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Brief behavioural intervention, delivered as standard care, to support physical activity engagement in men with prostate cancer: a pilot study protocol

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ABSTRACT

Introduction Physical activity is beneficial to men with prostate cancer, but there remain barriers to fulfilling the potential of National Health Service trusts to support men with prostate cancer to be physically active. This article describes protocols for two pilot studies, each conducted in a different setting, designed to assess the potential of a behavioural intervention to affect patients' motivation to exercise. The intervention is theory based and inspired by recent empirical observations.

Methods and analysis The intervention consists of a 10 min talk, delivered to patients by a man with a history of prostate cancer treatment and a good experience of exercise, as part of their standard care. This talk either takes place in a preradical prostatectomy seminar (study one), or a post-treatment seminar designed to assist patients in adjusting to life after treatment (study two). Outcomes will be compared between patients attending the existing seminar format, and patients attending the novel seminar format. The two primary outcomes are: (1) differences in self-reported physical activity before and 90 days after the seminar and (2) the likelihood of the patient seeing an in-house exercise physiotherapist in those 90 days. Data on quality of life, fatigue and exercise behavioural regulations will also be captured at the same time points.

Ethics and dissemination These two projects have been approved by internal clinical audit committees due to their focus on service improvement. Findings from these pilot studies will be presented at oncology meetings and submitted for publication in academic journals.

INTRODUCTION

Prostate cancer (PCa) is the most common cancer in men in the UK, with approximately 47 700 new cases diagnosed per year nationally.[1] In recent years, there has been an increasingly heightened interest among clinical researchers in exercise and physical activity (PA) as an adjunctive therapy in the treatment of PCa.[2 3] This interest has been driven by research showing exercise and PA to be potentially beneficial to men with PCa in a number of ways that encompass the areas of physical composition and function,[4–6] alleviation of treatment side effects,[7] psychological well-being[8] and PCa-specific survival.[9–14]

There is consensus that exercise is beneficial to people with cancer, and the amount of exercise recommended for people with cancer is the same as for healthy individuals.[15 16] Appropriately designed and administered exercise programmes are generally considered to be safe for men with PCa, including those with advanced disease or bony metastatic deposits.[3] This is reflected in UK national guidelines on the diagnosis and management of PCa (NICE-CG175), which currently recommend offering 'men who are starting or having androgen deprivation therapy supervised resistance and aerobic exercise at least twice a week for 12 weeks to reduce fatigue and improve quality of life' (p. 22).[17]

In reality, however, a translational gap remains in the UK regarding the systematic delivery of exercise support to men diagnosed with PCa.[18] This was recently highlighted in a useful study by Bourke *et al*[18] that described the state of exercise programme provision for men with PCa across 79 National Health Service (NHS) trusts across the UK. The results from a telephone and email survey indicated that 38 of these 79 trusts were considered 'moderately' or 'highly' capable of delivering an exercise programme to men diagnosed with PCa. However, responders from just two of these NHS trusts indicated that such exercise programmes were embedded into a standard PCa care pathway. A qualitative component within the same paper demonstrated the breadth of obstacles to providing

a robust, integrated service, with the identified themes covering patient motivation, patient capability, financial governance, organisational culture, organisational processes and the availability of relevant expertise.[18]

The interventional study protocol presented here aims to address patient motivation. We draw on preliminary evidence indicating that due to their shared experience, sometimes men with PCa can motivate other men with PCa to engage with exercise or PA behaviours, in a context that is undeliverable by a healthcare professional.[19–22] We aim to deliver a brief behavioural intervention, based on this observation, systematically to all men due to undergo radical prostatectomy for PCa within an NHS trust. Our aim is to capitalise on a phenomenon known in social sciences as the 'teachable moment'. In the healthcare setting, this generally refers to a period of time following a significant health event (eg, a cancer diagnosis), in which an individual may be particularly amenable to changing their health behaviour.[23]

Hence, the brief behavioural intervention to be piloted consists of a man with a previous history of treatment for PCa and a good experience of engagement with exercise, giving a 10 min talk to men who are due to undergo, or have recently undergone, radical prostatectomy for PCa. This intervention will be piloted in both mandatory presurgery seminars for men undergoing radical prostatectomy (enabling *all* men receiving radical prostatectomy for PCa to be targeted) and non-mandatory post-treatment health and well-being seminars.

