



The Prostate Cancer – Patient Empowerment Program reduces mental distress in men undergoing curative treatment: PC-PEP Randomized Trial

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Conflicts of interest: Dr. Gabriela Ilie

Type of affiliation / financial interest	Name of commercial company
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Receipt of honoraria or consultation fees	No
Stock shareholder	No
Other	No

OBJECTIVES



- Background: Mental distress & prostate cancer survivorship
- Description of the Intervention: Prostate Cancer - Patient Empowerment Program (PC-PEP)
- Study Objectives, Methodology and Results
- Conclusion and next steps



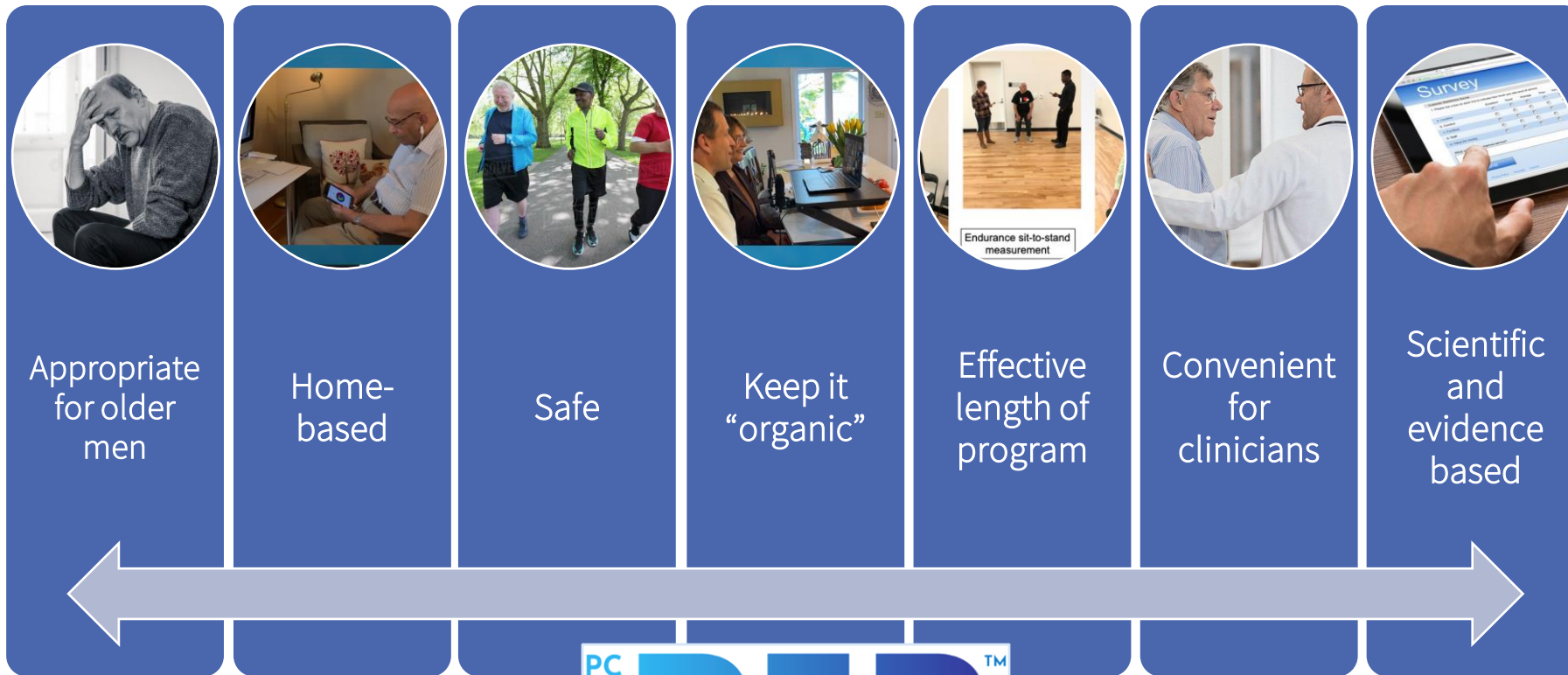
STUDY RATIONALE

- Maritimes survey 2017-2019 – high rates of urinary problems, intimacy and sexuality distress, loneliness, disconnect¹⁻⁸
- In our sample of 500 Maritime PC survivors : 19.5% screened positive¹⁻⁵
 - 18% had treatment regret⁸
- Atlantic path survey of 6585 healthy men^{4,5}
 - Men with history of prostate cancer screened 2-3 time higher of mental distress^{11s}
 - Compared with men without a history of cancer, or any other cancer!
- Canadian Longitudinal Study on Aging looking at 25,183 men⁹
 - 2-3 times higher depression compared with controls
- Meta analysis 2021 – ~ 17.08% depression & 16.86% anxiety; 9% and 8.5% of Canadian men without cancer screen positive for depression and an anxiety, respectively¹⁰
