STAMINA

Healthcare Professional Guide

(To be used in conjunction with STAMINA training)

# Aim of the STAMINA Programme

* To ensure exercise is recommended to all men with locally advanced or advanced prostate cancer on long-term Androgen deprivation therapy (ADT) unless contraindicated.
* To view exercise as a routine part of the ADT treatment package.
* To help healthcare professionals recognise the vital role they play in recommending exercise and how to do it effectively.

# NICE recommendations NG131 1.4.19

Offer people 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. **[2014]**

# What is the STAMINA intervention?

* 12 weeks of tailored, supervised aerobic and resistance exercise.
* Delivered twice weekly, either one to one or with similar others at Nuffield Health gym, with STAMINA trained exercise professionals.
* Delivered to patients diagnosed with prostate cancer on long-term ADT.
* Recommended and referred by STAMINA specific trained prostate cancer care healthcare professionals.

# What is required of you – the 5 R’s?

**RECOGNISE** - all men on ADT who are suitable for exercise

**RECOMMEND** - exercise and follow-up on how it’s going

**RECORD** - conversations for others to follow-up on

**REFLECT** – with the patient how they feel about exercise.

**REFER** –the patient to Nuffield Health

# Overview of the intervention behaviours

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| --- | --- | --- | --- | --- |
| Number & page number  | When? | Behaviour | Consultation to be recorded | Who? |
| 1 - Page 4 | **At any point of contact; diagnosis, ADT initiation and follow up**  | Recognise whether a patient is suitable for exercise  | Screening log | Any member of the clinical team |
| 2 -Page 4 | Recommend exercise training | In notes  | Any member of the clinical team |
| 3 -Page 4 | Record in patient notes the conversation | In notes | Any member of the clinical team |
| 4 - Page 5 | **When the team perceives appropriate.****At any point of contact; diagnosis, ADT initiation and follow up** | Discuss barriers and facilitators around exercise training | Record consultation | Key worker |
| 5- Page 5 | Provide patient with information pack and materials | Screening log | Key worker |
| 6 - Page 5 | Make referral for exercising training | Screening log/ Email referral | Key worker |
| 7- Page 6 | **Follow up**  | Read and interpret exercise progress report | n/a | Key worker |
| 8- Page 6 | Provide feedback to the patient on the exercise progress report | Record consultation | Key worker |

## 1. Recognise all people suitable for exercise

The NICE recommendations (NG131) state all people with prostate cancer on ADT should be offered supervised exercise including aerobic and resistance exercise; twice a week for twelve weeks. All suitable people should be identified and referred. The only direct contraindications to exercise are:

'Any acute or uncontrolled cardiovascular, respiratory, neurological or rheumatological condition or severe COPD'

## 2. Recommending exercise training

It is the responsibility of all members of the clinical team to be recommending exercise to people with prostate cancer on ADT.

To successfully recommend exercise:

- Share some of the benefits of exercise (physical, psychological and social), specifically for alleviation of ADT side-effects.

- Recommend exercise as a treatment component in the same way you would recommend ADT for the treatment of their prostate cancer.

- Ensure the patient knows their clinical team approve of exercise. Knowing you endorse the patient to exercise significantly increases the likelihood they will go and you will achieve the best clinical outcomes.

## 3. Record the conversation in patient notes

Record this conversation around exercise in the patient's notes so all other members of the team are aware what has been discussed and can follow up.

## 4. Discussing barriers and facilitators to exercise training

Research tells us that if healthcare professionals have a meaningful conversation around exercise with a patient, covering any concerns versus benefits the patient is more likely to uptake and continue exercise. Use pros and cons, addressing beliefs and working with ambivalence as addressed in training.

## 5. Provide patient with information pack and materials

There a number of helpful resources for the patient group that should be given to the patient prior to a referral. These are as follows:

1. A guide to androgen deprivation therapy and exercise

2. Exercise log book

3. A guide to Nuffield Health

4. Participant information documents

**If you are running low, please get in touch for more resources 0114 2253586.**

## 6. Make referral for exercise training

To provide an exercise referral, there a number of steps to follow:

1. Verbal consent from the patient, to ensure they are happy for their details to be passed on to the research team.

2. If they are, email sth.stamina@nhs.net with the following four details: **Hospital ID number, Full name, Date of birth and Contact telephone number**

3. If they are not, reassure the patient that is this okay and we have an open door policy. So the patient is able to access this programme at a later date.

