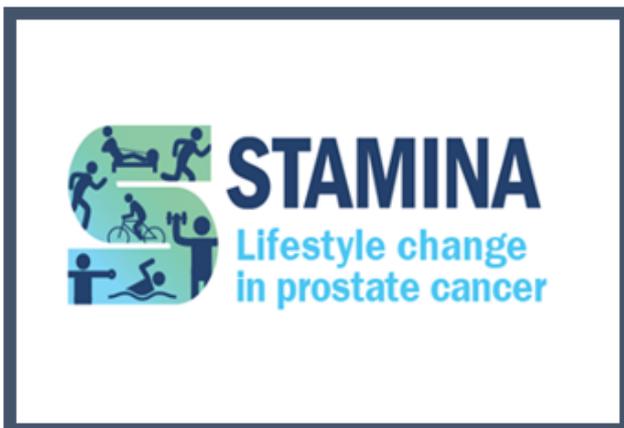
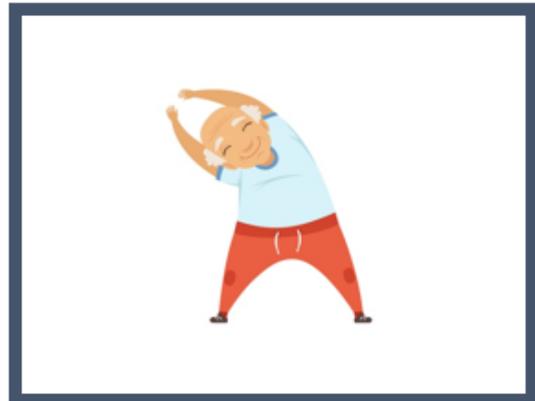
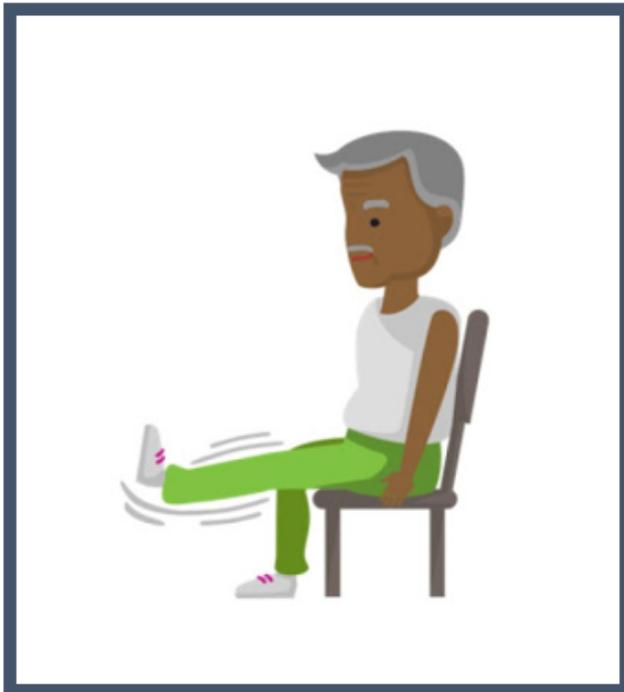


STAMINA Manual

for

Clinical Exercise Specialists

(This manual should only be used in conjunction with the STAMINA training programme)



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How to use the manual

This manual has been designed to support you during the completion of Clinical Exercise Specialist training and delivery of the STAMINA programme.

Section 1 provides an overview of the STAMINA programme and an overview of your role within STAMINA.

Section 2 provides you with pre-learning activities to complete before STAMINA training.

Section 3 provides step-by-step details to follow and resources to use during the STAMINA programme. This section should be referred to before/ during each patient contact.

Section 4 provides step-by-step details on how to identify if and what additional behavioural support men need, and top tips on how to deliver behaviour change support effectively.

Section 5 provides information related to storing and communicating data in line with protocol, good clinical practise and GDPR.

Section 1: Overview of the STAMINA programme

Overview of Prostate Cancer

What is prostate cancer?

The human body contains more than a hundred billion billion (100,000,000,000,000) cells. For best functioning, cells normally grow and divide to replace aging or damaged cells, and this is controlled by signals within the cells that trigger how much and how often the cells need to divide. If any of these signals become damaged or missing, cells may start to grow in an uncontrolled way and multiply too much. If this happens in the prostate, prostate cancer is formed.

Locally advanced prostate cancer is when the cancer cells have started to break out of the prostate or have spread to the area just outside the prostate. It may spread to the seminal vesicles, the bladder, the pelvic wall, the rectum, or the lymph nodes near to the prostate.

Advanced prostate cancer is when the cancer has spread to other parts of the body such as the bones. This can also be referred to as metastatic prostate cancer. Advanced prostate cancer is not curable, but treatments can keep it under control, sometimes for several years.

Who is affected by prostate cancer?

Prostate cancer is the most common cancer diagnosis in men in the UK, with over 41,000 new cases reported in 2017. Men tend to be older and have other health conditions. However, younger, healthy men can be diagnosed too.

Half of all men diagnosed with prostate cancer will receive androgen deprivation therapy (ADT; castration using hormones).

What is androgen deprivation therapy?

Androgen deprivation therapy is an effective treatment for controlling prostate cancer and can be referred to as ADT or hormone therapy. ADT will treat all prostate cancer cells, wherever they are in the body and will keep the prostate cancer under control, sometimes for several years.

ADT can also reduce some of the symptoms of advanced prostate cancer, such as bone pain. ADT can be offered in conjunction with external beam radiotherapy (to treat locally advanced disease) or chemotherapy (to treat advanced prostate cancer). ADT is typically administered by injection or tablet every 3 months.

How does androgen deprivation therapy work?

Testosterone is a hormone that controls the development and growth of sexual organs such as the prostate gland. Prostate cancer cells usually need testosterone to grow.

Androgen deprivation therapy can work in two ways.

- 1) It stops the body from making testosterone or,
- 2) it stops testosterone from reaching the prostate cancer cells. If testosterone is blocked or removed, prostate cancer will usually shrink, wherever it is in the body.

What are the side effects of treatment (ADT)?

Whilst ADT is effective at controlling prostate cancer, persistent side effects are common and can be debilitating thus impacting on overall quality of life. These include hot flushes, severe tiredness (i.e., fatigue), sexual difficulties, increased risks of dementia, diabetes, and heart disease.

Can the side effects of treatment be minimised?

Some ADT side-effects, including fatigue, mimic recurrent cancer and cause understandable concern, leading to unnecessary consultations/tests. To date, the only evidence-based treatment to demonstrate clinically meaningful improvements to fatigue and quality of life is exercise training. More specifically, supervised aerobic and resistance exercise.

Short-term improvements have been demonstrated when delivered by specialist staff in non-NHS research centres, but these benefits dissipate without ongoing support. Therefore, exploring methods to support men on ADT to initiate and maintain their exercise behaviour is essential to reduce side-effects and deliver sustained benefits.

"There is nothing you can dislike. The idea is to get your heart pumping and a sweat on. I had no complaints".

"It's made a complete difference to my life in general, my head you know, everything"

Overview of the STAMINA programme

STAMINA is a lifestyle intervention and large research trial involving men with prostate cancer on Androgen Deprivation Therapy (ADT; also known as hormone therapy). The lifestyle intervention has been designed to help alleviate the side effects of ADT and improve cancer specific quality of life.

STAMINA will run as a flagship programme at your site.

Over the next few weeks/ months your site will begin to receive exercise referrals from the NHS for men with prostate cancer on androgen deprivation therapy. This is part of a research study which will last for a minimum of 12 months per person.

Men will be referred from the NHS via the STAMINA research team (see below for more information).

The Patient Journey



1. Men will be diagnosed with prostate cancer by a member of their clinical team (NHS).
2. Men will be prescribed ADT then recommended and referred for exercise (NHS).
3. The STAMINA research team will check patient eligibility for the study and record baseline measurements. Safety to exercise will be confirmed.
4. Men will be referred to Nuffield Health for 12 months of supervised exercised.
5. Progress will be reviewed periodically by Nuffield Health.
6. The aim is for healthy behaviours to be maintained.

The STAMINA programme

All men will have an **induction session** with a clinical exercise specialist from Nuffield Health who will create a tailored exercise programme based on the individual's current fitness, health, medications, and exercise likes/ dislikes.



The patient will then receive **supervised exercise twice weekly for 12 weeks**, from a clinical exercise specialist who is trained to deliver exercise to men with prostate cancer on ADT.



Initially supervised exercise will be delivered one-to-one before a **smooth and quick transition to group supervision** (after approximately 4 weeks).



Between week 13 and 52, the **level of supervision will be reduced**. The level of supervision will be negotiated to once a month (max) or once every 3 months (minimum).