- Danish Nation-wide study of 25,126 men (1828 had a PC diagnosis)¹¹⁻¹²
 - 2-4 times higher rate of prescription for depression



References: ¹Ilie et al., 2019, 2020², 2021a³,b⁴,c⁵; Macdonald et al., 2021;⁶ Gillis et al., 2021,⁷ Bradley et al., 2021;⁸ Masseur et al., 2021;⁹ Moodie et al., 2020; ¹⁰Brunckhors et al., 2021; ¹¹Friberg et al., 2020; ¹²Friberg et al., 2021

Designing the PC-PEP Intervention



Designing the PC-PEP Intervention

Treatment Side Effects

Urinary incontinence
Fatigue
Erectile Dysfunction...



Mental Health Issues

Previous history
Social support
Relationship problems

ADT Side Effects

Hot flashes
Metabolic Syndrome
Osteopenia...

Medical Co-morbidities

Cardiovascular Disease
Diabetes
Obesity.....

- Risk of MI, stroke or CV Death in PC patients is 2% per year (and 4% per year if on ADT)



STUDY HYPOTHESIS AND METHODS

Hypothesis: Men scheduled for curative prostate cancer treatment in the PC-PEP intervention would have less mental distress, anxiety and depression at six months compared to men following the standard of care, and that this benefit would be maintained at 12 months.

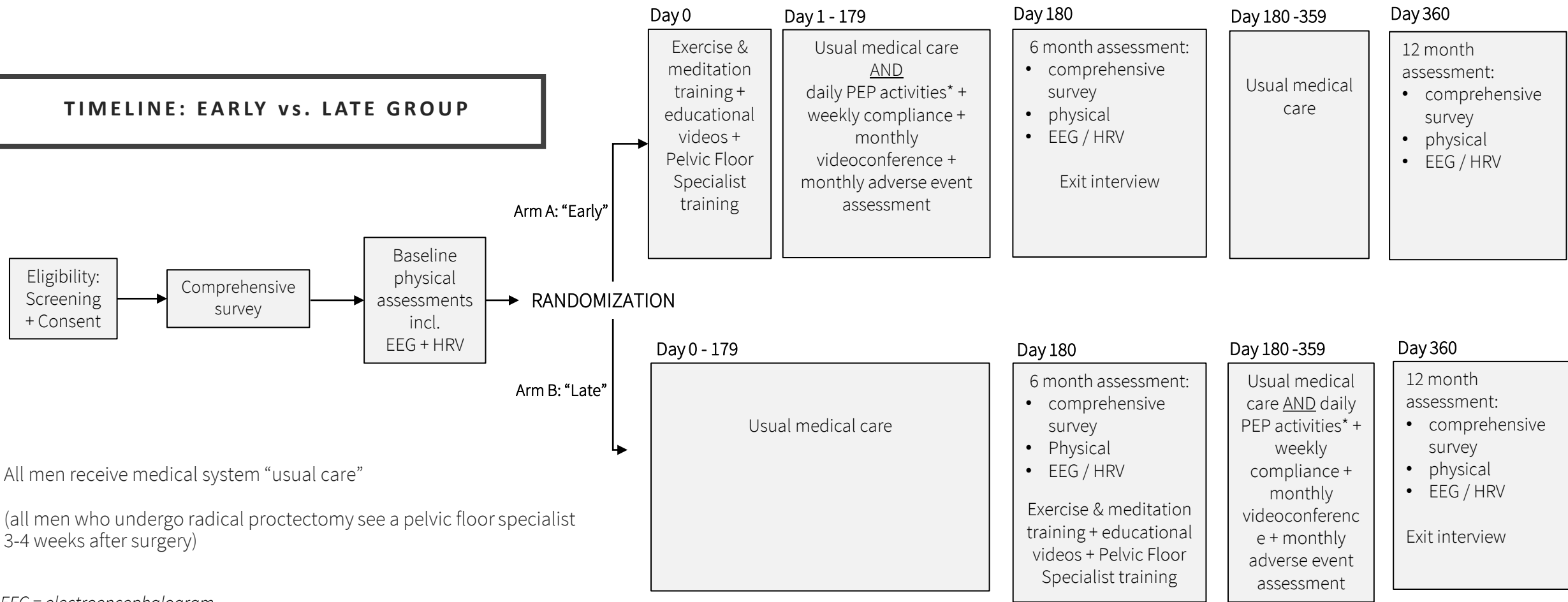
All patients had biopsy-proven prostate adenocarcinoma; recruited from 12/2019 to 01/2021. Study completed on 02/2022.

