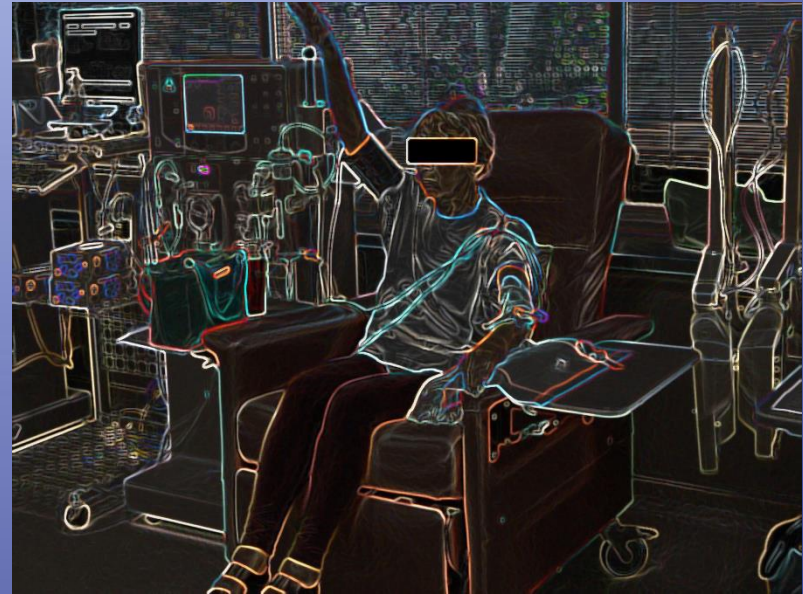
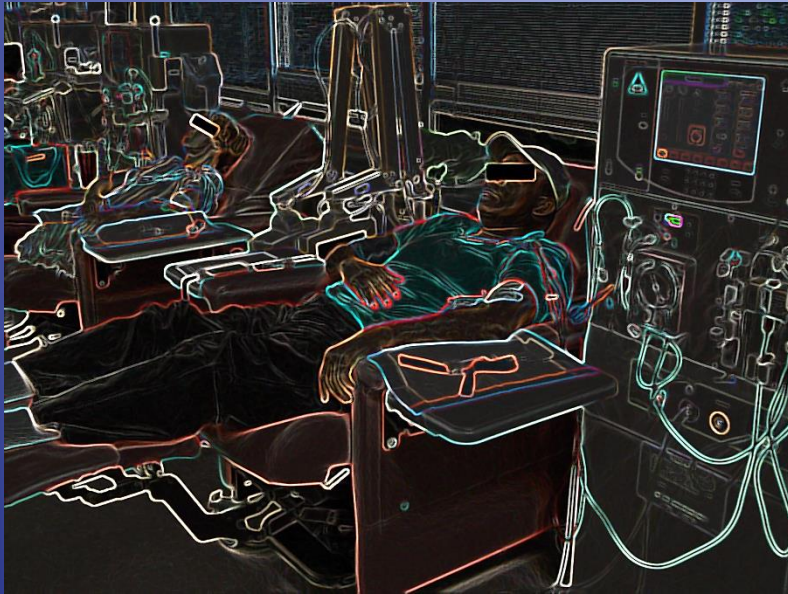


Application of Mind-body Therapies for End Stage Renal Disease



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Disclosures

- No financial conflicts of interest to report

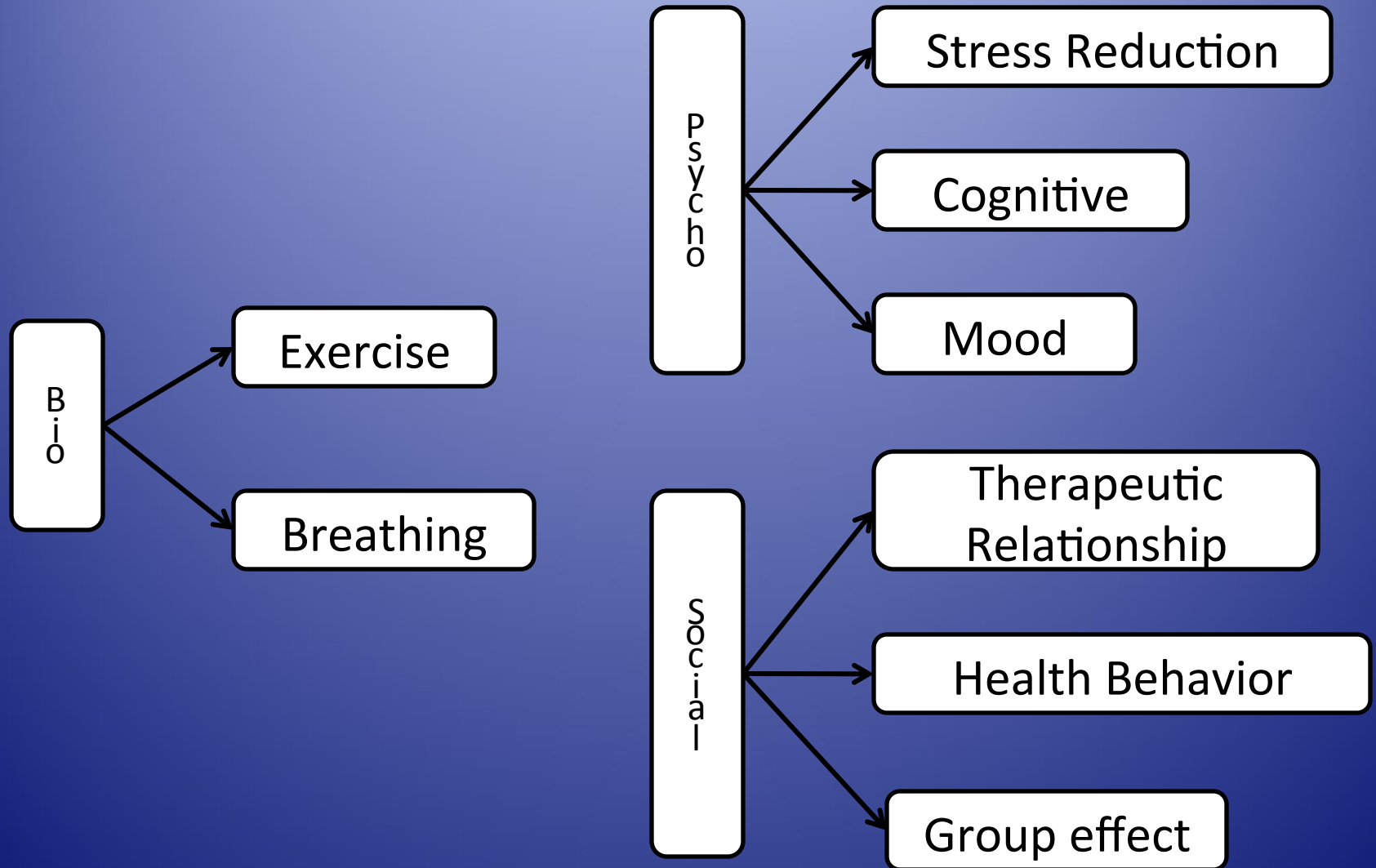
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Outline

