 will feature thumbnail of reconstruction illustrations (from U of M Your

Options booklet - available in project mBox folder).

- Participant can click a thumbnail to see a larger view
- Additional Procedures
 - Show for everyone:
 - Nipple reconstruction & tattooing
 - Fat grafting
 - Show for not Surgery Side = Both
 - Breast enlargement
 - Breast reduction
 - Breast lift
- Information will be layered in some manner to keep the page overview clean.
- **WHAT'S BEST FOR ME** (Second tab in navigation bar)
 - **Values Clarification**
 - Participant will work through a values clarification exercise.
 - **Comparison areas will include?**
 - Participant will then be shown the reconstruction option comparison view.
 - **Comparison Tool** (accessible from the menu at any time)
 - Participant can select up to 3 options to compare.
 - Reconstruction options will be visually ranked based on results from the participant's values clarification exercise.
 - **Patient Reported Outcomes** (general reconstruction option comparison statements derived from the outcomes data)
 - These will be framed as comparisons between the various reconstruction options.
 - Will be shown underneath the list of attributes for each reconstruction option being compared and will span across all columns as a general statement.
- **CREATE MY REPORT** (third item in navigation bar)
 - After reviewing the first two tabs, the participant will generate a report to help them prepare for talking with their doctor.
 - Report should include:
 - Options the participant indicated they are most interested in
 - Each option should summarize how the participant weighted its individual attributes.
 - A list of questions or concerns the participant might want to discuss with their doctor (by way of "Other" fields during the report generation process).
 - Patient activation strategies.
 - Generate a printable webpage of report.

- **DASHBOARD**

- Ability to add, edit or withdraw participants.
- Ability to generate unique access codes, associate them with a specific email address, and send the via email template to participants.
- **To discuss: how to determine the arm of the participant. Perhaps at the time of the access code creation, the RA can pick which arm to put the user into, based on their schedule, rather than having the system depend on the clock.**
- Ability to track enrollment – how many participant enrolled, what arm etc.
- Ability to add consultation date.
- Ability to add surgery date.
 - Will send an email message to participant inviting them to take survey 2.
- Ability to track each participant through the Brida system
 - There will be a series of significant checkpoints that will fill in as each participant passes through.
 - Can hover over checkpoint to see date completed
- Ability to export participant survey responses and paradata (delimited CSV file).
- Please see Brida Dashboard mockup 1.1 for more details on this and other dashboard features.

Wilkins Feature List v1.7

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Version 2 Features:

- **Open access to the website, requiring minimal or no account registration.**
- **Links to external resources (requested by focus group)**
 - Support group and survivorship websites
 - Implant manufacturers
- **Patient Outcome Photos (requested by focus group)**
 - Photos of representative outcomes for each option – with range of “best” to “average” outcomes.
 - Is there a repository of photos available that shows results from each reconstruction option? By race?
 - Have the subjects in these photos signed a release?
 - Need to blur out identifying marks (even good people have tattoos).