

# Therapeutic mammoplasty (TM) versus mastectomy for multiple ipsilateral breast cancers

## (MIBC) - the world first MIAMI randomized controlled trial

Professor Zoe Winters

On behalf of the MIAMI Trialists' Group

University College London Surgical & Interventional Trials Unit (SITU)



### Background

- Clinical effectiveness of treating multiple ipsilateral breast cancers (MIBC) with therapeutic mammoplasty (TM) is uncertain
- Alliance ACOSOG 11102 is evaluating clinical safety of TM in MIBC in a longitudinal cohort without a mastectomy comparison
- The world first NIHR-funded multi-centre MIAMI feasibility randomised trial comparing loco-regional recurrence of TM versus mastectomy +/- reconstruction for patients with MIBC

### Trial methodology

Women will be randomized in 1:2 ratio to in favour of intervention arm (Therapeutic Mammoplasty - all types)

#### Intervention:

Multiple lumpectomies and therapeutic mammoplasty (TM)

#### Comparison:

Mastectomy (+/- reconstruction)

#### Feasibility Objectives:

- Demonstrate sufficient number of eligible patients can be identified and randomized
- Determine reasons why patients accept or decline randomization

#### Inclusion criteria:

- >40 years with MIBC, with the largest clinical cancer measuring up to 50mm as part of multifocal or multicentric "disease sites"
- Two disease foci with a minimum of one invasive focus of breast cancer as defined within a "disease site"
- Suitable for therapeutic mammoplasty
- Fit for adjuvant therapy

#### Exclusion criteria:

- High risk or BRCA gene mutation
- Exclusive and extensive DCIS
- Bilateral breast cancers

#### Primary outcome of main trial :

5 year loco-regional recurrence

#### Trial amendments:

MIAMI trial posters in waiting rooms & offices

Widen eligibility criteria

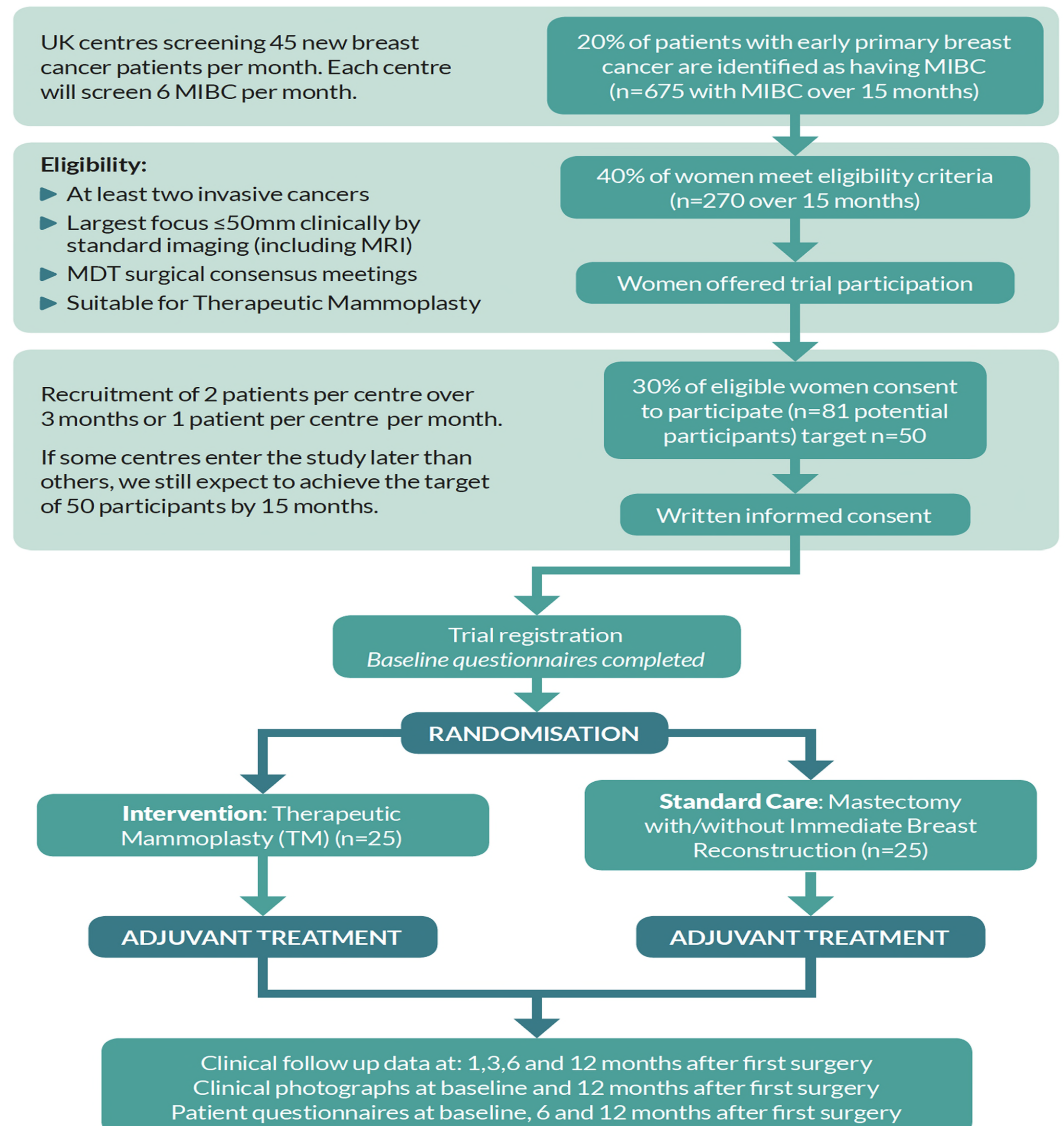
Stage-1 Registration & consent all MIBC (at diagnosis) for ICECAP-A PROM <Stage-2 randomisation

Interview trial decliners

Qualitative interviews of non-randomizing centres

### Trial flow diagram

#### MIAMI FLOW DIAGRAM



### Trial Status

#### Screened Invasive breast cancers:

2346 since March 2018 across 9 UK centres

#### Number with MIBC:

358 (15.3%)

#### Number excluded and eligibility:

262 excluded out of 353 with 91 eligible (25.8%)

#### Leading Exclusions:

<2 invasive foci  
Cancer too large  
Neoadjuvant therapy  
Bilateral breast cancers  
Not suitable for TM

Numbers randomised of those approached was 3 out of 14 giving a consent rate of 21.4%

If the rate of MIBC is 15% and the eligibility is 26% and the consent rate is 21%, then we need to screen 6105 people in order to recruit 50 potential participants.

Broadening eligibility\* criteria would permit 282 out of the 353 MIBC (64.6%) and the need to screen 2442 potential participants

\*Neoadjuvant therapy, Bilateral breast cancers