Standard Operating Procedure (SOP)

SOP Title	Recording consultations
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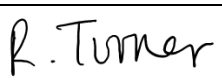
	Name	Title	Signature	Date
Author	Rebecca Turner	STAMINA PhD researcher		17/05/19
Reviewer	Liam Bourke	Programme director		17/05/19
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Version log			
Version	**Date Approved**	**Reason for Change**	**Author**
1.0			

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

1.0 Purpose

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

2.0 Scope

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

3.0 Background

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

1. Recommending exercise training
2. Consider eligibility
3. Provide patient information pack and materials
4. Discuss barriers and facilitators to exercise
5. Make an exercise referral
6. Read, interpret and complete patient progress reports and provide feedback to the patient

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

4.0 Responsibilities

- The NHS team have responsibility for recording and storing all data from the STAMINA study accurately and securely. The NHS team have responsibility for making sure that all transfer of research data to the SHU research team is done via the NHS.net email pathway.
- The NHS site PI has overall responsibility for patient safety.
- The SHU research team have responsibility of ensuring data is stored and communicated to NHS teams and with Nuffield Health sites accurately and securely.

5.0 Procedure

Procedure for recording discussions around barriers and facilitators to exercise

1. Identify potentially eligible patients for STAMINA.

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

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

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

6.0 References, Related SOPs, Web links


STAMINA
Lifestyle change in prostate cancer
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