- Yoga as a biopsychosocial intervention
- Model disease: End-stage renal disease
 - Need for intervention
 - Designing an intervention
 - Pilot-study of intervention

Potential Mechanisms of Mind-Body Practices

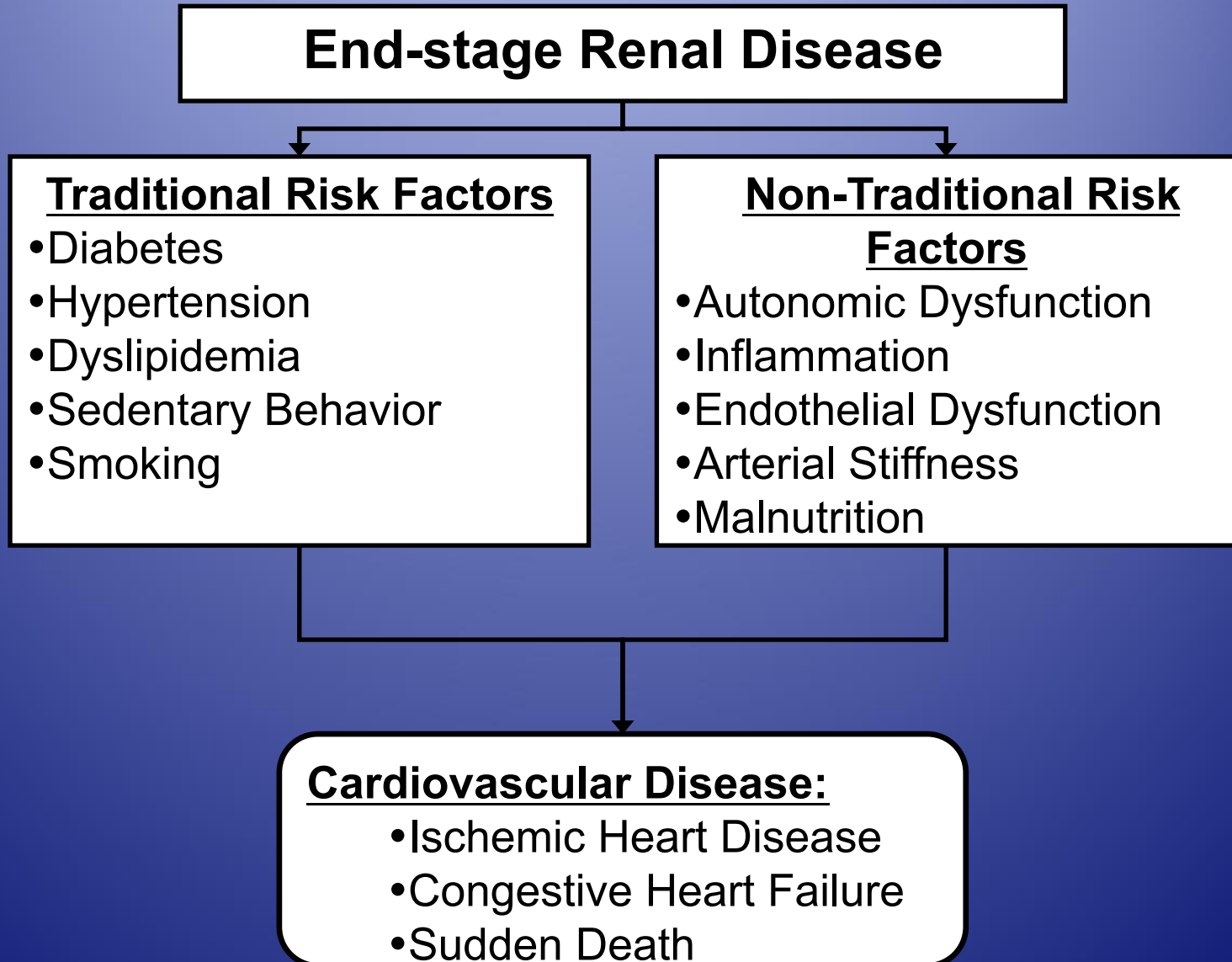


Patients with End-Stage Renal Disease

- Prevalence in 2013: 661,648
- Cost: 30.9 billion to Medicare
- 5 year survival rate of 35%
 - CVD accounts for half of mortality

(USRDS 2013 ADR)

Disproportionate burden of risk factors



Other factors associated with higher mortality

- Age and race

(USRDS ADR 2010, Charra Kidn Int 1992, Mallioux Clin Neph 1994)

- Compliance

(Unruh Am J Kid Dis 2005)

- Perception of illness

(Kimmel Kidn Int 1998)

- Poor physical functioning

(DeOreo Am J Kid Dis 1997, O'Hare Am J of Kid Dis 2003, Sietsema Kidn Int 2004)

Physical functioning among patients with ESRD

- Decreased cardiorespiratory fitness
 - Average 60 % peak oxygen uptake (VO_2 peak) as compared to age-predicted values

(Barnea Isr J Med Sci 1980, Moore Med Sci Sp Ex 1993, Painter Nephron 1986)

- Decreased physical function with performance testing
 - 6-minute walk test
 - Gait speed
 - Sit-to-stand test
- Self-reported physical functioning
 - SF-36

(DeOreo Am J of Kid Dis 1997, Hsieh Am J of Kid Dis 2006, Johansen Am J of Clin Nut 2003, Oh-Park Am J Phys Med Rehab 2002, Padilla J Nephro 2008, Painter Am J Kid Dis 2000)

Other conditions/symptoms among patients with ESRD

- Fatigue: 60-97% prevalence

- Physiological , psychological, and treatment related

(Cardenas Nephron 1982, Jhamb Am J Kid Dis 2008 , Murtagh Adv Chr Kid Dis 2007, Wiesbord J Am Soc Neph 2005)

