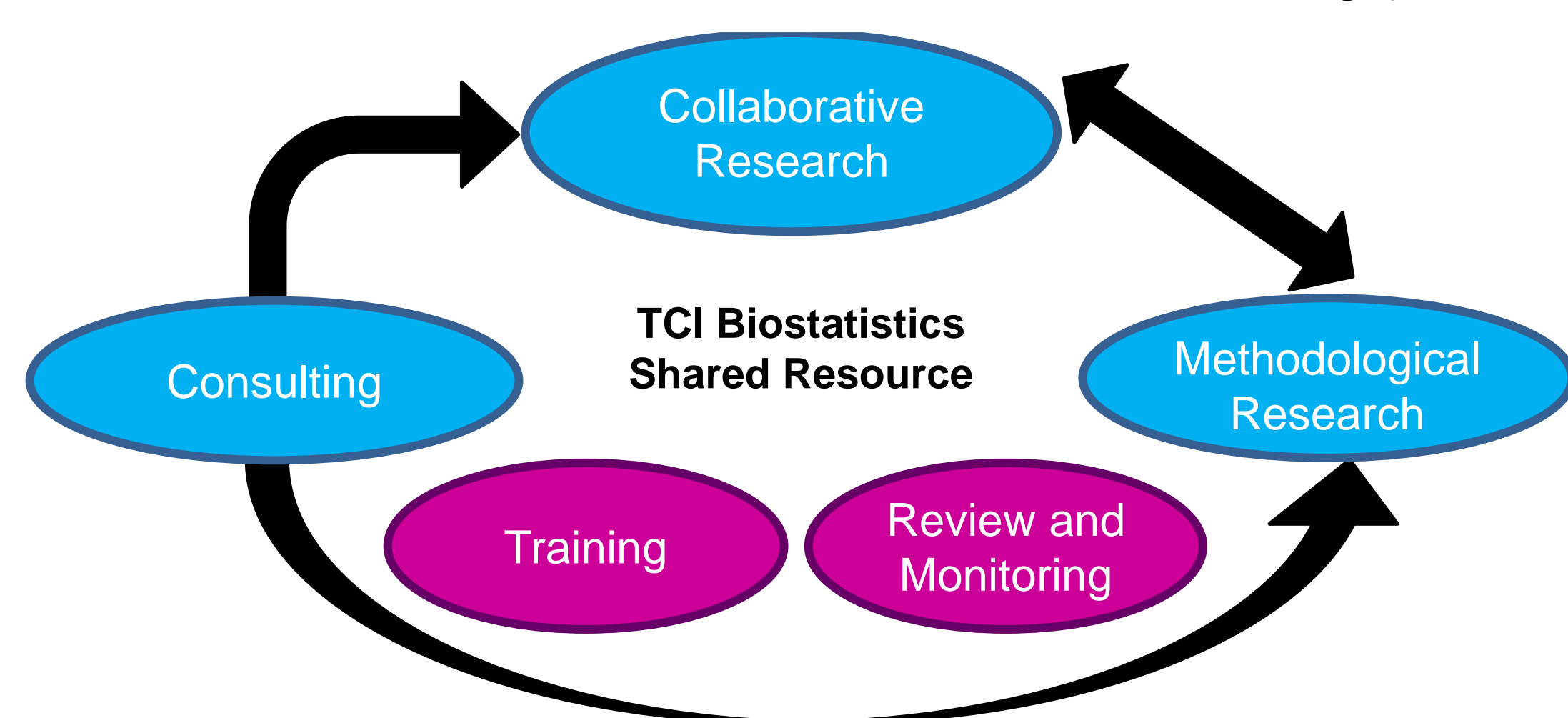


Mission Statement: Tisch Cancer Institute Biostatistics Shared Resource aspires to ensure availability of biostatisticians with expertise in all cancer types and all statistical methodologies.

