



How to Keep it Up: Strategies to Use Erectile Function Treatment for Men with Prostate Cancer

Christian J. Nelson, PhD, MA Public Affairs
Chief, Psychiatry Service
Associate Attending Psychologist
Memorial Sloan Kettering Cancer Center

Funding related to presentation: NIH R21 CA 149536; NIH R01 CA 190636



Memorial Sloan Kettering
Cancer Center



Disclosure

- **There are no financial disclosers to report**





Many Men are Diagnosed with Prostate Cancer





Prostate Cancer

- **Most common cancer in men**
- **Over 200,000 diagnosed yearly**
- **More common than breast cancer**
 - 1 in 6 men will develop prostate cancer
 - 1 in 8 women will develop breast cancer

American Cancer Society, Facts and Figures



Memorial Sloan Kettering
Cancer Center



Prostate Cancer

- **90% are diagnosed with early stage disease**
- **Excellent survival rates**
 - 5-year survival rate: 99%
 - 10-year survival rate: 91%
 - 15-year survival rate: 76%
- **Men diagnosed at a younger age**

American Cancer Society, Facts and Figures



Memorial Sloan Kettering
Cancer Center



Prostate Cancer

- **Early-stage treatments**
 - Radical Prostatectomy (RP)
 - Radiation
- **Those who select surgery**
 - Younger
 - Healthier
- **Trend toward surgery**
 - More treatment options if recurrence





All Prostate Cancer Treatments Impact Sexual Functioning





Erectile Function Recovery After RP: Meta-Analysis

- **Selection criteria**
 - > 18m post RP
 - > 50 subjects
 - Patient reported assessment
- **Yielded 22 studies (out of 212)**
- **Erectile function (EF) recovery range: 25-78%**
 - No uniform definition of EF recovery
 - “A few times; sometimes; occasionally”
- **Meta analysis erectile function recovery rate:**
 - 56%
 - Studies did not assess PDE5i use

Erectile Function Recovery After RP: Back to Baseline

Back to Baseline at 24m Post-RP

Subjects	N	With PDE5i	No PDE5i
Total Sample	180	43%	22%
Good Baseline Erections	132	36%	16%

Back to Baseline For Men with Good Baseline Erections by Age

Age	N	With PDE5i	No PDE5i
< 60	81	48%	23%
≥ 60	51	16%	4%

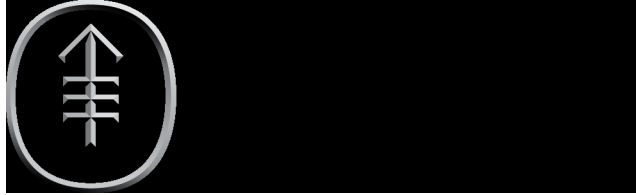


Sexual Dysfunction After Localized Treatment for Prostate Cancer

- **Of 1,236 men 4.3 years after treatment:¹**
 - 85% rated that erectile dysfunction (ED) was a problem
- **Of 553 men who had a RP, at 70m after treatment:²**
 - 17% had erections firm enough for intercourse

¹Schover et al., Cancer, 2002; ²Donavan et al., NEJM, 2016





So What?



Memorial Sloan Kettering
Cancer Center



What I hear

- **“Well...at your age, does it really matter?”**
- **“You shouldn’t be upset, your cancer is gone.”**
- **“You will get used to it.”**





Impact of ED

- **ED is associated with depression^{1,2}**
- **ED bother does not dissipate³**
 - Report lower general life happiness
 - No logical predictors
- **Significant relationship difficulties⁴**

¹Araujo et al., Psychosom Med, 1998; ²Nelson et al., JSM, 2010; ³Nelson et al., JSM, 2010; ⁴Muller et al., 2002



ED: Quality of Life

Predictors	Low physical satisfaction	Low emotional satisfaction	Low general happiness
No problems	1	1	1
Premature ejaculation	0.79	0.97	1.28
ED	4.38	2.40	2.48
Low desire	3.14	1.57	2.61

Laumann, JAMA, 1999



Memorial Sloan Kettering
Cancer Center



ED Bother

- **183 men with prostate cancer treated with surgery**
- **Pre-op, 12m, and 24m**
- **ED Bother**
 - ED a problem
 - Embarrassed or ashamed
 - Enjoyment of life
- **ED and ED Bother were correlated (.46)**
- **Bother did not decrease over time**
- **No significant baseline predictors**
 - Age, race, marital status, PSA, EF, sexual desire, sexual satisfaction

