Eficacia de una intervención terapéutica de incremento de actividad en supervivientes de cáncer de próstata

Tesis doctoral internacional

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Javier Martín Núñez

Directora: Marie Carmen Valenza

Departamento de Fisioterapia

Facultad de Ciencias de la Salud

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Autor: Javier Martín Núñez
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RESUMEN

El cáncer es uno de los diez principales desafíos sociosanitarios tanto en la actualidad como en el futuro siendo la principal causa de muerte en 2020. Las últimas estimaciones publicadas en GLOBOCAN presentan el cáncer de próstata como la segunda etiología oncológica con más prevalencia a nivel mundial, estimándose un total de 1.276.000 nuevos casos.

En hombres es el cáncer más frecuente diagnosticado seguido del cáncer de pulmón y colorrectal, presentando además mayor incidencia en los países desarrollados. En relación a la mortalidad, el cáncer de próstata no se encuentra entre las principales causas de mortalidad por cáncer debido que solo afecta a los hombres, lo que supone la novena causa de muerte por cáncer cuando se tienen en cuenta ambos sexos.

El cáncer es considerado una enfermedad genética debido a que los tumores se forman por la presencia de mutaciones que provocan la proliferación y crecimiento descontrolado de las células en tejidos sanos. En el caso específico del cáncer de próstata, no se conocen con precisión las causas exactas. Se considera que la mayoría de los casos son el resultado de una interacción de múltiples factores que incrementan el riesgo de desarrollo de esta enfermedad.

En relación a la etiología del cáncer de próstata, el adenocarcinoma de próstata que es la etiología más diagnosticada, alcanzando hasta el 98% de los casos diagnosticados y se origina en el tejido glandular prostático

El tratamiento médico del cáncer de próstata se compone principalmente de cuatro estrategias; cirugía, radioterapia con o sin hormonoterapia y vigilancia activa. Se sabe que el cáncer de próstata suele ser asintomático en sus etapas iniciales, sin embargo, a medida que el tumor crece y avanza pueden aparecer síntomas urinarios y sistemáticos que reflejen esta progresión de la patología como los dolores y fracturas óseas, compresión medular, pérdida

de peso inexplicable o alteración del sistema linfático y venoso, fatiga, disminución niveles de actividad física y funcionamiento físico reducido, ansiedad y depresión, trastornos del sueño y déficits cognitivos; que se ven afectados aún más como secuela del tratamiento médico oncológico.

La rehabilitación multidisciplinar de los pacientes con cáncer de próstata ha demostrado ser efectivo mejorando efectos secundarios a estos tratamientos médicos, en particular a la pérdida de masa muscular y ósea, síntomas genitourinarios, así como la fatiga promoviendo así una mejora del estado de salud físico y psicológico de estos pacientes, además las nuevas tendencias de tratamiento rehabilitador se centran en hacer partícipes de forma activa y ayudarlos con estrategias de motivación, actividades grupales, educación y uso de tecnología para que los efectos del mismo perduren en el tiempo.

Por ello el objetivo general de esta tesis doctoral es Establecer un perfil cínico de los pacientes de cáncer de próstata tras tratamiento médico y un marco terapéutico de referencia que permita mejorar la sintomatología de los pacientes con cáncer de próstata tras recibir tratamiento médico

El desarrollo de esta tesis doctoral se llevó a cabo mediante tres estudios en línea con estos objetivos. El primer estudio consistió en un estudio trasversal de cohorte que tenía como objetivo caracterizar r el perfil clínico de pacientes de cáncer de próstata un año después de haber recibido tratamiento radioterápico, observando como repercute este tratamiento en la calidad de vida, niveles de actividad, barreras al ejercicio y autoeficacia. Los resultados de este estudio mostraron que los pacientes con cáncer de próstata presentaban disminución de los niveles de actividad y mayores barreras a la actividad física, así como una calidad de vida y autoeficacia disminuida

El segundo estudio fue una revisión sistemática y meta-análisis que tuvo como objetivo Evaluar la efectividad de las intervenciones de autocuidado sobre la calidad de vida y la autoeficacia en pacientes con cáncer de próstata. Los

resultados de este estudio mostraron que las intervenciones de autocuidado tenían un efecto positivo en la calidad de vida y mejoraban la autoeficacia de estos pacientes

Y el tercer estudio tuvo como objetivo Evaluar la efectividad de la educación mejorada en la en los síntomas urinarios, el estado psicoemocional y la autoeficacia en pacientes con cáncer de próstata. Los resultados de este estudio mostraron que la educación mejorada tiene efectos positivos sobre los síntomas urinarios, el estado psicoemocional y la autoeficacia de estos pacientes.

En conclusión, os niveles de actividad física, las barreras a la actividad física, la calidad de vida y la autoeficacia son factores claves a tener en cuenta en aquellos pacientes de cáncer de próstata que reciben tratamiento oncológico. Por tanto, desarrollar la valoración de estos aspectos permitirán plantera intervenciones individualizadas y con una participación activa de los pacientes. Los programas basados en estrategias de automanejo y educación son una buena alternativa para mejorar la calidad de vida y la autoeficacia de los pacientes de cáncer de próstata, pudiendo ser una buena estrategia para mejorar el estado psicoemocional y los síntomas urinarios de estos pacientes, y por tanto en última instancia su supervivencia.

ABSTRACT

Cancer is one of the top ten health and social challenges both now and in the future and will be the leading cause of death by 2020. The latest estimates published in GLOBOCAN present prostate cancer as the second most prevalent cancer etiology worldwide, with an estimated total of 1,276,000 new cases.

In men, it is the most frequently diagnosed cancer, followed by lung and colorectal cancer, with a higher incidence in developed countries. In terms of mortality, prostate cancer is not among the leading causes of cancer mortality because it only affects men, making it the ninth leading cause of cancer death when both sexes are taken into account.

Cancer is considered a genetic disease because tumours are formed by the presence of mutations that cause the uncontrolled proliferation and growth of cells in healthy tissues. In the specific case of prostate cancer, the exact causes are not precisely known. It is believed that most cases are the result of an interaction of multiple factors that increase the risk of developing the disease.

Regarding the etiology of prostate cancer, prostate adenocarcinoma is the most commonly diagnosed etiology, accounting for up to 98% of diagnosed cases and originating in prostate glandular tissue.

Medical treatment of prostate cancer consists mainly of four strategies; surgery, radiotherapy with or without hormone therapy and active surveillance.

It is known that prostate cancer is usually asymptomatic in its early stages, however, as the tumor grows and progresses urinary and systemic symptoms may appear reflecting this progression of the pathology such as bone pain and fractures, spinal cord compression, unexplained weight loss or alteration of the lymphatic and venous system, fatigue, decreased levels of physical activity and reduced physical functioning, anxiety and depression, sleep disorders and cognitive deficits; which are further affected as a sequel to medical oncology treatment.

The multidisciplinary rehabilitation of prostate cancer patients has proven to be effective in improving the side effects of these medical treatments, in particular the loss of muscle and bone mass, genitourinary symptoms, as well as fatigue, thus promoting an improvement in the physical and psychological health of these patients. In addition, new trends in rehabilitation treatment focus on actively involving and helping them with motivational strategies, group activities, education and the use of technology so that the effects of the treatment last over time.

Therefore, the general objective of this doctoral thesis is to establish a cynical profile of prostate cancer patients after medical treatment and a therapeutic frame of reference to improve the symptomatology of prostate cancer patients after medical treatment.

The development of this doctoral thesis was carried out through three studies in line with these objectives. The first study consisted of a cross-sectional cohort study that aimed to characterise the clinical profile of prostate cancer patients one year after receiving radiotherapy treatment, observing the impact of this treatment on quality of life, activity levels, barriers to exercise and self-efficacy. The results of this study showed that prostate cancer patients had decreased activity levels and increased barriers to physical activity, as well as decreased quality of life and self-efficacy.

The second study was a systematic review and meta-analysis that aimed to evaluate the effectiveness of self-care interventions on quality of life and self-efficacy in prostate cancer patients. The results of this study showed that self-management interventions had a positive effect on quality of life and improved self-efficacy in these patients.

And the third study aimed to evaluate the effectiveness of enhanced education on urinary symptoms, psychoemotional state and self-efficacy in prostate cancer patients. The results of this study showed that enhanced

education has positive effects on urinary symptoms, psychoemotional state and self-efficacy of these patients.

In conclusion, physical activity levels, barriers to physical activity, quality of life and self-efficacy are key factors to take into account in prostate cancer patients receiving cancer treatment. Therefore, developing the assessment of these aspects will allow the planning of individualised interventions with the active participation of patients. Programmes based on self-management strategies and education are a good alternative to improve the quality of life and self-efficacy of prostate cancer patients, and may be a good strategy to improve the psycho-emotional state and urinary symptoms of these patients, and therefore ultimately their survival.

INTRODUCCIÓN

Contextualización

El término cáncer abarca un amplio grupo de enfermedades que pueden desarrollarse en la mayoría de los tejidos del cuerpo humano. Normalmente, las células de un organismo pasan por un proceso de crecimiento y división celular en respuesta a las necesidades del cuerpo, como son la cicatrización de heridas, la reparación de fracturas óseas, o el crecimiento y envejecimiento natural de una persona. (1,2) No obstante, este proceso de división celular puede alterarse debido a mutaciones disruptivas, lo que provoca que una célula adquiera la capacidad de dividirse de manera incontrolada e indefinida, transformándose en una célula cancerosa. (3)

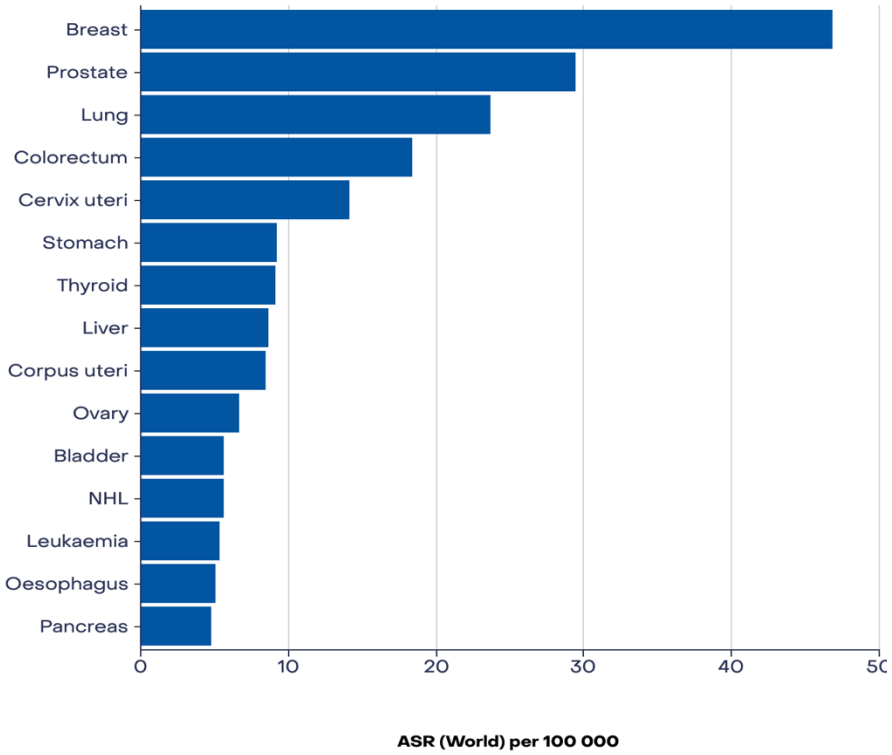
Cuando este proceso ocurre en tejido glandular prostático se determina cáncer de próstata. En esta etiología, el proceso tumoral se puede desarrollar en el tejido epitelial luminal, basal y/o estromal de la glándula del aparato reproductor masculino. (4)

Epidemiología

El cáncer es uno de los diez principales desafíos sociosanitarios tanto en la actualidad como en el futuro. Este grupo de enfermedades fue la principal causa de muerte en 2020 con aproximadamente 10 millones de muertes anuales.

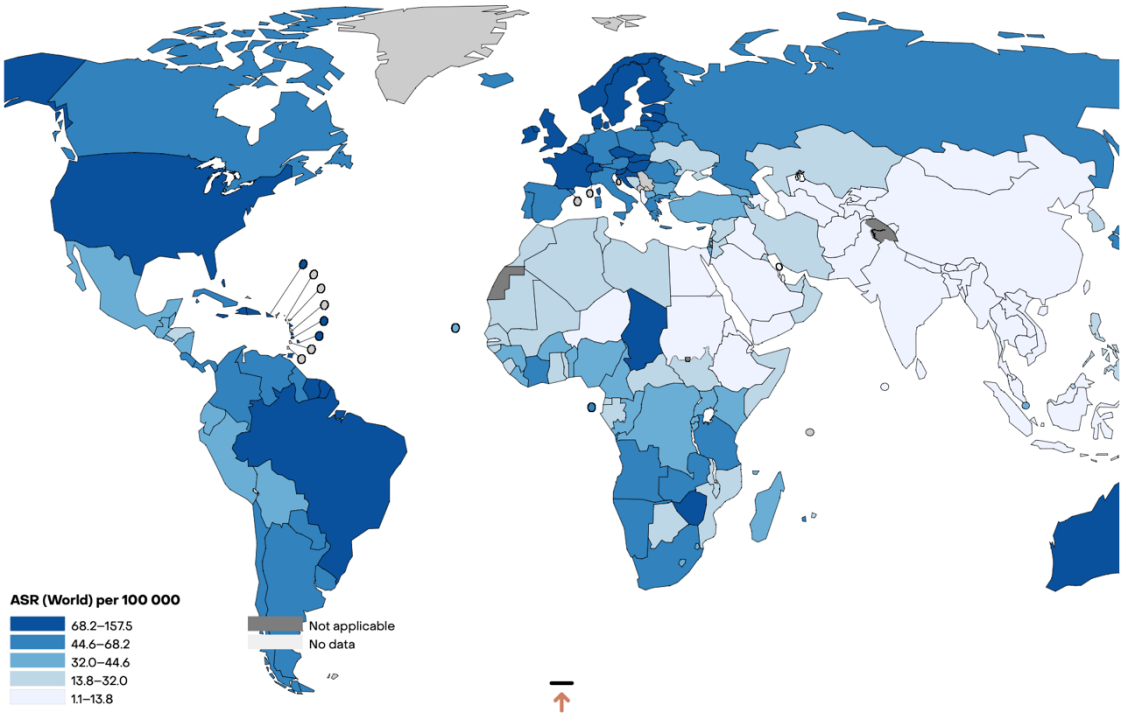
Las últimas estimaciones publicadas en GLOBOCAN presentan el cáncer de próstata como la segunda etiología oncológica con más prevalencia a nivel mundial, estimándose un total de 1.276.000 nuevos casos (Figura 1). (5,6)

Figura 1: Estimación de la ratio de incidencia mundial de los tipos de cáncer en hombres



En España, la incidencia representa un riesgo medio con respecto a la población mundial, con una estimación de 30.316 nuevos casos en 2024. La tasa de incidencia estandarizada por edad determina a España como uno de los países con mayor tasa, como se puede observar en la figura 2. (6)

Figura 2: Mapa de estimación de incidencia mundial de cáncer de próstata en hombres



En hombres es el cáncer más frecuente diagnosticado seguido del cáncer de pulmón y colorrectal, presentando además mayor incidencia en los países desarrollados. Además, se prevé una evolución creciente de la incidencia y que esta continúe en ascenso alcanzando hasta los 2.6 millones de casos en 2045, lo que representaría un 79% más de nuevos casos diagnosticados de cáncer de próstata. (6) En consonancia con estos resultados se espera que los casos de cáncer de próstata en España alcancen la cifra de 46 mil casos para los años 2045. (6)

Figura 3: Mapa de estimación de mortalidad mundial de cáncer de próstata en hombres

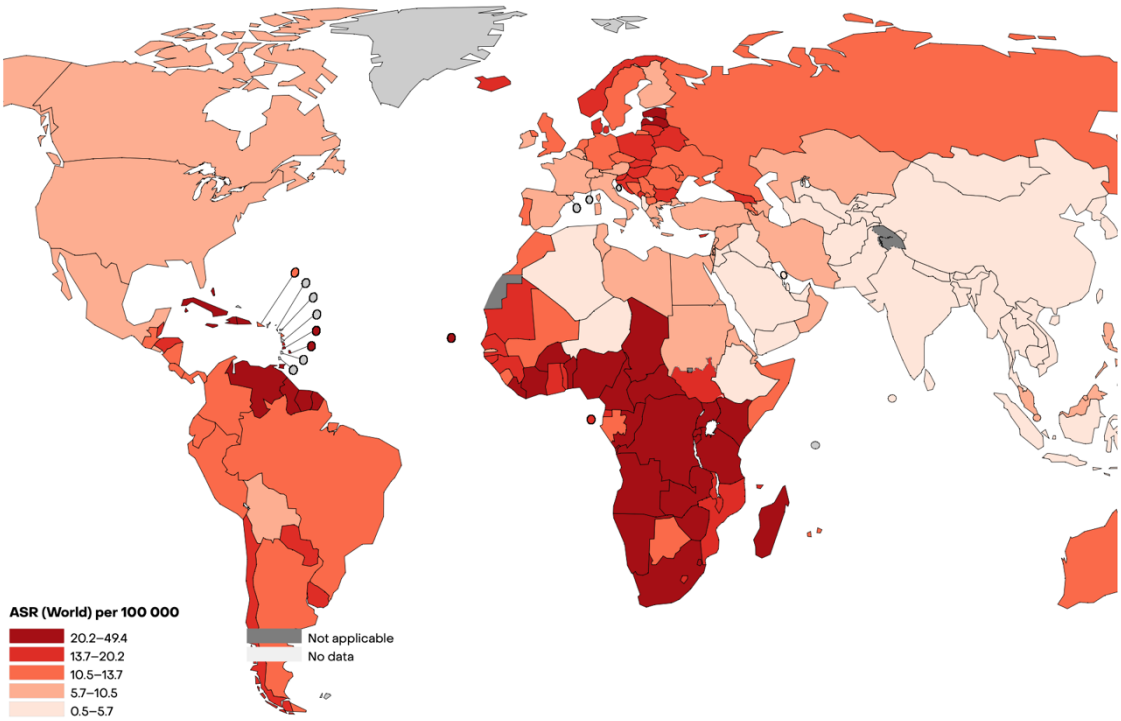
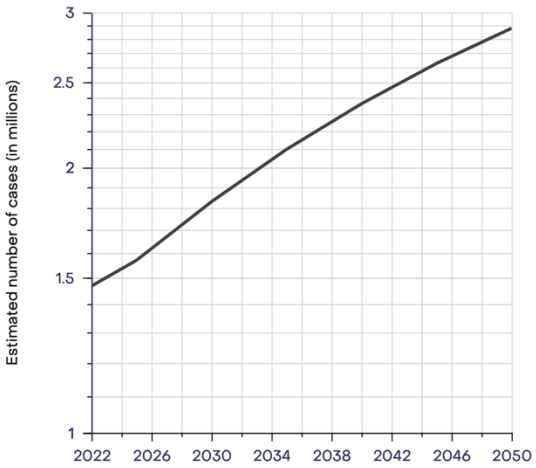