Services

- Planning of study design and power calculation
- Writing for statistical analysis plans
- Conducting statistical analysis
- Interpretation of findings in published literature
- Assistance with manuscript/grant preparation and revision
- Training on new topics
- Seminars on ongoing work
- Do's and don'ts of software use
- Review/Monitoring (PRMS and DSM)



Accessibility Policies

Access:

Biostatistics Shared Resource is available to any cancer investigator in the Icahn School of Medicine at Mount Sinai. These investigators include basic scientists, clinicians, epidemiologists, psychologists, and behavioral scientists. Investigators are able to access the facility via online requests for new projects through the facility website or by contacting the members directly for work on ongoing investigations.

Priority:

Requests for statistical support submitted via the online system are assigned to members by the shared resource director using the priority formulation of:

- P1A. Preparation of NCI/NIH grant submission
- P1B. Analysis of NCI/NIH funded projects (presentation to scientific meetings and manuscript submission are given higher prioritization)
- P1C. Planning of Investigator-initiated clinical studies
- P2A. Preparation of grant submission to non-NIH agencies
- P2B. Analysis for projects funded by non-NIH agencies (presentation to scientific meetings and manuscript submission are given higher prioritization)
- P3. All others (unfunded exploratory or training related work)

76 cancer investigators utilized this resource in 2014

Types of Analysis

- Survival analysis: Cause-specific and Competing risks/cumulative incidence
- Analytic procedures for missing data
- Trend analysis
- Prognostic and predictive modeling; validation
- Principal components factor analysis
- Structural equation modeling
- Tests for interaction effects in animal experiments testing new treatments
- Observational studies with multilevel modeling and propensity score matched analysis

Staff



Madhu Mazumdar, PhD
Shared Resource Director
Program Area: Liver Cancer, Neuro-oncology, Radiation Oncology, Imaging, Head and Neck



James Godbold, PhD
Associate Director
Program Area: Cancer Mechanisms GU, Heme-lymphoid, Heme-myeloid



John Mandeli, PhD
Biostatistician
Program Area: Cancer Immunology, Breast, GYN, phase I Expt Tx



Sylvan Wallenstein, PhD
Biostatistician
Program Area: Cancer Prevention & Control, GI



Gary Winkel, PhD
Biostatistician
Program Area: Cancer Prevention & Control, Breast



Umut Özbek, PhD
Biostatistician
Program Area: Cancer Immunology, Lung, Sarcoma, Melanoma, Pediatrics, Bone Marrow Transplant



John Spivack, PhD
Biostatistician
Program Area: Liver Cancer Head and Neck, HCC, Radiation Oncology



Kezhen Fei, MS
Biostatistician
Program Area: Cancer Prevention & Control, Breast, Ovarian, Prostate



Erin Moshier, MS
Biostatistician
Program Area: Cancer Mechanisms, GU, Heme-lymphoid, Heme-myeloid

Recent Publications

- Galsky MD, Krege S, Lin CC, Hahn N, Ecke TH, **Moshier E**, **Godbold J**, Oh WK, . . . Bamias, A. Cisplatin-based combination chemotherapy in septuagenarians with metastatic urothelial cancer. *Urol Oncol*. 2014 Jan;32(1):30
- Bickell NA, Geduld AN, Joseph KA, Sparano JA, Kemeny MM, Oluwole S, **Fei K**, Leventhal H. Do community-based patient assistance programs affect the treatment and well-being of patients with breast cancer? *J Oncol Pract*. 2014 Jan; 10(1):48-54
- Blank S, Wang Q, Fiel MJ, Luan W, Kim KW, Kadri H, **Mandeli J**, Hiotis SP. Assessing prognostic significance of preoperative alpha-fetoprotein in hepatitis B-associated hepatocellular carcinoma: normal is not the new normal. *Ann Surg Oncol*. 2014 Mar;21(3):986-94
- Solan S, **Wallenstein S**, Shapiro M, Teitelbaum SL, . . . Boffetta P, Landrigan PJ. Cancer Incidence in World Trade Center Rescue and Recovery Workers, 2001-2008. *Environ Health Perspect*. 2013 Jun;121(6):699-704

Statistical Methodology

- Estimating odds ratios under a case background design (Spivack)
- Meta-analysis of proportions of rare events (Mazumdar)
- Predictive modeling for cancer drug sensitivity (Özbek)

Types of Designs

- Phase I designs: Standard and Continual-Reassessment Methods
- Phase II designs: Standard and those with Bayesian stopping rule
- Phase III designs: Group-Sequential and Adaptive Designs
- Randomized block and factorial designs for animal experiments

Recent Trials

PI: Friedlander P. (Cancer Immunology)

Biostatistician: Godbold J.

