

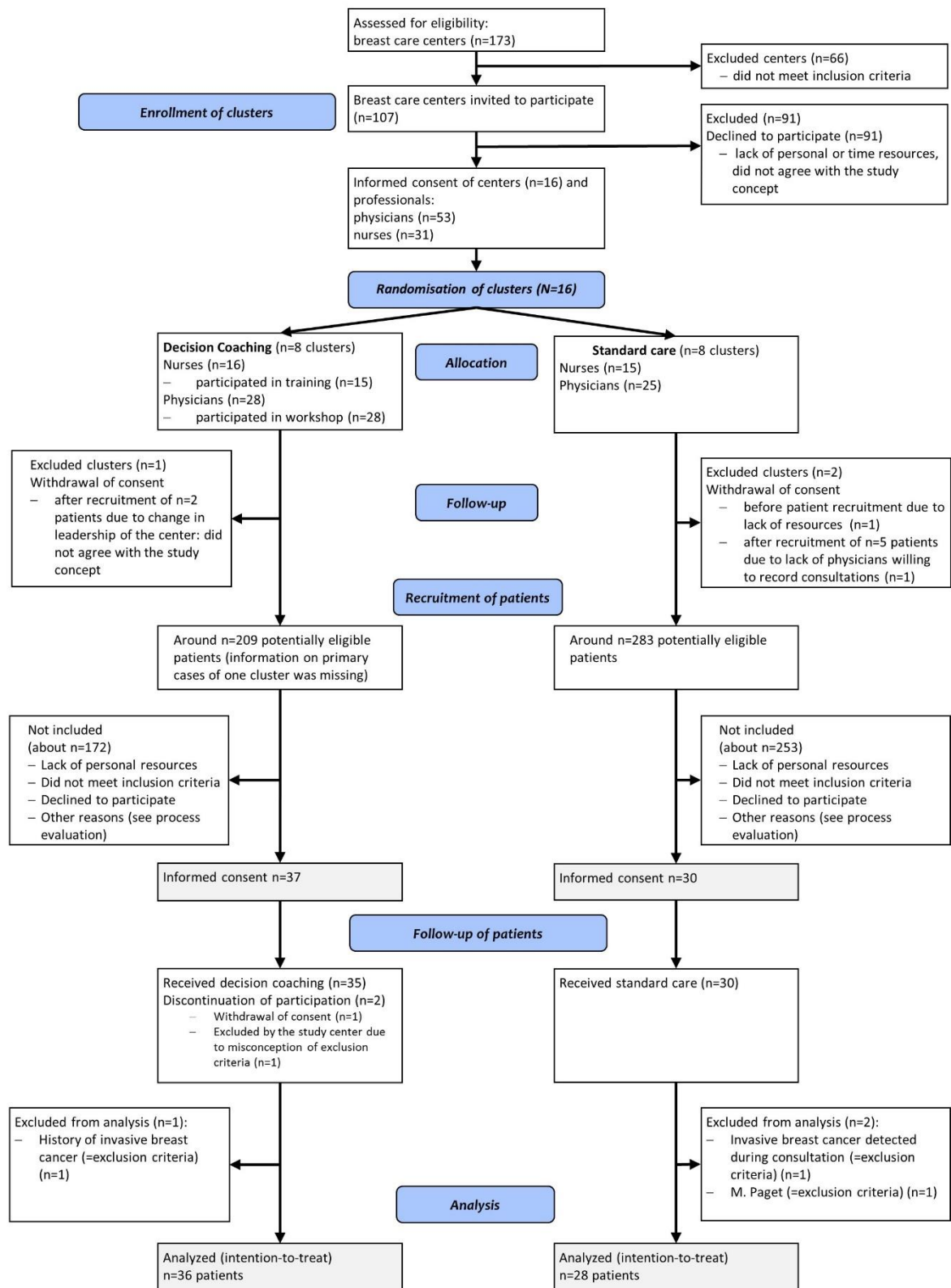
Basic results

ISRCTN46305518

Informed shared decision making supported by decision coaches for women with ductal carcinoma in situ

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Participant Flow:



Baseline Characteristics:

