Evaluating Fatigue of Ovarian Cancer Patients with Ecological Momentary Assessment

Karen Basen-Engquist, Ph.D.
Carl de Moor, Ph.D.
Dept. of Behavioral Science

THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER

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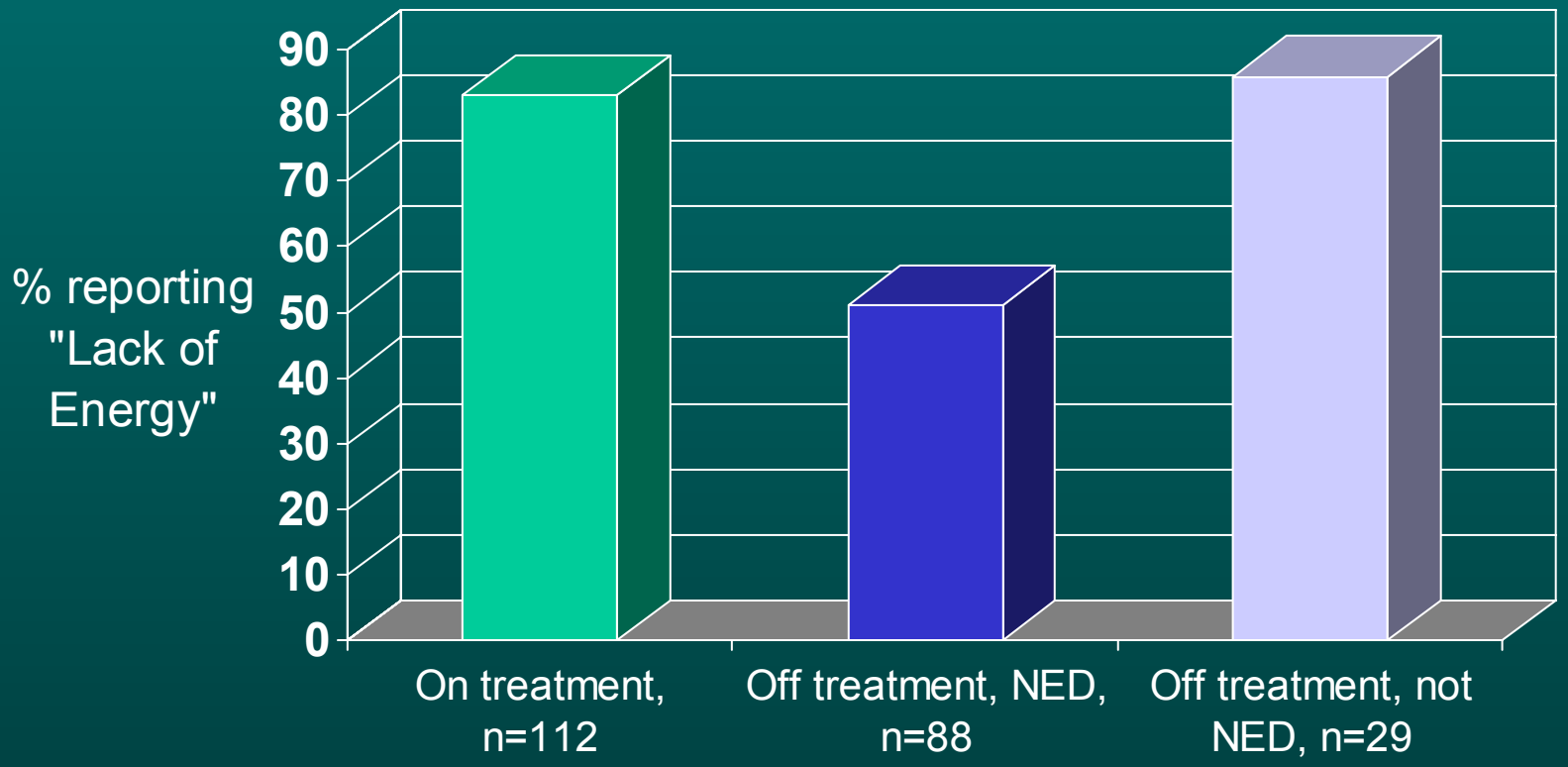
Collaborators

- **Behavioral Science**
  - Cindy Carmack, Ph.D.
  - Lorenzo Cohen, Ph.D.
- **Gynecologic Oncology Center**
  - Diane Bodurka, M.D.
  - Judith Wolf, M.D.
  - Michael Bevers, M.D.
  - Charles Levenback, M.D.
  - Andrzej Kudelka, M.D.
- **Fatigue Clinic**
  - Carmen Escalante, M.D.
  - Ellen Manzullo, M.D.
- **Current and Former Staff**
  - Geeta George, M.P.H.
  - Mariana Pope, J.D.
  - Mary A. Fitzgerald, M.A.

Ovarian Cancer

- Usually diagnosed at a late stage (III or IV)
- Generally responds to first line chemotherapy (~73%), but recurrence is common even among those with complete response (50%)
- 5 year survival ranges from 41% (Stage IIIa) to 11% (Stage IV)

Ovarian Cancer Patient Fatigue by Treatment Status



Specific Aims

- Pilot test EMA methods using palm-size computers for recording treatment-related symptoms of women with ovarian cancer
- Assess pattern of fatigue over a chemotherapy cycle
- Evaluate whether fatigue can be predicted by physical activity, mood, pain, and nausea
- Identify more efficient ways to sample time periods and collect data