Nelson et al., JSM, 2010



Memorial Sloan Kettering
Cancer Center



We Can Help



Memorial Sloan Kettering
Cancer Center

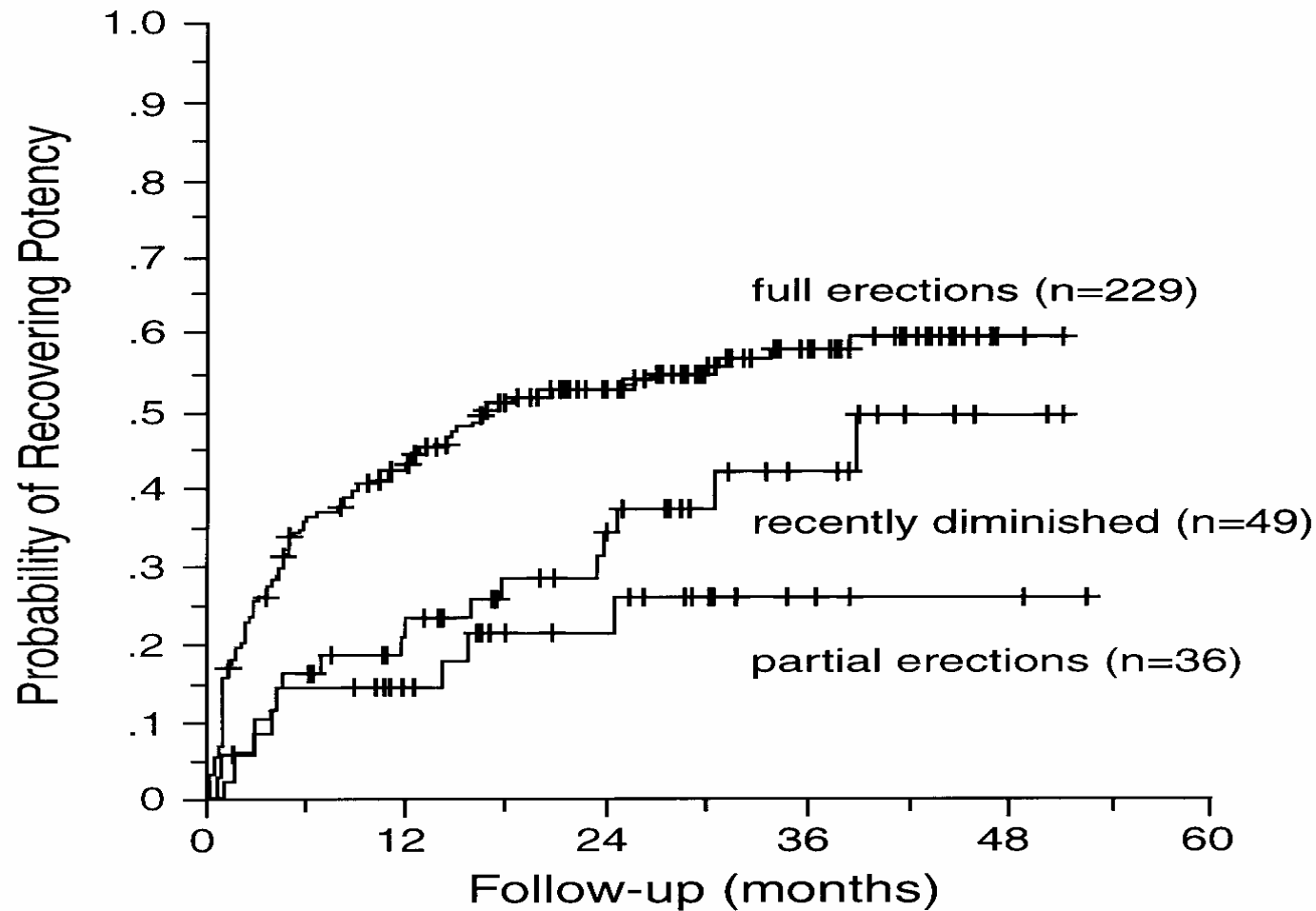


ED Treatments

- **Pills**
- **Penile injections**
- **Vacuum devices**
- **Muse**
- **Penile implant**



Recovery of Erections According to Preoperative Sexual Functioning



Rabbani F, Stapleton AM, Kattan MW, Wheeler TM, Scardino PT. J Urol 2000; 164:1929.