4. Explain that the research team will be in touch with them within 5 working days to discuss the project.

## 7. Read and interpret exercise progress report

The progress report will be received from Nuffield health via the research team at sth.stamina@nhs.net. The individual or team who is responsible for follow up will receive an email with the progress report attached.

Read through the progress report before seeing the patient.

## 8. Provide feedback to the patient

The progress report is an opportunity to provide feedback to the patient on their exercise behaviour and reinforce the recommendation of exercise. It also provides you with information on the sort of benefits or difficulties patients are experiencing.

# STAMINA Trial specific information

## Study information

STAMINA is a cluster randomized trial comparing optimised usual care to 12 weeks of a tailored, supervised exercise programme including both aerobic and resistance exercise + 12 months of access to Nuffield health gyms, with feedback to the clinical team. The exercise sessions will meet NICE recommendations and will be run at a drop in session with similar others or 1:1 depending on patient preference.

The aim of STAMINA is to reinforce long-term exercise and embed exercise into the prostate cancer care pathway and work in partnership with Nuffield health.

## Inclusion/Exclusion criteria

**Inclusion criteria**

- Men with prostate cancer within 12 months of starting ADT (at time of screening).

- Receiving continuous ADT for a planned minimum of 12 months treatment.

- Willing and able to provide informed consent

- Men not due to receive chemotherapy within 3 months or those having completed chemotherapy

**Exclusion criteria**

- Men with metastatic castrate resistant prostate cancer

- Men with unstable angina

- Uncontrolled hypertension and/ or diabetes mellitus

- Recent myocardial infarction (within past 6 months)

- Unable to provide informed consent (lack capacity)

- Painful or unstable bony metastases

- Fixed output pacemakers

- Men due to commence chemotherapy within 3 months

- Any other absolute contraindication to exercise as defined by clinical guidance e.g. ACPICR standards.

- Those lacking capacity, not able to complete study assessments or not able to provide informed consent

## Screening log

We ask you to keep a screening log for every patient that is potentially eligible for the study. This will be given to you in the site initiation visit and explained in detail.

## Recording consultations

Wherever possible we are asking you to record your consultations when discussing exercise with patients. This will help us to understand the best approaches to these conversations and how patients respond. We have generally found patients are happy to have these consultations recorded, particularly where the recording has been brought up at the start of the consultation. Patients are reminded all information is completely confidential and recordings are anonymous, and will only be seen by the research team.

Please refer to the standard operating procedure for use of the audio recorder (appendix 1). You can also access this online at [www.stamina.org.uk](http://www.stamina.org.uk)

# Resources and contact details

For any STAMINA related resources please visit [www.stamina.org.uk](http://www.stamina.org.uk)

Online resources from public health England to promote exercise in everyday practice: <https://www.gov.uk/government/publications/physical-activity-applying-all-our-health/physical-activity-applying-all-our-health>

**Email: STH.stamina@nhs.net**

**Telephone: 0114 2253586**

# Frequently asked questions

Q: What do I do if I this consultation isn’t the right time to discuss exercise (e.g. just after diagnosis)

A: We respect your clinical judgement about when is the right time to discuss exercise. It may be that in at the time of diagnosis exercise is brought up as an important part of treatment but something you can discuss more fully at the next appointment.

Q. What should I do if the patient doesn’t seem keen on exercise?

A: Try some of your skills around ambivalence. However, it is better to leave the 'door open' for someone to come back to exercise at another point, rather than just to push ahead without their agreement.

Q: What do I do if a patient initially declines an exercise referral but then changes their mind at a later date?

A: Follow normal referral process (page 5)

Q: What do I do if I am unsure whether a patient is eligible or not?

A: Refer patient to the research team, who will carry our further eligibility checks. You can always call us too on 0114 2253586

Q: What do I do if I run out of patient materials to give to them?