Patient seminars are an economically efficient and effective method of delivering crucial information to men undergoing radical prostatectomy.[24] It has been evidenced that patient seminars are effective at equipping patients with the information they need, while using just a small fraction of the nursing hours that would be required for multiple individual consultations (as low as 5.5%).[24] This makes patient seminars a useful medium through which to engage men with PCa in a dialogue about PA, given that overstretched uro-oncology clinicians do not have adequate time to engage in this dialogue with patients in a 1:1 clinic consultation.[25 26]

Patient seminars that are conducted at Guy's and St Thomas' NHS Foundation Trust and The Royal Marsden NHS Foundation Trust, where each of these two pilot studies will take place, already contain a 20 min segment on PA, which is delivered by someone with a background in exercise physiotherapy. This segment contains empirical promotion of the benefits of PA for men with PCa, guidance on what PA to do, and assurance that PA is safe for men with PCa. This approach aims to address some of the empirically suggested barriers to PA in this population.[22 27–30] Attendees are also given contact details for the local in-house Cancer Exercise Physiotherapy services. Thus, the seminar provides a useful way of systematically nudging large amounts of patients towards an already established behaviour change pathway, offered by Cancer Exercise Physiotherapy, while preserving the patient's autonomy, which is thought to be important in promoting sustained health behaviour change.[31] This established pathway engages patients with individualised exercise plans, established behaviour change techniques (such as motivational interviewing and goal setting) and long-term follow-up (up to 1 year). Early data have indicated that this pathway may be facilitating sustained PA behaviour change in men with PCa.[32]

These pilot studies aim to determine whether this support structure for PA engagement might be enhanced by supplementing the existing PA segment in the seminar with another 10 min PA segment delivered by a man with a history of treatment for PCa. The intervention acknowledges the theoretical framework of Ryan and Deci's resilient 1985 macro-theory of 'self-determination'.[33] Hence, the intervention aims to influence exercise 'behavioural regulations' via a process of social identification and comparison.[34–36] We thus hypothesise that: (1) patients who experience a physiotherapist talk supplemented with a patient talk will self-report a greater increase in PA 3 months following the seminar, compared with those who experienced a physiotherapist talk only; and (2) patients who experience a physiotherapist talk supplemented with a patient talk will be more likely to receive a consultation with a specialist cancer exercise physiotherapist in the following 3 months, compared with those who experienced a physiotherapist talk only. Self-reported quality of life, and exercise 'behavioural regulations', will be measured as secondary outcomes.

METHODS

Study design

Two pilot studies are being conducted. One study will take place at The Royal Marsden NHS Foundation Trust and will use *pre*surgery patient seminars; the other will take place at Guy's and St Thomas' NHS Foundation Trust and will use *post*-treatment seminars.

Each study will allocate patient seminars alternately to the existing seminar format (physiotherapist talk only) or the new seminar format (physiotherapist talk supplemented with patient talk) and will separately follow-up patients who experienced the existing seminar format or the new seminar format.

Participants

Participants at The Royal Marsden NHS Foundation Trust will be men who have been diagnosed with PCa and are scheduled for radical prostatectomy. Participants at Guy's and St Thomas' NHS Foundation Trust will be men who have been diagnosed with PCa and have already received any treatment (the majority of these will be men who have received radical prostatectomy). These two studies aim to gather data on 25 and 9 seminars, respectively (see sample size calculation below). Provided that they speak English, all men who attend the seminars will be eligible for inclusion in the study.

Procedures

The Royal Marsden NHS Foundation Trust seminars

Men due to undergo radical prostatectomy for PCa at The Royal Marsden Hospital all attend a mandatory presurgery seminar as part of their standard care pathway. This seminar lasts 1 hour and includes information on: what to expect on admission; the surgical procedure itself; what to expect immediately following the operation and during recovery; how to facilitate recovery from the procedure; and living beyond the procedure. The presurgery seminar takes place once per week and is normally attended by approximately five men (and their partners).