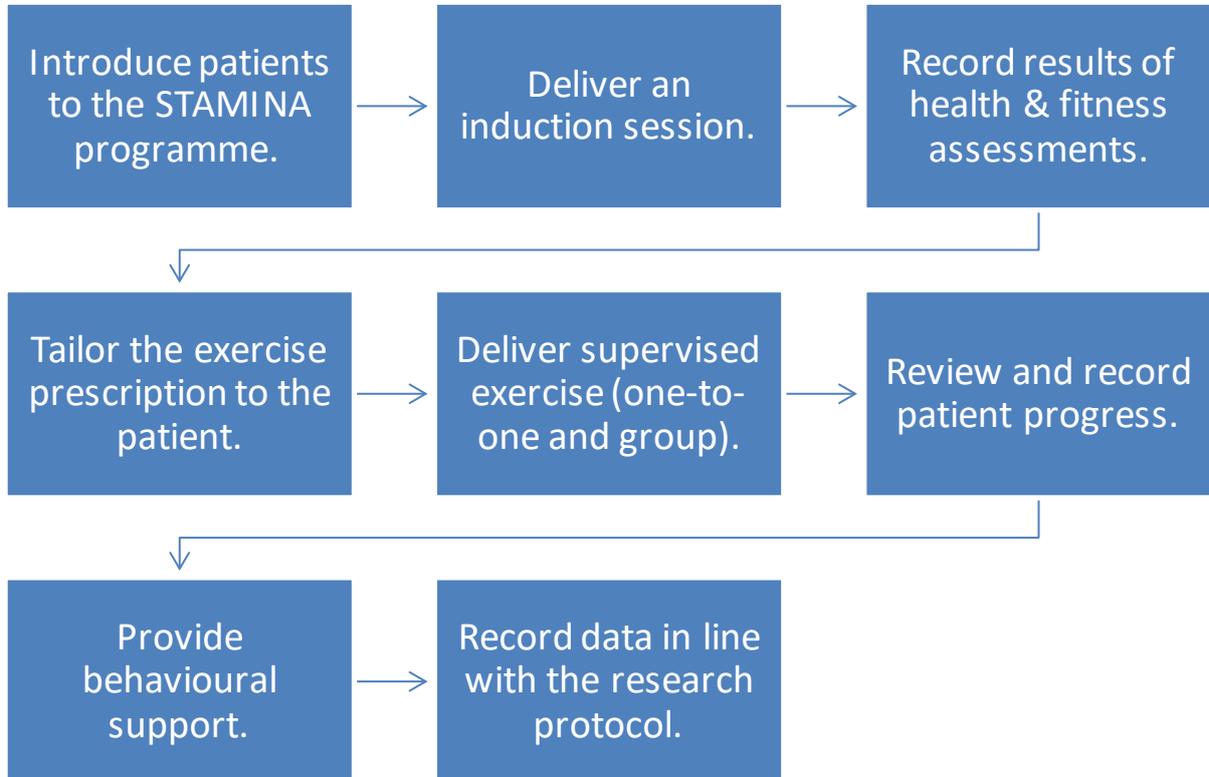
Each session will include tailored **aerobic and resistance exercise** lasting approximately 1 hour.

Participants in the STAMINA programme will be asked to participate in a maximum of 33 supervised sessions over a period of 12 months. These supervisory sessions are more heavily weighted to the start of the programme as follows:

Phase 1 (weeks 1 – 12): Participants should be invited to attend 24 supervised sessions over the first 12-week period provided as two sessions per week. The participant can be provided with an additional two weeks to complete the 24 sessions (i.e., 14 weeks maximum) if they go on holiday. Initially, supervision will be 1-2-1 with a rapid transition to group supervision (based on satisfactory progress).

Phase 2 (week 13 – 52): Participants will negotiate supervision at the 12-week review. You can offer a maximum of 1 supervised session per month and a minimum of 1 supervised session every 3 months. Men will be expected to continue exercising twice weekly, independently.

Your role in STAMINA



You will receive training to fulfil your role on the STAMINA programme.

On completion of training, you will be referred to as a Clinical Exercise Specialist. Further detail about your role, including checklists, resources and step-by-step guidance is provided in section 3.

Your goal is to support long term exercise behaviour (by promoting independence, habit formation and autonomy).

Section 2: Pre-learning activities

Pre-learning tasks

You will need to complete the following tasks before you attend the level 2 training day:



Complete Level 1 training on the Nuffield Health Academy (3 modules total)



Log on to the STAMINA website & familiarise yourself with the content



Design a supervised exercise session

1. Log on to the STAMINA website:

- To access the STAMINA website, go to www.stamina.org.uk.
- Click log in, in the top right-hand corner. (Use your Nuffield Health email address to log in – if you have forgotten your password you can reset it following the onscreen instructions)
- Once logged in, select members from the top menu

Your log in details provide you with access to the exercise professional and patient resources.

- Explore the exercise professional members area. Here you will find:
 - Information to support you delivering each component of the STAMINA programme.
 - Video demonstrations.
 - Standard operating procedures (SOPs) & Manuals
 - Copies of the patient booklets

2. Design an exercise session:

Imagine you have just received a patient referral from the NHS, via the STAMINA research team. The patient has advanced prostate cancer and is on androgen deprivation therapy. He has no other health conditions and very little previous exercise experience.

Please use the space below to outline an exercise session that you could deliver to this patient in their first supervised session. Consider, progressions and regressions.

Section 3: Delivering the STAMINA intervention

First patient contact:

The fitness manager at your site is responsible for the first patient contact. The fitness manager will receive patient referrals to their @nuffieldhealth.com email address. On receipt of the referral, the steps below should be followed, ideally within 48 hours.

	Ring the patient on their preferred contact number	<input type="checkbox"/>
	Introduce yourself (1 min)	<input type="checkbox"/>
	Check patient understanding of the STAMINA programme (3 mins)	<input type="checkbox"/>
	Check receipt of patient booklets & signpost to online resources (1 min)	<input type="checkbox"/>
	Schedule STAMINA induction (2 mins)	<input type="checkbox"/>
	Discuss future access & communication with Nuffield Health (1 min)	<input type="checkbox"/>
	Prompt use of STAMINA diary (1 min)	<input type="checkbox"/>

1. Ring the patient:

Contact the patient within 48 hours of receiving the referral. The call is to introduce yourself and arrange an induction session. Please use the preferred contact number the patient has provided and withhold your number if calling from a personal device. You can find the patient's contact details on the Nuffield Health referral form that the STAMINA research team emailed to you.

If the patient does not answer, leave a voice message with your name and why you are calling, and provide a time that you plan to call them again.

2. Introduce yourself:

During the first contact with the patient, introduce yourself, e.g., provide your name, your role as a clinical exercise specialist and that you are calling from Nuffield Health. Explain that the call may last 10 – 15 minutes and check now is a good time to talk.

3. Check patient understanding:

Men will have received a participant information sheet detailing the study and provided informed consent to participate. Ask the patient what they already know about the STAMINA programme. Provide missing detail to ensure that the patient is aware of what participating in the programme will involve for them, and correct any detail that is incorrect e.g.,

- Induction to exercise, including a fitness check on a treadmill or bike.
- Supervised exercise, tailored to the individual.
- Twice weekly 1-2-1 and small group supervision (with up to 4 other men on the programme).
- Includes aerobic and resistant exercise at moderate intensity (never maximal).
- Progress reviews, approximately every 6 weeks.
- Free 12-month membership (membership card will be processed on first visit to their local club)

4. Check receipt of the patient pack:

Check that men have received the following resources. If not, please email the STAMINA research team at sth.stamina@nhs.net and specify what items they are missing. The research team will post them out.

- Log in details for the STAMINA website*
- STAMINA training diary
- Information booklet: *'Lifestyle changes to promote quality of life during treatment'*

The STAMINA website hosts a participant member's area where men can access the booklets online and some short tutorial videos. Direct men to log onto the website with their account details and to have a look at the online support available to them. If they have lost or misplaced their log in details, please ask them to contact the STAMINA research team.

*This step is not mandatory and may cause additional pressure for those who do not have access to a computer or to those who are not IT literate.

5. Schedule first appointment:

Agree a date and time for the patient's induction session to the STAMINA programme. This should be a 60-minute appointment with a clinical exercise specialist. Explain that the first session is to introduce them to the gym and learn a bit more about them to ensure the programme is tailored to meet their needs.

Please remind the patient to wear suitable clothing for the treadmill or bike fitness check and inform them of the changing/ showering facilities available on site.

Book this appointment in the booking bug system, ensuring access to a Health MOT room. **Prompt the patient to write the date & time of their appointment on page 4 of the STAMINA diary.**

The Clinical Exercise Specialist who delivers the induction session will become the participant case manager and should schedule/ deliver all review appointments.

6. Prompt use of the STAMINA diary:

Ask men to complete the activities on page **12- 16** of the STAMINA diary (you have a copy of the activities on page 20-22 of this manual). Explain that you will explore the activities with them in more detail in the next session, and that there are no right or wrong answers.

7. Discuss access & communication:

Provide the patient with the address, travel instructions and information about the car park or local bus routes to your Nuffield Health site.

Next, inform the patient how they can contact you, e.g., provide them with the number for your site and inform them of the days/ times you are at work. You should tell them to leave a message and/ or name and number with reception if you are unavailable, and you will call them back.

Prompt the patient to write your contact information on page 3 of the STAMINA diary.

Example Nuffield Health Referral Form

Nuffield Health referral details	
Trial ID	EXA001
Name	Mr Simon Jones
Gender	Male
DoB	09/09/1949
Contact address	1 Example Road, Sheffield, EX1 ABC
Contact telephone number	123456789
Emergency contact name and number	Mrs Anne Smith - 987654321
Any modifications of exercise prescription required? (y/n)	YES
Has this participant been randomly allocated to receive a Heart Rate monitor	YES

Patient induction session

Induction sessions will be delivered by the Clinical Exercise Specialist, one-to-one. The purpose of the induction session is to familiarise patients with the gym environment and equipment, to find out more about their current health and fitness and to tailor the exercise prescription. Induction sessions will typically last up to 60 minutes.

 Provide a brief tour of the gym and facilities (10 mins)	<input type="checkbox"/>
 Explore patient attitude and expectations (10 mins)	<input type="checkbox"/>
 Provide support on how to use the RPE scale (5 mins)	<input type="checkbox"/>
 Conduct the exercise test (15 mins)	<input type="checkbox"/>
 Tailor and discuss details of the exercise prescription (10 mins)	<input type="checkbox"/>
 Explain membership details (5 mins)	<input type="checkbox"/>
 Discuss and arrange time for weekly supervised sessions (5 mins)	<input type="checkbox"/>
 Complete the SLI logbook	<input type="checkbox"/>

1. Provide a brief tour of the gym/ facilities

Provide the patients with a tour of your gym. Explain the difference between things like aerobic and resistance training equipment and how any electronic displays on machines work. For those patients who have never been in a gym before, it would be helpful to take them in to the changing rooms and show them how lockers work, how to access showers and the pool (where available).