Men scheduled for and complete surgery (n=62) or curative RT +/- HT (n=54) or salvage RT +/- HT (n=12)

Wait-list controlled RCT phase - Single-site, university, tertiary care

- **Primary Outcome:** Psychological distress (Kessler10 score > 20 indicates need for psychological treatment)
- **Secondary Endpoints:** Urinary, Bowel, Sexual, Hormonal Function, Quality of Life Metric, Physical measurements
 - Safety and cost

TIMELINE: EARLY vs. LATE GROUP

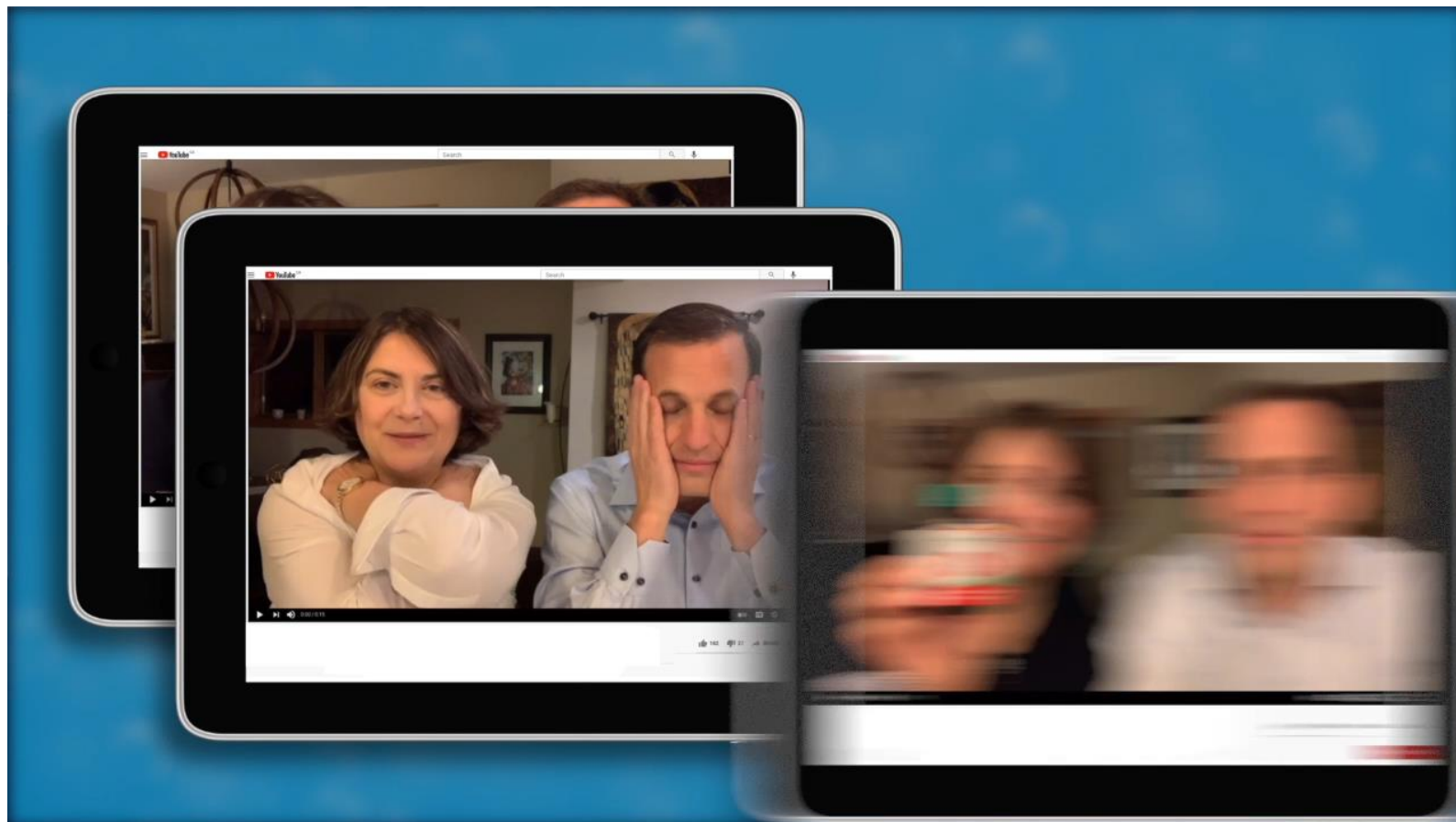


All men receive medical system “usual care”
 (all men who undergo radical prostatectomy see a pelvic floor specialist 3-4 weeks after surgery)

EEG = electroencephalogram
 HRV = Heart Rate Variability

PC-PEP Components

Daily PC-PEP Video Messages



PATIENT EMPOWERMENT PROGRAM DAY 167 – FRIDAY © 2021

Schedule for today

1. View Day 167 Video from Rob and Gabriela at <https://youtu.be/YUbaZK7Hu0> © 2021
2. Practice Relaxation using your Heart Rate Variability (HRV) Monitor 10-min: <https://youtu.be/ja-Hqv57aga> © 2021 or <https://youtu.be/Ppk8OJDNIIE> © 2021
3. Pelvic Floor Exercises (Kegels). Thrice a day standing 10, 10, and 10 as seen in <https://youtu.be/8X1AFKYd7Q> © 2021
4. Aerobic Activity: minimum 30 minutes.
5. Connection - Acts of service. Volunteer to help and ask for help to connect.
6. Diet - Cruciferous vegetables are the important veggies for prostate cancer.

EXTRA RESOURCES - You can find the links to the videos of all the talks, how to download and use the heart rate variability software, and mentor contact information at <http://soilseprostatecancerqualityofliferesearch.chc.dal.ca/wordpress/index.php/pc-pep-educational-materials/>. The confidential password is 1010.

Bless you all!

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PC-PEP Components

Aerobic exercise



Aerobic Exercise

- -30+ minutes per day, 6+ days per week
- -Any activity – think fun!
- -Not sitting for long periods

Strength training



Strength Training

- Twice per week – Monday and Thursday
- Body-weight and elastic bands
- Follow 30-minute videos
- 4 levels of difficulty
- Training by Exercise Specialist

Workout A **PEP**

Shoulder Press



Chest Press



Triceps Extension



Air Squat



Calf Raise



Side Lunges



Hydrant



Front Plank



Cat Cow



PC-PEP Components

Pelvic floor muscle training: 7-9 minutes, three times a day, +/- text reminders, new video each week