Rationale for using EMA

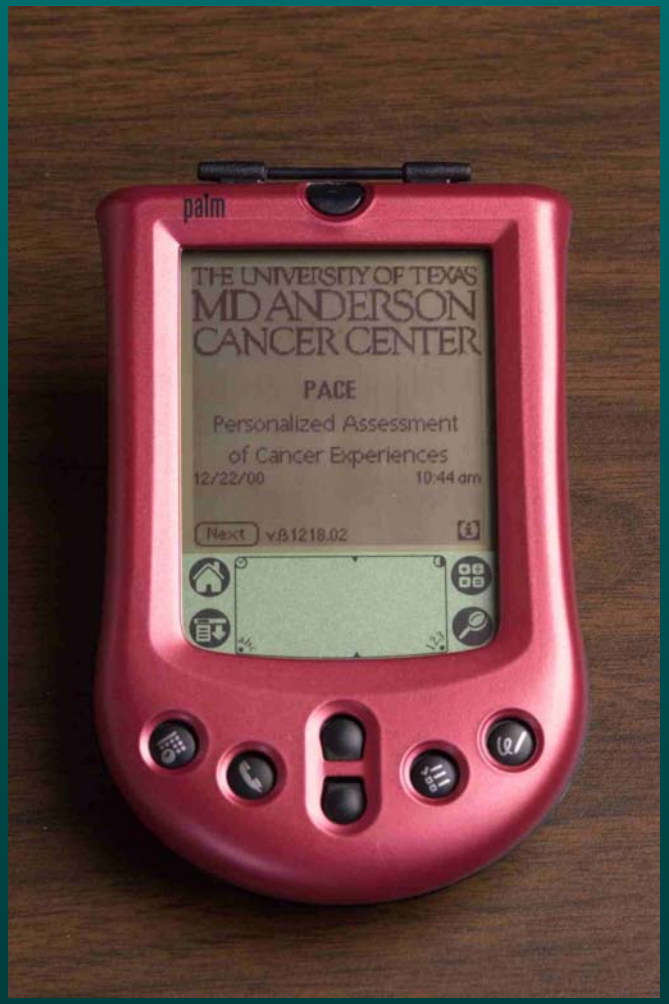
- Look at the patterns of fatigue over time
- Potentially better measurement of physical activity and other variables, less error due to recall issues
- Test relationships between physical activity and fatigue between and within persons; is energy conservation or exercise best way to deal with fatigue, short-term or long term effects of activity

Sample

- Patients with advanced ovarian cancer, receiving carboplatin and/or paclitaxel
- 19 newly diagnosed, 14 persistent or recurrent disease
- Average age, 58.5, range 27-81
- Education, 7 - high school or less, 12 - some post-high school education, 5 - college graduate, 6 - post-graduate

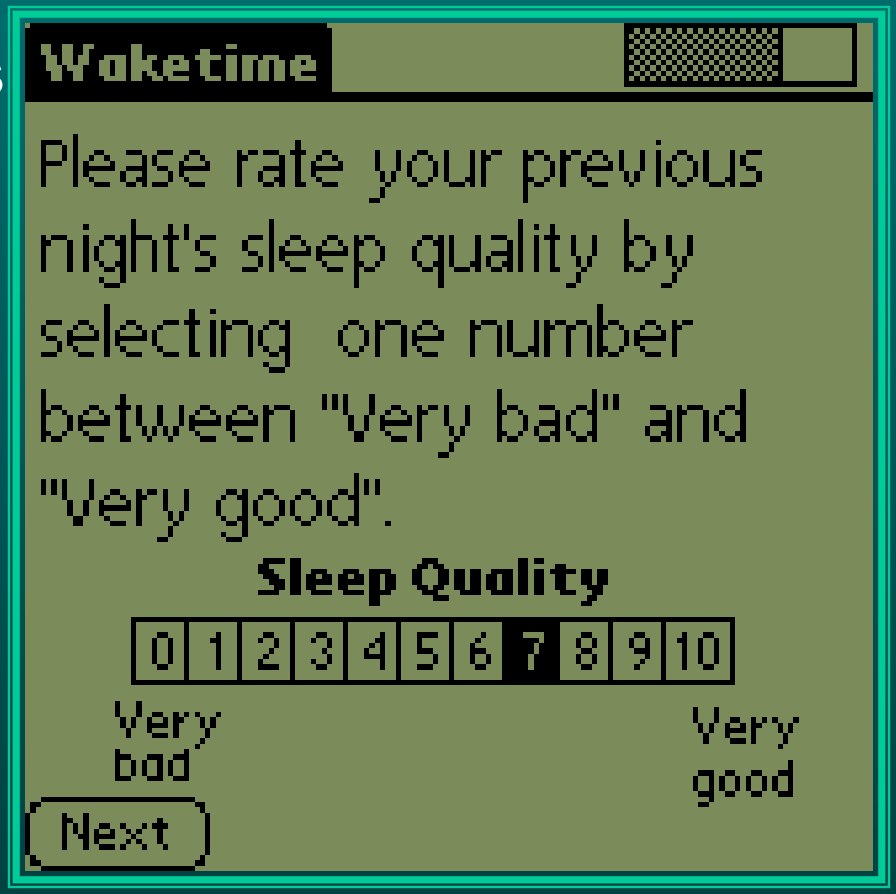
Data Collection Device

- Palm m100, m105
- Runs on 2 AAA batteries
- 4.7” x 3.1” x .7”
- 4.4 ounces
- 2 megabytes of RAM (8 MB in the m105)

