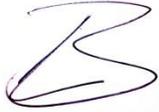


Standard Operating Procedure (SOP)

SOP Title	Nuffield Health patient induction SOP
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Version log			
Version	Date Approved	Reason for Change	Author
1.0			

1.0 Purpose

This procedure is aimed at establishing safe and reliable practises when patients attend Nuffield Health as part of the STAMINA pre-pilot study. It also covers recording and transferring data to the SHU research team.

2.0 Scope

This SOP is relevant to Nuffield Health staff that have been trained in the STAMINA intervention.

3.0 Background

As part of the STAMINA intervention in the pre-pilot, men with prostate cancer on ADT will take part in 12 weeks of supervised exercise at a local Nuffield Health gym. Prior to any contact with Nuffield Health, patients will have provided informed consent, undergone a health screening check and a baseline assessment in the NHS.

4.0 Responsibilities

- The SHU research team have responsibility of ensuring data is stored and communicated to NHS teams and with Nuffield Health sites accurately and securely.
- The Nuffield Health team have responsibility of recording and storing all data from the STAMINA study accurately and securely. The Nuffield Health team have responsibility for following the research protocol and 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.

5.0 Procedure

What you will receive from SHU

As part of the patient referral to Nuffield Health, the SHU research team will send you:

- Patient personal details including preferred contact phone number
- An exercise session CRF to record all exercise sessions that take place at Nuffield Health. This also includes details of any required run in period and specific exercises to avoid with this participant.
- Details of each participant's existing medical conditions, medications and any functional limitations

Contact patients

The first priority is to contact the patient to arrange an introduction visit to Nuffield Health. Please use the preferred contact number the patient has provided. This information is in the documents emailed to you by the SHU STAMINA research team via your nhs.net account.

Explain membership details and access

STAMINA participants will not necessarily have been in a gym or health and fitness facility before. Some will 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, where the changing rooms are, lockers, suitable clothing and basic gym etiquette.

The physiologist should refer the patient to the fitness manager for allocation of a PT. The fitness manager will issue the membership card and explain that the patient has access to the facilities for a total of 12 months, but supervision for only 12 weeks (i.e. the research element of the pre-pilot).

Tour of the gym and facilities

Provide the patients with a tour of your local 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.

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 can be done on either a treadmill¹ or exercise bike (only use the bike if it is unsafe to use a treadmill). The test is a basic graded exercise test. We have provided a CRF to record each individual's performance which you will be sent via email labelled 'submaximal exercise test CRF'.

Steps in performing the submaximal test:

1. Ascertain whether it is safe to conduct the test on a treadmill with each patient. 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.
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 in appendix 1 of this document.
3. Demonstrate safe use of the treadmill or bike.
4. Explain how the test works, what you will be recording during the test and how the CR-10 RPE scale works that will be used during the test.

5. Inform the participant that the test continues to voluntary exhaustion. Emphasise that this is not a maximal test. Patients should aim for at least 5 or 'hard' on the CR-10 scale,^{2,3} but can terminate before that if need be.
6. Set the initial level of intensity for the test - see appendix 1.
7. Record the RPE and heart rate at each minute using the 'submaximal exercise test' CRF.
8. At voluntary termination please record the participant's total time, heart rate and rating of perceived exertion.

Tailoring the specifics of the 12 weeks of exercise training

In the documents emailed to you by SHU via your nhs.net email account, you will have received details of existing co-morbidities, medications, functional limitations and exercises to avoid. In addition, in the supporting document 'Tailoring for clinical populations' we have supplied recommendations from clinical exercise guidelines of how to adapt prescriptions for common chronic conditions / health issues including:

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

Note: any *unexplained* chest pain during exercise needs to be referred to STAMINA team for discussion with PI.

Run-in period

Some STAMINA participants will arrive for their first session at Nuffield Health without any gym 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 attending the gym and building up exercise tolerance before the full STAMINA prescription is met. An example of how to set a run in period can be found below:

Target	Full STAMINA prescription	An example 'run-in' period*
Aerobic training frequency	Twice per week	Once per week
Aerobic training intensity	60-85% HRmax or 40-60% HRR or 3-5 i.e. moderate to hard on the CR-10 RPE scale	3 on the CR-10 scale i.e. moderate.
Aerobic training duration	30-45 minutes	15-20 minutes
Resistance training frequency	Twice per week	Once per week
Resistance training intensity	Approx 60% of 1RM or 3-5 i.e. on the CR-10 RPE scale.	3 on the CR-10 scale i.e. moderate.
Number of resistance exercises	Seven (Shoulders, glutes, upper legs, chest, upper arms, upper back, core)	Three (upper legs, shoulders, upper arms)
Number of resistance sets	Up to 4 sets	Up to 2 sets
Number of resistance reps	8-12	8

* The specifics of what is required for each run-in period, and how long it lasts, will differ from patient to patient. Remember, the goal of the run-in period is to get the patient in to a position where they can undertake the full STAMINA exercise training prescription.

After taking account of any existing health conditions and any necessary run-in period, you need to discuss and agree an initial exercise prescription with the patient. This needs to be within the scope of the STAMINA intervention, i.e.

- **Aerobic**
30-45 min of 60-85% HRmax or 40-60% HRR or 3-5 i.e. moderate to hard on the CR-10 RPE scale.
- **Resistance**
Up to 4 sets, 8-12 reps of major muscle groups, approx 60% of 1RM, or 3-5 i.e. on the CR-10 RPE scale.

However, after your discussion you will need to agree specifics for each patient including the preferred mix of exercise sessions e.g. gym work, STAMINA group circuits, swimming etc. specific aerobic ergometers to use in the gym, which major muscle groups you will be targeting for improving strength, initial intensity ranges (use the treadmill test result to guide you), initial duration of each session and plans for progression (we recommend reviewing the initial prescription after a maximum of six weeks).

Discuss and arrange times for weekly supervised sessions

There are a range of available drop in sessions and one to one training options available for patients. Discuss with patients how the STAMINA programme is running at your site. Agree what time, which day and with whom the patients first session will be with. Remind them how long the first session will last, what to wear, how to meet up with their allocated PT and how to arrange the second exercise training session.

Storing STAMINA research records

All paper copies of STAMINA CRFs need to be stored in a locked filing cabinet in a restricted access office.

6.0 References, Related SOPs, Web links

1. Kaminsky LA, Whaley MH. Evaluation of a new standardized ramp protocol: the BSU/Bruce Ramp protocol. J Cardiopulm Rehabil 1998;18:438-44.
2. Foster C, Florhaug JA, Franklin J, et al. A new approach to monitoring exercise training. Journal of strength and conditioning research / National Strength & Conditioning Association 2001;15:109-15.
3. Haddad M, Stylianides G, Djaoui L, Dellal A, Chamari K. Session-RPE Method for Training Load Monitoring: Validity, Ecological Usefulness, and Influencing Factors. Frontiers in neuroscience 2017;11:612.

Appendix 1.

Table 1. Treadmill test increments

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

Table 2. Bike test increments

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