- Muscle cramps/wasting

- Cramps- Intra-dialysis-33-86%

- Cramps- Inter-dialysis-25%

(Canzanello Sem Dia 1992, Chou J Rheum 1985, Kobrin Sem Dial 2007)

- Mental health disorders

- Depression-30%; Anxiety-40%

(Murtagh Adv Ch Kid Dis 2007, Taskapan Nephro 2005)

Health Related Quality of Life(HRQOL)

- Decreased quality of life
- HRQOL correlates with morbidity and mortality

(Evans NEJM 1985, Mapes Kid Int 2003, Merkus Am J Kid Dis 2000, Lopez Nephro Dial Tran 2004)

Survey of CAM Use among Patients on Hemodialysis

- Primary aims:
 - Describe CAM use, including mind body techniques, among patients on hemodialysis
 - Determine the willingness of patients on hemodialysis to learn mind body techniques, participate in a study on intra-dialysis mind body techniques, and be randomized for a study protocol

Birdee 2013 Evid Based Comp Alt Med

Flowchart for survey

**Hemodialysis patients at DaVita Dialysis
Center Boston, MA
n=122**

Exclude: 16

- **Demented:3**
- **Non-english:13**

Refuse: 17

Include: 89 patients

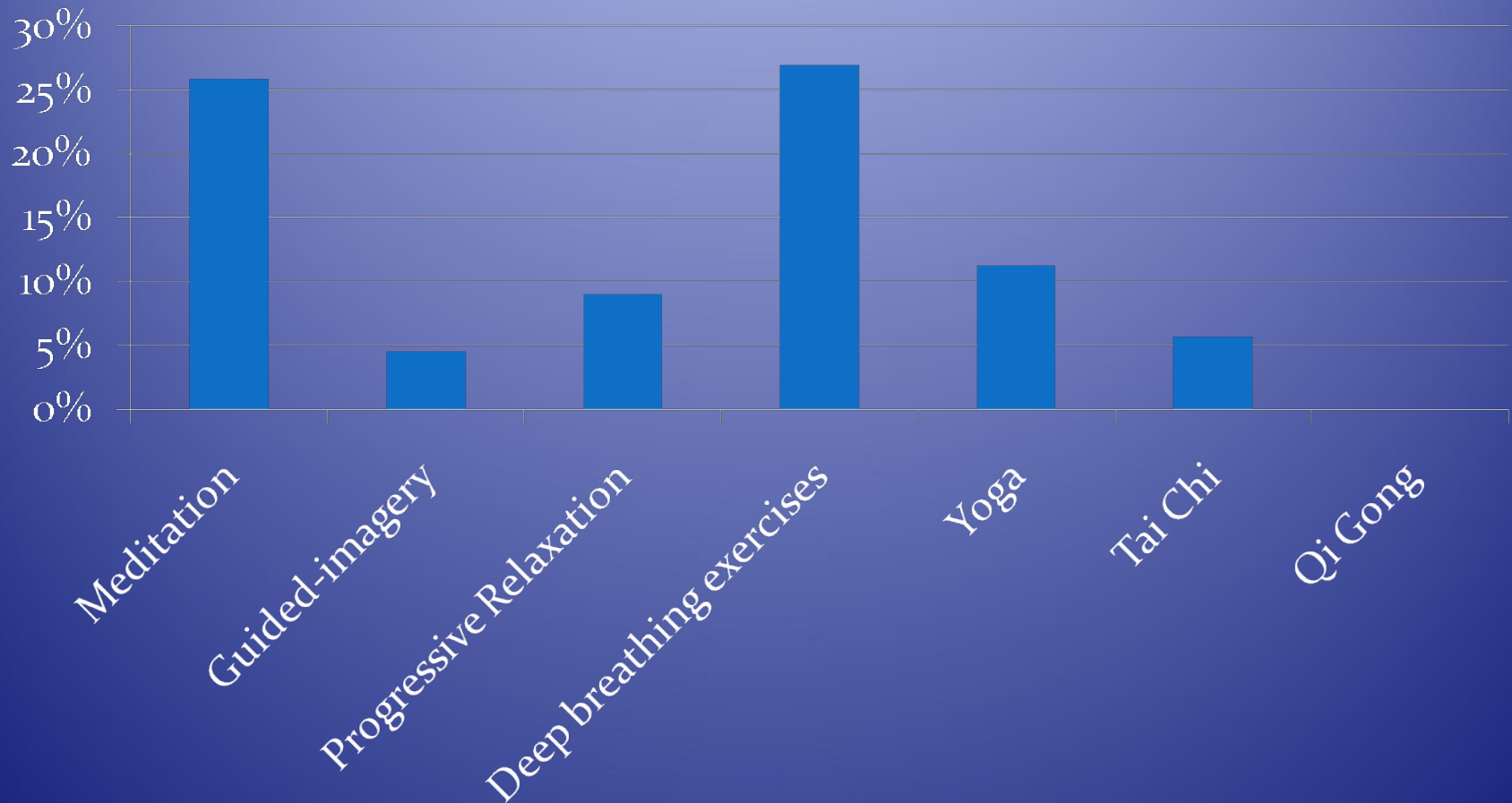
- **Response rate: $89/106 = 84\%$**

Patient Characteristics on HD

Characteristic	Frequency (%)
Age (years)	
<35	6
35-49	15
50-64	35
64-79	26
>80	12
Male	53
Race	
White	29
Black	61
Hispanic	7
Asian	1