Guy's and St Thomas' NHS Foundation Trust seminars

At Guy's Hospital, 'post-treatment' health and well-being seminars will be used. These take place once per month and have a capacity of around 30 people (and their partners). This post-treatment seminar last approximately 2 hours and contains talks by various allied healthcare professionals on returning to intimacy and sex; exercise/PA; healthy eating; continence and fluid intake; erectile dysfunction; and hot flushes (final session – optional for men who are on hormone therapy). Men who have undergone radical prostatectomy for PCa at Guy's Hospital all attend a 1-hour erectile dysfunction and continence seminar as a part of their standard care pathway. During this seminar, patients are encouraged to sign up for the post-treatment seminar and booked into the next post-treatment seminar accordingly.

Exercise/PA component

Among the content described above, the seminars will all contain a 20 min presentation by an exercise physiotherapist that, broadly, offers empirical promotion of exercise benefits for men with PCa, guidance of what PA to do and assurance that PA is safe for them. Those seminars using the new format will also contain a 10 min talk by a man with previous history of treatment for PCa, which carries a focus on the benefits of exercise. The patient speaker has had some general guidance on the content of his talk by the clinical care team. However, the patient speaker is ultimately given creative reign over the content and delivery style.

Measures

Self-reported PA

Self-reported PA will be documented at the time of the seminar (hereafter referred to as T_1), and then again 90 days following the seminar (hereafter referred to as T_2), providing a baseline and comparator measure via which changes in self-reported PA can be examined. Self-reported PA will be measured using the Short Questionnaire to Assess Health-Enhancing Physical Activity (SQUASH). The SQUASH asks responders how much walking, cycling and other activities they have been doing in a typical week over the last month and whether this activity was 'slow', 'moderate' or 'fast'. The SQUASH is advantageous for its brevity and has been demonstrated to have a reasonable level of reliability and relative validity.[37]

Frequency of referral to in-house exercise physiotherapists

In addition to self-reported PA (a measurement approach with substantial drawbacks[38]), the frequency of referrals to in-house exercise physiotherapists between T_1 and T_2 will also be measured, and differences in frequency between patients attending the old seminar format and the new seminar format will be determined, if any. At The Royal Marsden Hospital NHS Foundation Trust, this will be measured by asking the patient to confirm, at T_2, whether they have/have not seen an exercise physiotherapist at The Royal Marsden Hospital within the last 3 months. At Guy's and St Thomas' NHS Foundation Trust, frequencies will be determined by cross referencing a list of those who have attended the seminar with the patient database held by Cancer Exercise Physiotherapy, who document all referrals to them.

Exercise behavioural regulations

The character of patients' exercise motives, or 'exercise behavioural regulations', will be examined both at T_1 and T_2 using the Behavioural Regulations in Exercise Questionnaire-3 (BREQ-3).[39 40] This psychometric tool has been constructed within the framework of self-determination theory[33] and examines five domains of exercise motivation: amotivation; external regulation; introjected regulation; identified regulation; and intrinsic motivation. The BREQ-3 will be administered to all patients immediately prior to the commencement of the seminar. Data from BREQ-3 questionnaires that are not completed and returned before the seminar commences will not be used in the analysis, as measurement may be affected by the seminar.

Quality of life

Self-reported quality of life will be measured at T_1 and T_2 using the 5-level EQ-5D (EQ-5D-5L), developed by EuroQol.[41]

Fatigue

Self-reported fatigue will be measured at T_1 and T_2 using the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue).[42]

Continence

Self-reported continence will be measured by using the International Prostate Symptom Score (I-PSS) result closest in time to T_1 at Guy's Hospital. The I-PSS result from the patient's postsurgery follow-up clinic appointment will be used at The Royal Marsden Hospital, which takes place approximately 8 weeks following surgery. The I-PSS is administered to patients as part of the standard care pathway.