Sponsor: Dekk-TEC

Protocol: Safety and Tolerance of Intravenous 4-methyl-4cholesteryloxy carbonylpenlomedicine (DM-CHOC-PEN) in Patients with Malignancies Involving the Central Nervous System

PI: Oh WK. (Cancer Mechanisms)

Biostatistician: Godbold J.

Sponsor: Sanofi

Protocol: Prostate Cancer Intensive, Non-Cross Reactive Therapy for CRPC (Castration Resistant Prostate Cancer)

PI: Taouli B. (Liver Cancer)

Biostatistician: Mandeli J.

Sponsor: Icahn School of Medicine at Mount Sinai

Protocol: Fast MRI compared to ultrasound for diagnosis of HCC

Example of Interaction

PI: Redd WH. (Cancer Prevention & Control)

Biostatistician: Winkel G.

Sponsor: NCI

Protocol: Treating Cancer-Related Fatigue Through Systematic Bright White Light

- RCT comparing effects of 4 weeks of daily 30-minute exposure to Bright White Light (BWL) [like that used for seasonal affective disorder] and Dim Red Light (DRL) on fatigue (36 patients)
- At the end of the 4-week intervention, no patients in the BWL condition were still clinically fatigued (FACIT-Fatigue score >30), whereas 55% of patients in the DRL condition were still clinically fatigued.