If the patient is amenable (and is wearing suitable clothing) allow them to use a couple of pieces of aerobic and resistance equipment (e.g., 5 minutes on an aerobic ergometer and 1 or 2 sets of resistance exercise at a conservative intensity). Demonstrate safe use first of each piece of equipment and watch for proper technique whilst the patient is using the equipment.

2. Explore patient attitude and expectations:

One of the biggest influences of exercise behaviour is a person's feelings and motivation towards it. Therefore, understanding this before starting exercise will help you tailor the programme, so it is right for the individual. Past behaviour/experience is also a big predictor of future behaviour.

Benefits of Exercise

In 2014, the National Institute for Health and Care Excellence (NICE) produced guidelines recommending that men starting or having androgen deprivation therapy (ADT; also known as hormone therapy) should be offered supervised resistance and aerobic exercise twice a week for at least 12 weeks.

Research has demonstrated that a combination of aerobic and resistance exercise can help reduce side effects of ADT and has many physical and psychological benefits to health, such as reduced tiredness.

Please tick which are most significant to you?

- Reduce tiredness (fatigue)
- Improve cancer specific quality of life
- Reduce anxiety and depression
- Help me maintain a healthy weight
- Strengthen my muscles, joints, and bones
- Improve fitness and flexibility
- Increase my confidence
- Increase social interactions and make friends



Use page 12 - 16 of the STAMINA diary to explore patient attitude towards exercise and participating in the STAMINA programme.

Step 1: Discuss the benefits of exercise

Elicit what their expectations are using open-ended and follow-up questions so these can be aligned to reality. Inform them of the anticipated outcomes of supervised exercise for men on ADT, e.g., improve quality of life, feel less fatigue, reduce aches and pains.

Expectations and feelings about exercise

You may have mixed feelings about starting exercise or using equipment, and this is very common. It might be helpful for you to have a think about what you expect and make a list of any worries or concerns that you have. These can be discussed with the exercise specialist. Remember, there are no right or wrong answers.

It might be helpful to discuss these with your healthcare professional, a friend or family member.

Step 2: Explore worries and concerns

The patient may be feeling nervous about starting exercise, meeting new people or being in a gym environment - this is very common.

Use open-ended questions and follow up questions to find out how the patient is feeling.

Provide reassurance using evidence and challenge assumptions where appropriate.

Step 3: Explore exercise importance & confidence

Use the 0-10 rulers to find out how important exercise is to the participant right now. We recommend you provide them with the pen to provide autonomy.

Remember to use follow up questions to explore their score e.g., I notice you have scored yourself as a 4, what would it take to make it a 6? Why is it not a 2?

Repeat this activity to explore how confident the participant is to exercise.

How important is exercise to you?

Sometimes men are not sure how important exercise is to them or do not feel confident.

Look at the ruler below and rate how important it is for you to exercise now. Please circle the number which is most appropriate to you.



Please look at the ruler below and rate how confident you are to exercise.



If you score below a 7 on either of the scales, it might be useful to think about what would make exercise more important to you, or make you feel more confident. Trying the activities on the next two pages may help.

Pros and cons of exercise

Guidelines suggest a goal is to exercise at least **twice weekly** for **12 weeks**, but this is not always easy. Weighing up the advantages (e.g., feeling better) and any disadvantages (e.g., finding time) that are personal to you can be helpful.

Advantages of exercising

Disadvantages of exercising

Step 4: Explore Pros and cons

Use open ended questions to explore what the participant thinks are the benefits/ pros/ advantages of exercise for them.

Repeat this activity for the disadvantages/ cons of exercising. It is important to explore both.

Listen to the participant instead of telling them the advantages/ disadvantages that are relevant to you - remember everyone is different.

Challenge beliefs where appropriate.

Step 5: Problem solving

Use open-ended questions to find out if the participant has any barriers to participating in the STAMINA programme. If these are identified, guide the participant to come up with potential solutions. Ask the participant how confident they are that the solutions will work and how likely they are to do them. Use this method to identify one suitable solution.

Remember this should be participant led - do not tell them what to do

Problem solving

If you are feeling worried or concerned about exercising it may be helpful to create a list of things you could do to help your worries. These are things your clinical exercise specialist can support you with in your first session.

Barriers to participating in the STAMINA programme

Solutions to my barriers

3. Provide support to use the RPE scale*:

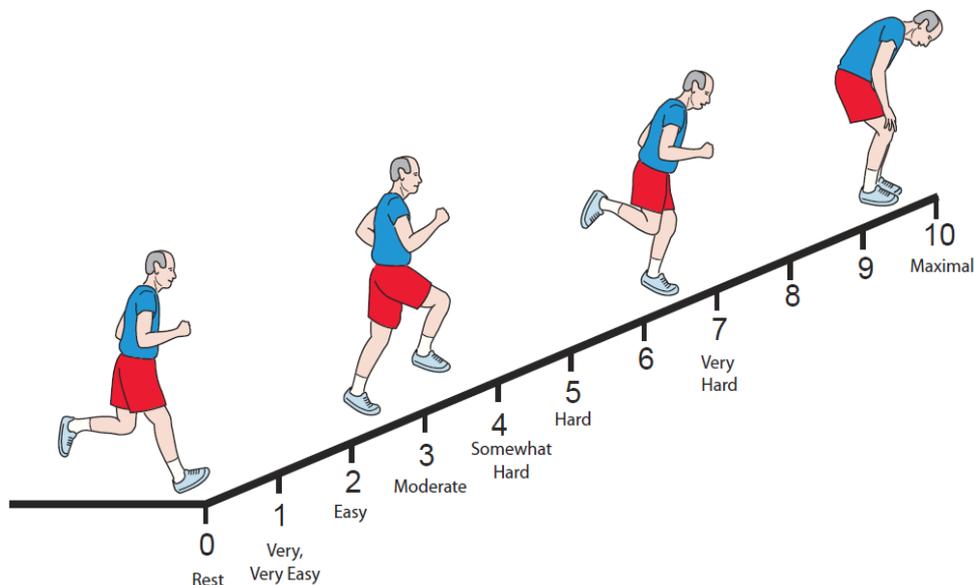
Explain to men that rate of perceived exertion (RPE) will be monitored throughout supervised exercise sessions as a method to monitor exercise intensity.

Explain to men that the RPE scale is not a typical 0 – 10 scale.

Instead, men will be asked to provide ratings using the words on the scale as cues. The target is to exercise between a 3 and 5 (moderate to hard).

Explain to men that during aerobic exercise you will ask them how hard they think they are working, including how hard their breathing is and general sense of effort.

Explain that during resistance exercise you will be asking them to report RPE in relation to the amount of effort required by the muscles they have been using for that exercise (as opposed to the whole body), at the end of each set.



Note – men have a copy of this scale in their STAMINA diary to refer to in each supervised exercise session (page 18 of the STAMINA diary).

*Some men will also be allocated a heart rate monitor. Do not use the heart rate monitor to monitor exercise intensity. Use RPE only.

4. Conduct the submaximal exercise test

To gain an indication of what level of exercise tolerance each patient has initially, each participant will need to undertake a sub-maximal exercise test. This should be repeated at 12 weeks, 6 months, and 12 months.

Step 1: Ascertain whether it is safe to conduct the test on a treadmill. If it is, use the treadmill for the test. If there are potential safety concerns e.g., issues around balance/stability/anxiety using the treadmill, use the bike test instead.

Step 2: Familiarise yourself with the increments of intensity at each time interval for the test so you are prepared to smoothly make indicated increases as the test goes on. These are on page 25.

Step 3: Explain how the test works, what you will be recording during the test and how the RPE scale works that will be used during the test.

Step 4: Inform the participant that the test continues to voluntary exhaustion or when they reach 8 on the RPE scale. Emphasise that this is not a maximal test. Patients should aim for at least a 5 or 'hard' on the RPE scale but can stop anytime.

Step 5: Demonstrate safe use of the treadmill or bike.

Step 6: Set the initial level of intensity for the test and go.

Step 7: Change the speed/ gradient in line with protocol.

Step 8: Record RPE at each minute in the SLI logbook. At the end of the test, record the patients final RPE, total time and reason for test termination (please refer to the key at the back of the SLI logbook).

If the test was not performed, please provide the reason in the SLI logbook.

Submaximal exercise test: Treadmill protocol

Increment	Time (m)	Speed (km/h)	Incline (%)
Start		2.7	0.0
1	1:00	2.7	3.5
2	2:00	2.7	7.5
3	3:00	2.9	10.0
4	4:00	3.4	11.0
5	5:00	3.9	11.0
6	6:00	4.2	12.0
7	7:00	4.7	13.0
8	8:00	5.2	13.5
9	9:00	5.6	14.0
10	10:00	6.1	15.0
11	11:00	6.6	15.5
12	12:00	6.9	16.0
13	13:00	7.4	17.0
14	14:00	7.9	17.5
15	15:00	8.2	18.0
16	16:00	8.4	19.0
17	17:00	8.7	19.5
18	18:00	9.0	20.0
19	19:00	9.2	21.0
20	20:00	9.5	21.5

Submaximal exercise test: Bike protocol

Increment	Time	Watts	RPM range
Start		30	45-55
1	2:00	50	50-60
2	4:00	75	60-70
3	6:00	100	65-75
4	8:00	125	65-75
5	10:00	150	65-75
6	12:00	175	65-75
7	14:00	200	65-75
8	16:00	225	65-75
9	18:00	250	65-75
10	20:00	End	End

5. Tailor the exercise prescription

Exercise will need to be tailored to account for:

- i) the patient's physical and mental health*
- ii) their confidence level and experience with exercise*

Step 1: Review the patient referral notes and copy these across onto page 2 and 3 of the SLI Logbook. These documents detail the patient's existing co-morbidities, medications, functional limitations, and exercises to avoid.