Figura 4: Estimación de incidencia mundial de cáncer de próstata para hombres en 2050



En relación a la mortalidad, el cáncer de próstata no se encuentra entre las principales causas de mortalidad por cáncer debido que solo afecta a los

hombres, lo que supone la novena causa de muerte por cáncer cuando se tienen en cuenta ambos sexos. Las últimas estimaciones de 2020 determinaron un total de 376.200 muertes, lo que representa un total de 3,8% del total de muertes por cáncer. (7) Sin embargo, cuando solo se considera a los hombres el cáncer de próstata supone la segunda causa de mortalidad en cáncer tras el cáncer de pulmón. En lo referente a la población española, el número de muertes ascendió hasta 6.217 en el año 2022. (6)

Sin embargo, gracias a la detección temprana y al avance en los tratamientos, la supervivencia de estos pacientes ha experimentado una notable mejoría en los últimos años. (8) Actualmente, es posible prevenir entre el 30% y el 50% de los casos de cáncer mediante la reducción de factores de riesgo y la implementación de estrategias preventivas basadas en la evidencia científica. De este modo, si se diagnostican de manera oportuna y se tratan de forma adecuada, las probabilidades de curación para muchos tipos de cáncer son significativamente altas. (1)

La tasa de supervivencia relativa a 5 años de todos los cánceres ha incrementado hasta un 67%. Concretamente el cáncer de próstata es la etiología con mayor tasa de supervivencia relativa a 5 años, alcanzando un 98%, (9) que se atribuye a una etapa más temprana en el diagnóstico mediante la prueba de (PSA), así como los avances en el abordaje de la patología. (10)

Fisiopatología

El proceso de crecimiento tumoral, conocido como carcinogénesis, se desarrolla en tres fases (Figura 4). Inicialmente, ocurre la transformación oncogénica de las células, influenciada por los radicales libres del entorno a través del daño oxidativo al ADN, la inhibición de los mecanismos regulados

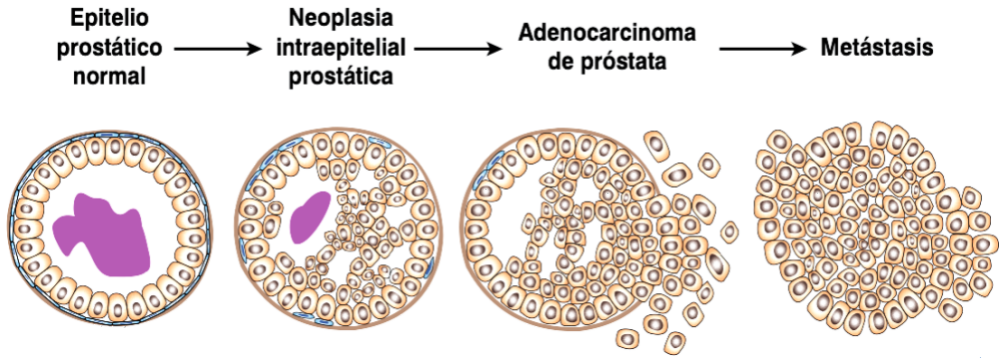
de apoptosis celular y la promoción de la expresión de los "oncogenes". Esta etapa se denomina fase de Iniciación. (11,12)

En la segunda etapa, denominada fase de promoción, se observa una división descontrolada de la célula mutada debido a la estimulación de la proliferación celular y la inhibición de la apoptosis, lo que resulta en la formación de la primera masa tumoral identificable, conocida como tumor primario. (11-13)

La fase final es la fase de progresión, en esta ocurren cambios celulares irreversibles. Las células desarrollan capacidad angiogénica para obtener un suministro eficiente de oxígeno y nutrientes, y se especializan en el crecimiento y la reproducción celular. (12) Esto conduce a la disfunción progresiva del órgano afectado, ya que el tejido especializado es reemplazado por tejido tumoral disfuncional.

Si el proceso no se detecta y trata a tiempo, puede ocurrir la metástasis. En la metástasis, el cáncer se extiende por la región local, infiltrando capilares sanguíneos y linfáticos, y se transporta a través del sistema linfático y sanguíneo colonizando otros tejidos en órganos distantes. (3) Este proceso de carcinogénesis se repite en el nuevo órgano afectado y continúa diseminándose, eventualmente comprometiendo órganos vitales y llevando a la muerte del individuo. (14)

Figura 5: Proceso de formación de la metástasis



Factores de riesgo

El cáncer es considerado una enfermedad genética debido a que los tumores se forman por la presencia de mutaciones que provocan la proliferación y crecimiento descontrolado de las células en tejidos sanos. En el caso específico del cáncer de próstata, no se conocen con precisión las causas exactas. Se considera que la mayoría de los casos son el resultado de una interacción de múltiples factores que incrementan el riesgo de desarrollo de esta enfermedad. (3) Se sabe que el factor genético es determinante en el desarrollo de cáncer de próstata, aumentando la de probabilidad de desarrollar la enfermedad en el doble en aquellos hombres con historial familiar. De la misma forma se produce un aumento del riesgo de padecer esta enfermedad cuando los miembros de la familia afectados fueron diagnosticados antes de los 65 años. (15,16)

El principal factor de riesgo es la edad, a más edad existe más probabilidad de diagnóstico de cáncer de próstata y además se suma una tasa de supervivencia más baja a este riesgo. El riesgo aumenta significativamente a partir de los 50 años, alcanzando el pico de máximo riesgo a los 75 años. (17,18)

Además de lo anteriormente nombrado se deben de tener en cuenta otros factores que se pueden dividir en modificables y no modificables. Entre los factores no modificables caben desatacar que los afroamericanos tienen una mayor incidencia y mortalidad que los blancos lo que parece relacionarse con el factor cromosómico BCL2 y niveles basales de PSA más altos. (19) De la misma forma se sabe que existen varios enes asociados al riesgo de desarrollar cáncer de próstata como son BRCA2.BRCA1, CHEK2, ATM y HOCB13, así como a un peor pronóstico de la enfermedad. (3)

Entre los factores modificables cabe destacar que una concentración elevada del factor de crecimiento similar a la insulina (IGF-1) por sus efectos mitóticos y antiapoptóticos; (20) el tabaco (21) y el alcohol (22) como hábitos tóxicos

que repercuten en los genes mediante el polimorfismo. El consumo excesivo de grasas saturadas (23) y la presencia de obesidad (24) también son un factor de riesgo para el desarrollo de cáncer de próstata por la asociación con niveles circulantes alterados de hormonas esteroides metabólicas y sexuales implicadas en el desarrollo de la próstata. Esta obesidad suele ir asociada a niveles de actividad física bajos, generando así una respuesta reducida de insulina y por tanto niveles elevados de insulina en sangre que resultan en un efecto estimulante de crecimiento y por tanto un riesgo biológico en la progresión del cáncer. (25) Se toma especial atención al riesgo asociado al desarrollo de cáncer de próstata en aquellos individuos que presentan infecciones o enfermedades de transmisión sexual y prostatitis. (26)

Etiología

En primer lugar, para entender la etiología del cáncer de próstata es esencial nombrar los diferentes tipos celulares divididos por sus características morfológicas y funcionales que presenta el tejido prostático. En primer lugar, la región luminal se compone de celular columnares altas, en segundo lugar, la membrana basal está formada por células cuboidales que junto a las luminales forman el tejido glandular y por último la membrana de células endocrinas que se encargan de la secreción de gránulos neurosecretores y neuropéptidos hormonales. (27)

El cáncer de próstata se compone principalmente de tres posibles etiologías; el adenocarcinoma de próstata que es la etiología más diagnosticada, alcanzando hasta el 98% de los casos diagnosticados y se origina en el tejido glandular prostático. (28) No obstante se deben de tener en cuenta otras etiologías posibles de cáncer de próstata como es el tumor carcinoide o el carcinoma neuroendocrino de próstata (carcinoma neuroendocrino de células pequeñas o de células grandes). (29)

El adenocarcinoma de próstata se caracteriza por presentar histológicamente patrones infiltrantes desordenados, estructuras glandulares pequeñas, patrones cribiformes con glándulas mal formadas o células individuales o en láminas sólidas sin formación glandular obvia, y muestran niveles altos de PSA. (30) Se debe de tener en cuenta que el adenocarcinoma de próstata a veces puede presentar una diferenciación neuroendocrina presentando focos dispersos de expresión inmunohistoquímica neuroendocrina ya sea bien como una patología primaria no tratada o más comúnmente como un fenómeno de resistencia posterior a la ADT y a la inhibición de los receptores de andrógenos. (31)

La definición del carcinoma neuroendocrino aún no está del todo clara y se considera como un tipo especial de diferenciación neuroendocrina del cáncer de próstata. Este tipo de neoplasia se caracteriza por presentar resistencia a la inhibición de la señalización del receptor de andrógenos (AR) con características tumorales agresivas y un pronóstico en gran medida sombrío. Suelen presentar niveles de PSA bajos o negativos debido a que se diferencian del adenocarcinoma de próstata por la presencia de células neuroendocrinas que no expresan este marcador genético. (32)

Por último, el tumor carcinoide de próstata se define como un tumor neuroendocrino bien diferenciado con asociación limitada o nula a la histología del adenocarcinoma de próstata (PSA negativa) que típicamente surge del parénquima prostático. (29)

Estadificación

La clasificación estandarizada para la estadificación del cáncer de próstata es el sistema TNM del American Joint Committee on Cancer (AJCC) (Tabla 1), basado en tres características: (33)

- T: Descriptor de la extensión del tumor primario. Incluye el tamaño, la invasión tumoral y la ubicación del tumor, presentando cinco subcategorías.
- N: Descriptor de la propagación a ganglios linfáticos adyacentes. Se clasifica en cuatro categorías según la ubicación de los ganglios linfáticos afectados.
- M: Presencia o ausencia de metástasis. Dentro de la posibilidad de metástasis, se diferencia entre metástasis intratorácica y extratorácica.

La estadificación TNM también se resume en cinco estadios, del 0 al IV, según la presencia del tumor y su diseminación. Además, se clasifican según la extensión del cáncer respecto al tumor primario, categorizándose como neoplasias "in situ", "localizadas", "regionales", "distantes" y "desconocidas". (33)

Tabla 1. Clasificación TNM del cáncer de próstata.

T: tumor primario	
Tx	Tumor primario no puede evaluarse
T0	Sin evidencia de tumor primario
T1	Tumor no evidenciado clínicamente mediante tacto retal o diagnóstico por imágenes
T1a(mi)	Adenocarcinoma mínimamente invasivo
T1a	Hallazgo histológico incidental de tejido tumoral en ≤5% del total de la muestra resecada
T1b	Hallazgo histológico incidental de tejido tumoral en ≥5% del total de la muestra resecada
T1c	Tumor identificado mediante punción biopsia con aguja (por ejemplo, debido a un PSA elevado
T2	Tumor confinado a la glándula prostática1
T2a	Tumor confinado a ≤50% de un lóbulo prostático
T2b	Tumor confinado a >50% de un solo lóbulo prostático
T2c	Tumor que compromete ambos lóbulos prostáticos
T3	Tumor que se extiende a través de la cápsula prostática2 (implica extensión extracapsular, no solo contacto capsular)
T3a	Extensión extracapsular (uni o bilateral)
T3b	Tumor que invade vesícula(s) seminal(es)
T4	Tumor fijo o que invade estructuras adyacentes: pared pelviana, recto, esfínteres externos, vejiga o músculos elevadores (excepto vesículas seminales)
N: ganglios linfáticos regionales	
Nx	Ganglios linfáticos regionales no pueden ser evaluados
N0	Sin ganglios linfáticos regionales comprometidos
N1	Presencia de metástasis en los ganglios regionales
M: metástasis a distancia	
M0	Ausencia de metástasis a distancia
M1	Presencia a metástasis a distancia
M1a	Presencia de metástasis en ganglio(s) linfático(s) no regionales
M1b	Presencia de metástasis en tejido óseo
M1c	Existencia de metástasis a distancia en otro(s) sitio(s) (con o sin compromiso óseo)

[1] El tumor que se encuentra en uno o ambos lóbulos mediante biopsia con aguja, pero que no se palpa o detecta mediante imagenología, se clasifica como T1c

[2] La invasión hacia el ápice prostático o hacia la cápsula prostática (pero no más allá) no se clasifica como T3, sino como T2.

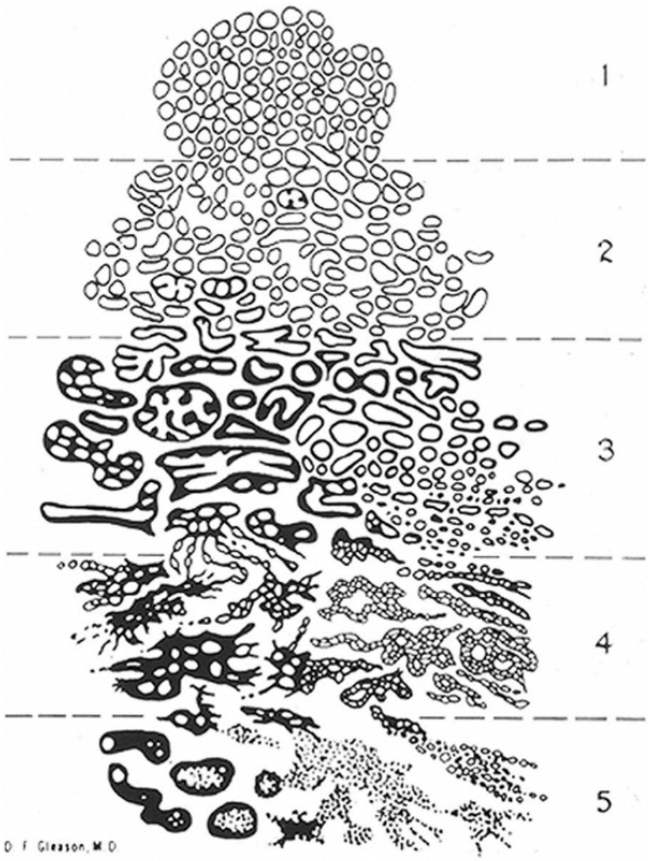
Sin embargo, debido a la gran prevalencia del adenocarcinoma de próstata con respecto a otras etiologías de cáncer de próstata, se ha desarrollado una escala específica para evaluar esta etiología. El índice de Gleason es un sistema de puntuación que clasifica el adenocarcinoma de próstata en función del grado de diferenciación de las células tumorales observadas en la biopsia, ayudando a predecir el comportamiento y agresividad del tumor. (34)
El adenocarcinoma se clasificará utilizando números del 1-5 en base al grado de similitud entre las células cancerosas y el tejido normal. Por tanto, cuando el tejido canceroso es similar al tejido prostático normal recibirá una puntuación de uno y cuando los patrones de crecimiento anómalos son extremos recibirá un 5.
Se debe de tener en cuenta que el adenocarcinoma de próstata a menudo presenta áreas con diferentes grados de anomalías, por tanto para ser más precisos este índice tiene en cuenta la suma de las dos áreas que forman la mayor parte del cáncer, colocándose en el primer lugar del resultado aquella puntuación que se aporta a la mayor parte del tumor (Ej: 2+3=5; quiere decir que la mayor parte del tejido canceroso recibe una puntuación de 2 y la menor de 3). (34-36) Aunque el puntaje de Gleason generalmente se basa en las dos áreas que predominan en el cáncer, existen excepciones. Estas ocurren cuando una muestra de un núcleo contiene una cantidad significativa de cáncer de alto grado o presenta tres grados distintos, incluido el cáncer de

alto grado. En tales casos, se ajusta la forma en que se calcula el puntaje de Gleason para reflejar adecuadamente la agresividad del cáncer.

Tabla 2. Clasificación mediante puntuación de Gleason

Grado	Puntuación de Gleason	Definición
1	2-6	Solo glándulas individuales, discretas y bien formadas
2	3+4=7	Predominante glándulas bien formadas con un menor componente de glándulas cribiformes, fusionadas o pobremente formadas
3	4+3=7	Predominante glándulas cribiformes, fusionadas y mal formadas con un menor componente de glándulas bien formadas
4	4+4=8	Solo glándulas cribiformes, mal formadas, fusionadas
	3+5=8	Predominantes glándulas bien formadas y un menor componente sin glándulas o con necrosis
	5+3=8	Predominante ausencia de diferenciación glandular o necrosis y un menor componente de glándulas bien formadas
5	9-10	Ausencia de diferenciación glandular o necrosis con o sin glándulas cribiformes, mal formadas o fusionadas

Figura 6. Evolución citológica del adenocarcinoma de próstata



Diagnóstico

El cáncer de próstata en la mayoría de los casos se diagnostica en la fase inicial con ausencia de síntomas y generalmente tras detectar una elevación anómala del PSA mediante analítica o a través de un tacto rectal donde al palpar la próstata esta altera su morfología fisiológica. (37)

El PSA es una proteína producida exclusivamente por las células en la glándula prostática (tanto normales como cancerosas) y se encuentra principalmente en el líquido seminal y en pequeñas cantidades en la sangre. Cuando hay síntomas o sospecha de un posible cáncer de próstata es una de las primeras pruebas a realizar, evaluando la cantidad de PSA en sangre mediante nanogramos por mililitro (ng/mL). (38) Cuando el valor de PSA es elevado existe una mayor probabilidad de cáncer de próstata, aunque actualmente

no existe un valor límite establecido que indique la presencia o no de cáncer de próstata se toma como intervalo límite entre 4-10 ng/mL o aumenta más de 0.75 ng/ml por año, teniendo en cuenta que aquellas personas que se encuentren por debajo de 4ng/mL no se encuentran exentas de sufrir esta patología y aquellas que se encuentran o bien el intervalo o por encima presenten cáncer de próstata. (40) Se debe de tener en cuenta ante una subida del PSA que esta puede estar generada también por la edad, prostatitis o traumatismos de la próstata, y por tanto en caso de una PSA elevada siempre se debe de acompañar de otras pruebas diagnósticas.