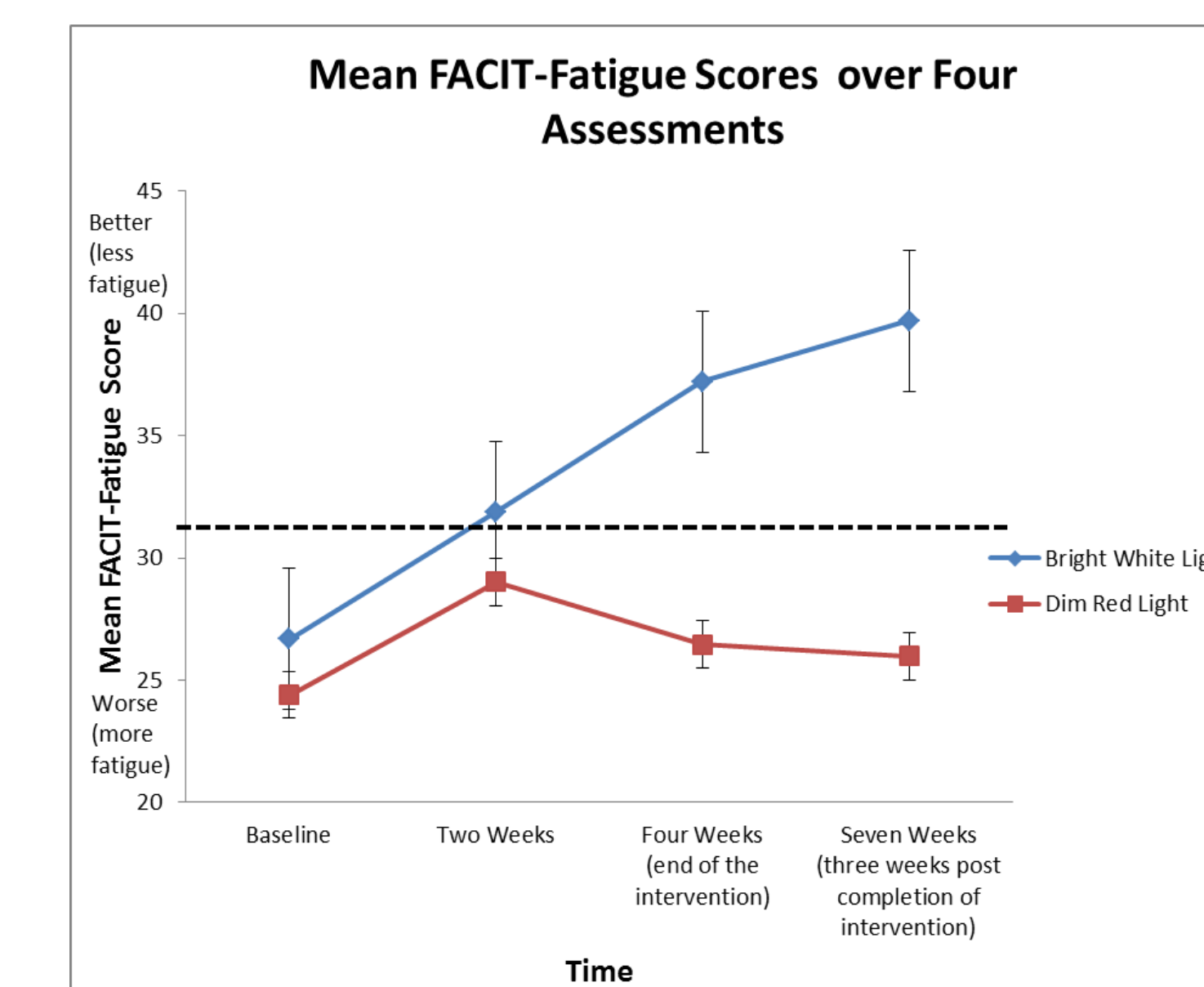


Figure 1
Mean FACIT-Fatigue scores for BWL and DRL conditions over four assessment time points. Higher FACIT-Fatigue score corresponds to less fatigue. FACIT-Fatigue score equal to or less than 30 constitutes clinically significant fatigue. Standard errors are given

- Using a linear mixed model repeated measures analysis (SAS Proc MIXED), there was a significant time effect ($F(3, 68) = 5.93; p = 0.0012$) suggesting that fatigue levels changed over time.
- There was a significant group effect ($F(1, 28) = 7.12; p = 0.0125$) suggesting that across all time points, the BWL group had less fatigue than the DRL group.
- In addition, there was a significant **time times** treatment effect ($F(3, 68) = 5.27; p = 0.0025$) indicating that the groups differed with respect to change in fatigue over time.

Redd WH, Valdimarsdottir H, Wu LM, **Winkel G**, . . . Ancoli-Israel S. Systematic light exposure in the treatment of cancer-related fatigue: a preliminary study. *Psychooncology*. 2014 Dec;23(12):1431-4

Our Activities

Journal Club

Aim: Discuss a new statistical methodology or novel applications of existing methods in the field

Format:

- *Two papers:* one clinical and one on the statistical methodology used by the clinical paper
- A TCI clinician is invited to provide a clinical perspective to the discussion
- Topics Recently Discussed [lead(s)]**
- Bayesian stopping rule for a single arm study (Godbold)
- Phase II utility design (Spivack)
- Detection of Publication Bias in Meta-analysis (Mazumdar)
- Evaluating health outcomes in the presence of competing risk (Wallenstein)

Typical Audience: 8-12 core members and their collaborators

Biostatistics Clinics

Aim: Discuss specific statistical methods and their applications in the context of ongoing projects

Format:

- Statistician pick the topic of their expertise or interest and ask people interested in learning about the topic to sign up in advance
- Attendees often send data or project information ahead of time
- Topics Recently Discussed [lead(s)]**
- GWAS in Cancer Research (Özbek)
- Statistical Design of Animal Experiments (Mandeli)
- Alternative Approaches to the Analysis of Longitudinal Data (Winkel)

Typical Audience: 4-8 TCI investigators

Open House

Aim: Facilitate and encourage the interactions among TCI investigators and the Biostatistics Core

Format:

- Investigators and their staff drop in and have conversations and lunch with biostatisticians
- A connection is made and, if needed, follow-up meetings are arranged
- Typical Audience:** 15-20 TCI clinical investigators attended and were informed about our core, activities, and services provided

BSRF Members Meeting

- Admin update from disease focus group meetings
- Modifications Made (eRAP forms, website)
- Discussion of ongoing/new projects and barriers