Memorial Sloan Kettering
Cancer Center



Prophylactic Therapy

- RP patients with functional erections pre-op
- Patient groups:
 - 58 in rehabilitation group
 - 74 in non-rehabilitation group
- Erectile rigidity ≥ 6 , 3 times a week
 - 12% responded to pills at 4 months
 - 29% responded to pills at 8 months
 - Non-responders moved to penile injections
- % of patients capable of having medication-unassisted intercourse at 18 months post RP:
 - 52% of rehabilitation group
 - 19% of non-rehabilitation group



Penile Rehabilitation

MSKCC protocol

- **Early postoperative evaluation**
- **Immediate trial of pills**
- **Move directly to injections if pills do not work**
- **Regular erectile activity (3 times a week)**
- **25mg (1/4 tab of 100mg) pill on days not injecting**
- **Re-challenge with full dose pill every two or three months**
- **Follow program for 18-24 months**

Mulhall et al., JSM, 2005; Montorsi et al., J Urol, 1997



Memorial Sloan Kettering
Cancer Center



Men Avoid and Drop-out of ED Treatment





Men Avoid & Drop-out of ED Treatment

- **Many drop out of treatment**
 - 50% of PDE5i users¹
 - 50% of injection users²
- **Self-report injection use³**
 - Only 60% continue at 4 months
 - Only 33% at a rate suggested for rehabilitation
- **Syringe count injection use⁴**
 - Mean injections/week: 0.9
 - Only 10% at a rate suggested for rehabilitation

¹IMS Health, 2001; ²Sundaram et al., Urology, 1997; ³Nelson et al., JSM, 2013;

⁴ Nelson et al., SMSNA, 2015



Memorial Sloan Kettering
Cancer Center



Pilot of Intervention to Improve Compliance with an Erectile Rehabilitation Program

NIH R21 CA 149536



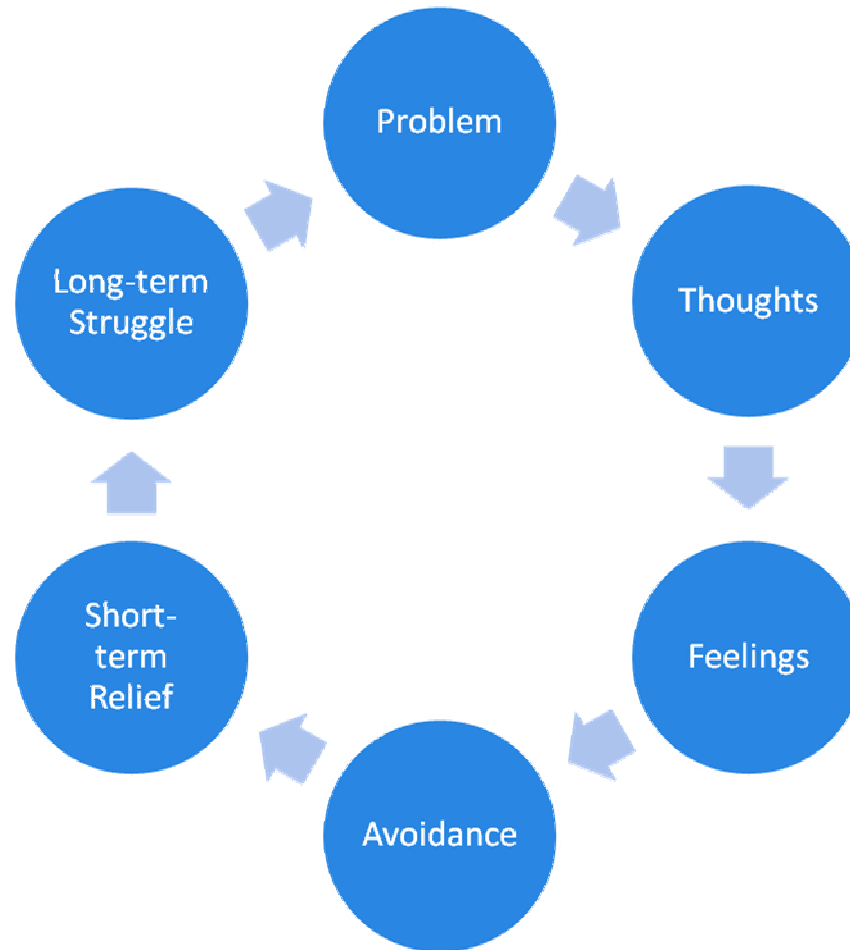
Memorial Sloan Kettering
Cancer Center



Phases of Intervention Development

- **Phase I:**
 - Qualitative study to help inform pilot intervention
- **Phase II:**
 - Pilot intervention using Acceptance & Commitment Therapy (ACT) concepts to improve compliance with penile rehabilitation
 - Aims: Feasibility and Efficacy