Una de las pruebas más utilizadas tras encontrar un PSA elevado es el tacto rectal, que consiste en la palpación de la próstata a través de la pared rectal con el objetivo de encontrar nódulos o algún área morfológica sospechosa a la palpación. (41) En caso de que ambas pruebas sean positivas o que la elevación de la PSA se haya confirmado con una segunda muestra los pacientes serán remitidos a otras pruebas como son la biopsia prostática o la resonancia magnética nuclear.

La biopsia prostática es el único método que permite confirmar el diagnóstico de cáncer de próstata, esta se realiza mediante aguja gruesa obteniendo muestras de ambos lóbulos de la próstata por vía transrectal o transperineal, acompañada normalmente mediante ecografía o bien con fusión de imagen a través de resonancia magnética. (42)

La resonancia magnética nuclear pélvica multiparamétrica es otra prueba que ayuda a la localización del tumor primario y permite valorar la posible extensión regional mediante imágenes de alta resolución de la pelvis y la próstata. (43)

Tratamiento Médico

El tratamiento médico del cáncer de próstata se compone principalmente de cuatro estrategias; cirugía, radioterapia con o sin hormonoterapia y vigilancia activa. A pesar de que existen otras terapias como la crioterapia, el láser o la terapia fotodinámica; estas no cumplen con la evidencia científica suficiente. De la misma forma la quimioterapia no es un tratamiento de primera elección para este tipo de cáncer y solo se contempla en casos de muy alto riesgo. (44,45)

La elección del tratamiento médico vendrá determinada en base al diagnóstico, teniendo en cuenta factores como que el tumor esté limitado a la glándula prostática, el tamaño y grado del tumor, la edad, el estado general de salud, el historial médico, los efectos secundarios al tratamiento y las preferencias del paciente. (46)

Teniendo todo esto en cuenta las opciones de tratamiento serán distintas basándonos en el riesgo de cada paciente. (47) De tal forma que cuando el riesgo sea bajo se recomienda vigilancia activa teniendo en consideración la radioterapia o cirugía; cuando el riesgo es intermedio se recomienda la vigilancia activa (solo cuando haya un pronóstico favorable) la cirugía y/o la radioterapia (con o sin hormonoterapia) y cuando el riesgo es alto el tratamiento principal será la radioterapia combinada con hormonoterapia prolongada, teniéndose en cuenta la cirugía en algunos pacientes. Cuando los pacientes se encuentran con una baja expectativa de vida por condiciones externas al tumor lo más recomendado es el tratamiento paliativo mediante hormonoterapia, mejorando así la sintomatología del mismo. (48-50)

La vigilancia activa consiste en una estrategia de manejo que implica monitorizar de cerca a los pacientes con cáncer de próstata de bajo y muy bajo riesgo, retrasando el tratamiento curativo hasta que haya indicios de progresión tumoral. (44,51) Esta estrategia se adopta para evitar o posponer

los efectos secundarios asociados con la cirugía, la radioterapia o la hormonoterapia manteniendo una calidad de vida elevada para los pacientes. (50,52) La vigilancia activa consiste en un riguroso seguimiento mediante pruebas de PSA y tacto rectal cada 3-6 meses, acompañado de resonancias magnéticas y biopsias en periodos de aproximadamente un año. Se debe de tener en cuenta que cerca de la mitad de los pacientes en vigilancia activa reciben tratamiento dentro de los primeros tres años, debido a la progresión del tumor o la ansiedad del paciente. (53)

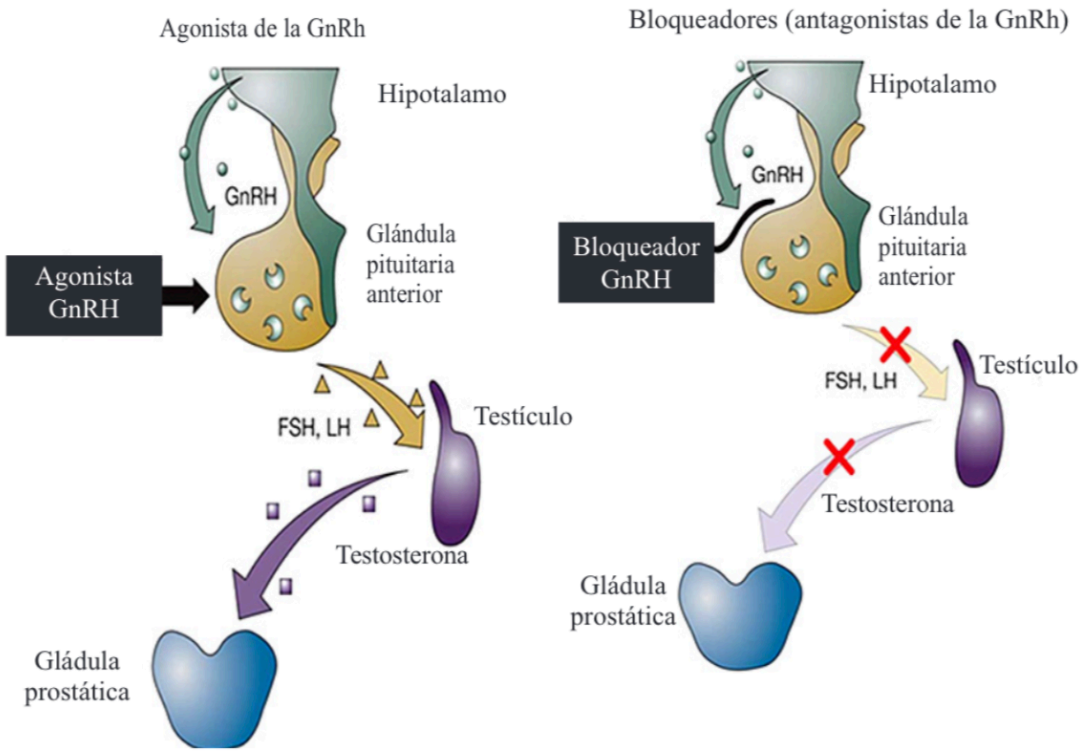
La cirugía consiste principalmente en la prostatectomía radical, que consiste en una intervención quirúrgica en la que se extrae completamente la glándula prostática y las vesículas seminales. (46,54) La cirugía puede realizarse mediante laparoscopia o técnicas robóticas, las cuales han demostrado resultados similares a la cirugía abierta, pero con ventajas adicionales en la recuperación y tiempo de hospitalización. (55) En caso de afectación extraprostática o ganglionar suele combinarse con tratamiento adyuvante de radioterapia y/o hormonoterapia. (45,56)

La radioterapia consiste en reducir o destruir células cancerosas y por tanto el tumor mediante la aplicación de una dosis terapéutica de radiación y minimizando la exposición de los tejidos sanos circundantes. (49,57) La radioterapia externa es la modalidad más utilizada y esta implica sesiones diarias durante 4-7 semanas. Nuevas técnicas como la radioterapia de intensidad modulada o la radioterapia guiada por imagen permiten administrar dosis altas con mayor precisión, reduciendo así los efectos secundarios. (58,59)

La hormonoterapia consiste principalmente en terapia de privación androgénica (TDA) que tiene como objetivo reducir los niveles de testosterona, ralentizando el crecimiento del cáncer de próstata. Los fármacos más utilizados son los análogos de GnRH y antiadrenérgicos bloqueando la

producción de hormona luteinizante y foliculoestimulante mediante un efecto directo en el eje hipotálamo-hipofisario.(44,46)

Figura 7. Fisiología de la terapia de privación androgénica.



Secuelas

El cáncer de próstata suele ser asintomático en sus etapas iniciales, sin embargo, a medida que el tumor crece y avanza pueden aparecer síntomas urinarios y sistemáticos que reflejen esta progresión de la patología. (60) Los síntomas son similares a los de la hiperplasia benigna de próstata entre los que destacan la disminución o interrupción del chorro de orina, aumento de la frecuencia de micción, dificultad y escozor o dolor a la micción, hematuria y hemospermia. (61) En fases más avanzadas del cáncer pueden aparecer síntomas sistémicos y complicaciones más graves relacionadas con la metástasis, entre ellos destacan los dolores y fracturas óseas, compresión

medular, pérdida de peso inexplicable o alteración del sistema linfático y venoso. (62,63)

La prostatectomía radical es el tratamiento más común dentro de la cirugía para el cáncer de próstata, no obstante, puede provocar varios efectos secundarios significativos. (64) Entre ellos destaca la incontinencia urinaria la cual puede variar en severidad y persistir incluso hasta años posterior a la cirugía. (65) Otros efectos secundarios importantes son la disfunción eréctil (por el daño potencial a los nervios eréctiles), dolor y molestia en la zona pélvica, así como posibles infecciones y problemas de cicatrización tras la operación que generan una combinación de signos y síntomas que comprometen la calidad de vida de estos pacientes. (64)

La radioterapia es otra de las opciones comunes en el tratamiento del cáncer de próstata, sin embargo, diversos efectos secundarios se asocian a esta terapia, entre las que destaca los síntomas urinarios (mayor frecuencia urinaria y disuria), así como trastornos gastrointestinales, hematoquecia y disfunción eréctil. (66,67) Además, esencial nombrar a la fatiga como uno de los síntomas secundarios más prevalentes a la radioterapia, la cual afecta al bienestar general del paciente y los niveles de actividad física. (64)

La fatiga también es un principal síntoma secundario derivado de la hormonoterapia, que además al combinarse con la radioterapia hace ser uno de los síntomas que más afecta a la calidad de vida de los pacientes con cáncer de próstata. (68) Esto es lo que se denomina fatiga relacionada con el tratamiento de cáncer, la cual se asocia a niveles de actividad física y funcionamiento físico reducido, ansiedad y depresión, trastornos del sueño y déficits cognitivos, lo que hacen a la fatiga un síntoma cardinal en la programación de la rehabilitación del paciente con cáncer de próstata. (69,70) Además, se deben de tener en cuenta otros síntomas asociados a la hormonoterapia como son los sofocos, disfunción eréctil, así como cambios

en la composición corporal que a largo plazo tendrán repercusión aumentando el riesgo de osteoporosis y enfermedades cardiovaculares. (71)

La sintomatología relacionada con el tratamiento médico oncológico del cáncer de próstata, especialmente en relación a la radioterapia y la terapia hormonal suele presentarse tanto durante el tratamiento como después de su finalización. Entre los efectos secundarios más comunes durante el tratamiento médico oncológico se incluye la fatiga, disfunción eréctil, síntomas urinarios y gastrointestinales; normalmente asociados a los cambios hormonales e inflamatorios de la radioterapia y la terapia hormonal. (72) Estos efectos adversos a menudo persisten o incluso empeoran tras la finalización del tratamiento. (73)

Tratamiento Rehabilitador

La rehabilitación de pacientes con cáncer de próstata que han recibido tratamientos como radioterapia, hormonoterapia y cirugía es un componente crucial en la mejora de su calidad de vida y en la mitigación de los efectos secundarios derivados de estos tratamientos. (74)

El abordaje de rehabilitación multidisciplinar ha demostrado ser efectivo mejorando efectos secundarios a estos tratamientos médicos, en particular a la pérdida de masa muscular y ósea, síntomas genitourinarios, así como la fatiga promoviendo así una mejora del estado de salud físico y psicológico de estos pacientes. (75-77)

Un aspecto esencial de la rehabilitación de los síntomas secundarios es la incorporación de ejercicio físico que ya ha demostrado ser eficaz no solo mejora la condición física general, sino que también puede reducir la fatiga relacionada con el cáncer y mejorar la función sexual y la calidad de vida en general. (75) Además, el ejercicio puede ayudar a contrarrestar los efectos secundarios de la hormonoterapia de pérdida de masa muscular y ósea,

siendo la incorporación del ejercicio monitorizado viable incluso cuando los pacientes se encuentran durante tratamiento de privación androgénica. (78)
Por tanto, la rehabilitación que presenta como eje principal de la intervención el ejercicio físico. La fisioterapia, junto a otras disciplinas como el abordaje psicológico y nutricional muestran un impacto significativo en la recuperación del paciente con cáncer de próstata tras tratamiento médico. (79) Sin embargo a pesar de los beneficios claros de la rehabilitación es esencial considerar la adherencia al ejercicio físico, la cual se ve influenciada por la motivación, el apoyo social y la presencia de comorbilidades, factores que parecen ser determinantes para la sostenibilidad de los beneficios a largo plazo. (75) Esto hace esencial o. La integración de intervenciones personalizadas y el uso de tecnología para monitorear y motivar a los pacientes podrían ser áreas prometedoras para futuras investigaciones. (78)

Nuevos abordajes terapéuticos

Las nuevas tendencias de rehabilitación para abordar los síntomas secundarios al tratamiento médico en el cáncer de próstata se centran en la implementación de programas de ejercicio físico individualizado y el uso de tecnologías avanzadas. (80) La individualización de los programas de actividad física es crucial, ya que permite adaptar las actividades físicas a las necesidades y capacidades específicas de cada paciente, teniendo en cuenta factores como la edad, la condición física general y la presencia de comorbilidades. Además, Este enfoque personalizado no solo mejora la efectividad de la rehabilitación, sino que también aumenta la adherencia de los pacientes al tratamiento, lo cual es esencial para la sostenibilidad de los beneficios a largo plazo. (81)
La adherencia al ejercicio físico está influenciada significativamente por la motivación, el apoyo social y las comorbilidades. La creación de comunidades

de apoyo, tanto en línea como presenciales, puede proporcionar a los pacientes un entorno motivador y de contención. (82,83) La participación en grupos de apoyo y la inclusión de familiares y amigos en el proceso de rehabilitación pueden mejorar el compromiso de los pacientes con sus rutinas de ejercicio. Además, las intervenciones que incluyen un componente social, como las sesiones de ejercicio grupales, pueden fomentar un sentido de pertenencia y responsabilidad, lo cual es crucial para mantener la motivación a lo largo del tiempo. (84)

La integración de tecnologías como aplicaciones móviles y dispositivos de monitoreo representa una tendencia prometedora en la rehabilitación del cáncer de próstata. Estas tecnologías permiten un seguimiento continuo y detallado del progreso de los pacientes, ofreciendo retroalimentación en tiempo real, así como recordatorios para realizar los ejercicios. Este enfoque tecnológico no solo optimiza la adherencia al ejercicio físico, sino que también fomenta la educación y el automanejo, permitiendo a los pacientes tomar un rol activo en su tratamiento. (85) El desarrollo de plataformas educativas y programas de automanejo puede ayudar a los pacientes a comprender mejor su condición y los beneficios de la rehabilitación, promoviendo una mayor independencia y responsabilidad en su propio cuidado. (86,87)

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HIPOTESIS

Los pacientes de cáncer de próstata presentan secuelas durante el tratamiento médico que se mantienen tras la aplicación del mismo y que repercuten en la recuperación y la calidad de vida de los mismos. La caracterización de estos pacientes permitiría el diseño de programas de rehabilitación individualizados que mejoren su estado de salud general.

OBJETIVOS

Objetivos generales

- Establecer un perfil cínico de los pacientes de cáncer de próstata tras tratamiento médico.
- Establecer un marco terapéutico de referencia que permita mejorar la sintomatología de los pacientes con cáncer de próstata tras recibir tratamiento médico.

Objetivos específicos

- Caracterizar el perfil clínico de pacientes de cáncer de próstata un año después de haber recibido tratamiento radioterápico, observando como repercute este tratamiento en la calidad de vida, niveles de actividad, barreras al ejercicio y autoeficacia. (Estudio 1)
- Evaluar la efectividad de las intervenciones de autocuidado sobre la calidad de vida y la autoeficacia en pacientes con cáncer de próstata. (Estudio 2)
- Evaluar la efectividad de la educación mejorada en la en los síntomas urinarios, el estado psicoemocional y la autoeficacia en pacientes con cáncer de próstata. (Estudio 3)

HYPOTHESIS

Prostate cancer patients present sequelae during medical treatment that are maintained after treatment and have an impact on their recovery and quality of life. The characterization of these patients would allow the design of individualized rehabilitation programs that improve their overall health status.

OBJECTIVES

General objectives

- To establish a cynical profile of prostate cancer patients after medical treatment.
- To establish a therapeutic frame of reference to improve the symptomatology of prostate cancer patients after medical treatment.

Specific objectives

- To characterize the clinical profile of prostate cancer patients one year after having received radiotherapeutic treatment, observing the impact of this treatment on quality of life, activity levels, barriers to exercise and self-efficacy.
- To evaluate the effectiveness of self-care interventions on quality of life and self-efficacy in prostate cancer patients.
- To evaluate the effectiveness of enhanced education on urinary symptoms, psychoemotional state and self-efficacy in prostate cancer patients.

METODOLOGÍA

La presente tesis doctoral se llevó a cabo en base a los objetivos específicos planteados anteriormente y por ello queda reflejada la metodología de cada uno de los estudios realizados.