A: Firstly, have the consultation as normal and refer if appropriate. Secondly, contact the research team as soon as possible to have more resources posted to you.

Q: I have forgotten how to make a referral, what do I do?

A: Either refer to this manual, section 1, point 6 or give us a ring to talk it through with us 0114 2253586

Q: I feel nervous about recording my consultations, it is putting me off bringing up the conversation around exercise.

A: Firstly, remember these are optional and secondly the purpose of recording is so we can understand these consultations better.

Q: The Dictaphone has stopped working.

A: Drop us an email on sth.stamina@nhs.net or call on 0114 2253586 and we can help you.

# Appendix 1

**Standard Operating Procedure (SOP)**

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| --- | --- |
| **SOP Title** | Recording consultations  |
| **Version Number** | 1.0 |
| **Approval Date** | 21/05/19 |
| **Effective Date** | 21/05/19 |

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This SOP has been produced in accordance with **ICH Good Clinical Practice (GCP) & Research Governance Framework.** This SOP will outline the procedure for healthcare professionals to record their consultations with patients with prostate cancer on Androgen Deprivation Therapy for the purpose to assess fidelity in the STAMINA research programme.

**1.0 Purpose**

This procedure is aimed at establishing safe and reliable practises when audio-recording healthcare professionals trained in the STAMINA intervention when discussing exercise and or patients progress in a clinical consultation. It also covers recording and transferring data to the SHU research team.

**2.0 Scope**

This SOP is relevant to healthcare professionals that have received the STAMINA training.

**3.0 Background**

As part of the STAMINA intervention in the pre-pilot, people with prostate cancer on ADT will be eligible to take part in a 12 week supervised exercise intervention. Healthcare professionals will be trained in the STAMINA intervention and expected to:

1. Recommending exercise training

2. Consider eligibility

3. Provide patient information pack and materials

4. Discuss barriers and facilitators to exercise

5. Make an exercise referral

6. Read, interpret and complete patient progress reports and provide feedback to the patient

The consultations that include discussion of barriers and facilitators to exercise (4) and the patient progress report (6) will be audio-recorded via an encrypted Dictaphone to assess fidelity. Fidelity is a primary outcome of the pre-pilot to help optimise and refine the intervention prior to the main trial.

**4.0 Responsibilities**

• The NHS team have responsibility for recording and storing all data from the STAMINA study accurately and securely. The NHS team have responsibility for making sure that all transfer of research data to the SHU research team is done via the NHS.net email pathway.

• The NHS site PI has overall responsibility for patient safety.

• The SHU research team have responsibility of ensuring data is stored and communicated to NHS teams and with Nuffield Health sites accurately and securely.

**5.0 Procedure**

**Procedure for recording discussions around barriers and facilitators to exercise**

1. Identify potentially eligible patients for STAMINA.
2. Turn on the Dictaphone prior to clinics where the potentially eligible patients will be seen, ensuring that the Dictaphone is fully charged.
3. If a patient is identified as eligible for the STAMINA programme, please make sure you record on the Dictaphone when you verbally request patient consent for the consultation to be recorded and their answer.
4. Please ensure the whole consultation is audio recorded.
5. Once finished recording, turn off the Dictaphone.
6. When not in use, store the Dictaphone in a locked cabinet, in a locked room that only STAMINA trained healthcare professionals can access.
7. The research team will collect data from the Dictaphones every 2 weeks (at a minimum).

Procedure for recording discussions around the progress report. Where a progress report has been received, follow the below procedure to ensure the consultation is recorded

1. Turn on the Dictaphone prior to clinics ensuring that the Dictaphone is sufficiently charged.
2. Follow the steps from section 5 to obtain verbal consent for recording.
3. Audio record the consultation.
4. Once finished recording, turn off the Dictaphone.
5. When not in use, store the Dictaphone in a locked cabinet, in a locked room that only STAMINA trained healthcare professionals can access.
6. The research team will collect data from the Dictaphones every 2 weeks (at a minimum).

**6.0 References, Related SOPs, Web links**