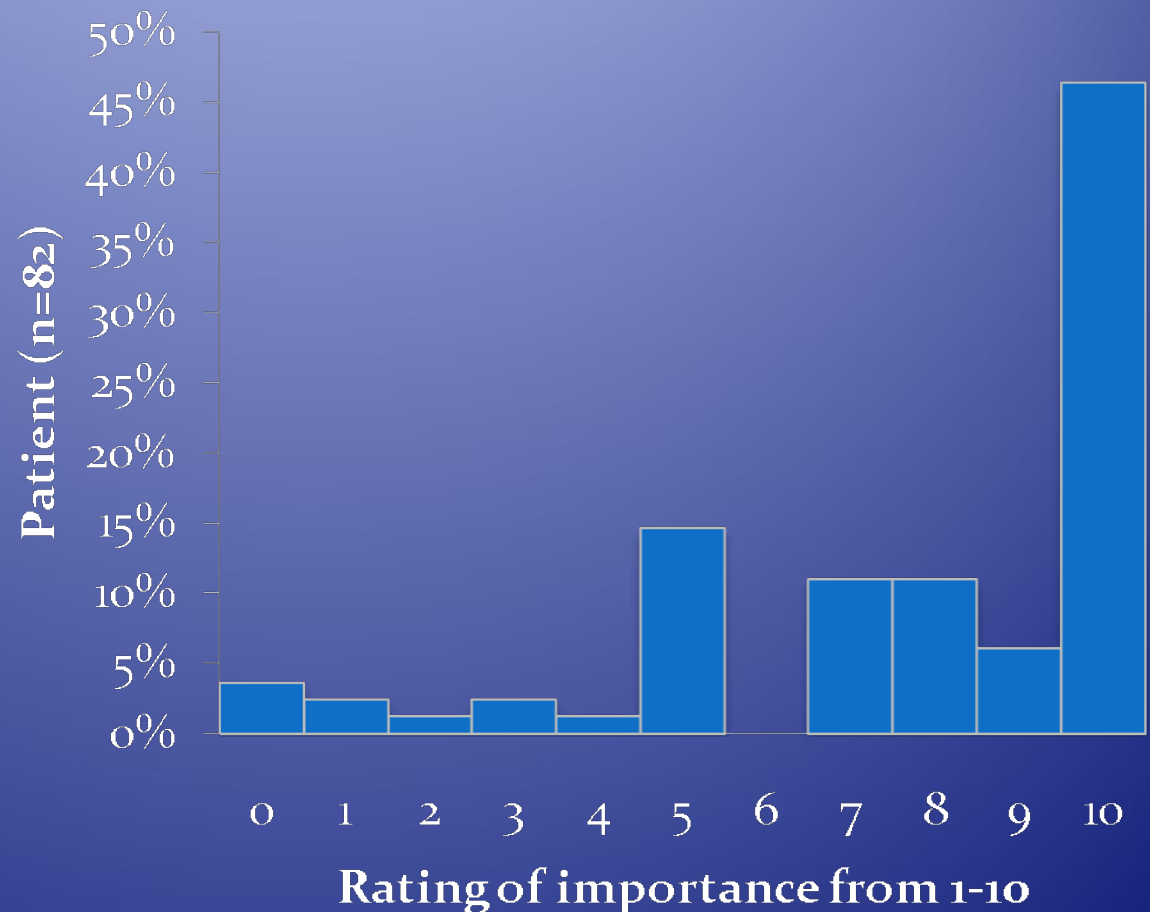
Characteristic	Frequency (%)
Duration on HD (years)	
< 1	5
1	34
2-4	20
5-9	9
10-23	27
Shift-M-W-F	49
Shift Schedule	
1 Morning	46
2 Aftern	36
3 Evening	18