- Barriers and applied activity, quality of life and self-efficacy in prostate cancer survivors 1 year after completing radiotherapy

Diseño	Participantes	Intervención	Variables Principales
Observacional de Cohorte Trasversal	120 pacientes de cáncer de próstata tras radioterapia	-	· Niveles de actividad · Barreras al ejercicio · Calidad de vida · Autoeficacia

- Systematic review of self-management programs for prostate cancer patients, a quality of life and self-efficacy meta-analyses

Diseño	Participantes	Intervención	Variables Principales
Revisión Sistemática, Meta-Análisis	pacientes de cáncer de prostata	GE: Intervenciones basadas en automanejo GC: Cuidados habituales o Cuidados habituales con educación	· Calidad de vida · Autoeficacia

- Efficacy in urinary symptom burden, psychological distress, and self-efficacy of education -enhanced interventions in prostate cancer patients: a systematic review and meta-analyses

Diseño	Participantes	Intervención	Variables Principales
Revisión Sistemática, Meta-Análisis	1991 pacientes de cáncer de próstata	GE: Intervenciones basadas en educación mejorada GC: Cuidados habituales	· Síntomas urinarios · Estado Psicoemocional · Autoeficacia

Aspectos éticos de la investigación y confidencialidad de datos

La presente investigación recibió la aprobación del Comité Ético de Investigación Biomédica Provincial de Granada. Se adhirió estrictamente a los principios establecidos en la Declaración de Helsinki de 2013, así como a las Normas Éticas Internacionales para la Investigación Biomédica en Sujetos Humanos de 1982. Todos los participantes fueron debidamente informados sobre el propósito del estudio a través de una hoja informativa y proporcionaron su consentimiento por escrito para participar. En todas las etapas de la investigación, se observaron rigurosamente las disposiciones del Reglamento General de Protección de Datos (RGPD) 3/2018

RESULTADOS

Los resultados de esta tesis doctoral se incluyen en los artículos específicos. Se incluyen por tanto en forma de envío como manuscrito a la revista de publicación correspondiente

Estudio 1

Barriers and applied activity, quality of life and self-efficacy in prostate cancer survivors 1 year after completing radiotherapy

Barriers and applied activity, quality of life and self-efficacy in prostate cancer survivors 1 year after completing radiotherapy

Javier Martín-Núñez[1]; Marta Linares-Moya[1]; Andrés Calvache-Mateo[1]; Antonio Lazo-Prados[2]; Alejandro Heredia-Ciuró[1]; Laura López-López[1]; Marie Carmen Valenza[1]

[1] Department of Physiotherapy, Faculty of Health Sciences, University of Granada, Av. De La Ilustración, 60, 18016 Granada, Spain

[2]Clínico San Cecilio University Hospital, Granada, Spain

ABSTRACT

Purpose The aims of the study were to assess self-reported physical activity (PA) levels, barriers to PA, quality of life and self-efficacy to manage chronic disease of prostate cancer survivor 1 year after radiotherapy treatment. **Methods** A cross-sectional case–control study was performed. Prostate cancer survivor patients treated with radiotherapy were recruited from the Radiation Oncology Service of the "Complejo Hospitalario Universitario" (Granada) and compared with age-matched healthy men. Outcomes included were perception of benefits for physical activity and potential barriers (Exercise Benefits/Barriers Scale), physical activity levels assessed by the International Physical Activity Questionnaire (IPAQ), quality of life (EuroQol five-dimension three-levels) and self-efficacy (Self-Efficacy to Manage Chronic Disease).

Results A total of 120 patients were included in our study. Significant differences were found between groups with worse results for the prostate cancer patient group in the variable perception of the benefit of physical activity, potential barriers, and physical activity. Regarding quality of life and self-efficacy, significant differences were also observed between groups with a greater score in the control group.

Conclusion In conclusion, the results of this study reveal that self-reported PA levels, as measured using the IPAQ, were low in prostate cancer survivors after treatment. Results also showed worse perception of benefits for PA and potential barriers by the cancer survivors. Similarly, the quality of life and self-efficacy to manage chronic disease of prostate cancer survivors was lower.

Keywords: Prostate cancer; Radiotherapy; Physical activity; Self-efficacy; Quality of Life

INTRODUCTION

The constant improvement of cancer treatments as well as diagnostic methods has significantly increased the life expectancy of cancer patients. Survival of a cancer diagnosis is expected to be greater than 60% [1, 2], which is a major health challenge [3]. A considerable number of cancer patients experience comorbidities and symptoms secondary to cancer, even years after initial treatment [4]. Patients who survive cancer treatment often experience persistent side effects such as sleep disturbances [5], pain [6] and fatigue [7]. In addition, they experience other comorbidities such as diabetes, osteoporosis, cardiovascular disease, functional impairment and ultimately an increased risk of new primary cancers [8].

Prostate cancer is a significant health burden expected to increase over the next years due to the recent survival data [9]. Despite earlier detection, prostate cancer patients use to receive treatment and exhibit side effects of therapy during long-term survival [10].

A relevant aspect of cancer survivorship is related to life-style behaviors, with a key role in physical activity [11–13]. According to previous studies, physical activity can improve survival, the risk of cancer recurrence and the quality of life of cancer survivors [14–16]. Most survivors do not engage in regular physical activity, and less than 30% achieve mini- mum levels, despite the benefits of physical activity [17, 18]. Different studies have explored factors related to

physical activity after a cancer diagnosis, finding education, age, body mass index, occupation and receiving specific cancer therapies among the most important [19, 20].

Results obtained in various meta-analyses have shown an inverse association between amounts of physical activity after diagnosis and cancer-specific mortality in prostate cancer survivors [21–23]. Those systematic reviews indicate that the highest levels of total, recreational, non-sedentary occupational, and vigorous physical activity, including higher metabolic equivalent (MET) hours per week, were significantly related to reduced risk for all-cause mortality.

Despite the volume of evidence indicating the benefits of regular physical activity for health and functioning [23, 24], people with cancer are far less likely to engage in physically active lifestyles, and the enrolment of these patients in physical activity (PA) programs remains unsuccessful [18, 25]. Little is known about why the majority of people with cancer fail to integrate regular physical activity into their lifestyle [26]. It has been suggested that an understanding of potential barriers that affect participation by cancer patients could provide important information necessary for developing interventions that have a greater likelihood of success [27]. Previous research has identified different aspects related to physical activity levels such as pain, cancer treatment-related side effects, fatigue, motivation, comorbid medical conditions and time [20, 28, 29]. Despite this, the literature referring to prostate cancer survivors examining barriers to physical activity [20, 30, 31] is very limited and has not explored the specific profile of long-term patients after radiotherapy.

The objectives of our study were to (i) measure self- reported PA levels, (ii) assess perceived barriers to PA, (iii) and determine quality of life and self-efficacy to man- age chronic disease of prostate cancer survivor 1 year after

radiotherapy treatment. All these factors are determinants in improving the enrolment of prostate cancer survivors in PA programs.

METHODS

Design and ethics

A cross-sectional study was conducted between January 2022 and April 2022. Before being included in the study, patients received detailed information about the study goals and procedure and gave their informed consent to participate. The study was approved by a local committee on research ethics.

Population

Prostate cancer survivor patients treated with radiotherapy were recruited from the Radiation Oncology Service of the "Complejo Hospitalario Universitario" (Granada). The eligibility criteria for the prostate cancer patients included histologically documented prostate cancer, 1 year after completion of radiotherapy treatment and no on-going cancer treatment. The control cohort included aged-matched healthy men with similar body weight and height, with no previous history of cancer. Control participants were recruited by word-of-mouth and were excluded if they exhibited any history of cancer. Matching for aged and BMI was achieved by individually selecting the control subject with the closest available match for age and BMI to the prostate cancer survivor patients.

Case and control participants were excluded if they had one of these conditions: under 18 years of age, neurologic pathologies limiting voluntary mobility, orthopedic and cardiovascular pathologies, learning disability or if telephone contact was inappropriate due to dementia, or other cognitive or communication impairment.

An a priori power analysis based on a pilot study (unpublished) of 10 subjects (effect size of 0.80) was performed with the G*Power 3.1.9.2 software (3.1.9.2v; Statistical Power Analyses for Windows, Universität Düsseldorf, Ger- many)

resulting in a sample size of 104 patients (52 per group) and a statistical power of 90%. Considering a hypothetical dropout rate of 10%, 58 patients were needed in each group. Recruitment ended when the required sample size was reached for each group.

Measurements

Participants were assessed by telephone always by the same investigators previously trained. An initial assessment inter- view was conducted to confirm that the patients met the inclusion criteria. Data regarding comorbidities, anthropometric data, prostate cancer characteristics and cancer treatment were obtained from the medical history. The Charlson index was used to assess comorbidities [32] which has been validated in several disorders and is one of the most widely used scoring systems for assessing comorbidities.

The participant's perception of benefits for physical activity and potential barriers was measured with the Spanish version of Exercise Benefits/Barriers Scale (EBBS) [33]. The scale includes 43 items separated into two subscales: 14 items refer to barriers and 29 items refer to benefits [34]. The scale is designed based on a 4-point Likert scale: strongly disagree (1), disagree (2), agree (3), strongly agree (4). For the benefits subscale, the answer range varies between 29 and 116 and the higher the score, the more positively the individual perceives exercise. For the barriers subscale, the answer range varies between 14 and 56, and the higher the score, the more negatively the individual perceives exercise. When all items are summed to obtain a total score, the bar- rier to exercise subscale items are reverse scored. In contrast, when only the barriers to exercise subscale is calculated, no inverse score is applied to these items [35]. When the total sum of barriers and benefits is summed, the score can range from 43 to 172. In this case, the higher the score, the more positively the individual perceives exercise [36].

The physical activity levels were evaluated with the Spanish version of the International Physical Activity Questionnaire (IPAQ) [37]. It has been validated and previously used in cancer patients. This questionnaire was designed to quantify physical activity in transportation, household chores, work and leisure time. Subjects are asked to report both the frequency and duration of activities performed during the last week divided into three categories: walking, moderate activities and vigorous activities. Activity is calculated as the total time spent in the three activity categories. A metabolic equivalent (MET) is used to weight the total task time, resulting in an estimate of activity that is expressed as MET- min/week and adjusted for body weight [38].

To assess quality of life, the five-dimension, three-level EuroQol (EQ-5D-3L) was used in its Spanish version, which is divided into two distinct sections [39, 40]. The first section is divided into 5 items related to mobility, usual activities, self-care, anxiety/depression and pain/discomfort. Each of the items has three response levels corresponding to "no problems", "some problems" or "extreme problems". The second part of the scale consists of a visual analogue scale (VAS) in which the respondents must self-assess their cur- rent health status by assigning a score between 0 (worst imaginable health status) and 100 (best imaginable health status). The EQ-5D-3L has previously been used in prostate cancer patients [41].

The Spanish version of the scale to measure Self-Efficacy to Manage Chronic Disease (SEMCD-S) was used to assess self-efficacy [42]. The scale consists of 4 items which are answered with a score from 1 (no confidence) to 10 (total confidence). To obtain the result of the scale, the mean of the 4 items is calculated. If more than one of the items is not answered, the final score cannot be calculated. The SEMCD- S has been used previously in cancer patients [43].

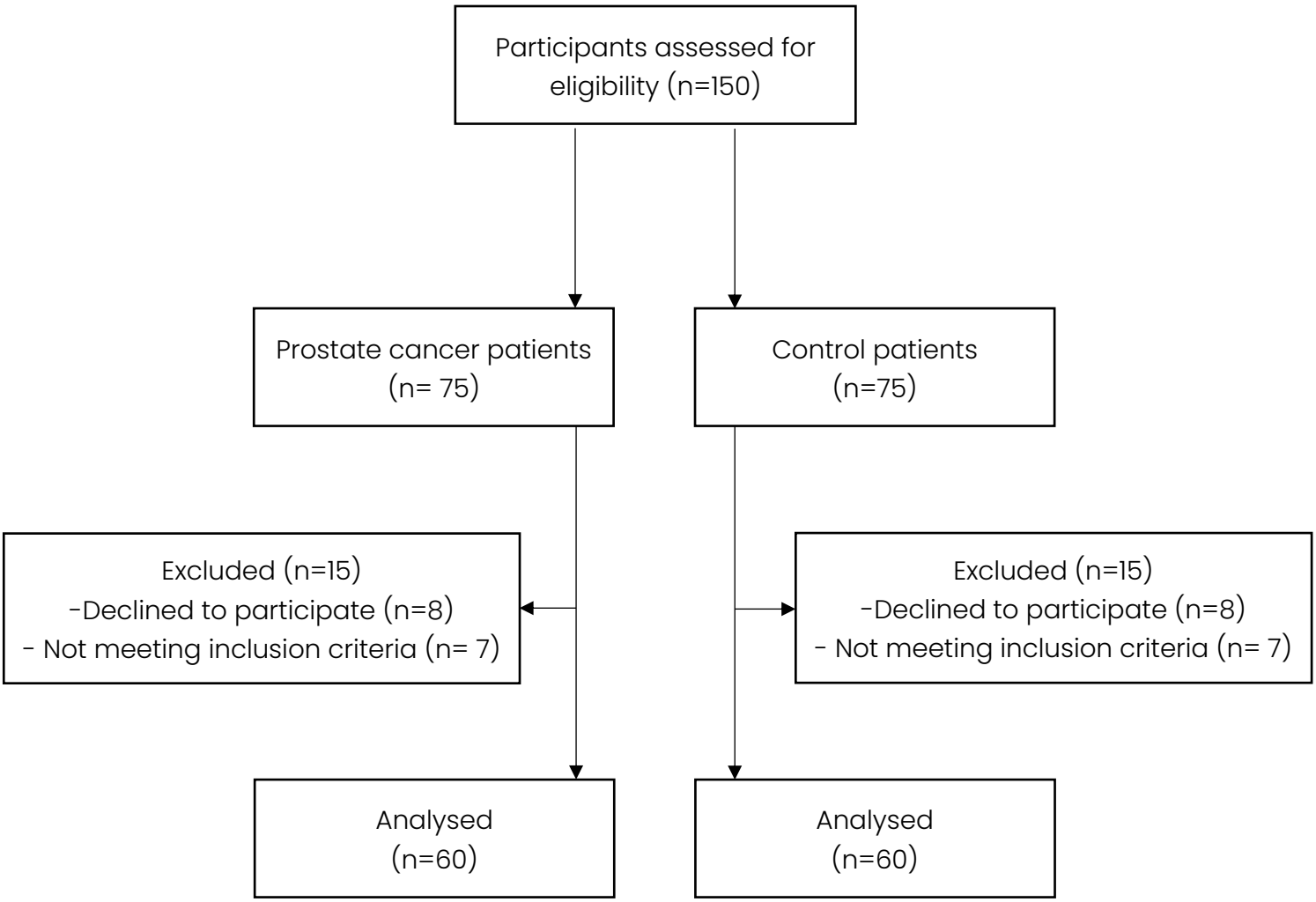
Data analysis

Statistical analysis was performed with IBM SPSS Statistics software for Windows, Version 20.0 (IBM Corp. Released 2011; Armonk, NY: IBM Corp). Descriptive statistics were used to describe sample baseline characteristics. Categorical variables are presented as a percentage (%), and continuous variables are presented as the mean ± standard deviation. The Kolmogorov–Smirnov test was performed to assess continuous data normality, prior to statistical analysis. For data with a normal distribution, Student's *t* test was performed, a Wilcoxon test to non-parametric variables and a $\chi 2$ test for nominal variables. The statistical analysis was conducted at a 95% confidence level. A *p* value $p < 0.05$ was considered statistically significant.

Results

A total of 120 men, 60 prostate cancer survivors treated with radiotherapy and 60 aged-matched controls were finally included (Fig. 1). The characteristics of the study population are summarized in Table 1.

Figure 1. Flow diagram of participants



A total of 120 men, 60 prostate cancer survivors treated with radiotherapy and 60 aged-matched controls were finally included. The characteristics of the study population are summarized in Table 1.

Demographic characteristics were similar in both groups. The mean of comorbidities of the patients was similar in the two groups. The cancer survivors group presented with a higher BMI.

Of the sample, a diagnosis of stage II (76.66%) and stage III (20%) cancer was most commonly identified. In addition to radiotherapy, almost the entire sample indicated that some type of cancer-related treatment had been received, with hormonal therapy being the most reported (30%), followed by surgery (18.33%).

Table 1. Participants characteristics per group.

Characteristics	Cancer patients (n=60)	Control patients (n=60)	p Value
Age (years±SD)	61.23±6.45	62.68±4.87	0.954
BMI (mean±SD)	27.89±5.68	26.45±10.72	0.671
Comorbidities (mean±SD)	3.56±1.14	2.96±0.37	0.382
Cancer Stage n (%)			
1	2 (3,33)	-	-
2	46 (76,66)	-	-
3	12 (20)	-	-
Treatment (%)		-	-
Hormonal Therapy	18 (30)	-	-
Chemotherapy	7 (11.66)	-	-
Surgery	11 (18.33)	-	-

In Table 2, barriers and applied activity measures were presented per group. Regarding perception of benefits for physical activity and potential barriers, significant differences were also observed between groups with worse results

in the cancer patients group for the benefits and barriers subscales and the overall score ($p < 0.001$). There were significant differences for the total physical activity levels ($p = 0.018$) with higher levels of physical activity in the control group.

Table 2. Barriers and applied activity measures per group.

Variables	Cancer patients (n= 60)	Control patients (n= 60)	p Value
Light activity subscore (IPAQ)	1434.09 ± 1699.90	1665.66 ± 3067.04	0.732
Moderate activity subscore (IPAQ)	243.98 ± 419.83	738.40 ± 948.93	0.020*
Vigorous activity subscore (IPAQ)	193.73 ± 657.10	1880.44 ± 3767.04	0.036*
IPAQ Total	1869.29 ± 1715.50	4206.50 ± 4472.46	0.018*
Exercise Benefits	95.31 ± 17.10	106 ± 9.87	P<0.001*
Exercise Barriers	30.62 ± 6.24	22,35 ± 5,31	P<0.001*
EBBS Total	139.67 ± 19.45	155,65 ± 11,88	P<0.001*

*p< 0.05; EBBS: Exercise Benefits/Barriers Scale; IPAQ: International Physical Activity Questionnaire.

In Table 3, quality of life and self-efficacy to manage chronic disease differences between groups are presented. Significant differences were found, the cancer patients group presented with poorer results in the following EQ-5D subscales: self-care ($p = 0.045$), usual activities ($p < 0.001$), pain/discomfort ($p < 0.001$), anxiety/depression ($p = 0.026$) and VAS ($p < 0.001$). Regarding self-

efficacy, significant differences were also observed between groups (p= 0.040) with a greater score in the control group.

Table 3. Quality of life and self-efficacy measures per group

Variables	Cancer patients (n= 60)	Control patients (n= 60)	p Value
EQ-5D			
Mobility subscore	1.13 ± 0.34	1.08 ± 0.27	0.332
Self-care subscore	1.07 ± 0.25	1.00 ± 0.00	0.045*
Usual activities subscore	1.23 ± 0.43	1.02 ± 0.14	P<0.001*
Pain/discomfort activities	1.53 ± 0.70	1.06 ± 0.24	P<0.001*
Anxiety/depression activities	1.33 ± 0.48	1.15 ± 0.36	0.026*
VAS	73.75 ± 14.07	85.87 ± 11.62	P<0.001*
Self-efficacy	54.19 ± 7.64	52.18 ± 6.88	0.040*

*p< 0.05; EQ-5D: EuroQol-5 Dimension; VAS: Visual Analogue Scale; IPAQ: International Physical Activity Questionnaire; SEMCD-S: Self-Efficacy to Manage Chronic Disease.

