APPENDIX A. Supplementary CONSORT 2010 checklist

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomized trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2-3
	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3-4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	3-4
	4b	Settings and locations where the data were collected	3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	3-6 Protocol Published in Ilie, Rendon et al. 2023, European Urology
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	3-6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	Published in Ilie, Rendon et al. 2023, European Urology
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			

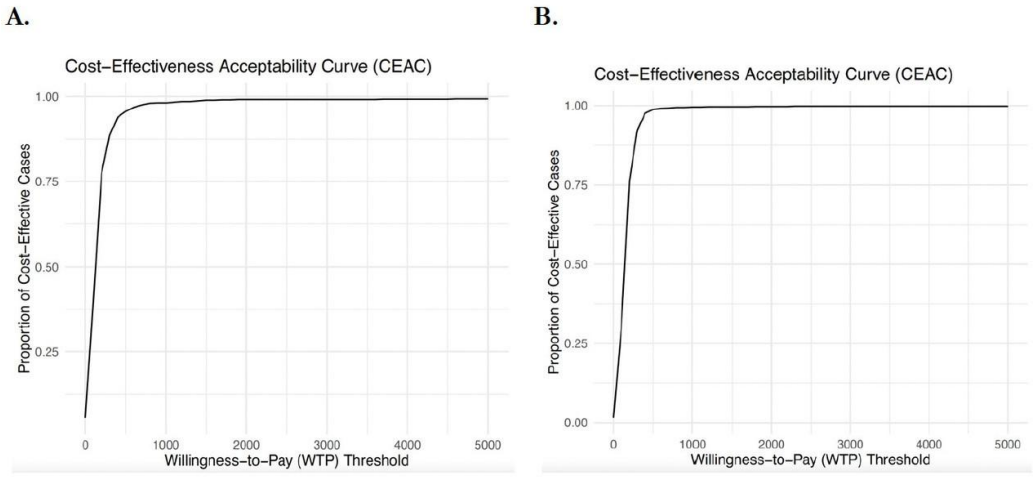
ɛquence generation	8a	Method used to generate the random allocation sequence	Published in Ilie, Rendon et al. 2023, European Urology
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8 and Published in Ilie, Rendon et al. 2023, European Urology
llocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	3 and Published in Ilie, Rendon et al. 2023, European Urology
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	3 and Published in Ilie, Rendon et al. 2023, European Urology
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	3 and Published in Ilie, Rendon et al. 2023, European Urology
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	6
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	6-13
	13b	For each group, losses and exclusions after randomisation, together with reasons	6-13
Recruitment	14a	Dates defining the periods of recruitment and follow-up	3,5
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	6-7
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	7-13
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	7-13

	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	7-13
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	7-13
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	no injuries or harms were reported
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13-21
Other information			
Registration	23	Registration number and name of trial registry	3,18
Protocol	24	Where the full trial protocol can be accessed, if available	Published in Ilie, Rendon et al. 2023, European Urology
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	18

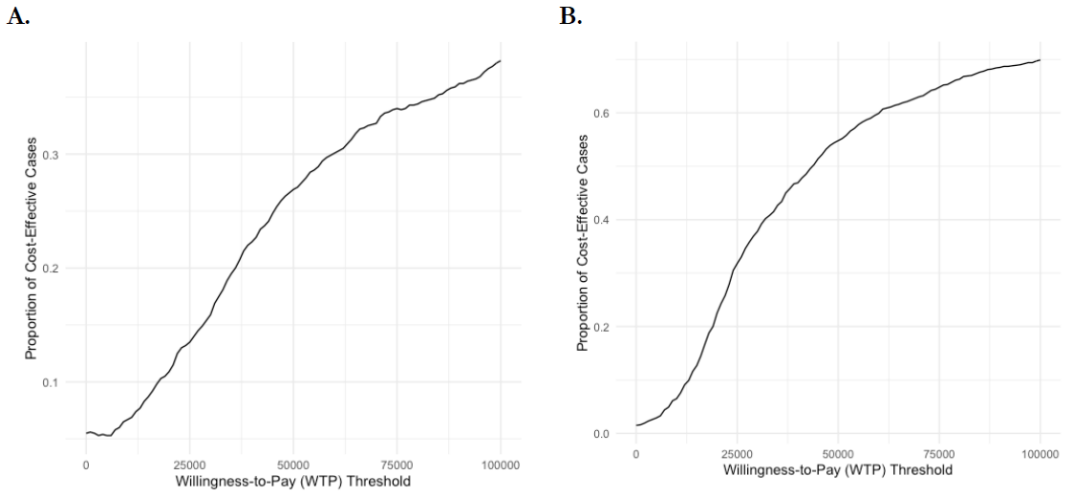
*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

APPENDIX B. Supplementary Figures and Tables

Supplementary Figure 1. Cost-effectiveness acceptability curves (CEAC) showing the probability that Prostate Cancer Patient Empowerment Program (PC-PEP) is cost-effective across willingness-to-pay (WTP) thresholds when using non-specific psychological distress as the effectiveness measure from (A) baseline to six months; and (B) baseline to 12 months.