Step 2: Confirm the information with the patient and add any additional notes that are required. If the patient provides any changes to their health that you are unsure of, please contact the STAMINA research team immediately.

Step 3: Refer to the 'tailoring for clinical populations document.' This document contains guidelines on how to adapt prescriptions for chronic conditions, including:

- Managed asthma or COPD
- Stable angina or any other managed heart condition
- Asymptomatic fasted glucose over 8.0 mmol or over 17.0 mmol for diabetics
- BMI over 35
- High total cholesterol

Step 4: Determine whether a run-in period is required. Some STAMINA participants will be referred to the STAMINA programme without any exercise experience and in a de-conditioned state. For these individuals, it might be appropriate to use a 'run-in' period before applying the full STAMINA intervention exercise prescription. This involves specifying a reduced overall training volume initially, to get the participant used to exercising regularly before the full STAMINA prescription is met. An example of how to set a run-in period can be found on the next page.

Step 5: Discuss details with the patient, including plans for optimisation.

Step 6: Document the details of any run-in period and notify the STAMINA research team as soon as possible providing as much detail as you can. An example can be seen on page 27.

Step 7: We may recommend that some men schedule an appointment with their GP to review their blood pressure. If this is highlighted on the patient's referral form, please remind the patient to book their appointment and make a record of this conversation in the SLI logbook.

Example run-in period

Full exercise prescription

	Aerobic Exercise	Resistance Exercise
Frequency	Twice per week	
Intensity	Moderate: 3 - 5 on the CR-10 Borg scale	
Time	30 - 45 minutes	Up to 4 sets of 8-12 reps of major muscle groups

Reduced exercise prescription (example run-in period*)

	Aerobic Exercise	Resistance Exercise
Frequency	Once per week with the aim to increase to twice per week as soon as possible.	
Intensity	(Moderate) 3 on the CR-10 Borg scale with the aim to increase to 3 – 5.	
Time	< 30 minutes, with the aim to increase to 30-45 minutes.	< 4 sets of 8-12 reps with the aim to increase to 4 sets of 8 – 12 reps.

* The specifics of what is required for each run-in period, and how long it lasts, will differ from patient to patient. You do not have to modify frequency, intensity, and time – you may choose to modify just one.

Remember, the goal of the run-in period is to get the patient to a position where they can undertake the full STAMINA exercise training prescription.

We recommend reviewing the initial prescription after a max. of 6 weeks.

6. Explain and agree the exercise programme:

After taking account of any existing health conditions and any necessary run-in period, you need to discuss and agree an initial exercise programme with the patient.

Within your discussion you will need to agree specifics for each participant including:

- how the programme will be delivered, i.e., one-to-one (week 1 – 4)
- example aerobic exercises
- which major muscle groups you will be targeting for improving strength
- initial intensity ranges (e.g., moderate)
- initial duration of each session
- plans for progression (we recommend reviewing the initial prescription after a maximum of six weeks).

Note: Please add detail of the agreed programme to the SLI logbook for other Clinical Exercise Specialists to follow

7. Explain membership details & access

STAMINA participants will not necessarily have been in a gym or health and fitness facility before. Some may be coming to the study from a background of a sedentary/chronically inactive lifestyle.

Explain what's available at the gym, opening times, parking, what the patients can access, how they can access various services/facilities, suitable clothing, and basic gym etiquette.

The clinical exercise specialist should refer the patient to the fitness manager to issue the membership card and explain that the patient has access to the facilities for a total of 12 months.

8. Schedule supervised exercise & reviews:

Prompting detailed planning of when the patient attends their twice weekly exercise sessions will support behaviour change and build habits. Agree what time, which day and with whom the patients first session will be with. Make sure this appointment is booked in the booking bug system.

Encourage the patient to write this down as part of a detailed action plan (page 4 of the STAMINA diary). Action plans should be specific, measurable, achievable, realistic and time bound. For example:

"I will attend Nuffield Health 10:00-11:00 on Monday and Wednesday mornings for the next 12 weeks"

Remind them how long the first session will last, what to wear, and to bring their STAMINA diary.

Next, schedule in the week 2-, 4-, 6- and 12-week review and document the dates on page 4 of the SLI Logbook (Week 1 – 12). An example can be found on page 30.

9. Complete the SLI logbook

By the end of the induction session, page 1 -6 of the SLI logbook (week 1 – 12) should be complete.

Page 1 and 2 – copy across information from the referral form

Page 3 – enter details about a run-in period where applicable

Page 4 – insert today's date and calculate when the review sessions are due

Page 5 – record details from the submaximal exercise test

Page 6 – confirm that the induction session is complete and insert the date

Record whether you have recommended the patient schedules an appointment with their GP to review their blood pressure (note: this is only required for a small sample of men and will be highlighted on the referral form).

Ask and record how far the distance is between the patient's home and the gym.

Examples – SLI logbook

Run-in period

Does the participant require a run-in period?*

Yes No

If yes, please provide details using the headings below:

Frequency of sessions:
TWICE A WEEK - NO CHANGE

Duration of aerobic:
20 MINUTES, AIM TO INCREASE TO 30-40 MINUTES IN 4 WEEKS.

Reps/ sets of resistance:
3 SETS OF 8 REPS. AIM TO INCREASE TO 3 SETS OF 10-12 REPS IN 4 WEEKS.

Intensity (RPE):
RPE OF 3-5 - NO CHANGE

When should the run-in period be reviewed?
Date: 10/11/2021

When did the run-in period end?
Date: 12/11/2021

***If yes, please email the STAMINA team the details of the run-in period within 48 hours**

Document the run-in period

Provide details of how the frequency, duration, reps/ sets, intensity will differ from the full prescription.

Add a date for when the run-in period should be reviewed (maximum 6 weeks).

Insert the date that the run-in period ended.

Progress Review Schedule

Participant progress should be reviewed at the end of week 2, 4, 6 and 12. Please determine the date of each review based on when the participant started the STAMINA programme.

Session	Date Due
Induction session	13/10/2021
2-week review	27/10/2021
4-week review	10/11/2021
6-week review	24/11/2021
12-week review (3 months)	05/01/2022

All review sessions should be scheduled one-to-one, in advance. We recommend scheduling review sessions during the previous review session. For example, please schedule the 4-week review during the 2-week review session.

Behavioural support should be provided in each review session. There are prompts on the review forms for which topics to discuss, and detailed instruction in your training manual.

Plan when the review sessions are due

Insert the date of the induction session.

Calculate when the 2-, 4-, 6- and 12-week reviews are due.

Schedule the review appointments in the booking bug system in advance.

Submaximal exercise test (baseline)

Date of submaximal exercise test	13/10/2021	
Name of Clinical Exercise Specialist	SOPHIE REALE	
Performed on a Bike <input type="checkbox"/> or a Treadmill <input checked="" type="checkbox"/>		

Time	RPE		
1:00	1		
2:00	2		
3:00	2		
4:00	3		
5:00	4		
6:00	4		
7:00	5		
8:00	6		
9:00	7		
10:00			
11:00			
12:00			
13:00			
14:00			
15:00			
16:00			
17:00			
18:00			
19:00			
20:00			
21:00			

Duration of test	9:11
RPE at test termination	7
Reason for test termination (See appendix 1)	GENERAL FATIGUE

If the test was not performed, please provide the reason below:
N/A

Record the results of the submaximal exercise test

Add the RPE after every minute and record the final RPE at test termination.

Use the key at the back of the logbook to provide a reason for why the test was stopped.

If the test was not performed, use the key at the back of the logbook to provide a reason for why the test did not go ahead.

Patient Induction

Has the patient completed an induction?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
If yes, date of induction	13/10/2021
Have you reinforced blood pressure recommendations from the referral information (page 2)?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable <input type="checkbox"/>

Travel

In the patient's induction session, please ask them how far they have travelled to get to their first session. If they are unsure, please ask them to provide an estimate and record the details below.

Distance from patient's home address to the gym	5	miles
Additional information: THIS IS AN ESTIMATION.		

Confirm the induction session is complete

Tick to say you have completed the induction and enter the date.

Select whether you have prompted men to see their GP to review their blood pressure. If this is not applicable, select not applicable.

Enter the travel distance from the participants home to the gym.

Delivering supervised exercise

Supervised exercise sessions will initially be delivered 1-2-1 before a quick and smooth transition to small groups (based on satisfactory progress). When delivering exercise, we recommend having a pen, notepad and watch to hand to ensure you are delivering the sessions as planned and can make a note of exercises performed.

	Check patient readiness to exercise	<input type="checkbox"/>
	Provide instruction, demonstration & feedback	<input type="checkbox"/>
	Monitor and feedback on exercise intensity	<input type="checkbox"/>
	Prompt recording in STAMINA diary	<input type="checkbox"/>
	Confirm date & time of next session	<input type="checkbox"/>
	Record attendance data on REDCAP	<input type="checkbox"/>
	Record full data in SLI Logbook	<input type="checkbox"/>

1. Check readiness to exercise*

Provide a brief introduction to the session e.g., session duration, intensity, and ask if the participant has had any changes to their health, medication, physical functioning etc. since their last session. If changes are reported, make a note of these in the SLI logbook and tailor the session accordingly. If you require support, contact the STAMINA research team.

Next, check that the patient is ready to exercise, e.g., appropriate clothing, feeling okay, access to water and medication where required (GTN for angina, blue inhaler for asthma).

*Some men will also be allocated a heart rate monitor. We will inform you which men have been allocated a heart rate monitor on the referral form. Prompt them to record the session and sync their data to Garmin Express. Do not use the heart rate monitor to monitor exercise intensity. Use RPE only.

2. Provide instruction, demonstration, feedback:

During the supervised sessions, aerobic exercises can be delivered individually or as a circuit. **Resistance exercise must be delivered as a circuit.**

Aerobic

(30 – 45 minutes total @ RPE 3 - 5)

Resistance

(Must be delivered as a circuit,
up to 4 set, 8 – 12 reps)

Please provide ongoing feedback on exercise technique and intensity guidance.