Prevalence of mind-body use ever among patients on HD

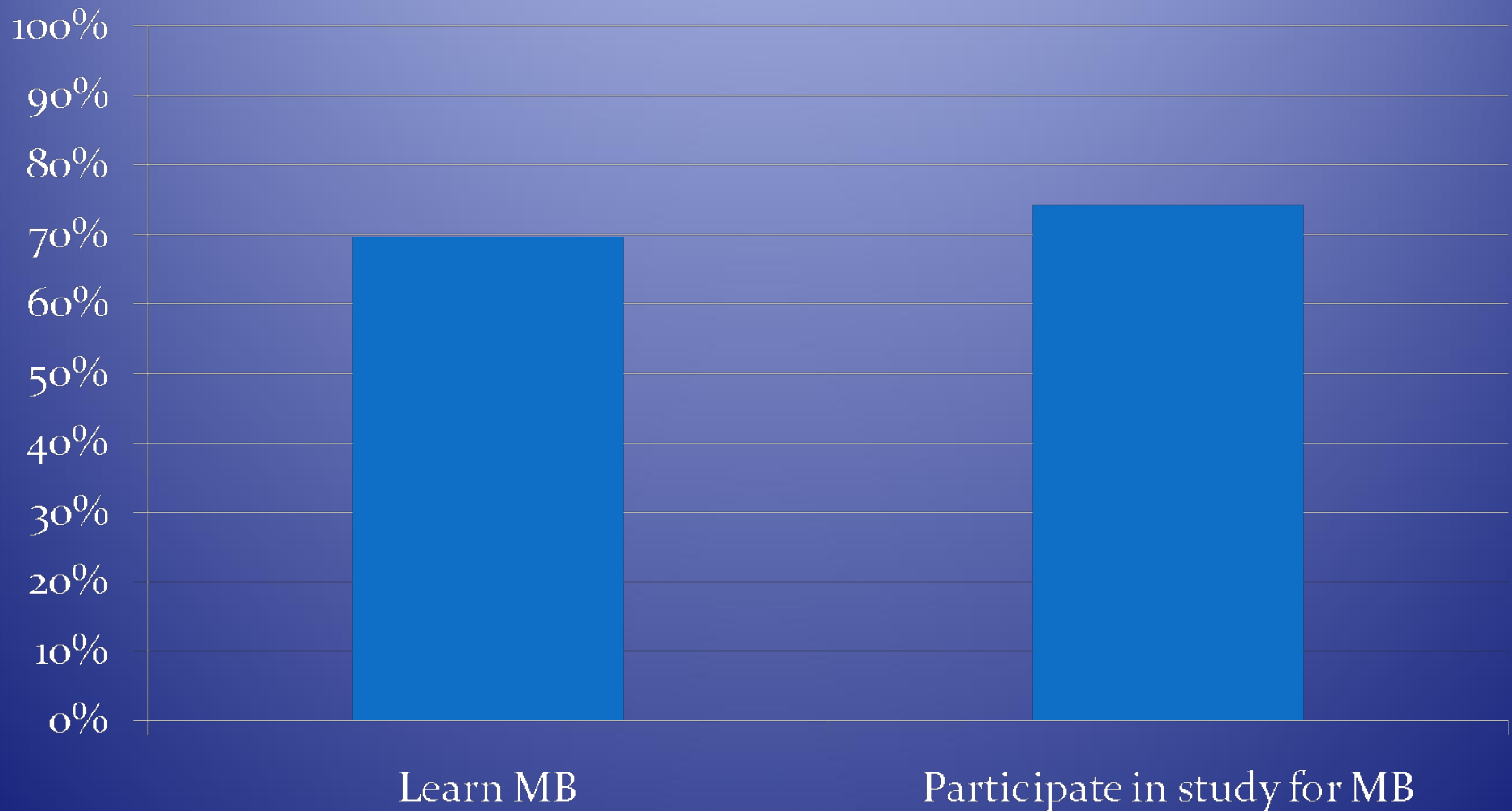


Importance of mind-body connection for health

- Median: 9
- Inter-Quartile range: 5



Prevalence of patients on HD interested in mind-body



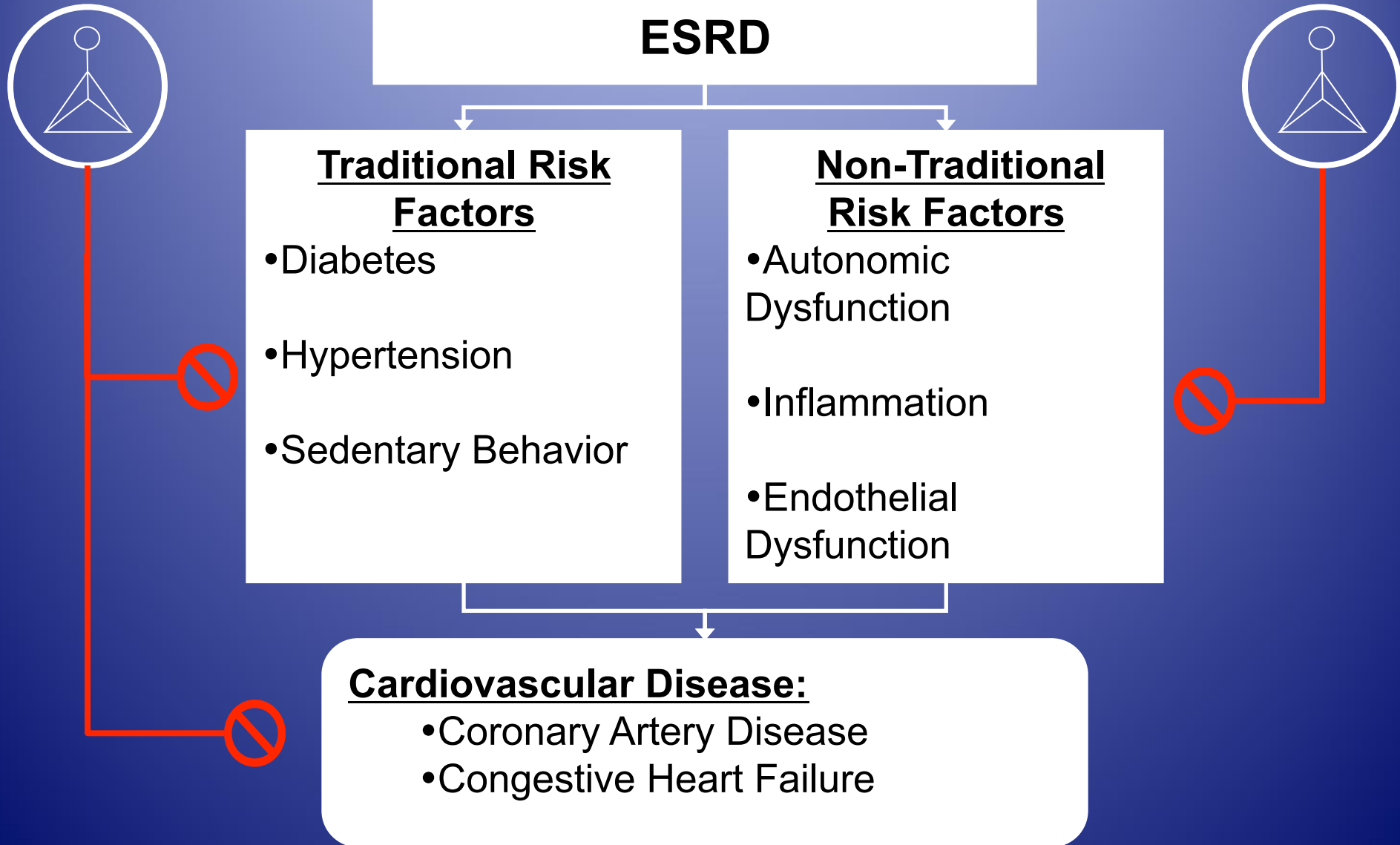
Translation of Mind-body for Patients with End-Stage Renal Disease



Tools of Mind-body Practice

- Movement e.g. asana in yoga
- Breathing-particularly slow
- Meditation e.g. visualization, mindfulness, body scan
- Other:
 - Sound
 - Lifestyle
 - Philosophy

MBP for Cardiovascular Diseases



MBP for other symptoms and co-morbid conditions

- Fatigue

(Latha 2003, Oken 2006, Oken 2004, Danhauer 2008)

- Muscle soreness/flexibility

(Boyle 2004)

- Depression and Anxiety

(Kirkwood 2005, Pilkington 2005)

- Quality of life in chronic disease

- e.g. CHF, MS, cancer, OA, asthma

Advantages to studying patients with ESRD

- Multiple co-morbidities resulting in chronic symptoms and poor quality of life
- Dialysis treatment 3 times a week/3-4 hours
 - Active intervention during idle time
 - Allows for high “dose” of mind-body practice
 - Longitudinal analysis to understand clinical effects and mechanisms

Yoga Protocol Development

- Primary aims:
 - Develop intra-dialysis yoga intervention specifically for patients with end-stage renal disease through expert consensus
- Secondary aims:
 - Document traditional yoga theory and medical rationale for intervention

Development of an intra-dialysis yoga protocol

- Yoga protocol developed through expert consensus
 - 3 expert yoga therapists
 - Mind-body researcher
- Bi-weekly meetings for 6 months
- Reviewed by: nephrologists, mind-body researchers, and expert yoga therapists in India

Intra-dialysis yoga protocol

- Designed for patients receiving hemodialysis in a chair
- Practiced during each hemodialysis session
- Total practice up to 60 minutes
- No movement of vascular access site

Intra-dialysis yoga

- Asanas (postures) with breathing techniques
 - Slow meditative movements
- Meditation and visualization techniques
- Progressive course
 - Initially breathing techniques
 - Progressive development of postures
- Cyclical practice
- Emphasis on attention and breathing control
- Modified to individual needs based on physical and mental capacities