Table 1: Baseline characteristics

Breast care centers	Intervention Group N=8		Control Group N=8	
Holder of institutions, n				
Clerical	3		6	
Public	3		0	
Private	1		2	
Foundation (non-profit)	1		0	
Certification body of centers, n				
Onkoziert	6		4	
Äkziert	2		4	
Primary cases of ductal carcinoma in situ in 2014, n, mean (SD), range, across centers*¹				
Total	197/8, 24.6 (12.9), 10-49		241/7, 34.4 (31.6), 14-104	
Treated with mastectomy	59/8, 7.4 (5.8), 1-19		52/6, 8.7 (8.0), 1-24	
Treated with BCT without radiation	55/8, 6.9 (9.5), 0-27		111/6, 18.5 (26.6), 2-70	
Treated with BCT and radiation	98/8, 12.3 (9.4), 0-26		147/6, 24.5 (21.2), 5-64	
Primary cases of ductal carcinoma in situ during recruitment period, n, mean (SD), range, across centers	209, 29.9 (31.1), 6-90		283, 40.4 (25.9), 18-94	
Nurses				
Total, n, per center	16, 1-3		15, 0-5	
Women/men, n	16/0		15/0	
Age, years, mean (SD)	47.7 (8.5)		53.2 (3.2)	
Average weekly working time, hours, mean (SD)	33.5 (6.4)		34.2 (6.6)	
Practice in nursing, years, mean (SD)	28.8 (9.2)		32.0 (5.4)	
Work experience in a breast care center, years, mean (SD)	9.7 (6.7)		8.6 (3.9)	
Work experience in the current breast care center, years, mean (SD)	9.3 (6.8)		8.2 (3.7)	
Released from regular duties on the ward, n	10/16		7/14	
If excused on the ward, hours per week, mean (SD)	29.7 (10.7)		31.3 (9.6)	
Training as oncology nurse	4/16		5/14	
Training as breast care nurse	12/16		5/14	
Training as head nurse	1/16		5/14	
Training in palliative care	4/16		1/14	
Study nurse	0/16		3/14	
Preceptorship	3/16		3/14	
Mamma Care trainer	3/16		1/14	
No further training	0/16		1/14	
Physicians	Participating physicians	Physicians who recruited patients	Participating physicians	Physicians who recruited patients
Total, n, range per center	28, 2-5	13	26, 1-5	8
Women* ² , n	18/26	6/11	20/24	4/7
Age* ² , years, mean (SD)	44.6 (7.7)	47.3 (6.7)	41.3 (9.7)	44.4 (11.3)
Work experience in breast care* ² , years, mean (SD)	12.6 (7.0)	14.1 (6.7)	9.6 (9.1)	13.1 (11.9)
Employed in the study center* ² , years, mean (SD)	7.2 (4.0)	8.1 (3.2)	4.9 (4.0)	6.0 (3.8)
Women with ductal carcinoma in situ				
Total, n, mean (range) per center	36, 5.1 (1-13)		28, 4.0 (1-7)	
Age, years, mean (SD)	58.3 (7.5)		57.8 (9.5) (3 missings)	
Highest education, n				
No graduation	1/34		0/28	
Lower secondary school	10/34		7/28	
Secondary school	13/34		14/28	
Upper secondary school	7/34		6/28	
College / university diploma	3/34		1/28	

Family status, n		
Single	1/34	1/28
In partnership	2/34	1/28
Married	25/34	20/28
Widowed	1/34	4/28
Divorced	5/34	2/28
Patients with children, n	28	22
1	7/28	10/22
2	14/28	10/22
3	7/28	2/22
Ductal carcinoma in situ screen detected by mammography, n	24/34	17/28
Affected side, n		
Left	19/34	21/28
Right	14/34	7/28
Two-sided	1/34	0/28
Grading, n		
1	5/34	1/27
2	20/34	15/27
3	8/34	10/27
unknown	1/34	1/27
Hormone-receptor status: estrogen, n		
Positive	21/31	18/27
Negative	4/31	2/27
Unknown	6/31	7/27
Hormone-receptor status: progesterone, n		
Positive	19/32	14/26
Negative	7/32	5/26
Unknown	6/32	7/26
HER2neu-status, n		
Positive	1/32	1/28
Negative	3/32	6/28
Unknown	28/32	21/28
Comedo necrosis, n		
Present	21/34	14/28
Absent	13/34	14/28
Microcalcifications, n		
Yes	30/34	26/28
No	4/34	2/28
Multicentricity, n		
Yes	2/34	0/28
No	32/34	28/28
Multifocality, n		
Yes	1/34	4/28
No	33/34	24/28
Diagnostic procedures, n		
Clinical breast examination	30/34	24/28
Mammography	33/34	24/28
Sonography	31/34	22/28
Stereotactic assisted minimal invasive biopsy	31/34	21/28
Breast MRI	7/34	0/28
History of cancer (except breast cancer), n	3/32	1/28