Instruction

When delivering exercise, it is important to provide a verbal description of the exercise. Provide as much information as possible and repeat this every time you see the participant. Do not make assumptions that the participant knows what the exercise entails or remembers from previous weeks.

Demonstration

Provide the participant with a demonstration of the exercise. Alter your body position so the participant can see clearly, and mirror what you are doing. You may want to demonstrate each exercise facing forwards and from a side profile.

Practise

Prompt the participant to have a go at each exercise and to practice, to increase habit and skill.

Feedback

Provide specific feedback about each exercise (i.e., feedback on technique and not a generic comment such as "*that was great.*")

You should also provide feedback on the outcomes of exercising (e.g., a 0.5kg weight loss following 6 weeks of exercise).

Providing feedback creates a supportive environment for the participant and encourages them to reflect on their progress. Feedback also allows participants to learn new skills and motivates continuity of exercise via a feeling of approval.

3. Monitor & feedback on intensity:

Your role is to ensure that participants are exercising between 3 – 5 on the Borg CR-10 rating of perceived exertion scale.

If the exercise intensity falls outside these parameters, then the exercise should be altered accordingly.

For aerobic exercise, ask “Can you describe how hard your breathing and general sense of effort feels right now?”

For resistance exercise, ask “Can you describe how hard *insert muscle name* are working right now?”

Rate of perceived exertion scale

Rating	Descriptor
0	Rest
1	Very, very easy
2	Easy
3	Moderate
4	Somewhat hard
5	Hard
6	
7	Very Hard
8	
9	
10	Maximal

4. Prompt recording in the STAMINA diary

The STAMINA diary has been designed to support exercise behaviour, using behaviour change techniques, in particular self-monitoring.

Self-monitoring has been proven to significantly increase exercise attendance and have positive outcomes on goal success.

Support the patient to record details of their exercise session in their STAMINA diary, including the name of each exercise performed, how much they did (reps, sets, duration) and the intensity of the session (RPE).

With time, encourage men to complete their STAMINA diary independently. This way they can maintain a record of their exercise when the level of supervision reduces from twice weekly to once a month (at 12 weeks).

EXAMPLE EXERCISE RECORD >

Details of the exercise	Session number			
	1	2	3	4
TREADMILL	✓	✓	X	✓
	Level 5, 5min	Level 5, 7min		Level 5, 10min
LEG PRESS	10kg 3x8	10kg 3x8		12kg 3x8
SHOULDER PRESS	5kg 3x8	10kg 3x8		10kg 3x8
Rate of Perceived Exertion (RPE)	4	4		5

5. Confirm patients next supervised session:

The final element of any supervised exercise session should be to confirm with the participant when the next session will take place and ensure both parties have a record in their diary.

1-2-1 sessions should be organised directly between the Clinical Exercise Specialist and participant.

Group sessions can be organised with the Clinical Exercise Specialist or at reception. Remember the participant can attend any of the group sessions on the timetable but they must be booked in as each group session is limited to 5 per group.

6. Record attendance data in REDCAP:

It is essential that during or immediately post supervised exercise sessions that you record session details for each participant, online. This is a very quick and easy process and allows the STAMINA research team to monitor participant attendance.

Exercise session details should be completed online at the following weblink:

<https://lictr.leeds.ac.uk/redcap/surveys/?s=9KT8M43FXH>.

We recommend you access the weblink on your mobile phone and add it to your home screen for easy access in the future (it looks like an APP – no log in required).

You will be asked to enter details about the session. It is very important that you enter details correctly – so please check for spelling mistakes. Failure to complete the exercise session details accurately may result in participants not receiving the support that they require.

You must also complete REDCAP for participants who did not attend the session so we can monitor non-attendance too.



The screenshot shows the 'Exercise Session Details' form for the STAMINA study. The header features the STAMINA logo with icons for various activities (running, cycling, swimming, etc.) and the text 'STAMINA Lifestyle change in prostate cancer'. Below the header, the title 'Exercise Session Details' is displayed. The form includes a 'Date of session' field with a calendar icon, a 'Today' button, and a 'D-M-Y' format indicator. A red asterisk and the text '* must provide value' are positioned below the date field. A 'Resize font' option is visible in the top right corner of the form area.

7. Record data in the SLI logbook:

You must complete the SLI logbook after every supervised exercise session. For each exercise session record the following information:

- date and time of the session
- if the patient recorded HR on their watch (yes/no)*
- whether the session was delivered a) 1-2-1 or b) group
- whether the session was delivered a) face-to-face or b) remote
- name of the Clinical Exercise Specialist delivering the session

*not applicable to everyone

More specifically, during aerobic exercise you will need to record:

- the name/ description of the exercises delivered
- duration of each exercise
- the patients average RPE (over the 30 – 45 mins)

During resistance exercise you will need to record:

- the name of the exercises delivered
- the total number of sets and reps completed
- the load (or specify if it is bodyweight, BW)
- the patients RPE on the final set of each exercise (**remember resistance exercise must be delivered as a circuit**)

If a patient does not attend a planned exercise session (i.e., the session was booked in advance), a DNA (did not attend) should be entered on the specified session and reason for non-attendance provided (where available).

If the patient's exercise prescription is not followed due to good reason (e.g., illness, difficulty with mobility) then detail should be added at the bottom of the table for that session.

NOTE: PLEASE WRITE IN CAPITAL LETTERS AS RECORDING OF DATA NEEDS TO ADHERE TO GOOD CLINICAL PRACTISE STANDARDS (I.E., CLEAR FOR ANOTHER CES OR STUDY AUDITOR TO REVIEW)

Examples can be found on the next page

Examples – SLI logbook

Did not attend

Resistance exercise description (Target: up to 4 sets, 8-12 reps)	Sets	Reps	Load	RPE
If the session was not attended, or the exercise prescription altered, please provide detail here: MR JONES DID NOT ATTEND TODAY AS HE HAS TESTED POSITIVE FOR COVID-19.				

Exercise prescription alteration

Resistance exercise description (Target: up to 4 sets, 8-12 reps)	Sets	Reps	Load	RPE
CHEST PRESS MACHINE	3	8	10Kg	5
SEATED ROW - CABLES	2	8	10Kg	4
BODY WEIGHT SQUAT	3	8	BW	5
SHOULDER PRESS -	3	6	5Kg	4
If the session was not attended, or the exercise prescription altered, please provide detail here: REDUCED VOLUME + INTENSITY TODAY AS MR JONES REPORTED FATIGUE FOLLOWING HIS INJECTION.				

Responding to an adverse or serious adverse event

****Please follow Nuffield Health internal policy ****

For Adverse Events (AEs)

Inform the regional lead and CC the rehab inbox & the STAMINA team

For Serious Adverse Events (SAEs)

Contact the regional lead and Paul Johnson and CC the rehab inbox & STAMINA team.

Clinical Escalations & Support

Rehab.programme@nuffieldhealth.com

Clinical Fitness National Lead: Paul Johnson

Paul.Johnson3@nuffieldhealth.com

Regional Leads

London: Adam.Byrne@nuffieldHealth.com

Central: Benjamin.Cunnington@nuffieldhealth.com

South West: Ramona.Tinei@nuffielddeath.com

Scotland: Olivia.Tyler@nuffieldhealth.com

STAMINA team

sth.stamina@nhs.net

Progress review and support

You will review patient progress approximately every 6 weeks. Progress reviews must be delivered face-to-face at week 12, 26 and 52. All other progress reviews can be delivered face-to-face or remotely (i.e., over the telephone or MS Teams).

 Schedule the review session/ call	<input type="checkbox"/>
 Repeat the exercise test (in week 12, 26 and 52)	<input type="checkbox"/>
 Discuss progress & provide feedback (5 mins)	<input type="checkbox"/>
 Apply/ review the progression criteria (3 mins)	<input type="checkbox"/>
 Negotiate/ review level of supervision (10 mins)	<input type="checkbox"/>
 Provide behavioural support (guided by the STAMINA diary)	<input type="checkbox"/>
 Complete the logbook & schedule the next review	<input type="checkbox"/>

1. Schedule the review session:

Progress review sessions should be scheduled in week 2, 4, 6, 12, 19, 26, 32, 39, 45 and 52 in addition to supervised exercise sessions. Review sessions must be delivered face-to-face in week 12, 26 and 52. All other review sessions can be delivered face-to-face or remotely (i.e., over the telephone or Microsoft Teams).

The first review session should take place in week 2 and the date and time should be organised in the patient's induction session. Thereafter, all review sessions should be scheduled in the previous review session and added onto the Nuffield Health's booking bug system.

A health MOT room (or similar private space) should also be booked in advance of face-to-face appointments. You should also prompt the patient to keep a record of the date/time of their appointment in their STAMINA diary or on their calendar.

2. Repeat the submaximal exercise test

At week 12, 26 and 52, the submaximal exercise test should be repeated using the same piece of equipment used in the induction session. For example, if the participant completed the test on the treadmill in the induction session, then the treadmill should be used at week 12, 26 and 52 unless otherwise not possible due to injury etc. **Do not repeat the exercise test at week 2, 4, 6, 19, 32, 39 or 45.**

Follow the protocol provided on page 25. Record RPE at each minute in the SLI logbook. At the end of the test, record the patients final RPE, total time and reason for test termination (please refer to the key at the back of the SLI logbook).

3. Discuss progress with the patient:

Use open-ended questions and follow-up questions to explore how the participant is finding the supervised exercise sessions, in particular probing around the intensity, content, and duration of the sessions and how confident they are feeling. If the participant expresses any difficulties, ambivalence, or lack of motivation/ confidence then provide appropriate tailored behavioural support (more information on page 54).

For patients in week 1 – 12 - you should review any run-in period that has been allocated and where required, update the exercise prescription accordingly.