Pelvic floor training

Relaxation Technique
2 minutes



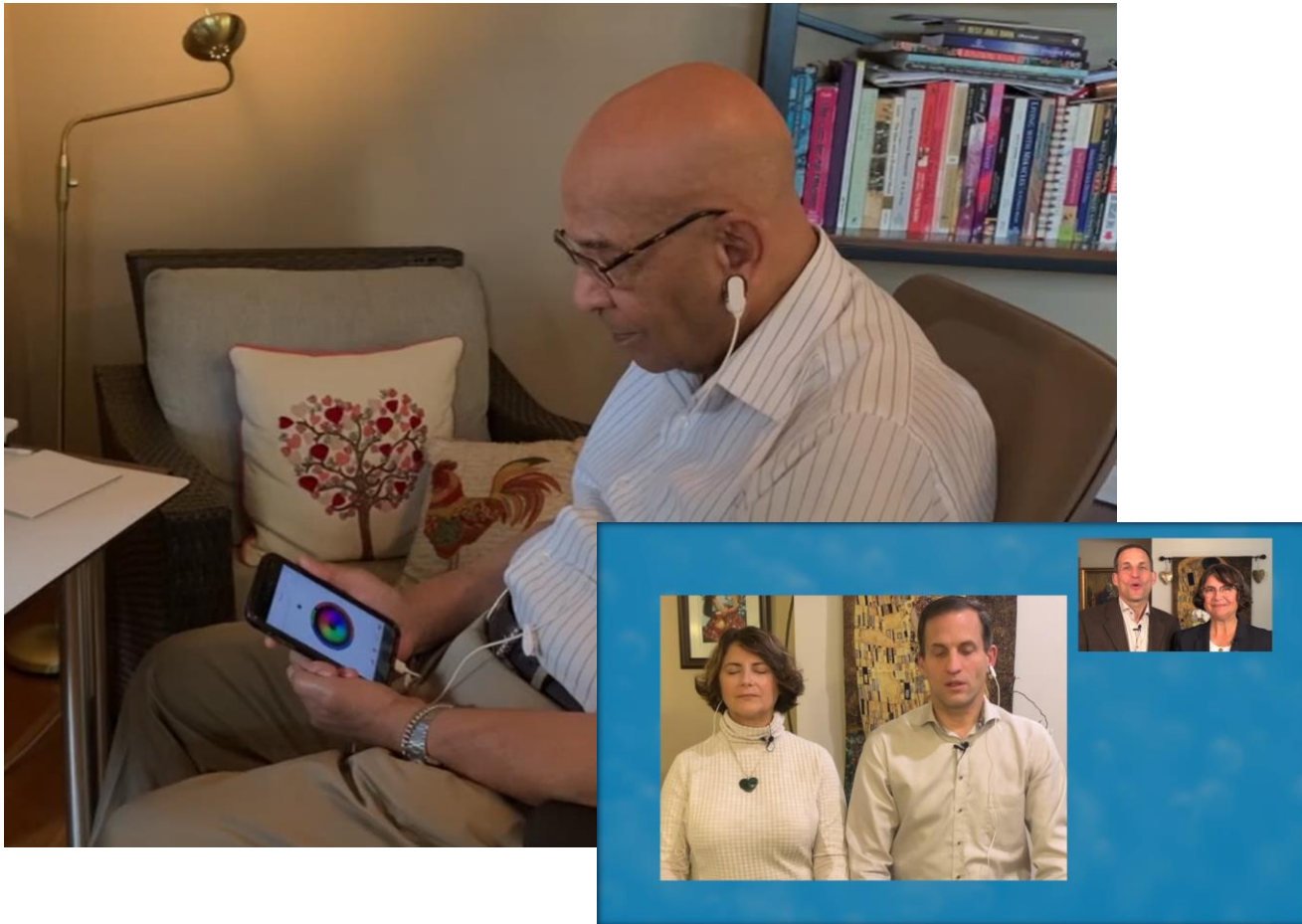
2 sets of Long Holds
2 Sets of Quick Flicks
5 minutes total



High-risk Practice
'Blow before you go'
1 minute

PC-PEP Components

Stress reduction with Biofeedback device



Meditation

- 10 minutes per day
- Heart-rate variability monitor
- HeartMath.org
- Strong science – practice improves:
 - Mental health
 - Multiple medical issues