Intra-dialysis Yoga Protocol

	Week 1	Week 2	Week 3	Week 4&5	Week 6&7	Week 8	Week 9 & 0	Week 11&12
Postures								
Reclined chair								
• Hip flexion	✓	✓	✓	✓	✓	✓	✓	✓
• Hip twist	✓	✓	✓	✓	✓	✓	✓	✓
• Anterior arm extension	✓	✓	✓	✓	✓	✓	✓	✓
• Rest	✓	✓	✓	✓	✓	✓	✓	✓
• Hip abduction		✓	✓	✓	✓	✓	✓	✓
• Knee extension			✓	✓	✓	✓	✓	✓
Upright chair								
• Knee extension			✓	✓	✓	✓	✓	
• Knee extension and foot flexion								✓
• Arm extension					✓	✓	✓	✓
• Foot flexion					✓	✓	✓	✓
• Forward bend					✓	✓	✓	✓
• Chest expansion						✓		
• Chest expansion and twist							✓	✓
Breathing/ Inspiratory:Expiratory Ratio								
• Free observed breath	✓	✓						
• Controlled breath/Inspiration<expiration			✓	✓	✓	✓	✓	✓
• Cooling breath//Inspiration<expiration				✓	✓	✓	✓	✓
Meditation								
• Visualize pleasant moving water	✓							
• Visualize pleasant moving water over body		✓						
• Visualize moving water with hand from abdomen to chest, and from chest away from body			✓	✓	✓	✓	✓	✓
• Visualize water moving with hand into body, up and down body, and then from chest away from body				✓	✓	✓	✓	✓

Randomized Pilot of Intra-dialysis Yoga among Patients with End-stage Renal Disease

Birdee 2015 J Ren Nut

Specific aims:

- Primary: Determine the safety and feasibility of a randomized pilot of intra-dialysis yoga with usual care versus usual care alone among patients with ESRD
- Secondary: Collect preliminary data on the effects of intra-dialysis yoga on disease specific quality of life and other self-reported measures.

Study Design: Randomization

- Subjects will be randomized by site to:
 - Active intervention: 12-week Intra-dialysis yoga protocol
 - Comparison intervention: 12-week Kidney School
- Method:
 - Treatment assignments generated by random number generator and assignments placed in sealed opaque envelopes.

Active Intervention: Intra-dialysis Yoga

- Classes available 3 x week
- During the first two hours of dialysis
- Yoga teacher: 4 certified yoga teachers
- Usual care as per dialysis center and nephrologist

Control Intervention: Usual Care

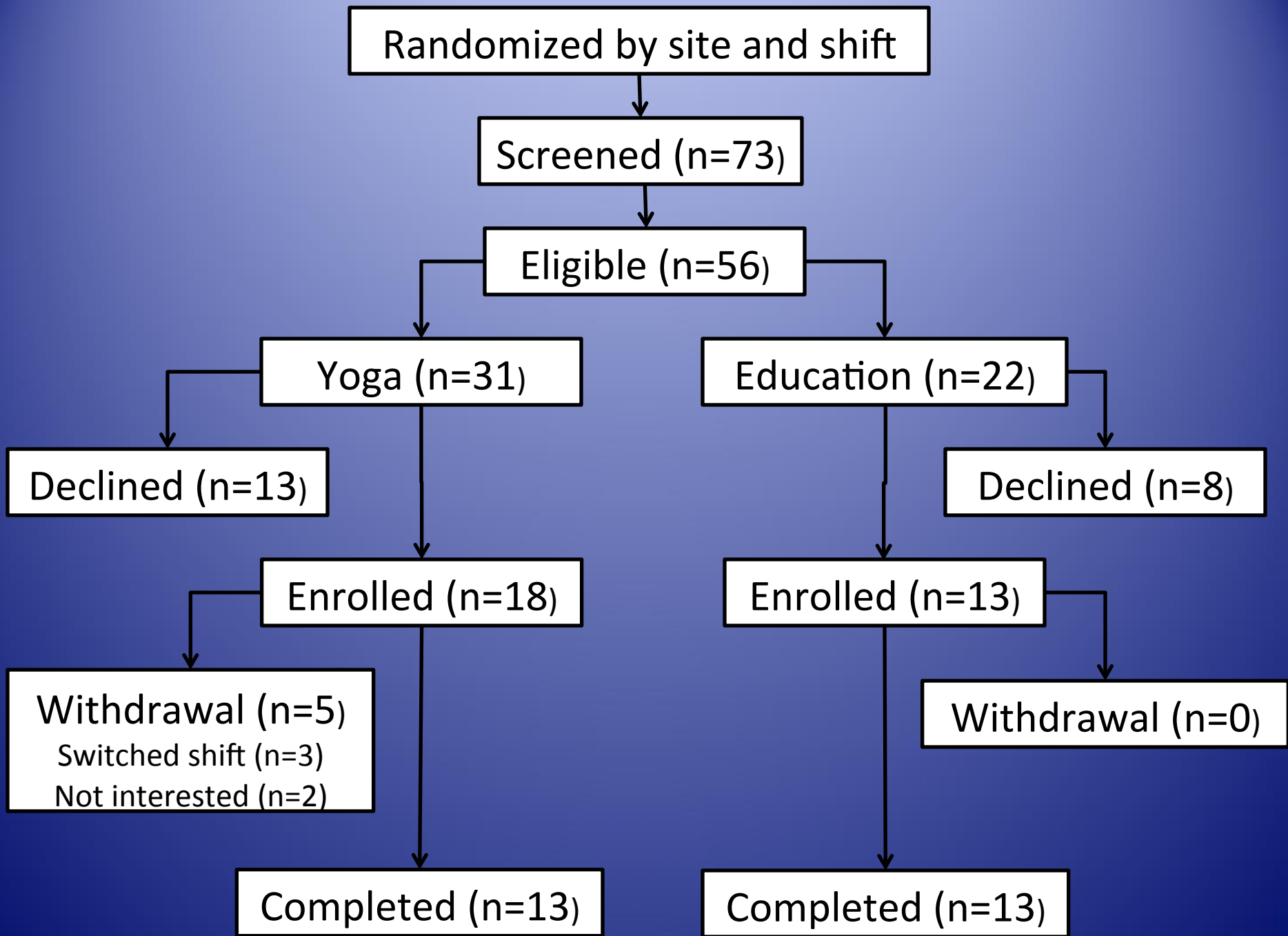
- Kidney School-12 weeks
 - Given weekly handouts
 - Encouraged to complete materials during dialysis
 - Divided in attempt to match yoga intervention for time
 - Assignments encouraged