For patients in week 13 – 52 – you should explore any independent exercise that the patient has been completing – remember participants should be exercising twice weekly.

Next, provide positive feedback to the participant regarding their exercise behaviour (e.g., number of sessions attended), results of the submaximal exercise test, goal attainment, and outcomes of the behaviour (e.g., changes in strength, fitness, mood, friendships, confidence, energy levels etc.). The details should be documented in the SLI logbook. Consider: what went well, what didn't go so well and what might help for the future.

4. Apply/ review the progression criteria:

The aim of the STAMINA programme is to support independent exercise maintenance. As such, we would like you to transition patients from one-to-one to small group supervision as early as possible, based on satisfactory progress. We anticipate most patients will transition between week 2 and 4, or at the latest week 6.

The progress criteria should be applied in week 2 and reviewed again in week 4 and 6. You should read each statement of the progression criteria in the SLI logbook and answer yes or no to each question. Then, log the outcome in the SLI logbook and explain to the patient how their tailored exercise programme will be optimised over the next two weeks.

If you answer yes to every question - explain to the participant that they will be transitioning to small group supervision and provide them with information about the group sessions, e.g., when the sessions are and how to book on. Also explain the benefits of group supervision and social support.

If you answer no to every question - explain to the participant that they will be continuing with one-to-one supervision with the aim of transitioning to group sessions following short-term additional support (e.g., 1 – 2 weeks).

If you answer no to one or two questions - use your judgement to determine how much additional support is required and explain this to the patient, e.g., a combination of one-to-one and group supervised sessions will be offered for one week before transitioning to group supervision.

Progression criteria

Progression criteria*
Does the participant demonstrate good technique from verbal instruction/ demonstration
Can the participant use the required equipment independently
Can the participant communicate difficulties/ preferences

*NOTE: The outcome is based on the progression criteria and not yours or the patient's preference for 1-2-1 or group supervision.

5. Negotiate/ review the level of supervision

STAMINA participants will be asked to attend supervised sessions over a period of 12 months. These supervisory sessions are more heavily weighted to the start of the intervention, i.e., twice weekly for the first 12 weeks. **Supervision should be negotiated at the 12-week review and reviewed thereafter.**

In the 12-week review, you should explain that between week 13 and 52 the level of supervision will be reduced to support men in becoming independent exercisers and forming healthy habits. You should inform men that they can attend a maximum of 1 supervised session per month and a minimum of 1 supervised session every three months. You should discuss and agree which option is most appropriate to the participant.

You should also emphasise and support the patient to develop an action plan to continue exercising twice weekly to maintain their exercise behaviour.

Please document the details of the agreed level of supervision in the SLI logbook and inform the STAMINA research team within 2 working days via email or telephone.

6. Provide behavioural support:

The STAMINA diary has been designed to guide you in delivering behavioural support. At each progress review, there are behaviourally informed activities or topics that you can discuss/ complete with the patient. These are particularly important for those with low-moderate attendance, low confidence, or low motivation.

You should use your judgement as to whether the activities are suitable for participants who have good attendance/ are highly motivated.

Each topic can be found on the relevant pages of the SLI logbook, and in the STAMINA diary. You should prompt the patient to complete the activity or read the information on the relevant pages for each topic where applicable (further detail about behaviour change techniques can be found on page 55 – 60).

Week 2 – Boom and Bust

Discuss the importance of managing energy levels and finding a balance.

Week 4 – Rewards

Discuss how small rewards can support progress and motivation.

Week 6 and 39 – SMART Goal Setting

Support the patient to set a SMART goal and explore their confidence to achieve it.

Week 12 – Social Support & Habit Formation

Discuss the benefits of social support & provide information about forming habits.

Week 19 – Maintaining motivation

Support men to identify their motivations for exercise and prompt them to refer to it.

Week 26 – Reflection and Imagery

Prompt men to imagine how they will feel when they have achieved their goals.

Week 32 – Setbacks

Explain that it is common to experience a setback after a period of improvement.

Week 45 – Recognising achievements

Prompt men to write a list of their achievements to date. Focus on the positives.

Week 52 – Action planning

Support men to develop an action plan to continuing exercising after STAMINA.

7. Complete the SLI logbook

Complete the programme review section of the SLI logbook following each review, including the name of the reviewer, date, mode of delivery and outcome.

Once the 12-week review details have been written in the SLI logbook, the week 1 – 12 SLI logbook will be complete. Data relating to the patient's comorbidities should be copied over from the week 1 -12 to the week 13 – 52 SLI logbook, including any notes that are relevant to the patient, e.g., the baseline and 12-week submaximal test results.

Please send completed logbooks to Q302, Parkholme Building, 30 Collegiate Crescent. Sheffield Hallam University, S10 2BP.

8. Schedule the next review

Agree the date and time of the next progress review and the format of this session, i.e., face-to-face, or remote. Record the details in the booking bug system and encourage the patient to write this in their STAMINA diary/ calendar.

Examples – SLI logbook

<p>4. What might help for the future?</p> <p>MR JONES HAS DECIDED TO CONTINUE EXERCISING WITH HIS BUDDY AT THE SAME TIME EACH WEEK TO SUPPORT HABIT FORMATION + MAINTENANCE. HE WILL FOLLOW THE PROGRAMME WRITTEN IN HIS DIARY.</p>
<p>5. What are the participants exercise plans for the next 12 weeks? (i.e., frequency and mode of supervision)*</p> <p><input checked="" type="checkbox"/> group supervision once a month (maximum)</p> <p><input type="checkbox"/> group supervision once every three months (minimum)</p> <p><input type="checkbox"/> other, please specify</p>

Examples – SLI logbook

Progress review (week 2): Boom & Bust	
Date of STAMINA review	10/11/2021
Individual conducting review	SOPHIE REALE
Mode of delivery	Face-to-face <input checked="" type="checkbox"/> OR remote <input type="checkbox"/>
Progression criteria	
1. Does the participant demonstrate good technique from verbal instruction/ demonstration?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
2. Can the participant use the equipment independently? (e.g., aerobic/ resistance machines, heart rate monitor)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
3. Can the participant communicate difficulties/ preferences where appropriate?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
4. Please provide feedback on participant progress: MR JONES HAS MADE A GREAT START ON THE STAMINA PROGRAMME, ATTENDING ALL 4 SESSIONS. HE HAS INCREASED THE AEROBIC DURATION FROM 20-25 MINUTES, THE AIM IS 30 MINS NEXT WEEK.	
5. For the next two weeks, the participant will: <input checked="" type="checkbox"/> receive one-to-one supervision <input type="checkbox"/> receive group supervision <input type="checkbox"/> other, please specify AIM TO TRANSITION FOLLOWING THE WEEK 4 REVIEW.	
6. Has the outcome been discussed with the participant? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
7. Have you discussed Boom and Bust with the participant? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	
8. Have you scheduled the next review session? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Date: 24/11/2021	

Section 4: Behavioural support

Behaviour Change Support

This section of the manual provides you with guidance on how to support men who may be having difficulties with the programme.

You will find detailed instruction on how to identify if additional support is required, what additional support to offer (to ensure it is tailored to the individual) and how to deliver behavioural support.

-  Deliver fortnightly behavioural support guided by the STAMINA diary.
-  Identify if additional support required.
-  Identify what additional support is required.
-  Deliver additional, tailored behavioural support.

What is behaviour?

Behaviour can be defined as the way that someone or something behaves in a particular situation.

What influences behaviour?

Theory suggests that human behaviour occurs in a system and is influenced by an interaction between three necessary components: capability, opportunity, and motivation. This is known as the COM-B model (Michie, Van Stralen et al. 2011).

According to the COM-B model, human behaviour (B) is influenced by the interaction between physical and psychological capabilities (C), to make use of social and environmental opportunities (O) via reflective and automatic motivation (M) (Alexander, Brijnath et al. 2014).

Definitions and more user-friendly terms can be found below:

Name of the component	Description of the component	Example of the component
Physical Capability	Physical strength and skill	Performing a squat, running
Psychological Capability	Knowledge	Understanding the benefits of exercise whilst on ADT
Social Opportunity	Social influences & norms	Support from family and friends
Physical Opportunity	External factors e.g., the environment, time, resources	Access to equipment and technology
Reflective motivation	Beliefs and intentions	Beliefs about doing exercise
Automatic motivation	Emotions	Feelings about exercising in a gym