ACT: Cycle of Avoidance and Control

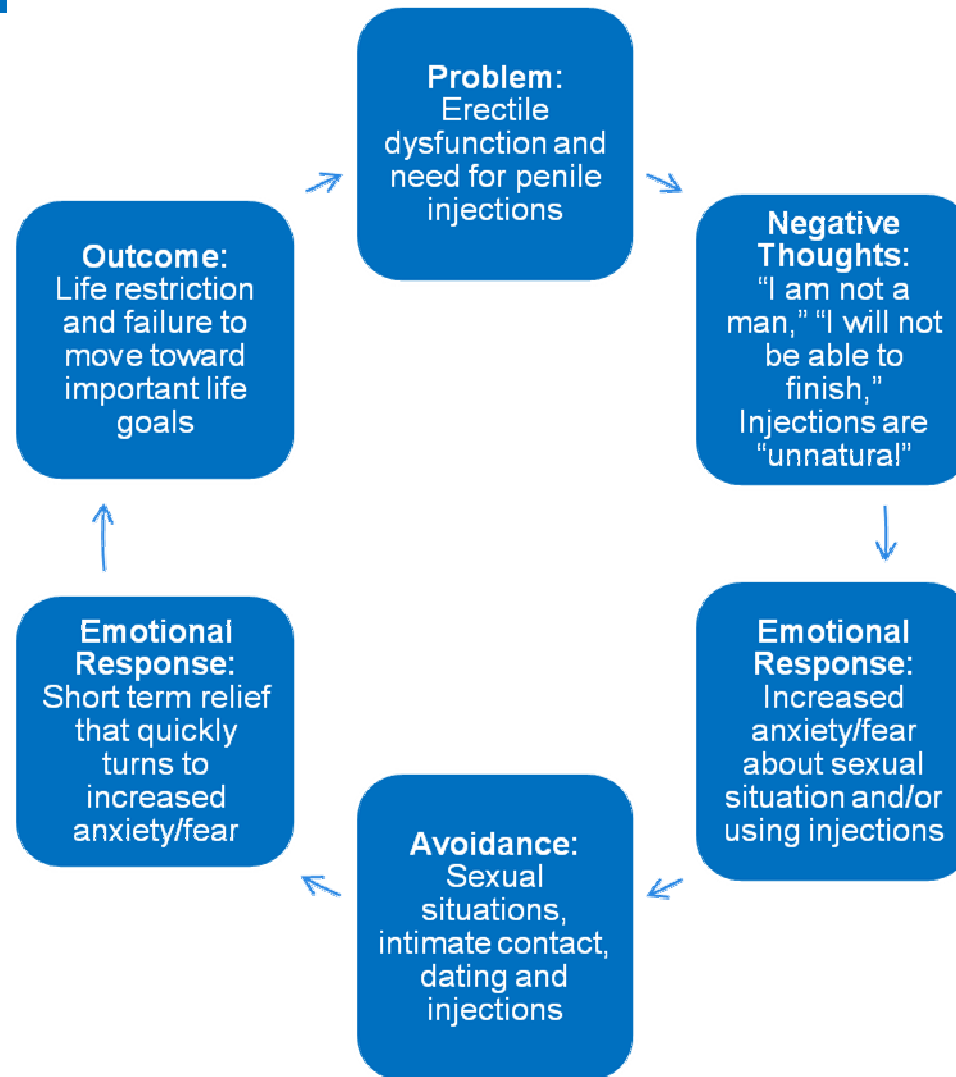


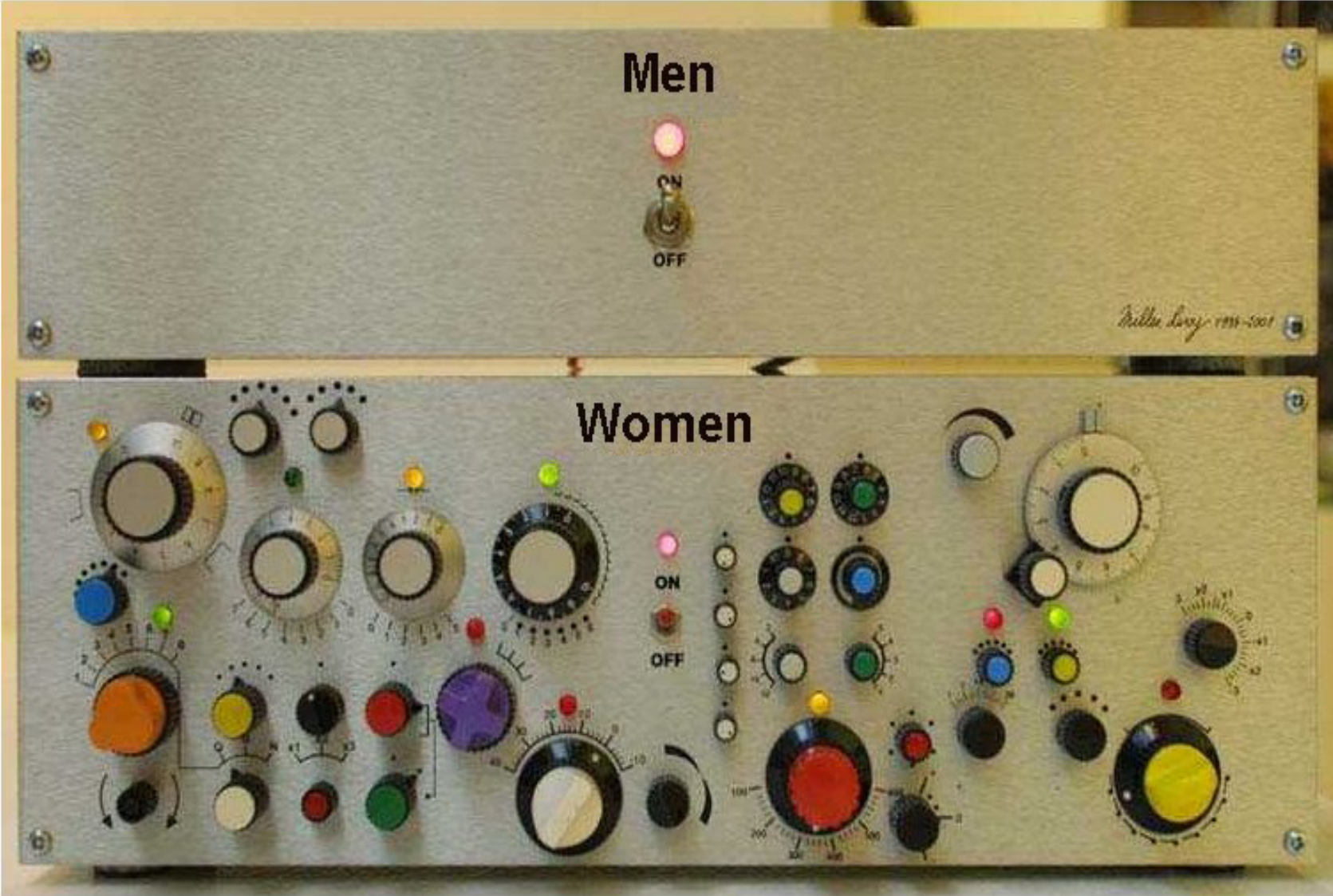


Qualitative Study: Cycle of Frustration and Avoidance

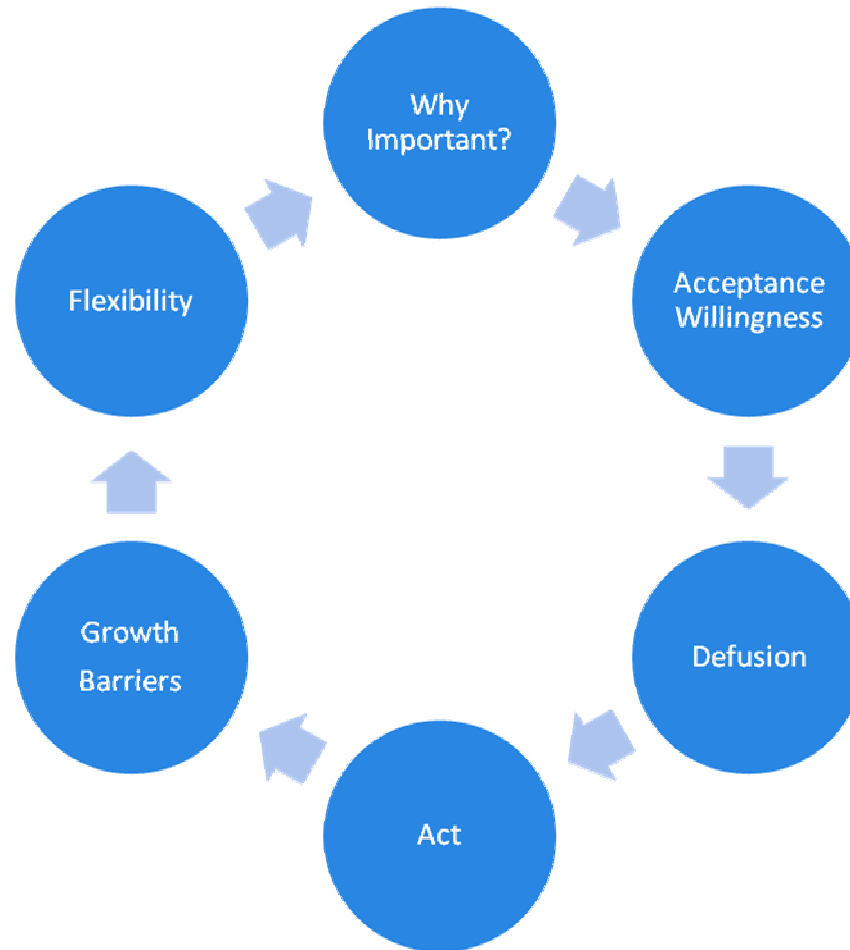
- **Disappointment/shame related to ED**
 - “I’m not a man”
 - Distress and depressive symptoms
- **Fear/anxiety of entering into a sexual situation**
 - Fear of not having a firm erection
 - “Injections are a turn-off”
 - “The whole process is humiliating”
- **Avoidance of sexual situations**
- **Loss of valued life experience**
- **Increased frustration/distress/depression**