*¹ Does not sum-up to total n presumably due to inclusion of re-operation

*² Due to missing data values not always refer to the total N

Outcome Measures:

Table 2: Primary and secondary outcomes

	Cluster level		
	Intervention group Mean value [95% CI] 7 cluster	Control group Mean value [95% CI] 7 cluster	Cluster mean difference [95% CI]
Whole decision making process: Observer instrument			
MAPPIN-O _{dyad} ^{a,b} Total	2.29 [1.77 to 2.81]	0.42 [0.00 to 0.88]	1.88 [1.26 to 2.50]
MAPPIN-O _{patient} ^a Total	1.78 [1.40 to 2.16] [†]	0.30 [0.00 to 0.68]	1.48 [1.00 to 1.95]
MAPPIN-O _{professionals} ^{a,b} Total	2.23 [1.79 to 2.67] [†]	0.32 [0.00 to 0.68]	1.91 [1.42 to 2.40]
Decision coaching: Observer instrument			
MAPPIN-O _{dyadDC}	2.09 [1.68 to 2.49] [†]	n.a.	
MAPPIN-O _{patientDC}	1.45 [1.08 to 1.81] [†]	n.a.	
MAPPIN-O _{nurseDC}	1.92 [1.49 to 2.34] [†]	n.a.	
Decision coaching: Participants' assessment			
MAPPIN-Q _{patient} ^c	3.82 [3.72 to 3.93]	n.a.	
MAPPIN-Q _{nurse} ^c	3.46 [2.93 to 3.99]	n.a.	
Concordance patient-nurse (weighted T)	0.69 [0.41 to 0.96]	n.a.	
Decisional Conflict Scale			
Decisional conflict ^d patient	7.20 [1.52 to 12.89]	n.a.	
Decisional conflict ^d nurse	18.44 [11.91 to 24.96]	n.a.	
Uncertainty subscore ^e patient	22.42 [12.09 to 32.75]	n.a.	
Uncertainty subscore ^e nurse	27.50 [23.05 to 31.95]	n.a.	
Informed subscore ^f patient	2.01 [0 to 4.59]	n.a.	
Informed subscore ^f nurse	10.01 [0 to 23.72]	n.a.	
Value clarity subscore ^g patient	8.23 [0.63 to 15.84]	n.a.	
Value clarity subscore ^g nurse	14.21 [8.89 to 19.54]	n.a.	
Support subscore ^h patient	6.09 [0.23 to 11.95]	n.a.	
Support subscore ^h nurse	21.29 [8.84 to 33.74]	n.a.	
Effective decision subscore ⁱ patient	8.18 [0 to 17.76]	n.a.	
Effective decision subscore ⁱ nurse	19.31 [10.53 to 28.09]	n.a.	
Physician consultation: Participants' assessment			
MAPPINQ			
MAPPIN-Q _{patient} ^c	3.87 [3.78 to 3.96]	3.82 [3.68 to 3.96]	0.05 [-0.10 to 0.20]
MAPPIN-Q _{physician} ^c	3.42 [3.09 to 3.74]	3.44 [3.04 to 3.83]	-0.02 [-0.47 to 0.43]
Concordance patient-physician (weighted T)	0.71 [0.57 to 0.85]	0.67 [0.44 to 0.89]	0.04 [-0.19 to 0.28]
Decisional Conflict Scale			
Decisional conflict ^d patient	6.44 [2.22 to 10.66]	6.47 [0.00 to 13.37]	-0.03 [-7.24 to 7.17]
Decisional conflict ^d physician	15.53 [7.91 to 23.15]	17.27 [3.56 to 30.97]	-1.74 [-15.70 to 12.23]
Uncertainty subscore ^e patient	19.42 [15.92 to 22.91]	9.98 [0.00 to 20.10]	9.44 [-0.79 to 19.67]
Uncertainty subscore ^e physician	19.01 [8.74 to 29.29]	15.30 [5.15 to 25.45]	3.72 [-9.14 to 16.58]
Informed subscore ^f patient	0.89 [0.00 to 2.32]	6.42 [0.00 to 15.15]	-5.53 [-14.27 to 3.21]
Informed subscore ^f physician	12.40 [4.94 to 19.86]	28.80 [5.40 to 52.21]	-16.40 [-40.00 to 7.20]
Value clarity subscore ^g patient	8.84 [0.01 to 17.67]	4.28 [0 to 9.12]	4.56 [-4.40 to 13.52]
Value clarity subscore ^g physician	17.66 [8.71 to 26.61]	18.43 [1.69 to 35.16]	-0.77 [-17.67 to 16.13]
Support subscore ^h patient	2.60 [0.00 to 5.60]	4.38 [0.00 to 10.00]	-1.78 [-7.45 to 3.89]
Support subscore ^h physician	12.10 [4.55 to 19.66]	15.71 [2.25 to 29.17]	-3.61 [-17.35 to 10.13]
Effective decision subscore ⁱ patient	9.17 [1.92 to 16.41]	6.48 [0.00 to 13.63]	2.68 [-6.38 to 11.75]
Effective decision subscore ⁱ physician	12.23 [1.94 to 22.51]	10.39 [0.00 to 21.83]	1.84 [-11.86 to 15.54]
Informed choice %	47.66 [12.64 to 82.68]	0.00 [0.00 to 0.00] [†]	47.66 [12.64 to 82.68]
Risk knowledge ^j	69.66 [52.32 to 87.00]	45.28 [40.13 to 50.43] [†]	24.38 [6.94 to 41.83]
No. of correct answers ^k	8.36 [6.28 to 10.44]	5.43 [4.82 to 6.05] [†]	2.93 [0.83 to 5.02]
Proportion of patients with ≥ 9 correct answers (%)	48.05 [12.77 to 83.33]	0.00 [0.00 to 0.00] [†]	48.05 [12.77 to 83.33]
Duration of consultations			
Total ^l min.	58.1 [44.1 to 72.1] [†]	24.3 [18.4 to 30.2]	
Decision coaching, min.	47.5 [37.3 to 57.6] [†]	n.a.	
Physician consultation, min.	12.8 [6.7 to 19.0]	24.3 [18.4 to 30.2]	
Time between enrolment and coaching, days	5.7 [4.3 to 7.0]	n.a.	