Discussion

This cross-sectional study aimed to measure self-reported PA levels of prostate cancer survivors after radiotherapy treatment, assess perceived barriers to PA in cancer survivors and determine quality of life and self-efficacy to man- age chronic disease. Those aspects can be related to PA levels after a prostate cancer radiotherapy treatment. Findings of this study appear to suggest that self-reported PA levels after a radiotherapy treatment in prostate cancer survivors were lower than control age-matched men with similar body weight and height and presented more barriers to physical activity.

The population characteristics in our study is similar to other studies [44, 45]. Due to the fact that the mean age of the samples studied is representative of those who are candidates for radiotherapy. In addition, the inclusion and exclusion criteria of this study have the potential to eliminate people with older ages due to the greater likelihood that they present comorbidities that could significantly influence the study variables.

Diagnosis of prostate cancer usually led to undergo radiotherapy treatment. This treatment can substantially raise some impairments on health-related quality of life and associated lifestyles impacting current and future health of patients. In this line, prostate cancer patient profile needs to identify particularly concrete variables that can impact morbidity and mortality.

Regarding the first aim, our results revealed that self- reported PA level was lower in prostate cancer survivors after radiotherapy than control aged-matched men, thus agreeing with previous studies which showed that the proportion of prostate cancer patient who undertake regular exercise is low [18, 46, 47]. Despite the fact that the recommendations of the American College of Sports Medicine are 150 min (min) of moderate intensity or 75 min of vigorous physical activity per week to improve their overall health in cancer patients, prostate cancer survivors showed fewer minutes of moderate ($p < 0.020$) and vigorous ($p < 0.036$) physical activity than controls. In line with our results, Ozdemir K et al. [48] observed that only 20.7% of prostate patients in their study were physically active.

Our second aim was to analyze whether cancer survivors presented barriers and knew the benefits of PA. Our findings clearly demonstrate that prostate cancer patients after treatment presented more barriers and lower knowledge about benefits of PA than controls. Our study is in line to previous reviews [49, 50] that explored the influence of benefits and barriers of PA in prostate cancer survivors, the importance of understanding the characteristics of physical

activity participation, the perceived barriers to exercise and the benefits of exercise are well known. These showed that the key facilitators to participation in PA include advice and guidance from healthcare professionals or specialists, avoiding the 'rest-paradigm' [51]. The study of Min J et al. [52] explored the relationship between PA levels and the most common barriers in prostate cancer, consistent with our results showing that prostate cancer patients present more of a barrier to activity than healthy controls. Our study shows that 1 year after diagnosis, prostate cancer patients remain inactive when compared to similar age and gender controls; this can be curious because control subjects have a similar number of comorbidities. One reason to those differences in PA levels between groups can be the information pro- vided to subjects about the relevance of PA on their clinical profile; another reason can be the differences among major cancer survivor groups' overall health behaviour. While a cancer diagnosis has been referred to as a possible 'teach-able moment' where cancer patients can be more motivated to make lifestyle changes to improve health outcomes, the marker of physical activity has been reported to be under- considered among prostate cancer survivors in the long term after diagnosis [53].

The third aim was to determine quality of life and self- efficacy to manage chronic disease after a prostate cancer radiotherapy treatment. Despite quality of life has a large spectrum and numerous factors can condition the state estimate, low physical activity levels influenced negatively in quality of life [54]. Our results showed that prostate cancer survivors with low moderate and vigorous physical activity levels presented a worse self-perceived health status. Along the same lines, previous studies observed that prostate cancer survivors with higher PA levels are associated with better self-perceived quality of life [55–57]. Similarly, levels of self-efficacy were low in prostate cancer survivors. Mosher CE et al. [58] showed that self-efficacy plays an important

role in PA and health promotion. The study of Yang R [59] et al. observed that information support program improved self-efficacy during oncological medical treatment; nevertheless, it is necessary to provide information support after coadjutant treatment.

Study limitations

We must take into account some factors to properly interpret the results of the study. To begin with, as this is a cross- sectional study, and therefore cross-sectional data collection, it is impossible to establish a direction of causality. In addition, the number of participants was suggested to be sufficient to complete an adequate sample size; however, the individuals in the convenience sample consisted of only one region, which may influence the external validity of the results. Finally, the adjuvant treatment that patients received may have interfered with the results of the study. Concretely, hormone therapy can be of interest, but at long term, the possible impacts of those treatments have been reported as minimal [60, 61]. In another side, other authors have described no significant differences on clinical profile according to adjuvant treatments on prostate cancer at long term [62]. Even so, this is an aspect that may be relevant, and future studies comparing patients with hormone therapy added to radiotherapy and those without hormone therapy are necessary to contrast the results.

Conclusion

In conclusion, the results of this study reveal that self- reported PA levels, as measured using the IPAQ, were low in prostate cancer survivors after treatment. Results also showed worse perception of benefits for PA and potential barriers by the cancer survivors. Similarly, the quality of life and self-efficacy to manage chronic disease of prostate cancer survivors was lower. These results sustenance the need to design intervention programs focusing on these outcomes

Author contribution: All the authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Javier Martín Núñez, Marta Linares-Moya, Alejandro Heredia Ciuró and Laura López López. The first draft of the manuscript was written by Marie Carmen Valenza, Javier Martín Nuñez and Andrés Calvache Mateo, and all the authors commented on previous versions of the manuscript. All the authors read and approved the final manuscript.

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Data Availability: The data that support the findings of this study are available upon request from the corresponding author.

Declarations

Ethics approval: This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Biomedical Research Ethics Committee of Granada (Granada, Spain).

Consent to participate: Informed consent was obtained from all individual participants included in the study.

Competing interests: The authors declare no competing interests.

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Estudio 2

Systematic review of self-management programs for prostate cancer patients, a quality of life and self-efficacy meta-analysis

Systematic review of self-management programs for prostate cancer patients, a quality of life and self-efficacy meta-analysis

Javier Martín-Núñez[1]; Alejandro Heredia-Ciuró[1]; Geraldine Valenza-Peña[1]; María Granados-Santiago[1]; Sofia Hernández-Hernández[1]; Araceli Ortiz-Rubio[1]; Marie Carmen Valenza[1]

[1] Department of Physiotherapy, Faculty of Health Sciences, University of Granada, Spain

ABSTRACT

Objective: To investigate the efficacy of self-management interventions on quality of life and/or self-efficacy in patients diagnosed with prostate cancer through a systematic review with meta-analysis.

Methods: A search was conducted from database inception to March 2022 across three databases. Randomized controlled trials were included. Two reviewers performed independent data extraction and methodologic quality assessment of the studies.

Results: A total of fifteen studies were included in the study. Self-management interventions were identified by the Practical Reviews in Self-Management Support. The meta-analysis showed that self-management interventions have a significant effect on self-efficacy

Conclusion: Self-management programs could have positive effects on quality of life and improve self-efficacy in prostate cancer patients.

Practice implications: Self-management components may be heterogeneous but show positive results in improving self-efficacy in prostate cancer survivors. Including self-management components in the rehabilitation of prostate survivors can improve their quality of life.

INTRODUCTION

Prostate cancer is the most common non-skin cancer in men world- wide and the second most diagnosed cancer, estimated at 1,600,000 cases and 366,000 deaths per year. [1,2] Due to the ageing of the population, the incidence of prostate cancer is estimated to grow to almost 2.3 million new cases and 740,000 deaths by 2040. [1].

Although prostate cancer treatment is improving, it continues to provoke frequent adverse consequences in the quality of life and urinary disease-specific symptoms. [3,4] Therefore, prostate cancer survivors present long-term symptom burdens that affect perceived health status. [5,6] Long-term symptoms are related to negative thoughts, psycho- logical distress, absence of self-efficacy and coping skills that can impact the quality of life. [7,8].

American Cancer Society guideline for prostate cancer highlights the necessity of self-management of symptoms in prostate cancer survivors.

[9] Prostate cancer survivors report a lack of information about long-term symptom management and their primary and speciality care providers. [10] Interventions discussed in this guideline include screening, long-term symptoms assessment and management associated with prostate cancer, surveillance for recurrence, health promotion, psychosocial issues and medical coordination [9].

Therefore, a change in the approach and relationship between the patient and the provider is needed. The active involvement of patients is increasingly playing a key role in chronic disease. [11–13] Self-management is defined as the ability to manage own disease symptoms as well as treatment and physical, social and lifestyle changes from decision-making, taking action, problem-solving, provider-patients relationship and resource utilization [14–16].

Nonetheless, the complex nature of the cancer disease causes self-management interventions are lagging behind other chronic conditions. [17] To

the best of our knowledge, there are no previous reviews where the effects of self-management interventions in prostate cancer patients are analyzed. Thus, the purpose of the current review was to examine the efficacy of self-management interventions on quality of life and/or self-efficacy in patients diagnosed with prostate cancer.

METHODS

A systematic review and meta-analyses have been conducted following the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement guidelines. The Cochrane Collaboration guidelines for reviewing interventions were also closely followed. The protocol of this systematic review was registered on PROSPERO (CRD42021292127).

2.1. Search Strategy

We conducted a wide search of the literature for articles indexed on Scopus, PubMed and Web of Sciences databases from their inception to March 2022. A search strategy in MEDLINE was developed using the following steps: (1) development of keywords by examining relevant key terms used in existing systematic reviews, (2) a thorough examination of the MeSH Database, and (3) expert guidance and review by a specialist. We also screened the reference lists of relevant reviews and refined the search strategy having tested and adapted in different databases.

We applied the PICOS [18] (Participants, Interventions, Comparisons, Outcome, and Study design) model to define the research question. The inclusion criteria were: (1) patients diagnosed with prostate cancer; (2) self-management interventions; (3) the self-management intervention had to be compared to a control intervention or no-treatment intervention; (4) quality of life and/or self-efficacy were included in the outcomes; (5) only randomized control trials were included.

The selection of self-management studies was based on previous published definition [19] in the Practical Reviews in Self-Management Support (PRISMS) which comprises 14 components that might be used to support self-management when delivered to someone with a long-term condition or their carers. Control interventions were considered as other interventions non considered self-management, concretely interventions without the objective to develop competencies in the self-care by the patients.

Duplicates were removed after obtaining records from different databases. Two reviewers independently performed the titles and abstract of the literature search to ensure eligibility. A third reviewer resolved all discrepancies between the reviewers.

Data extraction and methodological assessment were carried out when articles have been selected. The Downs and Black checklist [20] was used to assess the methodological quality of the studies. It consists of 27 items included in five subscales, which are: reporting, external validity, internal validity (study bias, confounding), selection bias, and study power. An excellent study is considered when a score of 26 or higher is achieved. Good between 20 and 25, fair between 15 and 19, and poor when it is less or equal to 14. [21,22] This tool is one of the six most-used methodological quality assessment scales for both randomized and nonrandomized clinical trials due to its high validity and reliability.

The risk of bias was assessed using the Cochrane Risk of Bias tool for randomized controlled trials. [23] It consists of 6 subscales (selection bias performance, detection bias, attrition bias, reporting bias, and other bias). Quality assessment is classified as follows: low risk of bias, when all domains obtained low risk; some concerns of bias, when one criterion does not meet [24] (i.e., high risk of bias for one domain) or two criteria are unclear but this is not a limitation that could invalidate the results; high risk of bias, when now

there are important limitations that could invalidate the results, and when two or more criteria are listed as high or unclear risk of bias.

2.2. Meta-analyses

The Review Manager 5 (RevMan 5) software was used to quantitative synthesis of all studies that presented quality of life and self-efficacy post-intervention means and standard deviations. We extracted quantitative data, including number of patients assessed, final mean values and standard deviations for each treatment arm to estimate the overall mean differences between experimental and control arms.

The authors of the included articles were contacted when they did not present sufficient data to calculate effect sizes (e.g., no means pro- vided, no standard deviation provided). We calculated missing standard deviations when n p-values or 95% confidence intervals were given via the embedded Review Manager calculator.

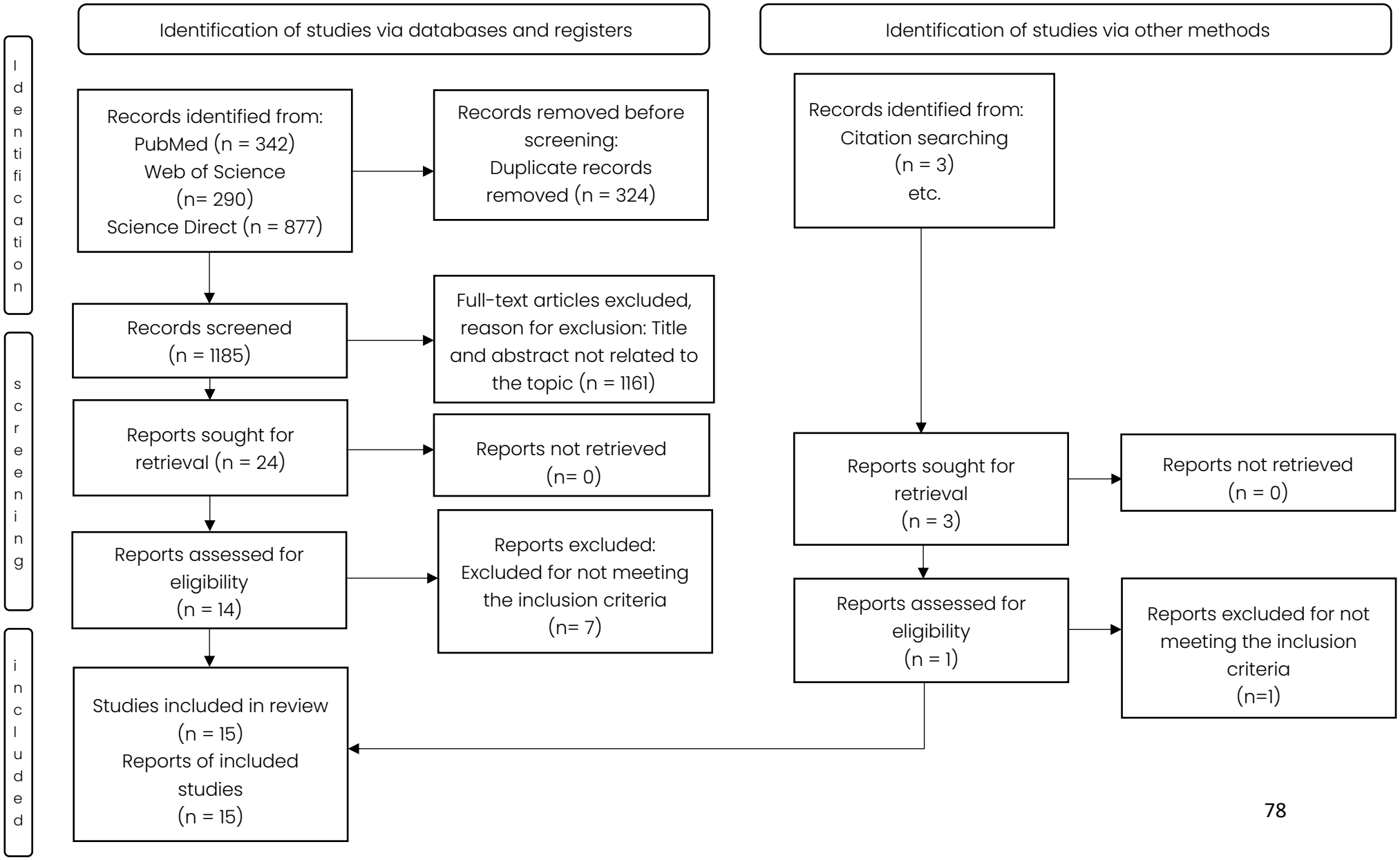
We assumed to measure the same underlying symptom or condition and therefore Standardized mean differences were used as all the scales. The overall mean effect sizes were estimated using random effect models or fixed effect models according to statistical heterogeneity I2 tests. Thresholds for the interpretation of I2 can be misleading, since the importance of inconsistency depends on several factors. A rough guide to interpretation is as follows: 0–40% might not be important; 30–60% may represent moderate heterogeneity; 50–90% may represent substantial heterogeneity; 75–200% considerable heterogeneity. The importance of the observed value of I2 depends on (i) magnitude and direction of effects and (ii) strength of evidence for heterogeneity (e.g., P value from the chi-squarred test, or a confidence interval for I2). Statistical heterogeneity is inevitable [23] We also undertaken a visual inspection of the forest plots for outlier studies, explored sources of

heterogeneity and conducted sensitivity analyses by excluding trials that were at a high risk of detection or attrition bias.

RESULTS

The flowchart of the search, screening and selection of study process is presented in Fig. 1. A total of 1509 studies were obtained from the electronic databases. After removing duplicates, 1185 records remained. Screening based on the title and abstract resulted in the selection of 24 articles. Of these 24 records, 10 articles were excluded following the evaluation of the full text for not meeting the inclusion criteria, meeting 14 studies' eligibility criteria. We check through the reference lists of relevant studies to see if these references include reports of other studies that might be eligible for the review and 1 study was identified by this method. Finally, a total of 15 studies were included in the qualitative synthesis [25–39], and 9 studies were included in the quantitative syntheses. [25–27,29,30,32–34,36].