ACT-ED: Cycle of Avoidance and Control





ACT: Cycle of Acceptance and Commitment



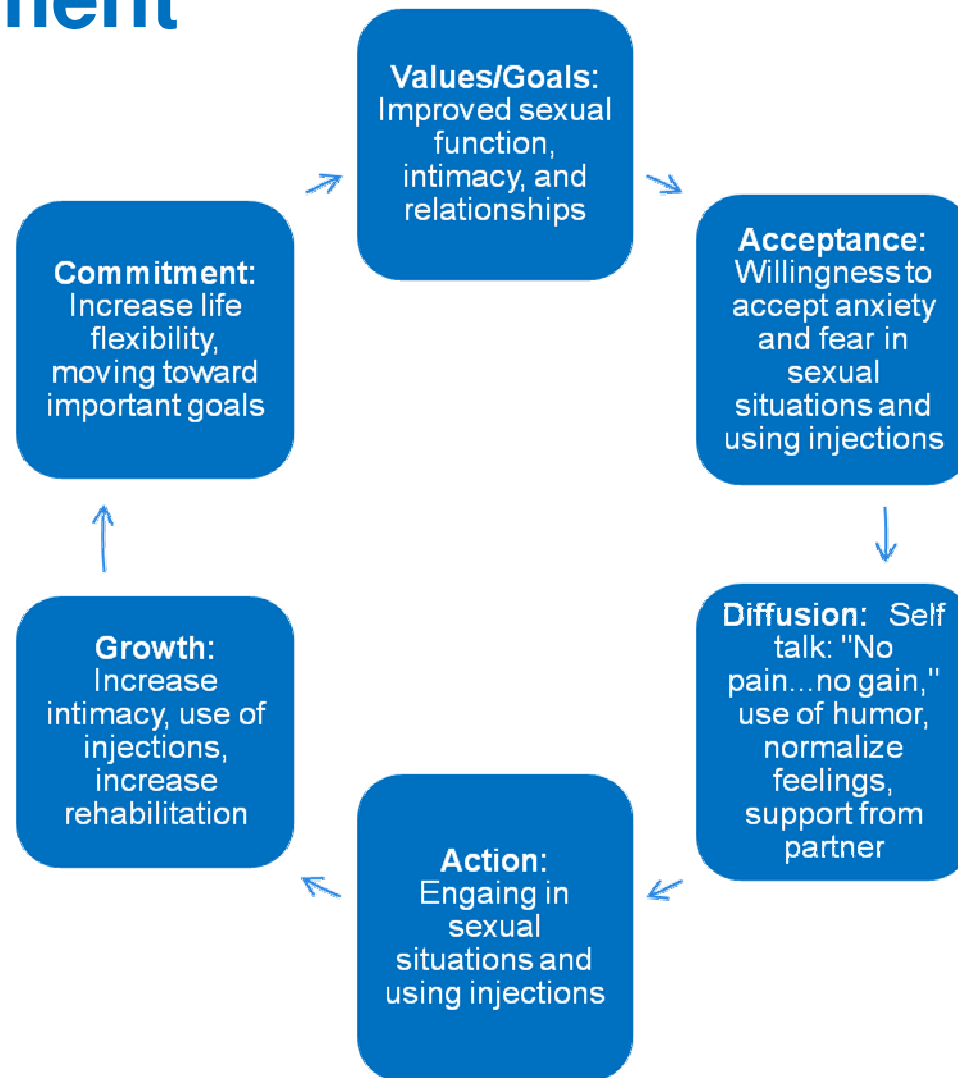


Acceptance and Commitment Therapy

- **Define important values**
- **Accept emotional pain or barriers to achieving valued activities**
 - Acknowledge the distress
 - Willingness to experience the emotional distress
- **Emotional processing of psychological distress**
 - “Exposure” therapy
- **Commitment**