Demographics and health details

Patients will also be given a questionnaire that asks them their age, ethnicity, education status, marital status,

employment status, smoking status (dichotomous yes/no), alcohol drinking status (dichotomous yes/no), height, weight and whether they have diabetes, hypertension or heart disease. This document will also seek consent to check the patient's operation notes to determine whether their radical prostatectomy operation involved a lymph node dissection, or a bladder neck reconstruction (both of which could affect PA levels).

ETHICS AND DISSEMINATION

These governance structures are appropriate for these pilot studies, given that our aim is to seek effective solutions within the framework of the standard care pathway and that the study procedures do not put patients at any conceivable risk of harm. All patients are informed that providing data for these projects is optional and their care will in no way be affected if they do not. Patients are informed that if they do decide to complete T_1 questionnaires, they are giving their consent to be contacted once again for the purposes of administering T_2 questionnaires.

Results from these analyses will be written up and submitted to academic journals for consideration of publication.

ANALYSIS

Sample size calculation

We performed a sample size calculation on the basis that we would expect to see participants reporting a baseline mean of 25.3 MET hours, and SD of 9.5 MET hours, of PA per typical week in the last month based on data from adult males retrieved from a previous application of the SQUASH questionnaire.[37]

For the study using *pre*surgery seminars, we assumed five participants per seminar from experience. Hence, it was calculated that the expected SD among self-reported PA data in this study would be 4.22 MET hours. For the study using *post*-treatment seminars, we assumed 20 participants per seminar from experience. Hence, it was calculated that the expected SD among self-reported PA data in this study would be 1.9 MET hours.

Our sample size calculation showed that, on the basis of the above assumptions, with a two-sided alpha of 0.05% and 80% power, the amount of seminars required to detect a relative increase of 5 MET hours in those participants experiencing the new seminar would be nine seminars at Guy's and St Thomas' NHS Foundation Trust and 25 seminars at The Royal Marsden NHS Foundation Trust.

Analysis

The self-reported MET minutes of baseline PA will be calculated among all patients who have provided data for both T_1 and T_2. The self-reported MET minutes of PA at T_2 will be calculated for the same participants. The differences between T_1 and T_2 will be calculated, and this measure will be the outcome in a mixed effects linear regression model to determine whether participants attending the new seminar increased their self-reported PA more than the other participants. The mixed model will account for variance both at the level of individual participants and at the level of seminar grouping (ie, accounting for a categorical variable of *date of seminar*).

To determine whether any time differences in PA are associated with *identified exercise behavioural regulation*, another mixed effects linear regression model will be used, in which the outcome will be T_1 to T_2 differences in self-reported PA, and the 'exposure' will be T_1 to T_2 differences in *identified exercise behavioural regulation*. Analysis to determine the relative frequencies of referral to an in-house exercise physiotherapist between participants attending the old seminar style and the new seminar style will use a generalised mixed effects linear regression model.

All models will account for the following potential covariates: (treatment type; days elapsed between last treatment and seminar; undergoing hormone therapy at T_1 (post-treatment seminar study only)); fatigue; ethnicity; marital status; employment status; education status; alcohol use (yes/no); smoker (yes/no); continence; relevant comorbidities; body mass index; lymph node dissection during surgery; bladder neck reconstruction during surgery; age at T_1; which physiotherapist presented at the seminar; and whether the physiotherapist or patient presented first.

Contributors LF conceptualised the intervention and designed the studies described, as part of a PhD degree. MVH provided assistance with study design and analysis methods. TW provided assistance with conceptualising the intervention and study design. DC provided assistance with study design and clinical insight. Louisa Fleure facilitates intervention delivery and provided clinical insight. JK facilitates intervention delivery and provided clinical insight. All authors contributed to the production of this manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Clinical Audit Committee at The Royal Marsden NHS Foundation Trust (study 1); Clinical Audit Committee at Guy's and St Thomas' NHS Foundation Trust (study 2). The project taking place at Guy's Hospital has received approval to be undertaken as a clinical audit via internal governance procedures for small-scale service improvement projects at Guy's and St Thomas' NHS Foundation Trust (project number: 8190). The project taking place at The Royal Marsden NHS Foundation Trust has received approval internally to be undertaken as a Quality Improvement Project (QIPSAG2).

Provenance and peer review Not commissioned; internally peer reviewed.

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