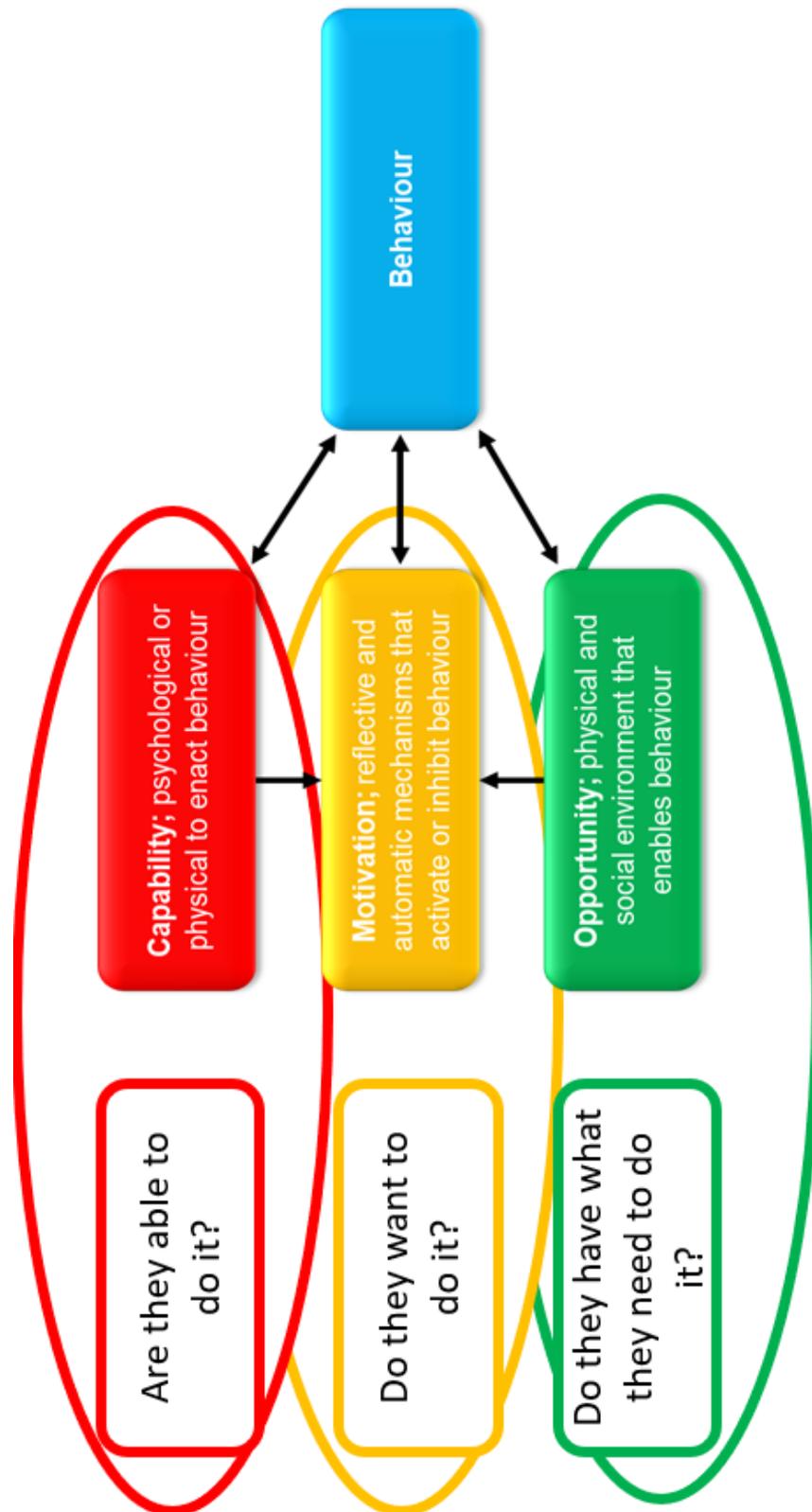


Figure 1: Influences of human behaviour (modified COM-B model)

1. How to identify if additional support is required:

We hope that men enjoy participating in the STAMINA programme and experience many positive outcomes to their overall health and wellbeing. However, after a period of improvement, it is not uncommon for men to experience small setbacks or require additional support. For example, men may experience a loss of motivation, have difficulties fitting exercise into their daily routine or experience a set back through illness or a holiday.

We hope that men will be able to communicate their difficulties with you through the development of good rapport and frequent contact. However, in some instances, men may be less open, and you will have to identify if any additional support is required.

Please see below for a list of things to keep an eye out for:

Resistant behaviour

You may experience resistance if you push for change when the patient is not ready. Often patients will have good reason for not feeling ready and it is your role to explore these for clarification and to encourage future change.

Signs:

- Interrupt the conversation
- Seem distracted or ignore you
- Become defensive or argumentative

Ambivalent behaviour

Ambivalence can be defined as "the coexistence within an individual of positive and negative (contrasting) feelings towards a person, object or action."

It is important to accept, but not necessarily agree with the patient's thoughts and feelings and remember that ambivalence is normal.

Signs:

- Expresses uncertainty
- Keeps changing their mind

Difficulty performing a skill or developing knowledge/ understanding.

Signs:

- Verbal cues
"I don't understand.... I don't know about..."
"I don't know how to... I can't...."
- Behavioural cues, e.g.,
Poor exercise technique, difficulty understanding the RPE scale, difficulty using technology.

Difficulties with time, access to resources or social support.

Signs:

- Verbal cues
"I don't have enough time to do that..."
"My family wouldn't like it if I do that..."
- Behavioural cues, e.g.,
Unable to attend sessions, miss sessions, appear to be secretive, no longer want to attend (sudden change of mind), difficulty accessing the required resources.

Lack of motivation, unhelpful beliefs, or emotions.

Signs:

- Verbal cues
"I don't see why I have to do that... It won't help".
"I'm scared to do that..."
- Body language, e.g.,
Less engaged, changes in emotions, defensive or argumentative, distracted.

2. How to identify what additional support is required:

When providing behavioural support, you must ensure you use techniques that are underpinned by evidence and theory to enhance the likeliness of success. To do this, we can use the COM-B model.

Firstly, you need to identify which component of the model the patient is having difficulty with from the list below:

- Physical strength or skill
- Knowledge, understanding or memory
- Social influences or social support
- External factors (environment, time, access to resources)
- Beliefs and intentions
- Emotions

Next, have a look at which techniques are associated with the component you want to target.

Description of the component	Behaviour support - techniques
Physical strength and skill	Instruction, demonstration, practise, graded task
Knowledge or memory	Instruction, prompts, monitor behaviour, feedback on behaviour, information about the benefits for health.
Social influences & norms	Discuss and provide social support opportunities.
External factors e.g., the environment, time, resources	Provide resources (via signposting), change timetable, recommend changes to the environment.
Beliefs or intentions	Importance rulers, pros and cons, action planning, problem solving, persuasion about capabilities, goal setting, self-monitoring.
Emotions	Rewards, habit formation.

Further information about each technique can be found on the next page.

3. Behaviour change techniques

Instruction

When delivering exercise, it is important to provide a verbal description of the exercise you would like the patient to do. Provide as much information as possible and repeat this every time you see the patient. Do not make assumptions that the patient knows what the exercise entails or remembers from previous weeks.

Demonstration

Provide the patient with a demonstration of the desired behaviour. Alter your body position so the patient can see clearly, and mirror what you are doing. You may want to demonstrate each exercise facing forwards and then from a side profile.

Practise & Grad

Prompt the patient to have a go at the desired behaviour and continue to practice until mastered.

Graded task

Break exercises up into small chunks or start by teaching the patient an easy exercise (e.g., a regression). Once mastered, make the skill more difficult (e.g., add progressions).

Prompts

Provide the patient with verbal cues or memory aids to help their memory and knowledge to complete a task., e.g., signpost to resources for syncing to Garmin Connect. Sometimes this can be as simple as writing something down for the patient or encouraging them to add things to their calendar or elements of their routine.

Feedback

Provide specific feedback about the desired behaviour (i.e., exercising twice a week) and not a generic comment such as "*that was great.*" You should also provide feedback on the outcomes of the behaviour (e.g., a 0.5kg weight loss following 6 weeks of exercise).

Providing feedback creates a supportive environment for the patient and encourages them to reflect on their behaviour. Feedback also allows patients to learn new skills and motivates continuity of that behaviour via a feeling of approval.

Information about the benefits for health

Provide evidence-based information about the benefits of exercise, the benefits of supervision, the benefits of exercising at a moderate intensity etc., to increase knowledge.

Social support

Social support from family and friends can positively influence exercise adherence/behaviour. However, negative comments are not uncommon and may be a hindrance. Please support men to address any unhelpful social support.

- Discuss the benefits of social support and exercising in a group (e.g., to support exercise behaviour, provide friendly competition, influence motivation, support goal achievement, meet similar others, develop friendships).
- Explore what social support the patient has and help the men identify any less helpful support they might want to address (you can refer men to page 31 of the STAMINA diary).

Provide resources

Signpost men to the resources available to them (that they are lacking or are unaware of), for example information in booklets, video examples online or the research team for replacement equipment.

Make changes to the environment

Support men to make changes to their living space and daily routine. For example, rearranging their daily activities, day/ time they exercise or exercise space.

Importance ruler

Importance rulers can be a useful behaviour change technique to use when patients are ambivalent to change. Your role is to prompt the patient to think about their current state and what it would take for them to score higher on a scale of 1 - 10.

Rulers can be adapted to ask questions specific to the patient's scenario. For example, you can explore readiness to change or confidence to exercise. You should draw a ruler or use the rulers on page 14 of the STAMINA diary, so the patient has a visual ruler to look at.

To increase autonomy and ownership, provide the pen to the patient so they can mark on their current state. Use open-ended questions to guide patients towards identifying what needs to change for them to score higher on the ruler.

Pros and cons

This technique is quite straight-forward in that the patient would think about or write a list of the advantages or disadvantages of thinking in a particular way or a specific behaviour. An example is: *"the advantages and disadvantages of attending Nuffield Health twice a week"*. Encourage the patient to complete this task on page 15 of the STAMINA diary.

The patient then reflects on this information. Encourage the patient to think about both sides to reassess their situation in a more balanced way. This technique could be used in several situations e.g., to consider group versus one-to-one supervised exercise sessions.

Action planning

Prompt detailed planning of how the patient will continue exercising following the STAMINA intervention or how they will achieve their goals. Patients should come up with their own plans, but you can support them by providing them with a few suggestions.

Encourage the patient to write down a detailed plan of how and when they will continue exercising- use page 54 of the STAMINA diary. Action plans should be specific, measurable, achievable, realistic and time-bound. For example:

"I will continue attending Nuffield Health 10:00-11:00 on Monday and Wednesday mornings following the exercise programme I have recorded in my STAMINA diary"

Setbacks & Problem solving

Problem solving offers a structured way to overcome real-life problems or difficulties. This technique is useful after a setback. Setbacks are not uncommon after a period of improvement. It is important to support men to identify what caused the setback and how they can get back on track using problem solving (see page 16 of the STAMINA diary).

The key to good problem solving is helping the patient work through the steps below and allowing them to choose the solution they think best suits them.

Step 1: Make a list of the problems.

Patients can often find the number of problems they have overwhelming, taking time to write them down can be an important first step to feeling in control.

Step 2: Choose a problem to address.

It is best to start with problems that the patient can control and are amenable to change.