Fig 1. Flow chart of literature search and study selection



Fifteen studies were included in the review as shown in the flow chart. 3 studies [27,33,39] recruited localized prostate cancer patients, 2 studies [34,37] (included prostate adenocarcinoma patients and 1 study [36] included benign prostate hyperplasia patients; while the other 9 [25,26,28–32,35,38] studies did not report which etiology was recruited. The majority of included studies did not report the stages of the patients recruited; [25,29–34,36,37,39] However, among those indicating the stages; 5 studies [26,27,32,35,39] included prostate cancer patients in early stages (I-III) while 1 study included patients with advanced-stage (III-IV). [28]. The treatment status of these patients was heterogeneous; 3 studies [25,26,37] (included patients in medical treatment moment, and 10 studies [27–31,34–36,38,39] applied the intervention after oncological medical treatment, while 2 studies [32,33] (included patients that were found during treatment or post-treatment. Medical oncological treatment is that treatment that contributes or helps to the solution of cancer, in the case of prostate cancer, hormonal therapy, radiotherapy and surgery are considered oncological treatments. [40,41] Among the studies involving patients during oncological medical treatment, 2 studies [26,37] only applied hormone therapy while prostate cancer patients included in the study of Mardani et al. [25] received hormone therapy, radiotherapy and/or surgery. The oncological medical treatment of the studies that recruited patients post-treatment was heterogeneous; 3 studies [28,36,38] included patients that only received hormone therapy; 1 study [29] included patients that only received surgery; 2 studies [34,35] included patients that received radiotherapy and/or surgery; 3 studies [27,30,31,39] included patients that received hormone therapy, radiotherapy, surgery and/or brachytherapy; while only 1 study did not report the oncological medical treatment. [33].

A total of 3918 prostate cancer patients have been included in this review, with a mean age of the participants ranging between 63,7 ± 7,6 to 71,32 ± 7,21 years

in the experimental group and 63,3 ± 7,51 to 70,39±5 years, the study´s quality scores ranged from 19 to 26. When the Cochrane Risk of Bias Assessment was applied, 6 studies presented high risk of bias, [26,33,34,36,38,39] 8 studies presented some concerns of bias [25,27,28,30–32,35,37] and 1 study [29] presented low risk of bias.

Table 1. Characteristics of studies

Study	TNM Cancer Stage	Treatment Status; Timing	Sample	Sample age (years±SD)	Quality Assessment Downs & Black (Risk of bias)
Mardani Et.al (2021)25	NR	During treatment (hormone therapy, radiotherapy and surgery)	GE: 35 GC: 36	GE: 69,40±5,77 GC: 70,39±5,35	23 (Some Concerns of bias)
Rui Yang Et. Al (2021)26	I-III	During treatment (hormone therapy)	GE: 47 GC: 53	GE: 67,94±5,87 GC: 66,11±7,92	23 (High risk of bias)
Tagai Et. al (2021)27	Localized prostate cancer with no regional lymph node or distant metastasis, I-III	Post-treatment (hormone therapy, radiotherapy and surgery)	GE: 217 GC: 214	GE: 63,8±6,67 GC: 63,3±7,51	21 (Some Concerns of bias)
Penedo Et. al (2020)28	III-IV	Post-treatment (hormone therapy)	GE: 95 GC: 97	GE: 68,81±8,54 GC: 68,87±9,23	21 (Some Concerns of bias)
Ferreira da Mata Et.al (2019)29	NR	Post-treatment (surgery)	GE: 34 GC: 34	GE: 63,9±6,4 GC: 64,2±5,8	23 (Low risk of bias)
Skolarus Et. al (2019)30	NR	Post-treatment (hormone therapy, radiotherapy and surgery)	GE: 278 GC: 278	GE: 66,2±7,1 GC: 67,2±5,7	21 (Some Concerns of bias)
Stanciu Et. al (2019)31	NR	Post-treatment (hormone therapy, radiotherapy and surgery)	GE: 48 GC: 48	NR	23 (Some Concerns of bias)

Craike Et. al (2018)32	I-III	Post-treatment and/or during (hormonotherapy)	GE: 47 GE: 83	NR	18 (Some Concerns of bias)
Galvao Et.al (2017)33	Localized prostate cancer; NR	During treatment or post-treatment	GE: 232 GC: 231	GE: 63,7±7,6 GC: 65,1±7,8	21 (High risk of bias)
McCaughan Et. al (2017)34	Prostate adenocarcinoma; NR	Post-treatment (radiotherapy, surgery)	GE: 26 GC: 8	GE: 67,5±6,54 GC: 63,8±6,95	21 (Poor Quality)
Traeger Et. al (2013) 35	I-II	Post-treatment (radiotherapy, surgery)	GE: 148 GE: 109	GE: 65,9±7,5 GC: 64,6±7,8	22 (Some Concerns of bias)
Chen Et. al (2012)36	Benign prostatic hyperplasia; NR	Post-treatment (hormone therapy)	GE: 119 GC: 103	GE: 71,32±7,21 GC: 69,98±8,33	19 (High risk of bias)
Carmack Taylor Et. al (2006) 37	Prostate adenocarcinoma; NR	During treatment (hormone therapy)	GE1: 46 GE2: 36 GC: 35	NR	24 (Some Concerns of bias)
Hazel Templeton Et.al (2004)38	NR	Post-treatment (hormone therapy)	GE: 28 GC: 27	NR	20 (High risk of bias)
Lepore Et.al (2003)39	Localized prostate cancer; I-III	Post-treatment (brachytherapy, radiotherapy, surgery)	GE1: 84 GE2: 86 GC: 80	GE1: 64,8±7,7 GE2: 64,8±8 GC: 65,6±6,6	24 (High risk of bias)

SD: Standard deviation; NR: Non reported; G: Group

To facilitate the understanding of the self-management interventions due to heterogeneity, they were classified using the PRISMS taxonomy. [19] Based on this classification the component of self-management support most used in the experimental interventions was "information about the condition and/or its management", [26–31,36–39] "lifestyle advice and support", [26,30,32–37], "social support" [34–37,39], "training/rehearsal for psychological strategies" [28,32,33,35] and "training/rehearsal for practical self-management activities". [28,29,36, 37].

Other components of self-management were less common in the intervention of the experimental group; such as "provision of/agreement on specific clinical action plans and/or rescue medication" [29,31,36, 37], "training/rehearsal for psychological strategies" [28,32,33,35] and "training/rehearsal for practical self-management activities" [28,29,36, 37] realized 4 studies. While some of the components are only found in the intervention of 2 studies such as "provision of equipment" [27,33] or 1 study such as "Practical support with adherence medication behavior" [29] "Provision of easy access to advice or support when needed", [33] "Training/rehearsal to communicate with health-care professionals" [38] and "Training/rehearsal for everyday activities". [25] Regarding control interventions, all studies applied usual care, of which seven provided education. [27,28,30,33,36,37].

The dose of self-management interventions was heterogeneous; the duration of intervention ranged between 4 and 24 weeks, the frequency of intervention varied between 1 and 6 times per week, and the intervention time ranged from 12 min to as much as 150 min. Table 1.

Regarding the form of application of the intervention, 7 of the studies [26,27,29,30,33,38,39] included in the review conducted a non-face-to-face intervention, while 6 studies [25,28,32,34,36,37] combined face-to face with distance forms of intervention. Among the reviewed studies only 2 of the

interventions were unsupervised, [26,27] while the majority of the included studies performed a combination of supervised and unsupervised interventions. [28–30,32,34–39] About the individualization of the sessions, the interventions were heterogeneous: 3 studies [34,35,39] conducted group sessions, 6 studies [26,27, 29,30,33,38] conducted individual sessions and 4 studies [25,28,32,37] combined both forms of intervention.

The most common outcomes explored in these studies were quality of life which was evaluated by 13 of the 15 studies, [25–28,30,31, 33–39] and self-efficacy by 8 of the 15 studies. [26–30,32,34,37]. The assessment tools for the quality of life and self-efficacy outcomes were heterogeneous and we had described in Table 2.

After treatment intervention, only 2 of the studies showed improvements in quality-of-life outcomes in the experimental group concerning baseline and compare to the control group. In terms of the self- efficacy outcomes, [33,36] 3 of the included studies [26,32,37] improved outcomes in the experimental group concerning baseline compared to the control group.

Table 2: Studies of the effectiveness of self-management intervention

Study	Experimental intervention	Control intervention	Program (week); Frequency (days/week); Dose (total minutes)	Face to face vs Distance Supervised vs Non-Supervised Individual vs Group	Outcomes	Results
Mardani Et al. (2021)	- Training/rehearsal for everyday activities	- Usual care	12;4; 60-150	- Mixed - Mixed - Mixed	- Quality of life (EORT QLQ-C30, QLQ-PR25)	No significant differences were found compare to baseline moment and control group in quality of life Cohen´s d = -0.19
Rui Yang Et al. (2021)	- Information about condition and/or its management - Training/rehearsal for psychological strategies - Lifestyle advice and support	- Usual care	12; 1-2; 50	- Online - No supervised - Individual	- Quality of life (AMS) - Self-efficacy: (UBPTPH)	GE improved significantly in d self-efficacy with respect to baseline moment GE improved significantly in self-efficacy Cohen´s d = 0.40

Tagai Et al. (2021)	- Information about condition and/or its management - Provision of/agreement on specific clinical action plans and/or rescue medication - Provision of equipment	- Usual care - Education	24; NR; NR	- Online - No supervised - Individual	- Quality of life (EPIC) - Self-efficacy (TSEFRE; T13-iSEFSCS)	No significant differences were found compare to baseline moment and control group in quality of life nor self-efficacy Cohen´s d = 0.13 / 0.15
Penedo Et al (2020)	- Training/rehearsal for practical self-management activities - Training/rehearsal for psychological strategies	- Usual care - Education	GI: 10; 1; 90 GC: 10; 1; 60	- Mixed - Mixed - Mixed	- Quality of life (FACT-G) - Stress Management skills self-efficacy (MOCS)	No significant differences were found compare to baseline moment and control group in quality of life nor self-efficacy
Ferreira da Mata Et al. (2019)	- Information about condition and/or its managements - Provision of/agreement on	- Usual Care	4; NR;12-15	- Online - Mixed - Individual	- Self-efficacy (TGAPSES)	No significant differences were found compare to baseline moment and control group in self-efficacy

	specific clinical action plans and/or rescue medication - Regular clinical review - Training/ rehearsal for practical self-management activities - Practical support with adherence (medication or behavioural)					Cohen´s d = 0.23
Skolarus Et al. (2019)	- Information about condition and /or its management - Lifestyle advice and support	- Usual Care - Education	16; NR; NR	- Online - Mixed - Individual	- Self-efficacy (PEPPI) - Quality of life (VR-12)	No significant differences were found compare to baseline moment and control group in quality of life nor self-efficacy Cohen´s d = -0.14 / 0.15
Stanciu Et al (2019)	- Information about condition and /or its management	- Usual care	NR	NR	- Quality of life (EQ-5D-5L)	No significant differences were found compare to baseline

	- Provision of/agreement on specific clinical action plans and/or rescue medication						moment and control group in quality of life
Craike Et al (2018)	- Training/ rehearsal for psychological strategies - Lifestyle advice and support	- Usual care	12;3;50	- Mixed - Mixed - Mixed	- Self-efficacy (Bandura)		GE improved significantly in self-efficacy concerning the baseline moment GE improved significantly in self-efficacy compared to CG Cohen´s d = 0.49 / 0.48
Galvao Et al (2017)	- Provision of equipment - Provision of easy access to advice or support when needed - Training/ rehearsal for psychological strategies	- Usual care - Education	Self-management: 24; NR; NR Education: 12; NR; 60	- Online - Unsupervised - Individual	- Quality of life (AQoL-8D)		GE improved significantly in quality of life with respect to baseline moment GE improved significantly in quality of life compared to GC Cohen´s d = 2

	- Lifestyle advice and support					
McCaughan Et al (2017)	- Regular clinical review - Social support - Lifestyle advice and support	- Usual care	9;1;120	- Mixed - Mixed - Group	- Quality of life (FACT-G) - Self-efficacy (LCSES)	NR
Traeger Et al (2013)	- Training/ rehearsal for psychological strategies - Social support - Lifestyle advice and support	-Usual care	10;1;120	- NR - Mixed Group	Quality of life (FACT-G)	No significant differences were found compare to baseline moment and control group in quality of life
Chen Et al (2012)	- Information about condition and /or its management - Training/ rehearsal for practical self-management activities - Social support - Lifestyle advice and support	- Usual care - Education	24;NR;NR	- Mixed - Mixed - NR	- Quality of life (BPH-QoL; IPSS)	GE improved significantly in quality-of-life since baseline GE improved significantly in quality of life compare to control group Cohen´s d = 0.92

Carmack Taylor Et al. (2006)	GEI-1: - Information about condition and /or its management - Provision of/agreement on specific clinical action plans and/or rescue medication - Training/ rehearsal for practical self-management activities - Lifestyle advice and support GEI-2: - Information about condition and /or its management - Provision of/agreement on specific clinical action plans and/or	- Usual care - Education	24; 16 + 1 cada quincena + 1 en los 6 meses; 112 horas total de cada una	- Mixed - Mixed - Mixed	- Quality of life (SF-36) - Self-efficacy	GE improved significantly in self-efficacy respect to baseline moment GE improved significantly in self-efficacy compare to control group

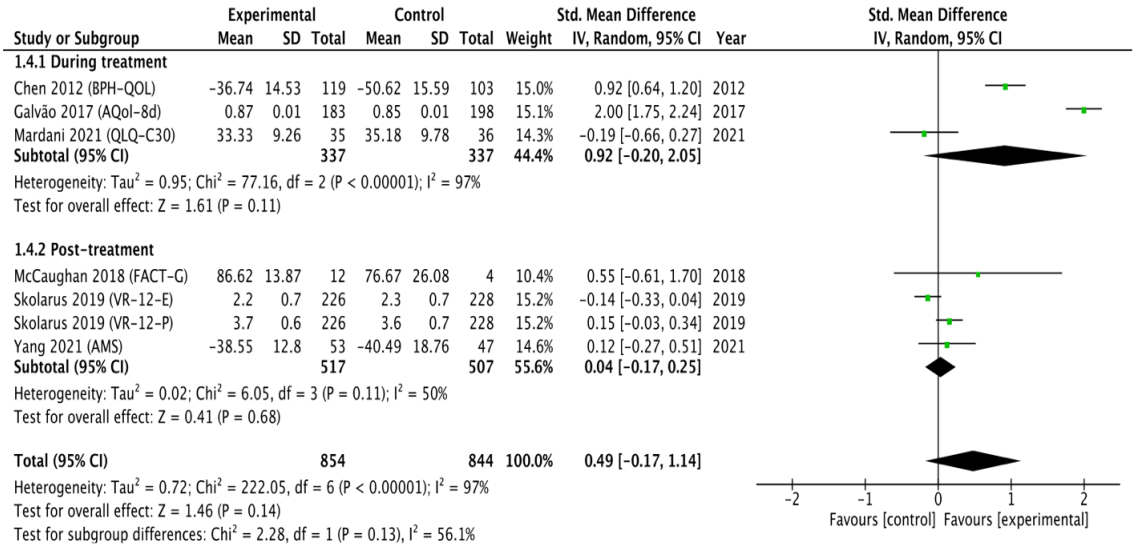
	rescue medication - Social support						
Hazel Templeton Et al. (2004)	- Information about condition and /or its management - Training/rehearsal to communicate with health-care professionals	- Usual care	NR;NR,NR	- Online - Mixed - Individual	- Quality of life (FACT-P)	GE improved significantly in quality of life respect to baseline moment No significant differences compare to control group
Lepore Et al (2003)	GE1: - Information about condition and /or its management GE2 - Information about condition and/or its management - Social support	- Usual Care	6;1;60 6;1;105	- Online - Mixed - Group	- Quality of life (SF-36, PCS, MCS)	No significant differences were found compare to baseline moment and control group in quality of life

NR: Non reported; EORT QLQ-C30: European Organization for Research and Treatment of Cancer. Quality of life Questionnaire- Core 30 Version 3; TSDHBAQ: The self-designed healthy behaviour adherence questionnaire; AMS: The Aging Males´ Symptom Scale; UBPTPH: Strategies used by people to promote health; TSEFRE: the self-efficacy for reentry scale; T13iSEFSCS: The 13-item self-efficacy for symptom control scale; FACT-G: 27-item Functional Assessment of Cancer Therapy-General; MOCS: Measure of Current Status; TGAPSES: The general and perceived self-efficacy scale; PEPPI: The perceived efficacy in patient-physician interactions; VR-12: The Veterans RAND 12-item health survey; EQ-5D-5L: EuroQol-5D-5L; AQoL-8D: Assesment of Quality of Life; BPH-QOL: BPH-Specific Quality-Of-Life Scale; SF-36: MOS 36-item Short Form Health Survey; PCS: Global Physical Health Component Score; MCS: Global Mental Health Component Score

Results obtained in meta-analyses

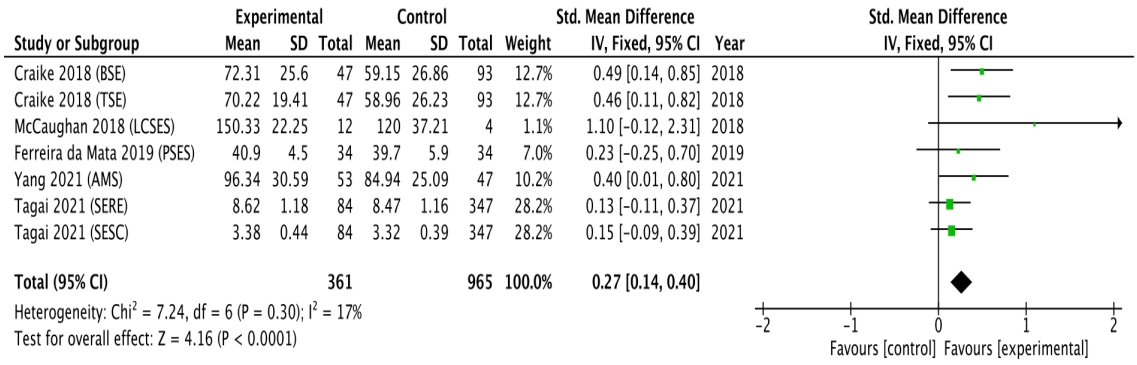
Fig. 2 presents the results of the meta-analysis of the quality of life of patients diagnosed with prostate cancer during and after oncological medical treatment. For quality of life during oncological treatment the pooled mean difference (MD) did not show a significant overall effect of self-management intervention compared to control group (MD =0.92, 95%, CI = - 0.2, p = .11). For quality of life after oncological treatment the pooled mean difference (MD) did not show a significant overall ef- fect of self-management intervention compared to control group (MD =0.04, 95%, CI = - 0.17, p = .11). The pooled mean difference (MD) did not show a significant overall effect of self-management interventions: in the experimental group compared with the control group (MD =0.49, 95%, CI = - 0.17, p = .14). The results show heterogeneity, detecting significant variability of I2 = 97%.