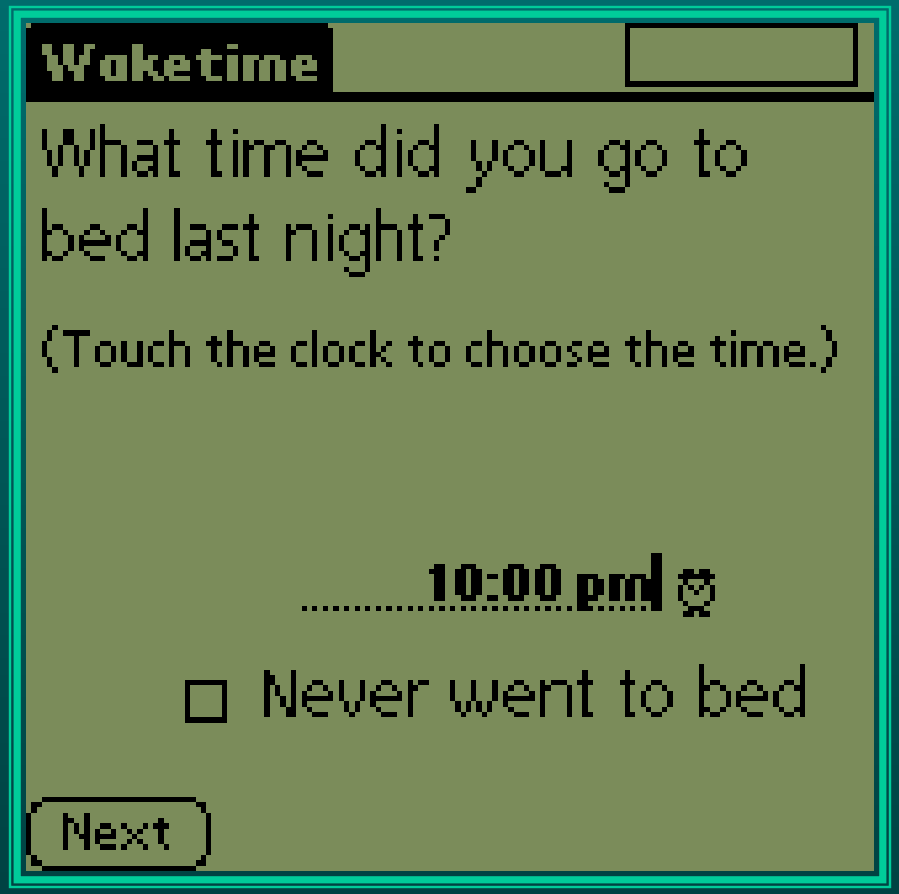


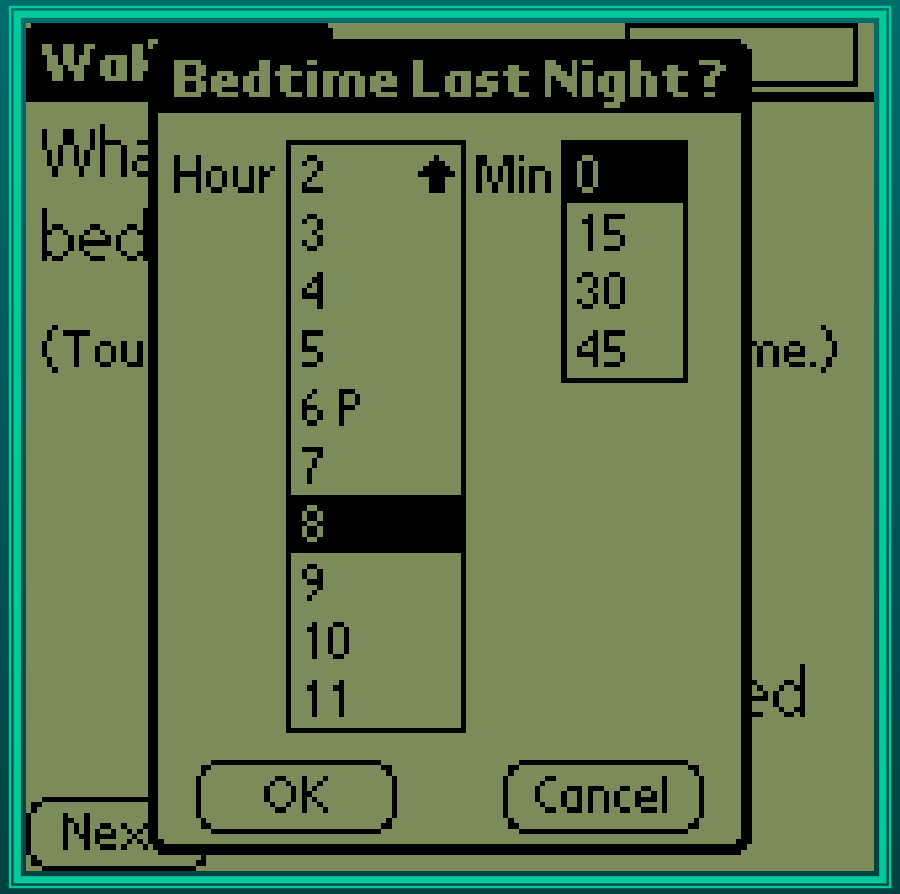
Scheduled Assessments

- 2 scheduled assessments
- Waketime: assessed sleep quantity and quality (Pittsburgh Sleep Diary)
- Bedtime: assessed fatigue (Brief Fatigue Inventory) and naps, caffeine and alcohol consumption, smoking