Supplementary Figure 2. Cost-effectiveness acceptability curves (CEAC) illustrating the probability that Prostate Cancer Patient Empowerment Program (PC-PEP) is cost-effective across willingness-to-pay (WTP) thresholds when using quality-adjusted life years (QALYs) as the effectiveness measure from (A) baseline to six months; and (B) baseline to 12 months.



Supplementary Table 1. Breakdown of the estimated intervention costs in 2022 for 80 participants is presented in CAD			
Items	**Units**	**$/Unit**	**Total cost**
Participant materials			
Inner Balance (Bluetooth model)	30	$183.25	$5497.50
emWave2 (Wired/handheld model)	10	$207.00	$2070.00
Resistance tubing (three tubes/participant)	80	$13.66	$1092.80
Exercise tube assist straps/handles (2/participant)	160	$2.24	$358.80
Exercise tube door anchors	80	$2.59	$207.20
Text messages (3/day for 182 days)*	21840	$0.05	$1179.36
Printing participant handouts	80	$2.50	$200.00
Mailing (50% of participants)**			
Parcel with participant materials	40	$20.00	$800.00
Return HRV device[1]	40	$20.00	$800.00
Envelopes, bubble mailers, stamps	40	$5.00	$200.00
Personnel time***			
Research assistant/coordinator	120 hours	$30.00/hour	$3600.00
Total			**$16 005.66**
Cost per participant			**$200.07**

[1]Inner Balance or emWave 2 Heart Rate Variability (HRV) HeartMath® devices were loaned to participants for six months and are reusable, contributing to cost efficiency. Costs are subject to variation based on fluctuations in the USD-CAD exchange rate. The displayed costs include a bulk discount. *The budget for text messaging reflects an estimated usage by 50% of participants, based on opt-in data from previous cohorts. **Mailing costs are estimated based on a 50% distribution, with half of the participants opting to receive materials by mail and the remaining 50% collecting materials in person. Additional savings could be realized if a greater proportion of participants choose to pick up materials directly. ***Personnel costs are estimated based on maximum projected hours worked and may vary depending on actual time spent on program activities.

Supplementary Table 2. The effectiveness of the intervention was measured as the average change in QALYs from baseline to six months and baseline to 12 months for the early PC-PEP intervention and waitlist-control (late PC-PEP) groups				
	PC-PEP early group (n=61)	**Waitlist-control late PC-PEP group (n=58)**	**Incremental QALY gain**	**p**
QALY per person at 6 months	-0.0045	-0.018	0.013	0.2
QALY per person at 12 months	0.00021	-0.034	0.034	0.13

PC-PEP: Prostate Cancer Patient Empowerment Program; QALY: quality-adjusted life years.

Supplementary Table 3. Cost-effectiveness analysis of the early PC-PEP intervention compared to the waitlist-control (late PC-PEP) group revealing a dominant economic model, from baseline to 6 months, and baseline to 12 months					
Period	**Group**	**Total cost/patient**	**Effectiveness QALY**	**Incremental cost savings per patient**	**Incremental effectiveness**
Baseline to 6 months	PC-PEP	$1569.02	-0.0045	$411.53	0.013
	Standard care	$1980.55	-0.018		
Baseline to 12 months	Early PC-PEP	$1981.25	0.00021	$660.89	0.034
	Late PC-PEP	$2642.14	-0.034		

Based on QALYs as the effectiveness measure presented in CAD. PC-PEP: Prostate Cancer Patient Empowerment Program; QALY: quality-adjusted life years.

Supplementary Table 4. Results of subgroup analyses testing cost-effectiveness by age and treatment modality for non-specific psychological distress (K10) and QALYs from baseline to 6 months, and baseline to 12 months			
Time frame	**Effectiveness measure**	**Subgroup**	
		Age	**Treatment modality**
Baseline to 6 months	K10	0.27	**0.016**
	QALYs	0.32	0.061
Baseline to 12 months	K10	0.22	**0.019**
	QALYs	0.82	0.5

QALY: quality-adjusted life years.