PC-PEP Components

Dietary recommendations



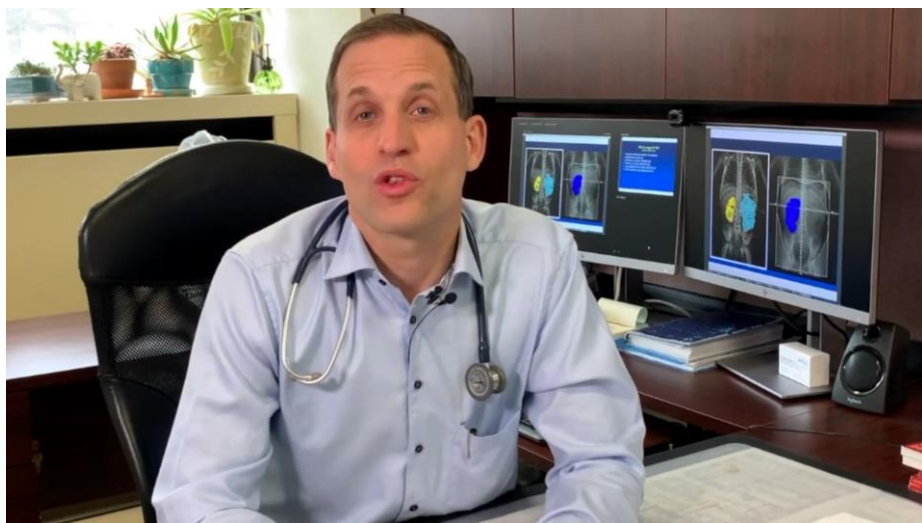
Dietary Advice

- Daily video message
- Transformation over 6 months
- Swap in healthier foods
- Decrease red meat
- Increase fruits and veggies
- Vitamin D!
- Connecting with loved ones

Prescribed Intimacy and Connection exercises



Intimacy, erectile dysfunction, & relationship teachings



- Daily video discussion
- Prescribed exercises:
 - E.g., Walking Wednesday, call someone at a distance
- Love Languages and types of intimacy
- Imago technique
- The role of forgiveness in healing
- Seeing another person's interest as your own
- Engage with the intent of joining



PC-PEP Components

Social Support

- Buddy System – weekly phone call
- Monthly zoom video conference
- Scientific update of activities
- Small and large group discussion



Weekly Compliance

- Every Sunday online survey -5 minutes
- Measures the frequency and length of time of each activity:
 - Aerobic exercise, strength, kegels, meditation, dietary, intimacy/connection
- Acts as a reminder / keeps men accountable

	Overall (n=128)	PC-PEP (n=66)	Control (n=62)
Age, mean, SD	66 years	65 years (6.8)	67 years (7.2)
<i>BMI, mean (SD)</i>	28.62	28.78 (4.96)	28.45 (5.04)
Household Income, >30,000 CAD/past year, %	82.8%	81.8%	83.9%
<i>Education, university or above, %</i>	53.1%	47.0%	59.7
Relationship status, married or currently in a relationship, %	93.8%	89.4%	98.4%
Risk Disease (non-salvage), n, %			
<i>Low</i>	3, 2.3%	1, 1.5%	2, 3.2%
<i>Intermediate</i>	82, 64.1%	42, 63.6%	40, 64.5%
<i>High</i>	31, 24.2%	13, 19.7%	18, 29.0%
Prescribed ADT n, %	48, 37.5%	40.9%	33.9%
Treatment modality			
<i>Radical Prostatectomy</i>	62, 48.4%	29, 43.9%	33, 53.2%
<i>Radiation therapy</i>	54, 42.2%	27, 40.9%	27, 43.5%
<i>Radiation therapy (Salvage)</i>	12, 9.4%	10, 15.2%	2, 3.3%
Charlson Comorbidity Index age adjusted, mean (SD)	2.55 (1.07)	2.45 (1.13)	2.64 (1.03)
<i>Time between randomization and treatment (days), mean (SD)</i>	67.27 (38.52)	64.41 (36.68)	70.32 (40.45)
Diseases status - no evidence of reoccurrence at 6 months	94.5%	95.5%	93.3%

