### Table 2: Randomization, data collection, analyses and results

<table>
<thead>
<tr>
<th>Ref</th>
<th>a) Randomization type</th>
<th>b) N, n-intervention, and n-control</th>
<th>Outcomes</th>
<th>Outcome source (Validity account*)</th>
<th>a) Statistical methods b) Randomization evaluated? (yes, no) If yes: variables, potential differences and possible adjustment performed noted? c) Numbers included in analyses d) Intention-to-treat analyses (yes/no/not mentioned)</th>
<th>Main results</th>
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<td>[19]</td>
<td>a) Stratified, cluster (stratification at surgeon level (experience of surgeon’s breast cancer practice); Within each stratum randomization was performed in blocks of four. b) N(Surgeons)=60; N(Patients)=335, n-CM=169, n-control=166</td>
<td>Primary: cancer-specific therapies received (after 6 months) Secondary: patient evaluations of the decision-making process; arm function on affected side. (2 and 12) months after diagnosis.</td>
<td>Primary: medical records audit (A summary measure of receipt of appropriate therapy was created based on published consensus recommendations; ref) Secondary: home interview based on pilot tested questionnaires on logistics, decision-making, satisfaction and tamoxifen prescription (?) and objective assessment of arm functions (?).</td>
<td>a) Differences in baseline characteristics and in outcomes between control and intervention groups were assessed using Chi-square. (Cluster effect at surgeon level was adjusted for.) b) Yes. No difference found (demographics, cognitive function, and stage of disease) c) Primary outcome: n-CM: 169 and n-control 166 Secondary outcomes: ? d) Yes</td>
<td>Primary: More women in the intervention group saw a radiation oncologist at their initial evaluation (36.0 vs. 19.3%, P=0.006), received breast-conserving surgery (28.6 vs. 18.7%, p=0.031) and radiation therapy (36.0% vs. 19.0%; P=0.003). Secondary: Intervention group was significantly more satisfied (more components; p&lt;0.05) and had significantly more normal or near-normal range of arm motion (93 vs. 84%, p=0.037). (Several subgroup analyses: “Women with poor social support were most likely to benefit from the nurse CM intervention.”)</td>
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<td>[23]</td>
<td>a) Simple, two-arm randomization. b) N=210, n-int=106, n-control=104</td>
<td>-Quality of Life (QoL) (At enrolment + 1, 3, 6, 12, 18, 24 months after enrolment.) -Cost data (24 months after date of diagnosis).</td>
<td>-QoL measured with three self-administered questionnaires: 1. MUIS: uncertainty 2. POMS: mood 3. FACT-E: well-being/ QoL on six dimensions. (yes, all validated + ref) -Charges and reimbursements were collected from billing systems. Length of hospitalization and number of visit to health care</td>
<td>a) -Univariate analyses of QoL data: t-test + chi-square /Fisher’s exact test. Multiple regression for repeated QoL measures using baseline scores as a covariate. b) Yes (variables: demographics and disease characteristics). Difference found: Intervention group women had lower Uncertainty: Intervention group had less uncertainty at 1, 3 and 6 months (p&lt;0.05). Effect size not specified. Mood and well-being: no sign. diff. between int. and control group. Overall costs: no difference found including subgroup analyses. (Some subgroups benefitted significantly from APN, e.g. unmarried women and women with no family history of breast cancer).</td>
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### Ref 25

- **Randomization type**
  - a) Three-arm simple randomization
  - b) N=166, Numbers assigned to each of the “arms” N/A.

- **Outcomes**
  - a) Outcomes of interest*
    - (Time of measure)
  - b) Outcome source
    - (Validity account)

- **Main results**
  - a) Statistical methods
  - b) Randomization evaluated?
    - (yes, no)
  - If yes: variables, potential differences and possible adjustment performed noted?
  - c) Numbers included in analyses
  - d) Intention-to-treat analyses
    - (yes/no/not mentioned)

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<td>25</td>
<td>-Measures of Patient Psychosocial Responses (Five interviews at 6-week interval; first before group assignment.) -Number of hospitalizations -Length of Stay (LOS) (continuously through 24 weeks).</td>
<td>-Cost of APN services were based on time logs.</td>
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<td>-Psychosocial responses: Interview questionnaire (in-person or telephone?); Scales: Symptom distress (The Symptom Distress Scale); Pain (McGill-Melzack Pain Questionnaire); Current Concerns (Weisman and Worden’s Inventory of Current Concerns); Mood state (Profile of Mood States) Functional status (General Health Rating Index) (ref to all above) -A Medical Record Review Instrument was developed.</td>
<td>-histology (p=0.04) and more received adjuvant hormone therapy (p=0.03); adj. performed. c) QoL: ? Cost data: N=152 (n-int=78, n-control=74; 58 excluded because of missing data) d) Not mentioned</td>
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**Main results**