ACT-ED: Cycle of Acceptance and Commitment





ACT-ED Intervention

- **Coaching vs. Therapy**
- **Explore importance of sexuality**
- **Accept short-term anxiety for long-term goal**
 - Listen to patients’ “predictions” about injections
 - Willingness to experience anxiety and frustration
- **Defuse anxiety and frustration**
 - Cognitive/emotional processing
 - Humor
 - Focus on physical sensations in sexual situation
- **Discuss barriers and solutions**
- **Commitment**
 - Set injection target





Willingness

“Courage is simply the willingness to be afraid and act anyway.” – Robert Anthony





Pilot Intervention

- **Randomized:**
 - Injection Training + ACT-ED
 - Injection Training + Nurse Practitioner (NP) Information Phone Calls
- **ACT-ED lasts 4 months**
 - 4 individual sessions (in person/phone, 30-45min)
 - 3 check-in phone calls (5-10min)
- **NP information phone call**
 - Enhanced monitoring (EM)
 - 7 phone calls on the same schedule as ACT-ED





Pilot Intervention

- **Inclusion criteria**

- Within 9 months post-RP
- Had good erectile functioning pre-surgery
 - ≥ 24 IIEF Erectile Function Domain
- Advised to start penile injections

- **Exclusion criteria**

- Specific injection phobia
- A history of bipolar disorder or psychotic disorder
- Current major depression





Primary Outcomes

- **Feasibility**
 - Acceptance rate
 - Completion rate
- **Injection Use (syringe count)**
 - Objective way to assess use of injections



