**Standard Operating Procedure (SOP)**

|  |  |
| --- | --- |
| **SOP Title** | Nuffield Health intervention support (WP4) |
| **Version Number** | 1.0 |
| **Approval Date** |  |
| **Effective Date** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Name** | **Title** | **Signature** | **Date** |
| **Author** | Sophie Reale | Research Fellow |  | 08/10/2021 |
|  |  |  |  |  |
| **Reviewer** | Liam Bourke | Professor of cancer research |  | 19.11.21 |
| **Authoriser** | Liam Bourke | Professor of cancer research |  | 19.11.21 |
|  |  |  |  |  |

|  |
| --- |
| **Version log** |
| **Version** | **Date Approved** | **Reason for Change** | **Author** |
| 1.0  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**1.0 Purpose**

This procedure is aimed at standardising the process for providing Nuffield Health with intervention and research support during work package 4 and 5 of the STAMINA programme.

**2.0 Scope**

This SOP is relevant for the SHU research team and Nuffield Health operational team.

**3.0 Background**

* Up to 24 Nuffield Health sites will be recruited and paired with an NHS site for the delivery of work package 4 and 5 of the STAMINA programme.
* Nuffield Health staff will receive bespoke, role specific, training that is mandatory before the delivery of the STAMINA programme.
* Trained STAMINA exercise professionals, who will be referred to as Clinical Exercise Specialists, will be responsible for the delivery of the STAMINA lifestyle intervention (SLI).

**4.0 Responsibilities**

The SHU research team have responsibility for training and supporting Nuffield Health staff to deliver the SLI.

**5.0 Procedure**

**Telephone support**

Nuffield Health sites will receive tapered intervention and research support from the SHU research team following Level 1 and Level 2 STAMINA training.

Week 1 – 4: Weekly 30-minute calls will be organised between SHU and the CES team at site to discuss any intervention or research uncertainties. Times for the weekly call will be organised in level 2 STAMINA training and SHU will circulate calendar invites. Where possible all CES team members will join the call, but shorter, individual calls can be made where required. Calls can be via the telephone or MS team’s dependent on the site’s preference. A brief topic guide will be followed (appendix 1).

Week 5 – 52: All sites delivering STAMINA will be added to a STAMINA Microsoft Teams channel. Fortnightly 60-minute calls will be scheduled at the same time/day every other week on the dedicated MS Teams channel. All sites can drop-in to the fortnightly calls however attendance is not mandatory. Intervention and research uncertainties will be discussed. The attendance and time of the calls will be reviewed and amended where required to meet demand. A brief topic guide will be followed (appendix 1).

CESs can also call the SHU research team directly on Monday to Friday’s, 09:00 – 17:00 (0114 225 3586). All SHU researchers will be trained to respond to general queries. The SHU research team will a) answer the query or make a record of the feedback, b) transfer the call to Sophie for specialist support or c) take a message and inform them when Sophie will be able to call them back.

**Email support**

CESs can contact the SHU research team via email (sth.stamina@nhs.net) at any time. The SHU research team will respond within 2 business days, Monday to Friday. All SHU researchers will be trained to respond to general queries. Specialist queries should be escalated to Sophie.

**MS teams support**

All sites delivering STAMINA will be added to a STAMINA Microsoft Teams channel. CESs can post intervention or research queries at any time. Responses will be provided by SHU and NH research teams (or other CES’s). CESs will be trained to keep posts strictly confidential (in line with GCP and GDPR). If a CES withdraws from STAMINA, then their access to the MS teams’ channel will be revoked.

**Access to resources**

CES’s will be provided with the protocol, SOPs, and a Clinical Exercise Specialist training manual. CES’s will also have access to the Exercise Professional members area of the website which hosts further training materials and copies of the patient booklets. The website can be accessed via [www.stamina.org.uk](http://www.stamina.org.uk). If a CES withdraws from STAMINA, then their access to the members area will be revoked.

**Additional training**

Additional training will be offered to sites where a) there has been staff turnover or b) where the need for further support has been flagged as part of the adaptive intervention (See the adaptive intervention SOP for further information)1.

*The following data should be recorded in the Access database hosted on the J drive: i) the time and date of the call/ email, ii) site name, ID and name/ role of people involved (SHU and NH), iii) the call purpose (specifying whether research or intervention related or both), iv) outcome of the call, including details of the action required and date the action was resolved and v) duration of time spent on intervention queries.*

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

1The Adaptive Intervention SOP.

**Appendix 1: Topic Guide**

* How is the STAMINA programme going at your site?
* What has been going well?
* What has been going less well?
* Do you have any questions?
* Have you had any new staff members start?

Prompts:

* + Scheduling sessions
	+ Creating the group timetable
	+ Completing REDCAP
	+ Completing the SLI logbook
	+ Delivering supervised exercise
	+ Completing the sub-maximal exercise test
	+ Tailoring the prescription
	+ Delivering progress reviews
	+ Delivering behavioural support
	+ Negotiated supervision