- **Psychosocial Responses**
  - Significant difference between the profiles of the two nursing groups and the office care group with regards to adjusted Symptom Distress (P=0.03) and adjusted Enforced Social Dependency (P=0.02) in favour of home care nursing. The OC group rather steadily reported improved health perceptions over time, whereas the two treatment groups reported worse health perceptions (p<0.05). No of hospitalizations and LOS: No significant differences
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|     | a) Randomization type  
b) N, n-intervention, and n-control | **Outcome of interest**  
(Time of measure) | **Outcome source**  
(Validity account) |
|     | **Outcomes of interest** | **Outcome source**  
(Validity account) |
|     | a) Simple randomization.  
b) N=375, n-intervention=190, n-control=185 | Primary: Length of survival  
(up to 44 months of follow up)  
Secondary: To identify psychosocial and clinical predictors of patient survival (i.e. depressive symptoms, symptom distress, functional status, co-morbidities, length of hospital stay, age, and cancer stage).  
(baseline, 3, and 6 months) | Survival status was ascertained by letter, telephone, or death certificates (?)  
Demographics: “obtained at accrual” (?)  
Stage of disease: Surgical pathology reports and physician’s discharge summary (?)  
Psychosocial questionnaires: Center for Epidemiological Studies-Depression Scale (CES-D), Symptom Distress Scale (SDS), and Enforced Social Dependency Scale (ESDS) (ref to all) |
| [24] | a) Stratified log-rank test was used to compare groups. Kaplan-Meier curves stratified by stage of disease at diagnosis.  
Cox’s proportional hazards regression model to compute adjusted hazard ratios (=HR; Proportional hazards assumption was Schoenfeld tested)  
b) Yes (demographics and clinical variables; more late stage patients in intervention group (p=0.013). Adjusted and stratified analyses performed.  
c) Survival status for all 375 included patients were obtained  
Psychosocial questionnaires responderse: time 0: n-int=190 n-UC=185; time 3 months: n-int=163, n-UC= 153; time 6 months: n-int=158, n-UC=147)  
d) Not mentioned | Non-stratified analyses revealed no difference in survival status between groups (p=0.129).  
Stratified analyses:  
Late-stage patients’ 2-year survival were 66.7% in int. group vs. 39.6% in control group (p<0.05). Adjusted for psychosocial and clinical covariates:  
Usual care had death-HR=2.04 (95% CI 1.33-3.12, p=0.001)  
Late stage usual care patients had adjusted death-HR=4.55 (CI 2.92-7.08; p<0.001)  
Outcomes of psychosocial questionnaires were not mentioned at all in results paragraph. |
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| [26] | **Outcomes of interest**<sup>*</sup>  
(Time of measure)  
- Patients’ evaluations of patient/provider communication, satisfaction with care and attitudes about participation in treatment planning (enrolment, at 3 and 6 months)  
- Surrogates’ experiences with the health care system. (3 months post-enrolment.)  
- Costs (end of study)  
- Advance directives (AD) and do-not-resuscitate and intubate (DNR[I]) (enrolment, 3 and 6 months) | Patient/provider communication, satisfaction with care: Investigator-constructed, 10-item scale (questionnaire or interview?)  
Participation in treatment planning was assessed by a single item (questionnaire or interview?)  
Surrogates’ experiences (problems in 7 domains were averaged to create a single overall rating): Modified EOL Family Interview (questionnaire or interview?) | **Main results**  
Patient satisfaction with care: Significant group-by-time interaction in favour of the AICCP group (Effect size 0.18, \( P = 0.03 \)).  
(Effect size is the ratio of the estimated treatment effect.)  
Surrogates post-test scores: Fewer problems (with the spiritual and emotional support delivered) reported by AICCP surrogates than UC surrogates (effect size 0.39, \( p = 0.03 \))  
Costs: No stat. sign diff.  
AD: Median time to completion of first AD: AICCP=46 days vs. UC= 238 days (log-rank \( P=0.02 \))  
Proportion of patients having completed at least one AD, and the mean numbers of ADs per patient were sign. higher for the AICCP group at both 3 and 6 months (\( p=0.01 \)). |
| a) Block-randomization (blocks of 10; rationale not outlined)  
b) N=275; n- AICCP=133, n- UC=142 ; N-surrogates (relatives)=168, n- sAICCP =76, n- sUC=92. | a) Statistical methods  
b) Randomization evaluated? (yes, no)  
If yes: variables, potential differences and possible adjustment performed noted?  