Waketime Assessment

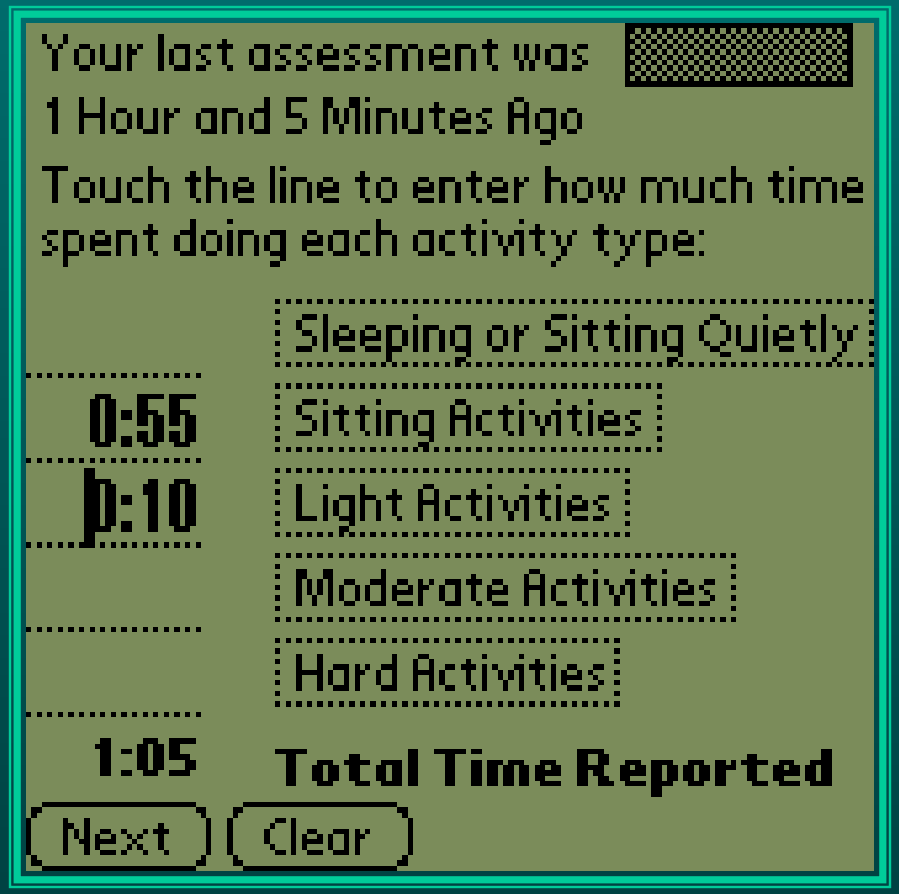




Random Assessments

- Four random daytime assessments
- One before noon, two between noon and 6 pm, one after 6 pm, not less than 1 hour between assessments
- Repeated alarms if no response, must complete assessment within 30 minutes
- Assessed fatigue, pain, nausea, trouble concentrating, mood, PA

Random Daytime Assessment



Participant Training

- At start of data collection research coordinators demonstrated data entry, let participants try it on a demo computer
- Participant manual
- Called participants the first 3 days
- Could call research coordinator when problems arose
- Met with participants once a week

Feasibility: Recruitment (Site 1)

- A total of 59 M. D. Anderson patients approached; 30 (51%) enrolled in the study
- Reasons for not participating
  - 10 had concerns about study demands, disruptiveness, using computer
  - 12 not interested in participating in research, or already involved in another study (8)
  - 1 had too much going on, difficult time
  - 6 gave no specific reason for refusing

Feasibility: Recruitment (Site 2)

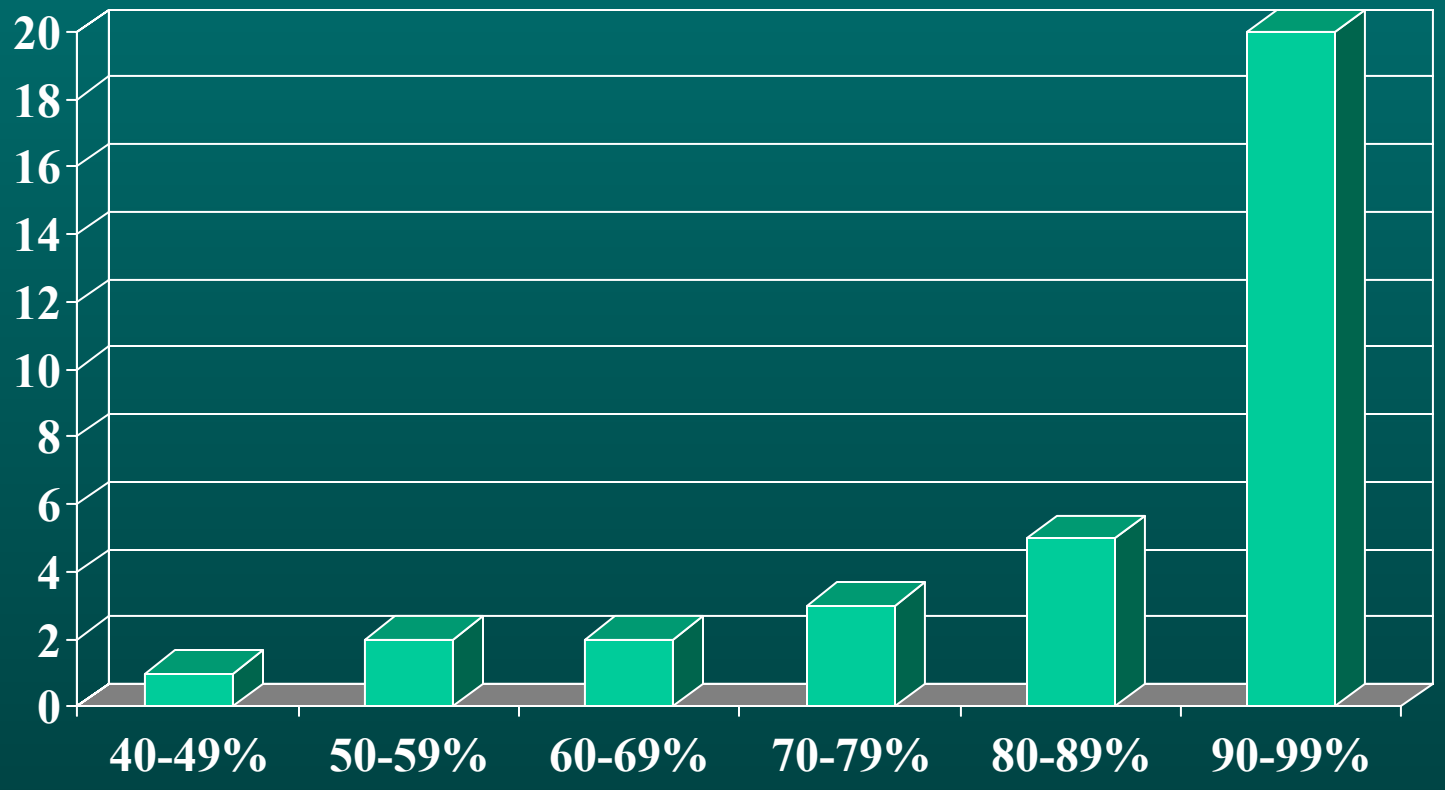
- First stage of recruitment done by chemotherapy nurse at 2nd site, no data on the number who refused to meet with our research coordinator (“most agreed”)
- Of those patients who met with research coordinator, none refused
- 12 patients were enrolled at this site