Figure 2. Meta-analysis. Forest plot illustrating changes in quality of life.



Results obtained in self-efficacy are shown in Fig. 3. The pooled mean difference (MD) showed significant overall effect of the self- management interventions: the experimental group compared with the control group (MD =0.27, 95%, CI =0.14, p < .0001). The results not show heterogeneity, detecting significant variability of I2 = 17%.

Figure 3. Meta-analysis. Forest plot illustrating changes in self-efficacy



DISCUSSION

This current review aims to examine the efficacy in self-management interventions on quality of life and/or self-efficacy in patients diagnosed with prostate cancer. The main findings of this review were the benefits of self-management programs on quality of life and their significant improvement in self-efficacy. Our results should be interpreted with caution due to the differences of the component of self-management intervention, differences in implementation time, doses and form of application of the studies analyzed. Our results are in line with other reviews that recruited that recruit other etiologies of cancer, such as breast, colorectal, hematologic and/or lung patients. [42,43] Those systematic reviews reported positive results for the use of self-management interventions in adults diagnosed with cancer.

The timing of intervention and the heterogeneity of cancer clinical profiles is a subject of debate in relation to the efficacy rate. [44–46] In our case, most of the studies performed the intervention at an early stage of the pathology, which could be reflected in the efficacy of the self-management interventions. the study by McCabe et al. [46] observed that patients at an advanced stage presented a greater affectation of the global health status.

As for the treatment status, there is also a discrepancy among the included studies, most of the studies included in our review perform the intervention after medical treatment as the studies of Galva˜o et al. [47] However, previous

studies showed the need to perform the intervention during medical treatment due to the presence of side effects that already appear during the application of the treatment. [48] Because of all these heterogeneities we focus our systematic review on the components of the program, while the meta-analysis is the focus of the common assessed variables.

Concerning the intervention, due to the number of components considered according to the PRISMs guidelines, [19] the heterogeneity found was to be expected. However, the most frequently used intervention components were information about the disease, changes in healthy lifestyles and the implementation of self-management techniques. Kandasamy et al. [49] have already noted the importance of providing information to prostate cancer patients for both treatment decisions and management. Similarly, the review of Davies et al. [50] observed that healthy lifestyle changes had a positive effect on the quality of life of these patients. To our knowledge, no previous review has studied the effect of self-management components in patients with prostate cancer, but we do know of their positive effect in other etiologies. [51].

The meta-analyzed results showed a significant effect of self- management on self-efficacy, which is consistent with the results obtained in the review by Singleton et al. [52] on breast cancer. In another line, the study of Amano et al. [53] analyze the relation of symptoms and quality of life over time in patients before and after prostatectomy, future studies need to analyze evolution over time after therapeutic interventions taking into account different clinical profiles in prostate cancer.

Limitations

This study has several limitations to be taken into account. No homogeneity was observed in the stage and treatment status of prostate cancer patients which made it difficult for us to categorize the results. Some trials may have

been missed despite reviewing multiple electronic databases of published and unpublished studies. In addition, a meta- analysis of the results of the follow-up was not possible due to a lack of data.

CONCLUSION

In conclusion, self-management programs showed significant improvements in self-efficacy and benefits on the quality of life. However, this review cannot support nor refute the use of self-management interventions to improve the quality of life in patients with prostate cancer. Our review cannot support the best time to apply a self-management intervention since we were only able to meta-analyze post-treatment outcomes for self-efficacy variables and in the case of quality-of-life variables no significant differences were shown regardless of the time of treatment. Therefore, further research is needed to analyze at what stage and stage of treatment they are most likely to be effective.

Implication for practice

Self-management components may be heterogeneous but show positive results in improving self-efficacy in prostate cancer survivors.

Including self-management components in the rehabilitation of prostate survivors can improve their quality of life.

Conflict of interest

The authors have no funding or conflicts of interest to disclose

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Estudio 3

Efficacy in urinary symptom burden, psychological distress, and self-efficacy of education-enhanced interventions in prostate cancer patients: a systematic review and meta-analyses

Efficacy in urinary symptom burden, psychological distress, and self-efficacy of education-enhanced interventions in prostate cancer patients: a systematic review and meta-analyses.

Javier Martín Núñez[1]; Julia Raya Benítez[1]; Laura López López[1]; Andrés Calvache Mateo[1]; Alejandro Heredia Ciuró[1]; Alba Navas Otero[1]; Marie Carmen Valenza[1]

[1] Faculty of Health Sciences, Department of Physiotherapy, University of Granada, Av. De la Ilustración, 60, 18016, Granada, Spain.

ABSTRACT

Background: Worldwide, prostate cancer is both the second-most diagnosed cancer and most common solid tumor in men. Prostate cancer patients present with a symptom burden that is compounded by the impact of medical oncology treatment, affecting different domains of their perceived health status. Education active techniques are a key role in chronic disease to increase participation in their recovery.

Purpose: The purpose of the current review was to examine the efficacy of education-enhanced in urinary symptom burden, psychological distress, and self-efficacy in patients diagnosed with prostate cancer.

Methods: A wide search of the literature was conducted for articles from their inception to June 2022. Only randomized controlled trials were included. Data extraction and methodologic quality assessment of the studies were carried out by two reviewers. We previously registered the protocol of this systematic review on PROSPERO (CRD42022331954).

Results: A total of six studies were included in the study. After education-enhanced intervention showed significant improvements in any of perceived urinary symptom burden, one in psychological distress, and one in self-efficacy in the experimental group. The meta-analysis showed that education-enhanced interventions have a significant effect on depression.

Conclusion: Education-enhanced could have positive effects on urinary symptom burden, psychological distress, and self- efficacy in prostate cancer survivors. Our review was unable to demonstrate the best timing to apply education-enhanced strategies.

Keywords: Urinary symptom burden; Psychological distress; Self-efficacy

INTRODUCTION

Worldwide, prostate cancer is both the second-most diagnosed cancer and most common solid tumor in men. [1, 2] Estimated 1,414,259 cases and 307,000 deaths, becoming the fifth leading cause of cancer death in men. [2, 3] In addition, it is estimated to grow to almost 2.3 million new cases by 2040 due to the growth and aging of the population. [2]

Prostate cancer is a commonly diagnosed cancer, and due to the large number of new prostate cancer diagnoses each year, millions of prostate cancer survivors are present worldwide. [1] These survivors present with a symptom burden that is compounded by the impact of medical oncology treatment, affecting different domains of their perceived health status (e.g., urinary symptoms, sexual function symptoms, bowel incontinence, psychological distress, and self-efficacy). [4, 5]

Among the high symptom burden of prostate cancer survivors, there is a high prevalence of symptoms related to sexual and urinary function. The presence of high symptom burden as well as specific factors of the disease and treatment influence the likelihood of experiencing psychological distress. [6] Among psychological symptoms, depression in prostate cancer patients is often an unidentified and underdiagnosis factor. [7]

Additionally, prostate cancer survivors who have received androgen deprivation therapy presented a higher risk of developing depression than other therapies. [8] Also, those individuals experiencing depressive symptoms

had lower self-efficacy. [9] A key role in chronic disease is to increase active participation in their recovery and self-management: a comprehensive approach to the management of chronic (this suggests the need to implement education active strategies in prostate cancer survivors). [10, 11] Those techniques can improve the person's quality of life by removing the behavioral barriers that may get in the way of those improvements, achieving lasting generalization of both quality of life and behavioral improvements. [12] Among those techniques, education enhanced may be defined as the application of biomedical techniques to increase educational skills. These techniques include psychological strategies, support through clinical action plans or equipment, and even social support or the practice of self-management activities, among others. In this way, it allows patients to perform a comprehensive and active functional assessment of their own behavior. [12] To the best of our knowledge, there are no previous reviews that analyze the effects of education-enhanced programs on prostate cancer patients. Thus, the purpose of the current review was to examine the efficacy of education-enhanced in urinary symptom burden, psychological distress, and self-efficacy in patients diagnosed with prostate cancer.

METHODS

A systematic review and meta-analyses were performed to identify randomized clinical trials reviewing the effects of education-enhanced in psychological distress, symptom burden, and perceived self-efficacy. The guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) were used to achieve the systematic review. The Cochrane Collaboration guidelines for reviewing interventions were also closely followed. We previously registered the protocol of this systematic review on PROSPERO (CRD42022331954).

Search strategy

A wide search of the literature was conducted for articles indexed on PubMed, Scopus, and Web of Science data- bases from their inception to June 2022. A MEDLINE search strategy was developed based on the examination of keywords used in existing systematic reviews, such as the terms: “prostate,” “cancer,” “education,” “urinary symptom,” “psychological distress,” and “self-efficacy,” as well as comprehensive review of MeSH terms, expert guidance, and specialist review. Additionally, we screened the reference lists of relevant reviews related to the term and considered non-English language studies for inclusion if the translation was possible.

Articles were included if they met the following criteria: (1) prostate cancer survivors; (2) education-enhanced interventions; (3) education-enhanced had to be compared to an isolated education intervention; (4) urinary symptom burden, psychological distress, and self-efficacy were included in the outcomes; (5) only randomized control trials were included.

Two researchers carried out a search process that included removing duplicates and screening titles, abstracts, and eligible full texts. Also, the researchers independently performed the literature search, and disagreements were resolved through a consensus discussion with a third independent investigator to reduce the selection bias potential.

After selected articles data extraction and methodological assessment were carried out. Methodological quality assessment was evaluated by The Downs and Black Checklist, [13] one of the most used methodological quality assessment scales for randomized clinical trials. This tool consists of 27 items, including five subscales, which are: reporting, external validity, internal validity (study bias and confounding), selection bias, and study power. Poor quality is considered when a score of 14 or less is achieved, fair quality between 15 and

19, good between 20 and 25, and excellent study when it is higher or equal to 26. [14, 15]

Cochrane Risk of Bias Tool was used to assess the risk of bias for randomized controlled trial. A total of 6 subscales make up this tool subscales (selection bias, performance bias, detection bias, attrition bias, reporting bias, and another bias). [16] The methodological quality depends on the risk of each of the subscales: high quality (low risk in all domains), fair quality (high risk in one domain or two unclear domains), and poor quality (two or more unclear domains or there are important limitations that could invalidate the results). [17]

Meta-analyses

Quantitative synthesis of studies presenting means and standard deviations of symptom burden, psychological dis- tress, and self-efficacy was carried out using Review Manager 5 software (RevMan 5). Quantitative data, including the number of patients assessed, final mean values, and standard deviations for each treatment arm, was extracted to estimate the overall mean differences between experimental and control arms.

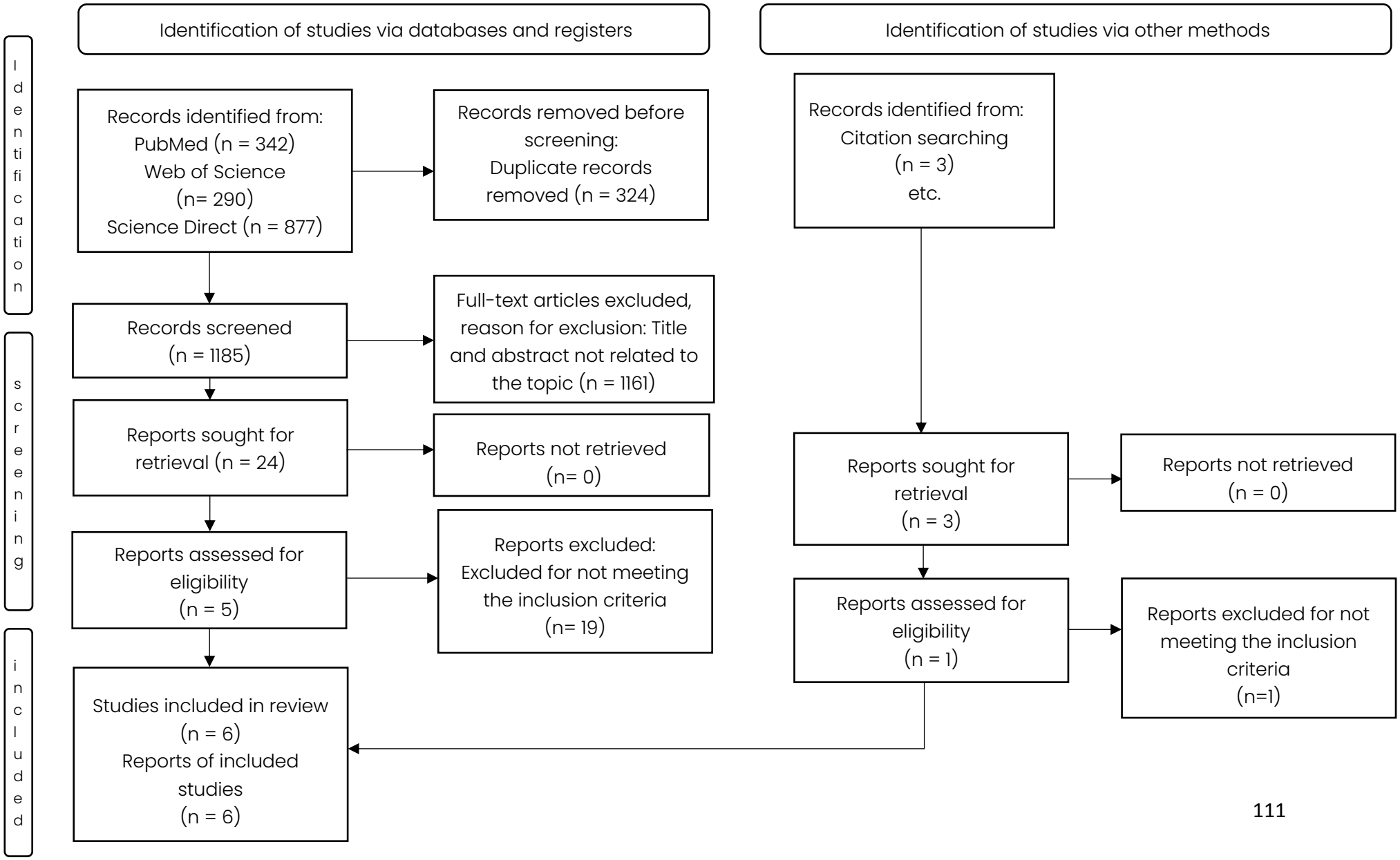
When the studies did not present sufficient data to calculate the effect size (e.g., no means provided, no standard deviation provided), the authors were contacted. We calculated missing standard deviations when *n p*-values or 95% confidence intervals were given via the embedded Review Manager calculator. We assumed to measure the same underlying symptom or condition, and therefore standardized mean differences were used as all the scales. The overall mean effect sizes were estimated using random effect models or fixed effect models according to statistical heterogeneity I2 tests (for sizes of less than 50%, fixed effect models were used). [16] We also undertook a visual inspection of the forest plots for outlier studies, explored sources of

heterogeneity, and conducted sensitivity analyses by excluding trials that were at a high risk of detection or attrition bias.

RESULTS

Figure 1 presents the process of the search, screening, and selection of studies. We collected a total of 1509 studies from the three electronic databases. In total, 1185 records remained after removing duplicates. A total of
24 articles were selected when we screened based on the title and abstract results. Of these 24 records, 19 articles were excluded due to the evaluation of the full text for not meeting the inclusion criteria, meeting 5 studies' eligibility criteria. While 1 study was identified by other methods. Finally, a total of 6 studies [18–23] were included in the qualitative syntheses, and 5 studies were included in the quantitative syntheses. [18–21, 23]

Fig 1. Flow chart of literature search and study selection



As shown in the flow chart, we finally included 6 studies in the review. Details about the characteristics of the studies are reported in Table 1. A total of 2 studies [18, 21] recruited prostate cancer patients, 1 study [23] included prostate adenocarcinoma patients, 1 study [22] included benign prostate hyperplasia patients, and 2 studies [19, 20] did not report the etiology. Of the included studies, 4 studies [20–23] did not report the stage of the patients; however, 1 study [18] included patients with early stages (I–III) and 1 study [19] included patients with advanced stages (III–IV).

Regarding treatment status, 4 studies [18–20, 22] included patients after oncological medical treatment, 1 study [23] applied the intervention in medical treatment moment, and 1 study [21] included patients that were found during treatment or posttreatment. The oncological medical treatment present in the studies was radiotherapy and/or surgery in 3 studies [18, 20, 21] whereas hormone therapy was presented in 5 studies. [19–23]

A total of 1991 prostate cancer patients have been included in this review, with the mean age of the participants ranging between 63.7 ± 7.6 and 71.32 ± 7.21 in the experimental group and 63.3 ± 7.51 to 70.39 ± 5. The studies' quality scores ranged from 19 to 24. When the Cochrane Risk of Bias Assessment was applied, 4 studies presented fair quality [18–20, 23] and 2 studies presented poor quality. [21, 22]

Table 1. Characteristic of studies.

Study	TNM Cancer Stage	Treatment Status; Timing	Sample	Sample age (years±SD)	Quality Assessment Downs & Black (Risk of bias)
Tagai Et.al (2021)18	Localized prostate cancer with no regional lymph node or distant metastasis, I-III	Post-treatment (radiotherapy, surgery)	EEG: 217 CG: 214	EEG: 63,8±6,67 CG: 63,3±7,51	21 (Some Concerns of bias)
Penedo Et.al (2020)19	III-IV	Post-treatment (hormone therapy)	EEG: 95 CG: 97	EEG: 68,81±8,54 CG: 68,87±9,23	21 (Some Concerns of bias)
Skolarus Et.al (2019)20	NR	Post-treatment (hormone therapy radiotherapy, surgery)	EEG: 278 CG: 278	EEG: 66,2±7,1 CG: 67,2±5,7	21 (Some Concerns of bias)
Galvao Et.al (2017)21	Localized prostate cancer; NR	During treatment or post-treatment (hormone therapy radiotherapy, surgery)	EEG: 232 CG 231	EEG: 63,7±7,6 CG: 65,1±7,8	21 (High risk of bias)
Chen Et.al. (2012)22	Benign prostatic hyperplasia; NR	Post-treatment (hormone therapy)	EEG: 119 CG: 113	EEG: 71,32±7,21 CG: 69,98±8,33	19 (High risk of bias)

Carmack Taylor Et.al (2006)23	Prostate adenocarcinoma; NR	During treatment (hormone therapy)	EEG 1: 46 EEG 2: 36 CG: 35	NR	24 (Some Concerns of bias)

TNM: TNM Classification of Malignant Tumor; SD: Standard Deviation; EEG: Education enhanced group; CG: Control Group; NR: Non-Reported

Details about the intervention and results are reported in Table 2. The components of the education-enhance programs were heterogeneous: provision of agreement on specific clinical action plans and/or psychological strategies realized in 3 studies, [18, 20, 23] psychological strategies realized in 3 studies too, [19–21] provision of equipment realized in 2 studies, [18, 21] rescue medication, [18, 23] training/rehearsal for practical self-management activities realized in 2 studies, [19, 22] social support realized in 2 studies [22, 23] and access to advice on support when needed realized in 1 study. [21] In relation to control group, all of them received education and usual care as an intervention.