c) Numbers included in analyses  
d) Intention-to-treat analyses (yes/no/not mentioned) | a) Patients’ evaluations: Scores were examined for effects of group, time, and group-by-time interaction using a random effects regression model.  
Surrogates’ exp.: Post-intervention scores t-test compared.  
AD: Chi-square comparison and Kaplan-Meier curves comparison of group membership and time to completion of ADs.  
Costs: F test  
Effect sizes were calculated for most outcomes.  
b) Yes, (Patients’ demographics and diagnoses (and later survival), no diff.; surrogates: No of participants, sex and relationship: no diff.)  
c) Patients and surrogates evaluations: ?  
Mean per case AICCP costs: Data for 70 VAMC patients.  
Other costs:169 VAMC patients (AICCP=93, UC=76).  
AD etc: data on 180 VAMC patients (AICCP= 85 and UC=95)  
d) Yes, all outcomes (18 patients crossed over to AICCP, two |
| Ref | a) Randomization type  
b) N, n-intervention, and n-control | Outcomes | Outcome source  
(outcomes of interest*  
(time of measure)) | a) Statistical methods  
b) Randomization evaluated?  
(yes, no)  
If yes: variables, potential differences and possible adjustment performed noted?  
c) Numbers included in analyses  
d) Intention-to-treat analyses  
(yes/no/not mentioned) | Main results |
|-----|-------------------------------------------------|----------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|
|     | a) Stratified randomisation (six strata; three strata based on unmet need status, and two strata based on gender).  
b) N=259, n-CM=130, n-control=129 | -Unmet needs (assessed by patients)  
-Reported symptom severity  
-Several dimensions of QoL  
-Formal service utilization (data collection: At baseline, at 3 and 6 months) | -Aspects of daily living (three unmet needs-categories) (ref)  
-Standard questions on symptom severity (?)  
-Spitzer’s physical “QoL Index”(ref), five-item mood state score from SF-36 (ref), and a specially developed 4-item scale measuring patient experienced disruptions in treatment (?)  
All above: Telephone interviews  
-Service utilization: Patients’ reports and audit of patients’ medical records. | a) Chi-square and analysis of variance to test differences between intervention and control groups  
b) yes (no difference found on baseline demographic, medical and need status)  
c) 3 months: n-CM=109, n-control=108, 6 months: n-CM=93, n-control=92  
d) Not mentioned; unclear if 11 CM group patients who refused CM services were followed up and in which group they were analysed (?) | No statistically significant differences were observed on any outcome measure for the overall sample as well as for selected “at-risk” patient subgroups. |
| Ref | a) Randomization type  
b) N, n-intervention, and n-control | Outcomes | a) Statistical methods  
b) Randomization evaluated?  
(yes, no)  
If yes: variables, potential differences and possible adjustment performed noted?  
c) Numbers included in analyses  
d) Intention-to-treat analyses  
(yes/no/not mentioned) | Main results |
|-----|---------------------------------|---------|-------------------------|---------------------|
| 27  | a) Stratified randomisation according to hospital and treatment intent (rationale and numbers of strata not outlined)  
b) N=203 (n-nurse led follow-up=100, n-control=103) | Primary: QoL and patients’ satisfaction at three months (assessed at baseline, 3, 6, and 12 months)  
Secondary: Overall survival, Symptom-free survival, Progression-free survival. GPs’ satisfaction (at the end of study participation). Service use (3, 6 and 12 months) and cost effectiveness | -EORTC QLQ-C30 and module about lung cancer. (ref)  
-Patient satisfaction questionnaire incorporating three validated measures and tested in a pilot study (ref)  
No information on source of secondary outcomes. | Int. group had less dyspnoea (p=0.03; a QoL score) and significantly higher satisfaction in each subscale at three months.  
Int. group had longer time to symptomatic progression (p=0.01). Significant change in pattern of service use, but no difference in readmission rates. Significantly more patients in int. group died at home (p=0.04).  
No difference in costs, and GP satisfaction. |

* Not to be found in the article

* Outcomes of interest: if primary and secondary was not indicated, “-” are used in front of each

*Validity account categorised as follows: ?: validity not mentioned at all; ref: reference(s) quoted; yes: it is mentioned that measure is validated