Feasibility: Retention

- 42 participants enrolled
- 4 were taken off study because chemotherapy regimen changed
- 5 dropped out
  - 3 dropped out before they started the data collection
  - 2 dropped out because the computer was too disruptive
- 33 patients completed the study

Feasibility: Data Completeness

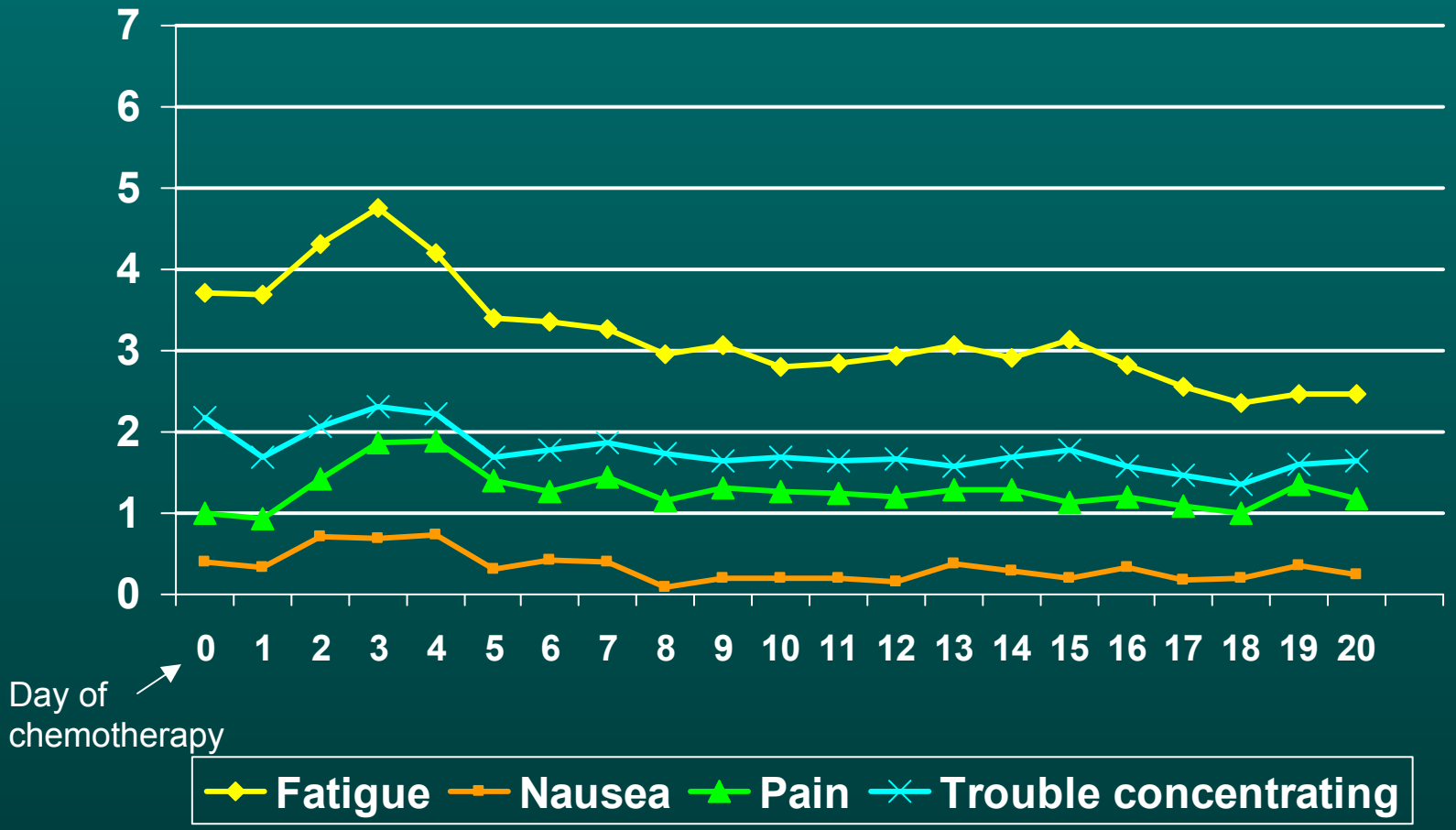
Average % of assessments completed: 86%



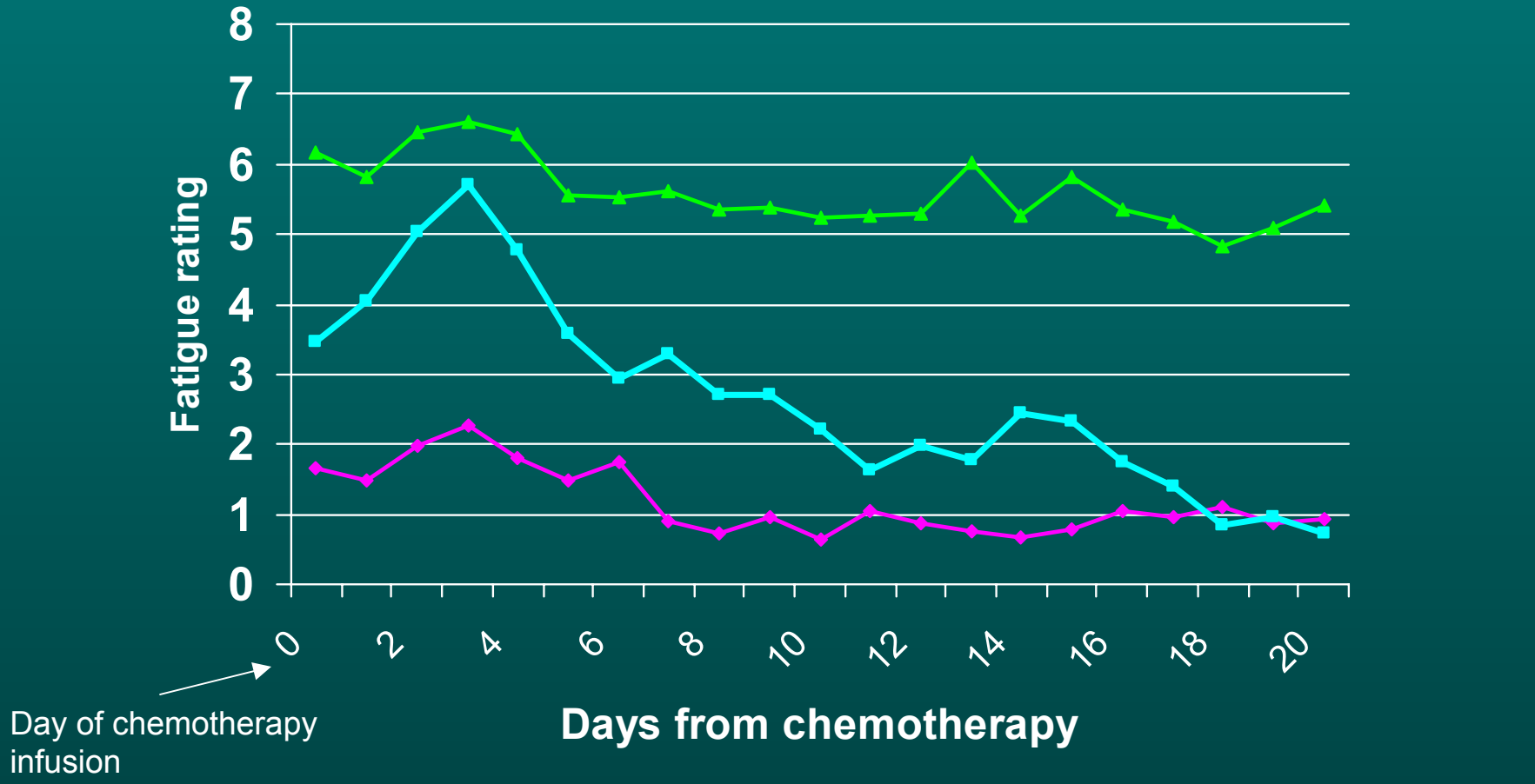