Regarding the dose of education-enhanced, the frequency of intervention was expressed in only two studies and ranged from 1 to 2 days per week, and the intervention time ranged from 60 min to as much as 1800 min.

The outcomes explored in this review were urinary symptom burden, which was evaluated by 5 of the 6 studies, [18–22] self-efficacy, which was evaluated in 4 studies, [18–20, 23] and psychological distress, which was evaluated in 3 studies. [19, 21, 23]

After experimental intervention, 4 studies [19, 20, 22] showed significant improvements in any of perceived urinary symptom burden in the experimental group concerning baseline and compared to the control group. In relation to self-efficacy, only 1 study [23] improved significantly in the experimental group concerning baseline compared to the control group. In terms of psychological distress, only 1 study [20] showed improvements in anxiety in the experimental group concerning baseline and compared to the control group and 1 study [22] improved significantly only with respect to baseline moment.

Table 2. Studies of the effectiveness education-enhanced intervention

Study	Education Enhanced Interventions	Program (week); Frequency (days/week); Dose (total minutes)	Outcomes	Results
Tagai Et.al (2021)18	- Education - Provision of equipment and agreement on specific clinical action plans and/or rescue medication	24; NR; NR	- Urinary Symptom burden (EPIC) - Self-efficacy (TSEFRE; T13-iSEFSCS)	EEG improved significantly in urinary incontinence, urinary irritation, sexual function with respect to baseline moment EEG improved significantly in urinary incontinence, urinary irritation, sexual function compared to CG
Penedo Et.al (2020)19	- Education - Training/rehearsal for practical self-management activities and psychological strategies	10; 1; 90	- Cancer-related anxiety (MAX-PC) - Cancer-Specific distress (IES-R) - Depression (PROMIS) - Perceived stress (PSS) - Positive affect (ABS) - Urinary Symptom burden (EPIC)	EEG improved significantly in sexual function, self-efficacy, cancer related anxiety with respect to baseline moment EEG improved significantly in sexual function, self-efficacy, cancer related anxiety compared to CG

			- Stress Management skills self-efficacy (MOCS)	
Skolarus Et.al (2019)20	- Education - Provision of agreement on specific clinical action plans and/or psychological strategies	16; NR; NR	- Urinary Symptom burden (EPIC) - Self-efficacy (PEPPI)	EEG improved significantly in incontinence, irritative and obstructive domains with respect to baseline moment EEG improved significantly in incontinence, irritative and obstructive domains compared to CG
Galvao Et.al (2017)21	- Education - Provision of equipment, easy access to advice or support when needed and psychological strategies	24; NR; 60	- Psychological distress (BSI) - Urinary Symptom burden (EPIC)	EEG improved significantly in psychological distress with respect to baseline moment No significant differences compare to control group
Chen Et.al. (2012)22	- Education - Training/ rehearsal for practical self-management activities - Social support	24; NR; NR	- Urinary Symptom burden (IPSS)	EEG improved significantly in symptom burden with respect to baseline moment EEG improved significantly symptom burden compared to CG
Carmack Taylor Et.al (2006)23	EEG 1: - Education - Provision of agreement	24; 1-2; 1800	- Anxiety (STAI) - Depression (CES-D)	EEG1 and EEG2 improved significantly in self-efficacy respect to baseline moment

on specific clinical action plans and/or rescue medication and practical self-management activities EEG 2: - Education - Provision of/agreement on specific clinical action plans and/or rescue medication - Social support	- Self-efficacy	EEG1 and EEG2 improved significantly in self-efficacy compared to CG

NR: Non-Reported; EPIC: The Expanded Prostate Cacer Index Composite; TSEFRE: The self-efficacy for re-entry scale; T13-iSEFSCS: The 13-item self-efficacy for symptom control scale; EEG: Education enhanced group; CG: Control Group; MAX-PC: The Memorial Anxiety Scale for Prostate Cancer; IES-R: The 22-item Impact of Event Scale.Reveised (IES-R);PROMIS: Patient-Reported Outcome Measurement Information System ;PSS: Perceived Stress Scale ;ABS: Affect Balance Scale;MOCS: Measure of Current Status; PEPPI: The Perceived Efficacy in Patient-Physician Interactions; BSI: Brief Symptom Inventory; IPSS: International Prostate Cancer Score; STAI: Scale of the State Trait Anxiety Inventory; CES-D: The Centers for Epidemiologic Studies Depression

Results obtained in meta-analyses

Figure 2 presents the results of the meta-analysis for urinary symptom burden of patients diagnosed with prostate cancer, divided by the different symptom. Although some symptoms showed results in favor of education-enhanced interventions compared to control group, none showed significant improvement in symptoms: urinary function (MD = - 0.67, 95%, CI = - 1.43, *P* = 0.08), urinary irritation (MD = - 0.28, 95%, CI = - 0.81, *P* = 0.29), sexual function (MD = - 0.54, 95%, CI = - 0.21, *P* = 0.16), and bowel function (MD = - 0.24, 95%, CI = - 0.58, *P* = 0.15). In the same lane, with respect to total urinary symptom burden measure reported, the pooled mean difference (MD) did not show significant overall effect of education-enhanced interventions compared with control group (MD = - 0.15, 95%, CI = - 0.46, *P* = 0.15). The results show heterogeneity, detecting significant variability of *I*2 = 97%.

Figure 2. Meta-analysis. Forest plot illustrating changes in urinary symptom burden.

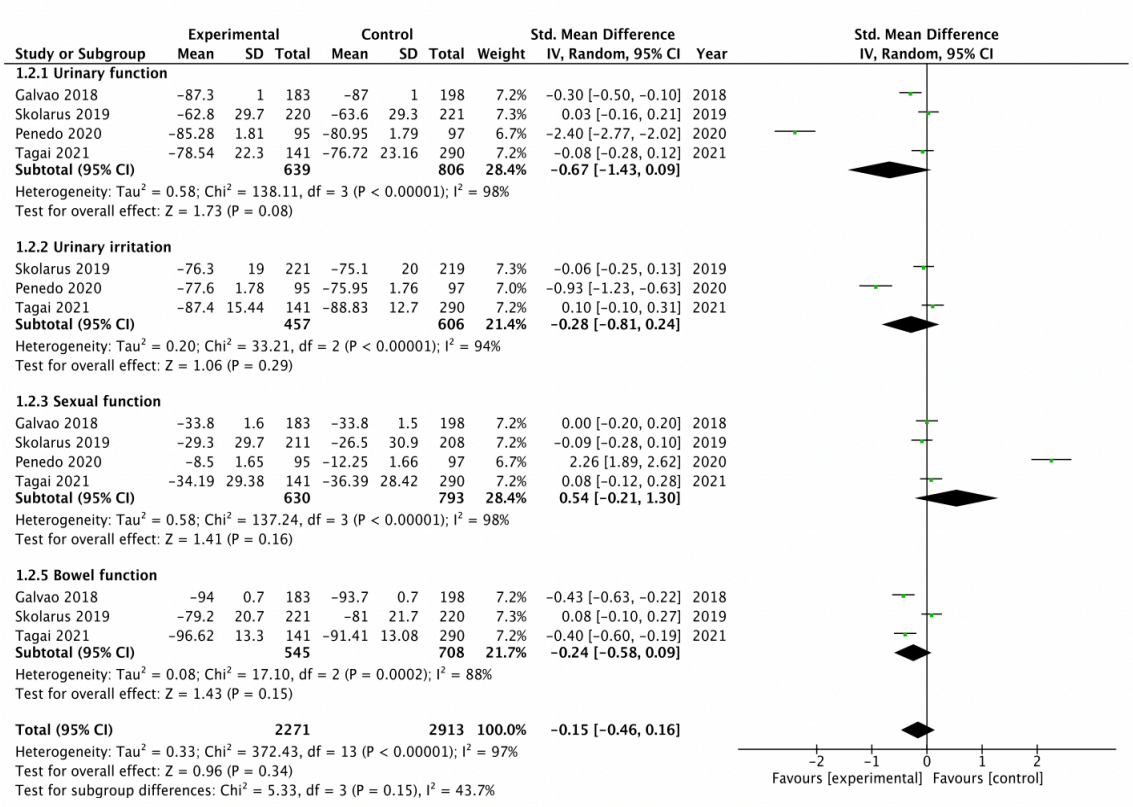
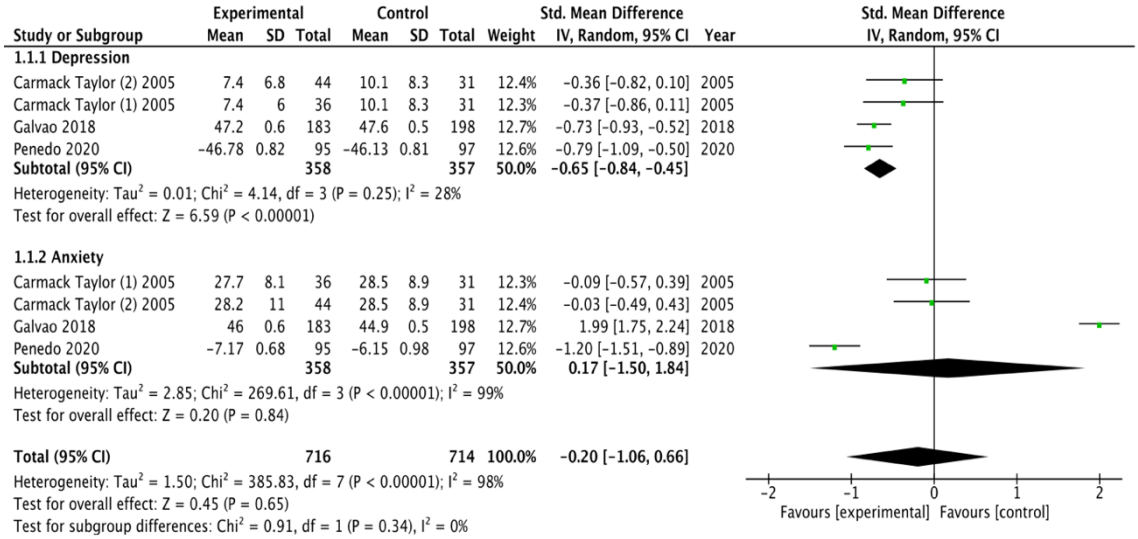


Figure 3 presents the results of the meta-analysis of psychological distress of patients diagnosed with prostate cancer, divided by the different psychological disorders. For depression disorders, the pooled mean difference (MD) showed a significant overall effect of education-enhanced interventions compared to control group (MD = - 0.65, 95%, CI = - 0.84, *P* < 0.00001). For anxiety disorders, the pooled mean difference (MD) did not show significant overall effect of education-enhanced interventions compared to control group (MD = 0.17, 95%, CI = - 1.50, *P* = 0.84). With respect to total psychological distress measure reported, the pooled mean difference (MD) did not show significant differences in favor of education-enhanced interventions compared to control group (MD = - 0.20, 95%, CI = - 1.06, *P* = 0.34). The results showed high heterogeneity, detecting significant variability of *I*2 = 98% that was not attributable to chance.

Figure 3. Meta-analysis. Forest plot illustrating changes in psychological distress



DISCUSSION

The aim of this current review was to examine the efficacy of education-enhanced interventions in urinary symptom burden, psychological distress, and self-efficacy in patients diagnosed with prostate cancer. However, our results should be interpreted with caution due to the number of education

strategies implemented and dose of experimental intervention in the studies analyzed. Previous reviews showed results in agreement with ours, which suggest that education-enhanced interventions lead to beneficial effects in urinary symptom burden and psychological dis- tress in different etiologies of cancer. [24, 25] In line with our results, education-enhanced seems to improve urinary symptom burden and psychological distress in patients diagnosed with cancer.

In relation to the urinary symptom burden, urinary function and urinary irritation only showed significant improvements in some studies, [18, 20, 22] while sexual and bowel function had less impact in the included studies. Previous studies showed that urinary incontinence and function were a substantial enough problem after medical oncology treatment (especially after radiotherapy). [26, 27] As for the meta-analysis, although no statistically significant improvements were found, improvements were shown in all variables except bowel function. As indicated by the studies of Merrick and Elshaikh, [28, 29] the use of alpha-blockers improves urinary flow and irritation. In our case, all the studies included hormone therapy as a medical oncological treatment, except for the study of Tagai et al. [18]

With respect to psychological distress, anxiety and depression were both the most common mental disorders among prostate cancer patients in the included studies. [18, 21, 23] Previous research has observed that prostate cancer survivors included in their studies also presented anxiety and depression as the most common psychological disorders. [8, 30] Moreover, the studies of Sharp [31] and Occhipinti [32] associated a high urinary symptom burden with the likelihood of impaired psychological well-being. Similarly, low levels of self-efficacy inter- fere with the development of psychological stress. [9] The association of these variables suggests an improvement after the intervention.

Limitations

Several limitations we have to take into account in this study. No homogeneity was observed in the stage of prostate cancer patients, which has an impact on the classification of the results. Some studies included a sample of patients with prostate cancer during medical oncology treatment as well as after undergoing treatment, which should be taken into account when interpreting the results. Neither the beginning nor the complete duration of the medical oncological treatment is specifically expressed, which has a great impact on the development of signs and symptoms in these patients; therefore, it would be of interest that future studies include this information. In addition, despite reviewing multiple electronic databases of published and unpublished studies, it is possible that some articles may have been omitted. Finally, it was not possible to perform a meta-analysis with the follow-up data.

CONCLUSION

In conclusion, education enhanced could have positive effects on urinary symptom burden and psychological distress in prostate cancer survivors. Our review was unable to demonstrate the best timing to apply education-enhanced strategies. Although the meta-analysis showed results in favor of the experimental group for both the perception of urinary symptoms burden and psychological distress, only statistical differences were shown in the experimental group in depression.

Author contribution: The author, Valenza Marie Carme, had the idea for the article, had full access to all the data in the study, and takes responsibility for the integrity of the data and accuracy of the data analysis. Martín-Núñez Javier and Calvache-Mateo Andrés had full access to all the data in the study and took responsibility for performing the literature search and data analysis. López-López Laura, Heredia-Ciuró Alejandro, Raya-Benítez Julia, and Navas-

Otero Alba contributed substantially to draft and critically revising the work and the writing of the manuscript.

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Conflict of interest: The authors declare no competing interests.

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DISCUSIÓN

Estudio 1

La reducción de los niveles de actividad física es un factor importante a tener en cuenta en los pacientes de cáncer de próstata que han recibido tratamiento médico oncológico. La disminución de los niveles de actividad física autoinformada de estos pacientes se relacionaron con una mayor presencia de barreras al ejercicio que el grupo control. En relación a la calidad de vida y la autoeficacia se observó que era menor en aquellos pacientes que presentaban menores niveles de actividad física y más barreras al ejercicio. Todo esto justifica la necesidad de establecer programas de rehabilitación de ejercicio individualizado donde se tengan en cuenta estas variables para diseñar de forma oportuna las posibles intervenciones terapéuticas

Estudio 2

La calidad de vida de los pacientes con cáncer de próstata se ve afectada no solo tras el tratamiento médico oncológico si no durante la aplicación del mismo. Las intervenciones de automanejo han demostrado resultados positivos en la calidad de vida y una mejora significativa en la autoeficacia de estos pacientes. Este tipo de intervenciones permiten que el paciente intervenga de forma activa en su rehabilitación estableciendo cambios saludables en el estilo de vida y por tanto mejorando su estado de salud general.

Estudio 3

La educación mejorada mediante la cual los pacientes aprenden estrategias de educación activas que le permiten hacerse participe de su recuperación parece mejorar la carga de síntomas urinarios y el estado psicoemocional de los pacientes con cáncer de próstata. La presencia de la carga de síntomas urinarios y la alteración de la función sexual tiene una repercusión sobre el estado psicoemocional de aquellos pacientes con cáncer de próstata que se

encuentran o han pasado por tratamiento médico oncológico. De manera similar, los niveles bajos de autoeficacia también intervienen en el estado psicológico de estos pacientes, por tanto, la asociación de estos síntomas sugiere una mejoría tras la aplicación de una intervención mediante educación proactiva.

CONCLUSIONES

Conclusiones específicas

Estudio 1: Los niveles de actividad física autoinformados fueron inferiores en los pacientes de cáncer de próstata tras el tratamiento médico. Estos pacientes mostraron peor percepción de los beneficios y más barreras a la actividad física. De la misma forma la calidad de vida y la autoeficacia para el control de la patología fueron menores en estos pacientes

Estudio 2: Los programas de automanejo muestran mejoras significativas en la autoeficacia y beneficios en la calidad de vida. A pesar de que no pudimos demostrar cual es el mejor momento para aplicar una intervención basada en autocuidado, este tipo de estrategias parecen ser efectivas para la autoeficacia y la calidad de vida independientemente del momento de su aplicación.

Estudio 3: Las intervenciones basadas en una educación proactiva podrían tener efectos positivos sobre los síntomas urinarios y el estado psicoemocional de pacientes de cáncer de próstata.

Conclusiones generales

Los niveles de actividad física, las barreras a la actividad física, la calidad de vida y la autoeficacia son factores claves a tener en cuenta en aquellos pacientes de cáncer de próstata que reciben tratamiento oncológico. Por tanto, desarrollar la valoración de estos aspectos permitirán plantera intervenciones individualizadas y con una participación activa de los pacientes. Los programas basados en estrategias de automanejo y educación son una buena alternativa para mejorar la calidad de vida y la autoeficacia de los pacientes de cáncer de próstata, pudiendo ser una buena estrategia para mejorar el estado psicoemocional y los síntomas urinarios de estos pacientes, y por tanto en última instancia su supervivencia.

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