Step 3: Define the problem clearly.

The problem should be broken down into as many components as possible. This enables the patient to see that large problems can be overcome in small chunks.

Step 4: Think about solutions to the problem (positive & negative).

For each element of the problem identify as many solutions as possible. Often the first solutions an individual suggests are the most obvious or socially acceptable.

Probing more ideas is critical here. For example: -

- 'What else'? 'What else?'
- 'Have you tried that before, did it work?'
- 'Do you know what other people have tried?'

Step 5: Help the patient to choose the best solution.

This needs to be the solution most likely to work for this individual. It is critical the solution is within the patient's capabilities. It is better for someone to take many small, successful steps. This will increase their confidence and decrease negative feelings towards problem solving.

Step 6: Make an action plan and review.

A specific action plan should be made along the lines for SMART goals. Check how confident the individual feels about achieving their goal on a scale of 1-10 with scores of 7/8 optimal.

Goal setting

Support the patient in setting a **SMART goal** (specific, measurable, achievable, relevant, time specific) ensuring it is relevant to the STAMINA programme and patient led. Encourage the patient to record these on page 26 of the STAMINA diary.

The aim is for an individual to succeed at their goal and therefore increase their self-efficacy for the behavior. This will reinforce belief in their ability to take control over their problems.

- It can be helpful to ask an individual to rate their confidence on a scale of 1-10 (where 1 is not confident at all, 10 is very confident). A goal of 7 or 8 is most likely to lead to success so higher or lower scores than this should be probed to check if they are at the right level.

Short Term Goals

Short term goals are very specific and describe the behaviour change in detail. It is important to consider:

- If the goal addresses a problem relevant to the patient's difficulties?
- Is the goal within the scope of what the patient can influence and change?
- Does the goal address what the patient/ STAMINA programme is trying to achieve?

Intermediary Goals

These deal more specifically with the behaviours that need to be changed but are still relatively vague and removed from present behaviour levels.

Long Term Goals

These tend to be for some time in the future and require considerable behaviour change. How these changes will be made is not well specified.

Breaking goals into smaller steps

Goals may need to be broken down into small manageable steps. There may be a logical sequence to the steps e.g., if a patient would like to walk 100 yards, this goal may need to be broken down further to a shorter distance of 50 yards before the final goal can be achieved.

Encourage self-monitoring

Self-monitoring can help patients to identify how they have progressed and where changes may be required to achieve their goals. Self-monitoring has also been shown to significantly increase exercise attendance and have a positive outcome on goal success.

Please encourage patients to keep a log of their exercise behaviour in their STAMINA diary. It should be emphasised that the STAMINA diary is personal to the patient and will not be read by others, unless requested. For example, some patients may want support completing their STAMINA diary. We recommend that patients record in their diary as close to session completion as possible.

Recognising achievements and reward

Support men to identify what they have achieved so far in the STAMINA programme. Encourage them to think back to how they felt at the start of the programme and what goals they set. Focus on the positives (i.e., what they have achieved as opposed to not achieved).

Discuss how rewards can support progress and provide motivation for achieving goals. Emphasise that rewards do not have to be edible and can include phoning a friend or watching a favourite film. Support the patient to identify what rewards may be suitable for them and encourage them to complete the task on page 25 of the STAMINA diary. Some people work towards a bigger reward e.g., by putting money saved from smoking towards a holiday, but this is for the individual to decide.

Forming and maintaining habits

Inform patients that habits are behavioural patterns that are formed through repetition and tend to occur without thinking about them. For example, putting your seatbelt on when you get into a car. Once habits are formed people are more likely to continue with that desired behaviour e.g., continue exercising twice a week.

Explain that habits are often related to triggers/ cues that they do before a desired behaviour. Therefore, to help maintain an exercise habit it is helpful to encourage patients to think about the behaviours that they always do before they exercise – there is a task on page 32 of the STAMINA diary. Then encourage participants to continue with these behaviours to promote habit maintenance. For example, 'always packing a gym bag the night before a scheduled session'.

4. How to deliver behavioural support:

A significant part of behaviour change is good communication.

In all communication it is important to remember that individuals have different levels of understanding, education, and health literacy.

Some individuals may also have a level of cognitive impairment, either related to their age or other co-morbidities. It is therefore particularly important to avoid using medical or psychological jargon.

Ensure that you are following the top tips below, and on the next page.



USE PATIENT
TERMS



BE GUIDED BY
THE MAN



OPEN-ENDED
QUESTIONS



REFLECTIVE
LISTENING



PROVIDE
AUTONOMY



DON'T TELL,
DRAW OUT IDEAS



COLLABORATIVE
CONVERSATION



EXPRESS
EMPATHY



ROLL WITH
RESISTANCE

Section 5: Data & Communication

1. Data

When do I need to record data?

- Patient induction session
- Supervised exercise sessions
- Progress reviews

What data do I need to record?

Patient induction session – complete the SLI logbook Week 1 – 12	
Page 1	Please copy the patients name and trial ID from the Nuffield Health referral form and enter your name. Next insert today's date and the date in 12 weeks' time.
Page 2	Please copy over the details regarding the patients' comorbidities, medications, and exercises to avoid from the Nuffield Health referral form.
Page 3	Following the submaximal exercise test, please indicate whether the participant has been allocated a run-in period. If yes, please provide detail of the run-in period and the date it should be reviewed. Next, email across the details of the run-in period to the STAMINA research team. This can be a typed or scanned copy of page 3.
Page 4	Please enter the date of the induction session and then calculate when the 2-, 4-, 6- and 12-week reviews are due.
Page 5	Please record the results of the submaximal fitness test including the equipment used, RPE at each minute interval, duration of the test, RPE at test termination and reason for test termination using the key at the back of the booklet. If the test was not performed, please provide the reason.
Page 6	Please record the date that the induction session was complete. Then indicate whether you have advised the patient to have their blood pressure reviewed (note: this is only applicable to those where it is highlighted on the referral form). Next, ask the participant how far they have travelled from their home to get to your site. Please record the distance in miles and add any additional information that is required in the box below, e.g., travel in the car.

Data must be written in the SLI logbooks only. For additional copies, please contact the research team, sth.stamina@nhs.net).

Supervised exercise session – complete the SLI logbook & REDCAP	
SLI logbook	The two-page exercise records in the SLI logbook should be completed during or immediately following supervised exercise sessions.
	For every session, please find the relevant week number and enter the session number. Then record the date and time of the session, if the patient recorded HR on their watch (yes/no), the mode of delivery and the name of the Clinical Exercise Specialist delivering the session.
	For aerobic exercise record the name/ description of the exercises completed, the duration of each exercise and the patients average RPE (over the 30 – 45 mins).
	For resistance exercise record the name of the exercises delivered, the total number of sets and reps completed, the load (or specify if it is bodyweight, BW) and the patients RPE on the final set of each exercise.
	If a patient does not attend a planned exercise session (i.e., the session was booked in advance), a DNA (did not attend) should be entered on the specified session and reason for non-attendance provided (where available).
	If the patient's exercise prescription was not followed due to good reason (e.g., illness, difficulty with mobility) then detail should be added at the bottom of the table for that session.
REDCAP	It is essential that during or immediately post supervised exercise sessions that you record session details for each participant, online. This includes participants who were booked onto the session but did not attend.
	Exercise sessions details should be completed online here: https://lictr.leeds.ac.uk/redcap/surveys/?s=9KT8M43FXH
	You will be asked to enter details about the session (date, participant ID, name of CES, did they attend, mode of delivery, was aerobic/ resistance exercise performed).

Progress reviews– complete the SLI logbook	
For each progress review, there is a form to complete in the SLI logbook during or immediately following appointments. You will need to record the date, mode of delivery and name of the person delivering the review session. You will need to provide feedback and future exercise plans. You will also need to indicate whether you have delivered the behaviour change activity/ discussion for that session.	
At week 12 (month 3), week 26 (month 6) and week 52 (month 12), you will need to repeat the submaximal exercise test and record the results as detailed on page 64.	
At week 12, you will also need to copy across information from SLI logbook (week 1 – 12) to SLI logbook (week 13 – 52). Please complete page 1 -3 as detailed on page 64.	

Where to send data

SLI logbooks should be returned to the STAMINA research team at the end of week 12 and the end of week 52 (Q302, Parkholme Building, 30 Collegiate Crescent, Sheffield Hallam University, S10 2BP).

In the interim, copies of the progress reports from week 12 (month 3), week 26 (month 6) and week 52 (month 12) should be scanned and emailed to the STAMINA research team within 48 hours of the review. The email should be sent from your @nuffieldhealth.com address to sth.stamina@nhs.net. If you do not have access to a scanner, please contact the STAMINA research team via email to discuss alternative methods.

Following the patient induction, the CES will need to email the STAMINA research team with a detailed description of any allocated run-in period.

Following the 12-week review, the CES will need to email the STAMINA research team detailing the agreed negotiated supervision for week 13 – 52.

Where to store data

All data collected during the STAMINA programme must be kept strictly confidential and in line with good clinical practice (GCP).

Data must be stored in a restricted access room where only STAMINA trained professionals can access it.

2. Communication

All communication between the research team, NHS trusts and Nuffield Health will be via telephone or a secure and confidential email communication pathway.

Sending or receiving STAMINA related emails to/ from your personal email account will be a breach of patient confidentiality and protocol.

What information should I include in my emails?

Please ensure your fitness manager is CC'd into all STAMINA related lines of communication between team members at your site and the STAMINA research team.

Please ensure all subject headings contain the patient's unique trial ID number e.g., STAMINA_EXA002

How to maintain patient confidentiality in group emails

You must use the BCC function for every group email sent as a method to maintain patient confidentiality.

BCC prevents people in the email from seeing who else you have sent the email to.

Other options include sending individual emails only.

Contact Details

Telephone: 0114 225 3586

Email: sth.stamina@nhs.net