Outcomes Measuring and Testing:

- Primary
 - Safety and Feasibility
- Secondary
 - Baseline, 6 week, and 12 week
 - HRQOL
 - Fatigue
 - Mood
 - Satisfaction with dialysis
 - Sleep quality
 - Longitudinal measures (over 12-week period)
 - Blood pressure (pre-dialysis and post-dialysis)

Outcomes: Secondary

Instrument	Measure	Items
Kidney Disease Quality of Life-36	HRQOL	36
Functional Assessment of Chronic Illness and Therapy-Fatigue	Fatigue	33
Profile of Mood States	Mood	65
Patient Health Questionnaire 9	Depressive symptoms	9
ESRD: Patient Satisfaction	Satisfaction Tx	6
Pittsburgh Sleep Quality Index	Sleep	17



Characteristics	Yoga	Kidney School
Gender, (n)	13	13
Male	6	8
Female	7	5
Race		
White	1	1
Black	12	12
Other	0	0
Age (years)	49 (35-61.5)	48 (32-58)
Weight (kg)	78.61 (68.31-102.29)	89.56 (71.22-106.20)
Height (m)	1.65 (1.58-1.71)	1.80 (1.69-1.84)
BMI (kg/m ²)	28.00 (24.00-36.40)	31.40 (23.85-34.70)
Comorbidities		
HTN	12	11
CHF	0	3
Diabetes	3	3

Results

- Feasibility
 - 77% of patients were eligible
 - 65 % of all subjects interested
 - Yoga: 63%
 - Education: 64%
 - Completion: 74%
 - Yoga: 72% (89% excluding shift changes)
 - Education: 100%
 - Lost to follow-up: 1 subject in yoga arm

Results: Feasibility

	Yoga, median
Total potential practice sessions	32.5 (28.00-34.25)
Total practiced sessions	20.5 (14.75-27.50)
Participation frequency (%)	0.70 (0.52-0.88)
Yoga dose	
Total over 12 weeks	407 minutes
Per dialysis session	22 minutes per session

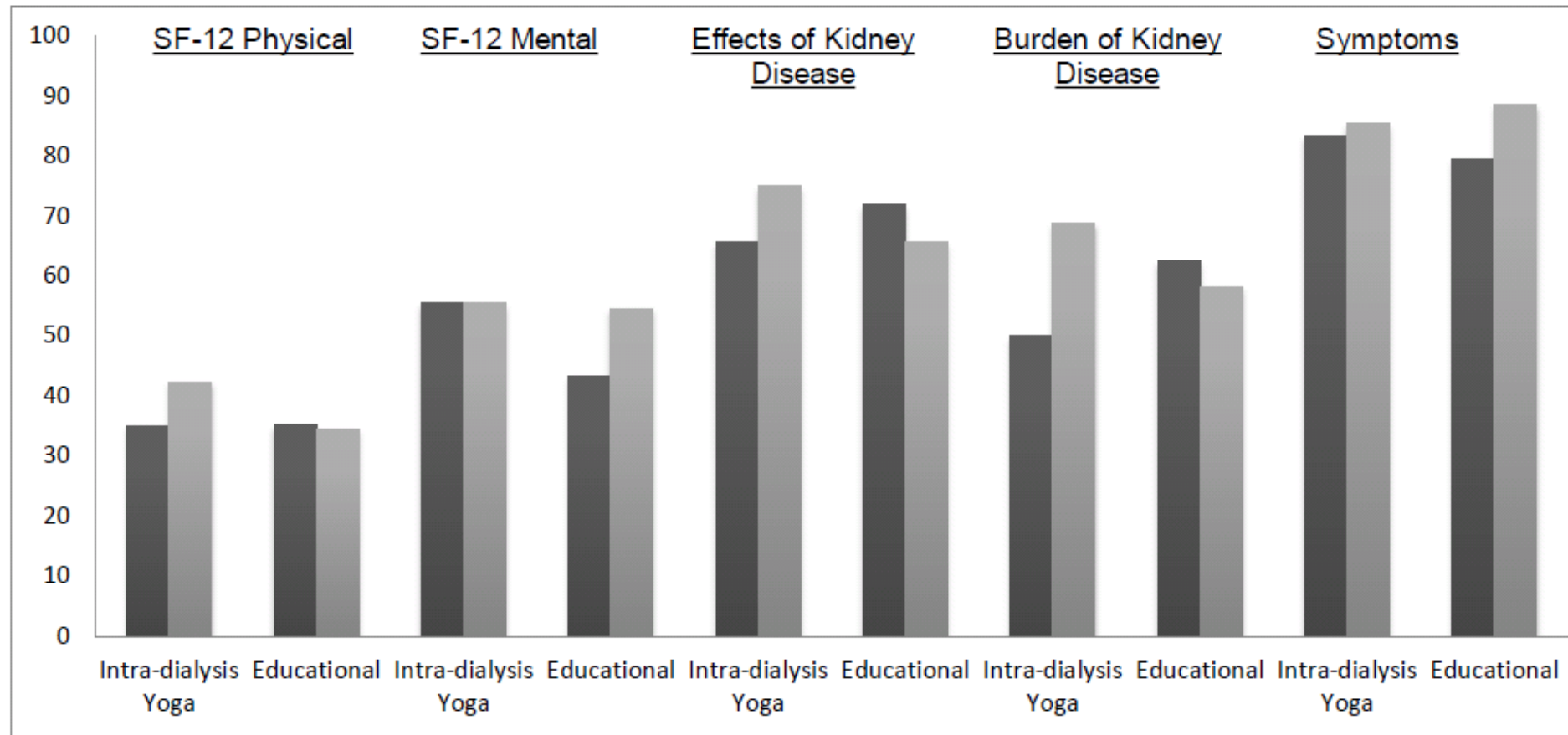
Results: Feasibility

Reasons for not practicing	Yoga, frequency (%)
Injury	0
Fatigue:	22 (19%)
NV	8 (7%)
Anxiety:	1 (0.9%)
Interference with patient care	0
Medical Complications:	2 (1.7%)
Patient Refusal:	21(18.26%)
Absence from dialysis:	23 (20%)
Other:	38 (33%)