Analysis – Fatigue Patterns

- Descriptive analyses
- Regression of fatigue on days from chemotherapy infusion
- Hierarchical cluster analysis of regression parameters from each patient's data
- Differences among clusters tested with chi-square, analysis of covariance, multi-level models

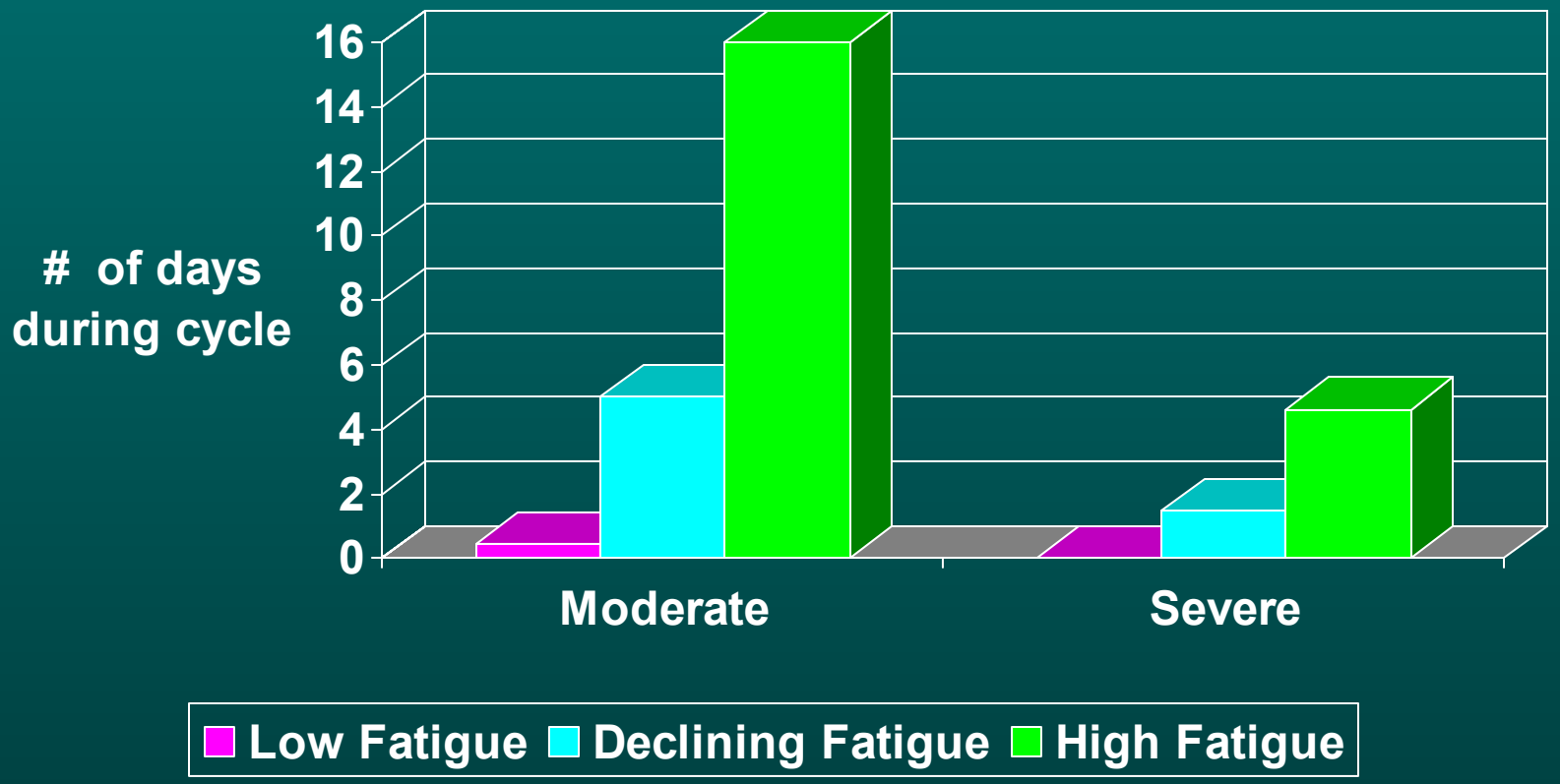
Patterns of Fatigue and Other Symptoms over Chemotherapy Cycle