Time between coaching and physician consultation, days	4.3 [0.2 to 8.4]	n.a.	
Time between enrolment and physician consultation, days	9.9 [5.2 to 14.5]	0.2 [0.0 to 0.7]	

n.a.=not assessed/not applicable; decision coaching was only part of the intervention group

[†]=only data of six clusters were available for analysis

[‡]scores: 0=the behavior was not observed; 1=the behavior was observed as a minimal attempt; 2=the basic competency was observed;

3=the behavior was observed to be a good standard; 4=the behavior was observed to be an excellent standard

^bin control group: Shared decision-making-behavior of physicians; in intervention group: mutual shared decision-making-behavior of nurses and physicians

^cscores: 0=fully disagree; 4=fully agree

^d0=no decisional conflict; 100=extremely high decisional conflict

^e0=feels extremely certain about best choice; 100 feels extremely uncertain about best choice

^f0=feels extremely informed; 100=feels extremely uninformed

^g0= feels extremely clear about personal values for benefits and risks/side effects; 100=feels extremely unclear about personal values

^h0=feels extremely supported in decision making; 100=feels extremely unsupported in decision making

ⁱ0=good decision; 100=bad decision

^j% correct answers

^kmaximum 12 points

^lcontrol group: duration of physician consultation; intervention group: duration of decision coaching and physician consultation

Adverse Events:

There were no adverse events associated with this trial.