Preliminary Results: Safety

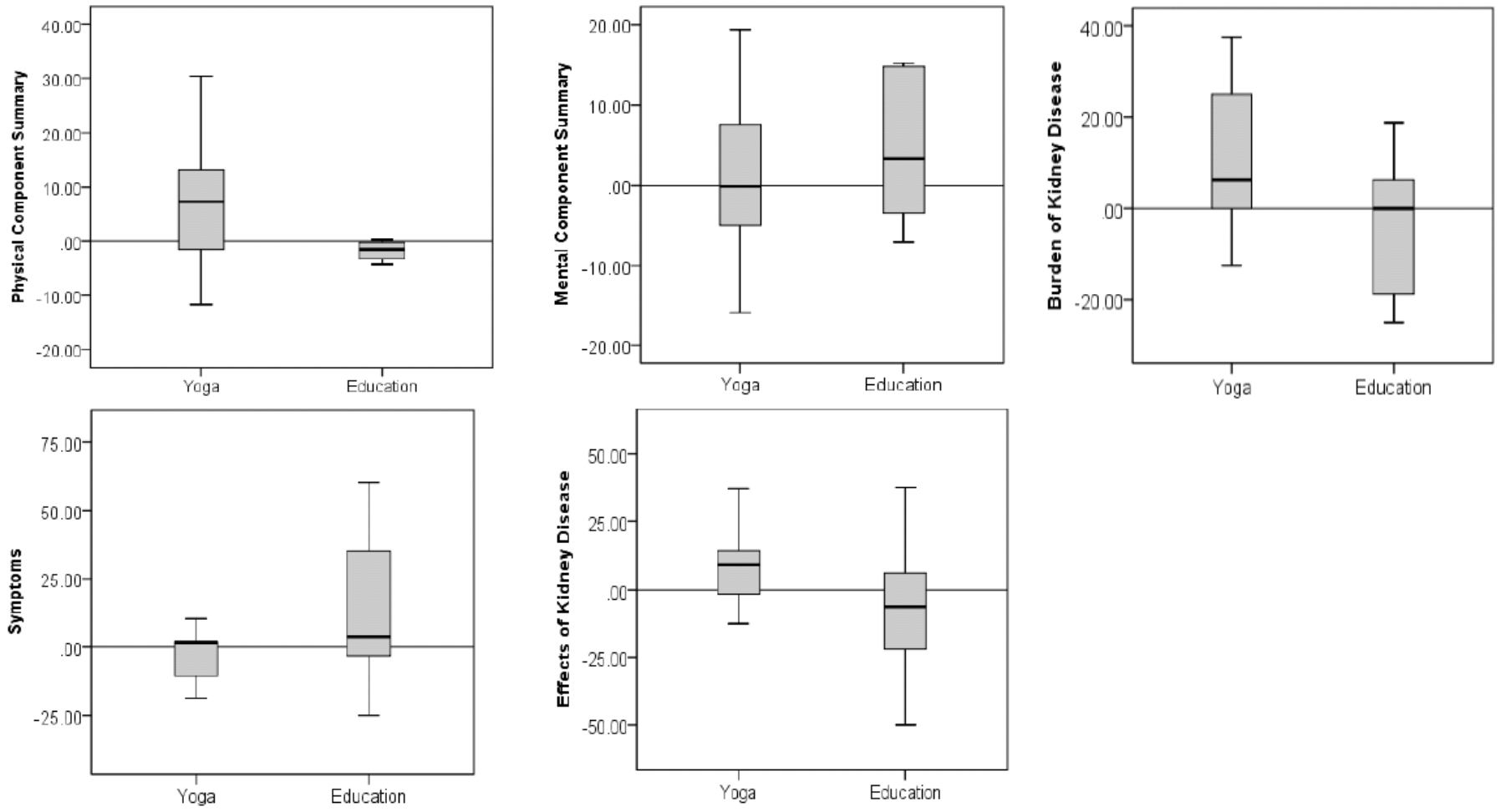
- No serious adverse events were observed in active intervention group related to the intervention over 12-week study period
- Non-serious adverse events were observed that were related to yoga practice
 - Lightheadedness
 - Sore muscles

Figure 2. Changes in Kidney Disease-Related to Quality of Life Measures at Baseline and 12-weeks¹



¹ Median values (Interquartile range)

Figure 2b. Changes in Kidney Disease-Related to Quality of Life Measures from Baseline to 12-weeks¹



Patient narrative 1

“She explained the newfound awareness of the experience of tension in her body ...during dialysis, other medical procedures, and throughout various daily activities. She shared that the breathing exercises had been helpful to her outside of medical settings as well. Upon experiencing the death of a very close family member and the subsequent tension-provoking situations (e.g., family interactions, phone calls, funeral arrangements) that arose as a result, the patient found herself utilizing and benefitting from some of the breathing practices she had learned through the study. She even found herself to be more aware of the feelings of others and, thus, better able to comfort them”

Patient narrative 2

- *Upon asking the patient what kind of day he was having, it became very apparent that he was eager to be done with dialysis. He expressed his feelings of tiredness, hunger, and readiness to go. The patient's general impression of the yoga practices was that it was "a good thing." He admitted that he sometimes dreaded the yoga, yet he has found the practices to be helpful when he is feeling "heavy-chested" or when his breathing is "out of whack." The patient also explained that he typically feels bad when he is in dialysis; concentrating on breathing helps him shift his focus from these, mostly, negative experiences.*

Patient narrative 3

The patient responded to the first question by stating, “It’s good.” When I prompted her to elaborate, she added that she is sometimes unable to do the practices because of stiffness in her legs; however, she admitted feeling better regularly after doing the practices. In this patient’s opinion, the duration of the practices sometimes seems to last a “little too long”.

Patient narrative 4

- This patient indicated that she was not having a very good day. She spontaneously offered up a scaling response of “eight,” indicating that on a scale of one to ten (one being good, ten being bad) she was significantly closer to the “feeling bad” side. The patient indicated that she thought the yoga practices were a “good idea.” She experienced the practices as “comforting” and “relaxing.” She also indicated that they help her “relieve pressure.” She expressed that everyone should do yoga practices. This patient likes the way the instructor talks. The practices help her feel better. Afterward, she feels like she has accomplished something. The patient also indicated that the yoga practices give her time to think about things she would not normally think about.*

Limitations

- Subjects switching shifts
- Difficult to group patients together
- Complex patient population
- Complex intervention

Next step

Larger RCT (n=68)

- Enrollment completed
- Interventions to be completed 11/2016
- Outcome assessments to be completed 2/2017

Summary

- Mind-body is novel therapy that patients in ESRD may consider
- Preliminary results of intra-dialysis yoga suggest high safety profile and feasibility with high adherence

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