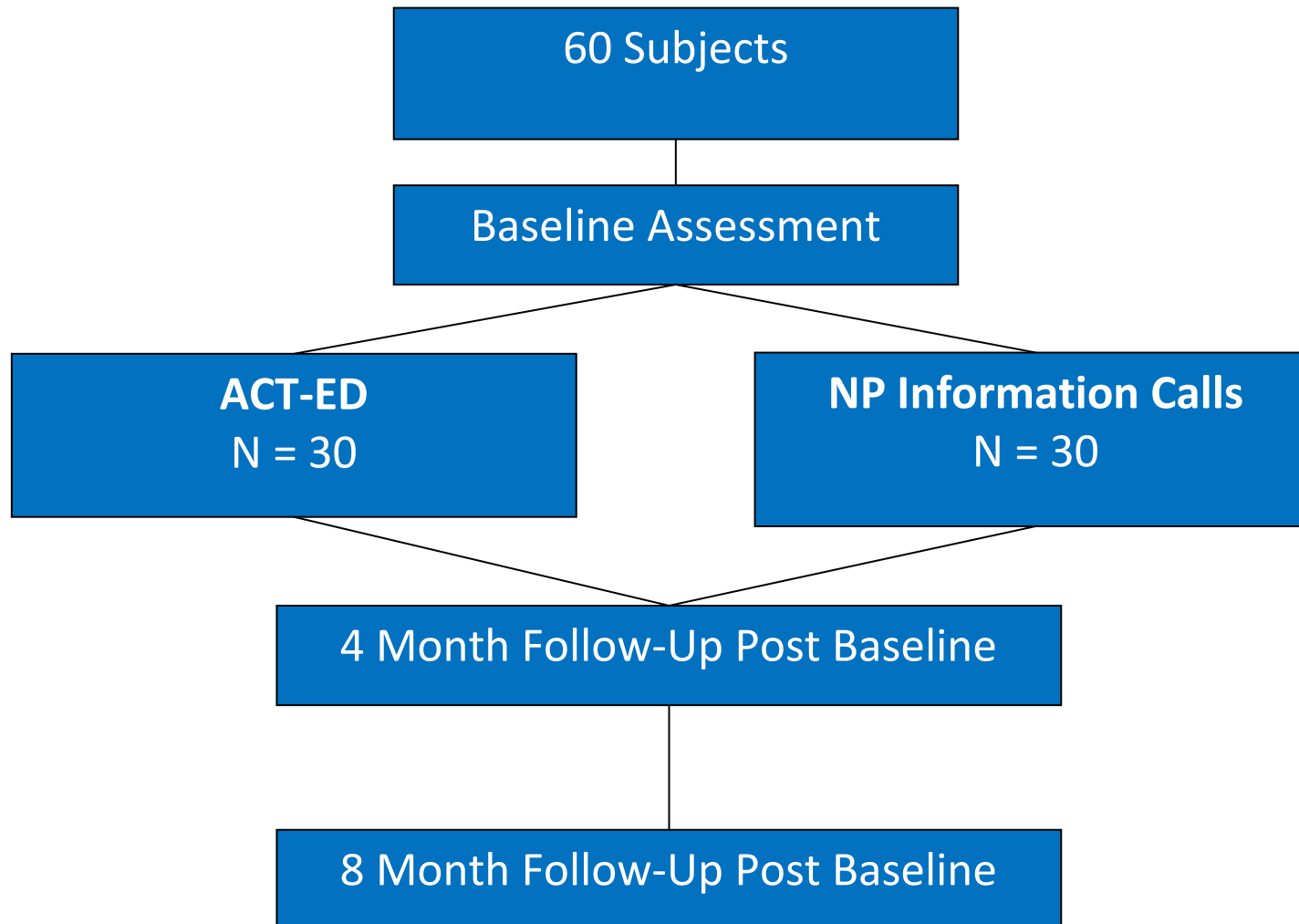


Secondary Outcomes

- **ED treatment satisfaction (EDITS)**
- **Sexual self-esteem and relationship quality (SEAR)**
- **Sexual bother (SB)**
- **Prostate cancer treatment regret**



Pilot Intervention Design



Sample Characteristics

Sample Characteristics		
Total N		53
N by Group:	Intervention	26
	Control	27
Mean Age (years)		60 \pm 7
Race	White	82%
	Black	18%
Relationship Status:	Partnered	73%
	Single	37%
Months Post-Surgery		4 \pm 2
EFD w/Injections	Intervention	24.5 \pm 6
	Control	25.8 \pm 6





Primary Outcome: Feasibility

- **Acceptance rate**

- 63% (53 out of 84)
- 84 subjects approached
- 63 subjects recruited
- 53 subjects started the study

- **Completion rate for intervention group**

- 71% (21 out of 26)
- No difference compared to EM group



Primary Outcome: Injection Use - 4 Months

Injection Use at 4 Months

Variable	Control	Intervention	p
Mean Weekly Injection Use	0.9	1.7	0.001
% Adherence (≥ 2 x weekly)	10%	44%	0.04

Secondary Outcomes: 4 Months

Variable	Intervention vs. Control	p	d
ED Treatment Satisfaction (Range = 0-44)	↑ 6.6 points	0.09	0.71
Sexual Self-Esteem (Range = 0-100)	↑ 9.5 points	0.03	0.76
Sexual Bother (Range = 0-15)	↓ 1.2 points	0.20	0.51
Prostate Cancer Treatment Regret (Range = 0-25)	↓ 4 points	0.01	1.18

Cohen's d effect size: 0.2 = weak; 0.5 = moderate; 0.8 = strong



Primary Outcome: Injection Use - 8 Months

Injection Use at 8 Months

Variable	Control	Intervention	p
Mean Weekly Injection Use	0.7	1.2	0.03
% Adherence (≥ 2 x weekly)	0%	18%	0.18

Secondary Outcomes: 8 Months

Variable	Intervention vs. Control	p	d
ED Treatment Satisfaction (Range = 0-44)	↑ 5.4 points	0.15	0.61
Sexual Self-Esteem (Range = 0-100)	↑ 9.1 points	0.05	0.70
Sexual Bother (Range = 0-15)	↓ 0.9 points	0.40	0.39
Prostate Cancer Treatment Regret (Range = 0-25)	↓ 3.9 points	0.02	0.93

Cohen's d effect size: 0.2 = weak; 0.5 = moderate; 0.8 = strong



ACT-ED Intervention

- **Preliminary pilot data suggests ACT-ED is:**
 - Feasible
 - Effective
- **Significantly increased:**
 - Number of injections per week
 - Adherence to erectile rehabilitation program
- **Moderate to large effects on secondary outcomes**
- **Novel intervention:**
 - Proactively helping men regain erections and mitigating negative psychosocial implications of chronic ED
 - Integrates psychosocial with medical best practice





Current ACT-ED Study

- **R01 Funded Study**
- **Accrual goal: N=310**
- **RCT**
 - Arm 1: Injection Training + ACT-ED
 - Arm 2: Injection Training + Enhanced Monitoring and Education
- **Aims:**
 - ACT-ED will demonstrate better erectile functioning at 24 months post surgery
 - ACT-ED will demonstrate greater sexual self-esteem, less ED bother, depressive symptoms, anxiety, and treatment regret
 - Frequency of injections will mediate above relationships
- **Three in-person sessions, 12 brief phone calls over a year**



Penis broken.
Please use
Finger!

Thanks


SAFETY

CANCEL

1884

Cancer Center

ing



**“Two of the most important things
you can do as a clinician are to
listen to your patients and care for
your patients.”**

Patrick Walsh, MD

Prostate Cancer World Congress, Cairns Australia, 2015



Memorial Sloan Kettering
Cancer Center