Fatigue Pattern Clusters, 3 Cluster Solution



Number of Days with Moderate and Severe Fatigue by Cluster



p=.000 for moderate fatigue
p=.036 for severe fatigue

Relationship of Demographic and Medical Variables to Cluster Membership

- Few significant differences between clusters
  - High fatigue cluster had higher BMI, p= 0.02
  - Decreasing likelihood of being married as fatigue level increased (p=0.07, linear trend)
  - increasing age with fatigue level of cluster (p=0.10, linear trend)
  - Declining fatigue cluster more likely to have newly diagnosed disease, p=0.119
  - High fatigue cluster more likely to be taking anti-depressants or anxiolytics, linear trend p=0.009

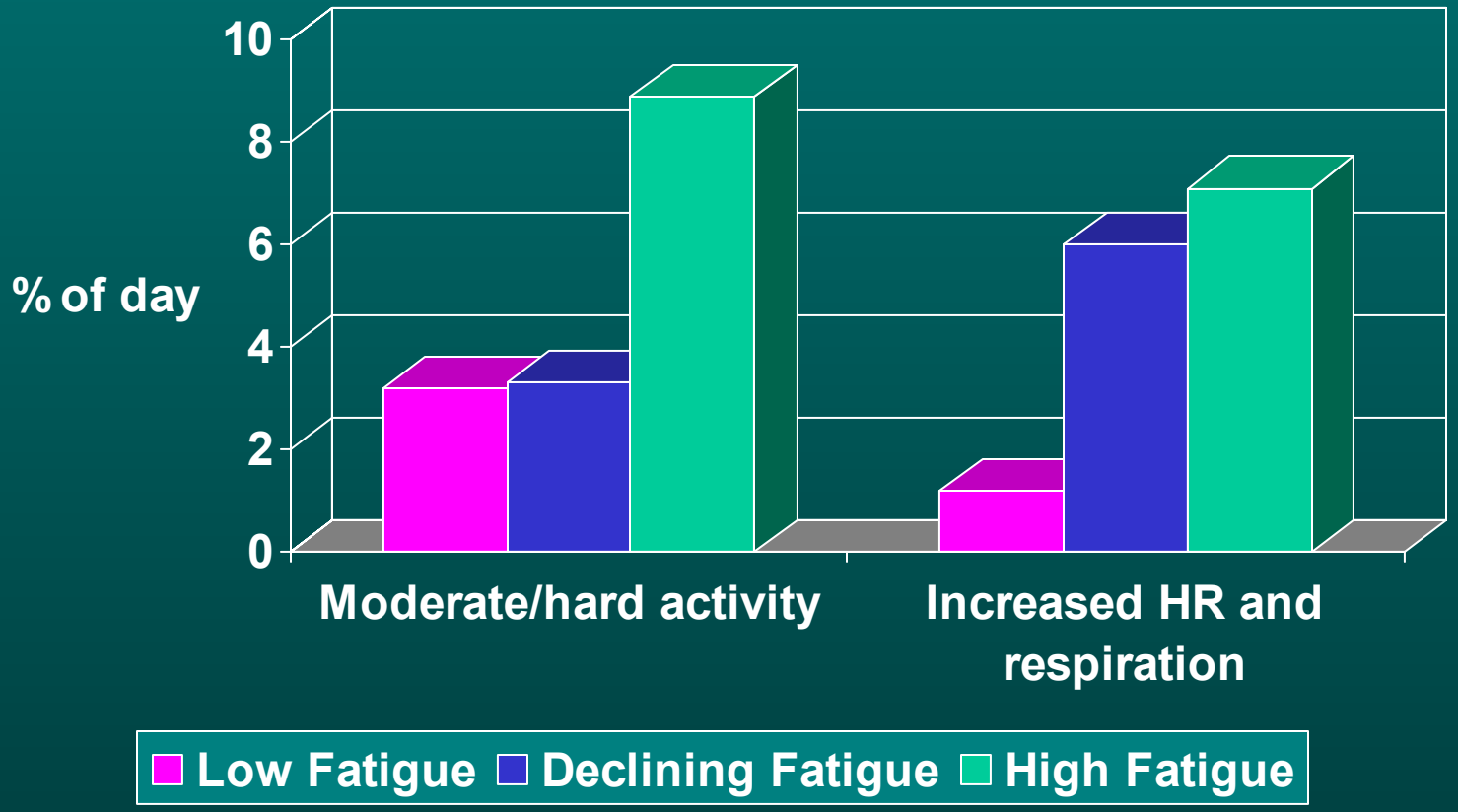
Differences among Clusters in Baseline Quality of Life, Sleep, and Depression

- High fatigue cluster had poorest quality of life in physical and functional domains and ovarian cancer-specific concerns (p=0.003, 0.022, and 0.000, respectively)
- High fatigue and declining fatigue clusters had poorer overall sleep (p=0.001). Clusters also differed significantly in subjective sleep quality, sleep latency, and sleep disturbance.
- Depression strongly associated with cluster.