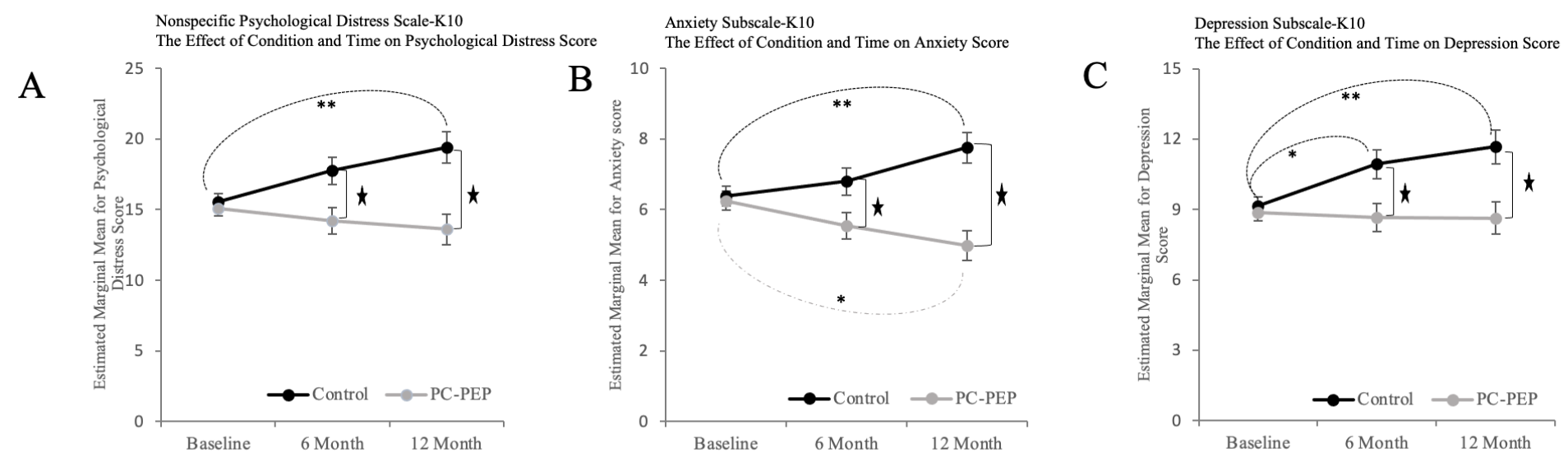
Baseline Characteristics

(n=128 eligible)

Balanced groups

RCT Results at 6 months and 1 year post Intervention (European Urology, 2022, in print)

Figure 1. Effect of PC-PEP intervention on non-specific psychological distress, depression and anxiety from baseline to 6, and 12 months among 128 curative prostate cancer patients treated in Nova Scotia, Canada (p values: *<0.05, **<0.01)



* p<0.05; ** p < 0.01

- Medium effect sizes were observed for all significant interactions (Cohen’s d 0.5 to 0.8), calculated as $d=2*\sqrt{F/df}$
- The removal of the salvage radiation group from the sample, at 6 and 12 months

Clinically Significance

- At 6 months: Control group had 3.59 times chance for screening positive for psychological distress in need of treatment compared to those who received the PC-PEP
- At 12 months risk was 2.57 times higher ($p=.056$)
- High compliance on all aspects of the program assessed through weekly compliance surveys.



Limitations

- Whether the beneficial effects we observed at six and 12 months are sustainable over longer periods after diagnosis remains unclear.
 - A Phase 4 implementation trial is set to test this
- The intervention was time-and effort-intensive (70+ minutes of prescribed activities daily).
- The trial design may have worsened the mental health of the men randomized to the wait-list control group by delaying their access to the intervention.

Strengths

- Successful at decrease distress, anxiety and depression
- Program appears safe, home-based
- No attrition & high compliance
- Can be administered from a distance
- Urban, rural and international access
- Cheap to administer
- Easily expanded to other types of cancer & diseases
- PC-PEP activates the role of the patient in their own care
- High patient endorsement 9.4/10
- Brings the medical system, patients and community organizations together to better serve the patients and their families

MEET SOME OF OUR TEAM



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PC-PEP NZ Lead



Gabriela Ilie
PC-PEP Program Lead



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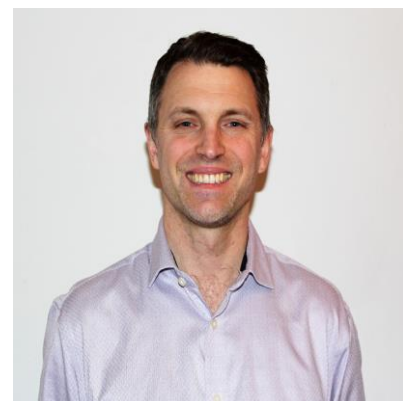
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MEET SOME OF OUR TEAM



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THANK YOU

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