Physical Activity and Fatigue

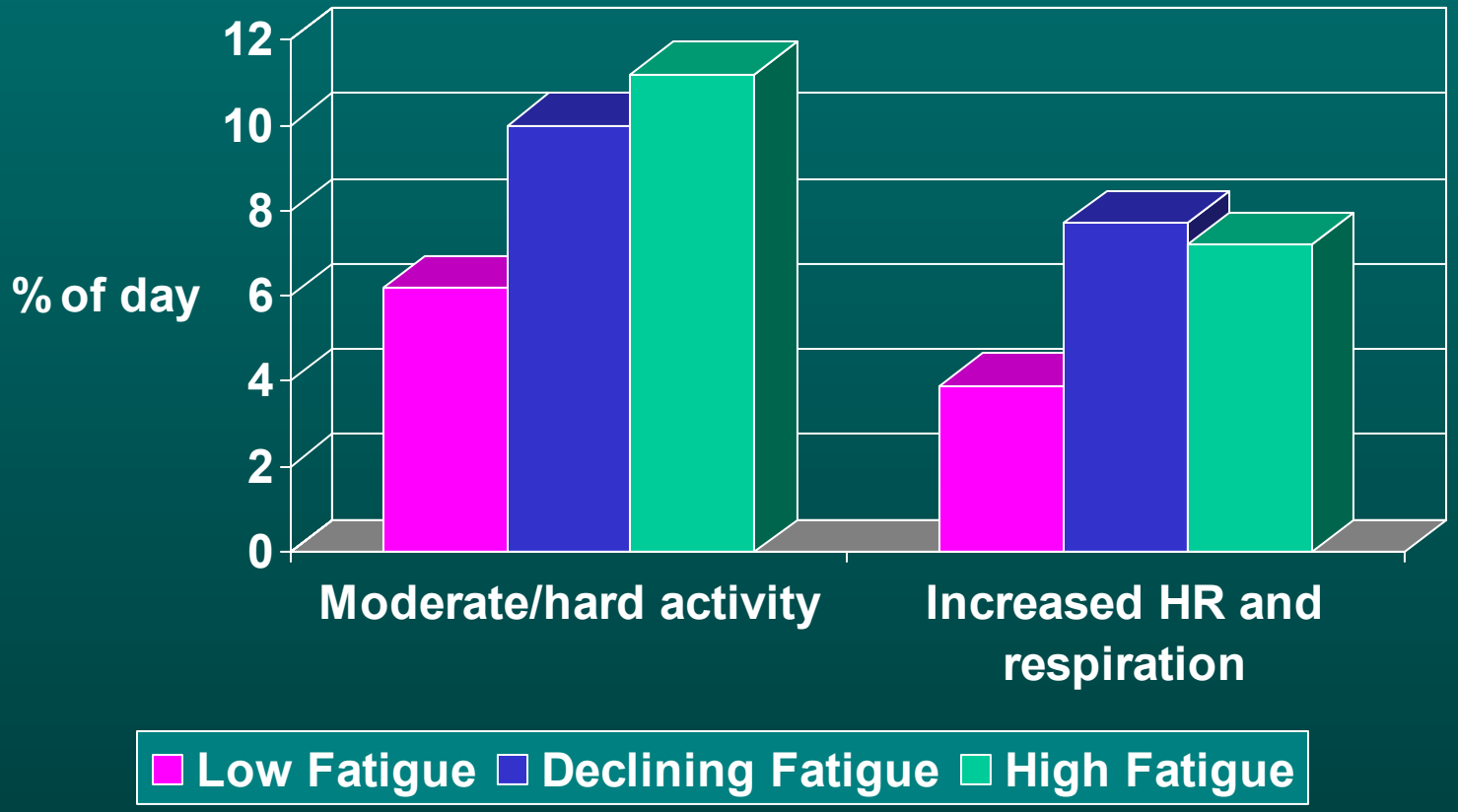
- Were participants in the low fatigue group engaging in more moderate or greater intensity physical activity than those in the high fatigue group?
- Activity aggregated to the day level, activity variables included:
  - % of the day they were engaged in moderate or more intense activity
  - % of day engaged in activity that increased their heart rate and respiration

Physical Activity During Week after Chemotherapy and Cluster Membership



Moderate/hard activity, p=0.007 (controlling for BMI, p=0.016)
Increased heart rate/respiration, p=0.016 (controlling for BMI, p=0.027)

Physical Activity During Weeks 2 and 3 after Chemotherapy and Cluster Membership



Moderate/hard activity, p=0.230 (controlling for BMI, p=0.213)
Increased heart rate/respiration, p=0.112 (controlling for BMI, p=.054)

Conclusions

- EMA is a feasible approach for symptom assessment, although some patients may be uncomfortable with the demands or have disabilities that limit their use of the computer
- Relatively high refusal rate, at least partly due to demands of study and/or using computer

Conclusions

- Three distinct patterns in fatigue over the chemotherapy cycle: low, high, declining
- Groups differ in baseline quality of life,but few differences in medical variables
- High fatigue cluster had highest level of moderate/hard physical activity
  - Differences due to different population, treatment?
  - Differences in type of activity - intentional exercise vs. lifestyle physical activity

Lessons Learned: Hardware

- Problems with power loss, rechargeable batteries may be better
- Need device with a vibrating alarm – less disruptive and more accessible to patients with hearing loss
- Some patients complained of difficulty seeing screen because of glare and size of font – backlit screen would help, need to be mindful of font size

Lessons Learned: Design

- Less repetition, shorter assessments
- Multiple random assessments during the day may not be necessary to measure fatigue
- Participants found random assessments more disruptive and annoying than scheduled assessments
- Participants wanted assessments to be more tailored - didn’t want to answer repeated questions on nausea if that was not a problem for them