WP8 – study

Standard Operation Procedure (SOP) for Staff Time Assessment (Primary Study Variable)

This SOP for the staff time assessment includes the description on how staff time should be assessed in the Sleep Revolution WP8 clinical trial. Importantly, staff time assessment is linked to the diagnostic procedure from start to end of a particular diagnostic activity and the procedure for providing information to the patient at the end of the diagnostic process (diagnosis and treatment recommendation). Notably, time associated with information around the use or follow up of CPAP therapy as the second part of the WP8 study should not be considered in this context.

Primary study endpoint in the WP8 protocol:
"Staff time consumption for the diagnostic procedure comparing the SR assessment and the standard care diagnostic pathways – non inferiority assumption".

Estimates for the power calculation by study protocol:

The different components of the staff time to be captured are summarized in the table below (copied from the study protocol). The table was used for the power calculation of the study.

Table 3: Estimates of staff time (minutes) for the three different diagnostic principles used in the study: PSG=polysomnography, HSAT=Home Sleep Apnea Testing (Cardiorespiratory polygraphy, Sleep Revolution=Self Applied Somnography 3 nights)

Work modules	Standard PSG (minutes)	Standard HSAT (minutes)	Sleep Revolution (minutes)
Preparation technical pre/post	15	10	35
Instructions/Hook up	20-40	5-20	5-30
Performance of the sleep test	120-480	0 (patient)	0 (patient)
Evaluation of the sleep test	30-120	5-30	30-90
Questionnaires	5	5	10
Additional equipment	0	0	15
Doctor: interpretation, communication	30-60	15-30	45-60
Staff time: Estimated range of the mean	220-720	40-95	140-240
Staff time: Estimated standard deviation of the mean	180	30	60

1. **Activities <u>not</u> monitored in the staff time sheet:**

Procedures strictly linked to the clincal study protocol procedure itself but not to the clincal management of the patient

- Patient recruitment: Systematic review of the clinic referrals for potential candidates for study participation
- Patient recruitment: Introduction of the patient to the study objectives, methodologies, patient´s time to respond to questions relation to the general overview of the study procedures, time used to provide information to the patient about details about participation in the study
- Time related to the signed informed consent procedure per se
- The randomisation procedure in general

2. Sleep Revolution diagnostic arm of the study

The following working steps need to be monitored in the WP8 Study Time Sheet

a. BEFORE ARRIVAL OF THE PARTICIPANT

- Assure that information needed to complete the phone call used to recruit the participant has been recorded (some extra but useful pieces of informstion include: mail, type and brand of the smartwatch in order to determine if the device uses Android or IOS).
- Prepare the box with everything needed for the participant (including instructions, identification number, email and password for the participant's login to the app and site) on the day prior to the study.
- You can set the device (A1S) for auto start
- You may prepare the batteries but it is not recommended to put them in the device or in the pulse oximeter in order to prevent them from loosing power. Förstår inte denna mening. Är det korrekt så som nu justerat.
- CHECK AND CHARGE the Withings Scanwatch. Prepare it according to the guidelines and perform a factory reset before starting it.ember to include the charger in the bag caried by the participant.

b. DAY OF THE STUDY

- Welcome the participant
- Create and start the participant's eCRF on RedCap so you have a checklist and a possibility to note necessary information (unless you want to do the collection manually) (https://wiki.sleep.ru.is/doku.php?id=esada_instructions:timeline_esada_ecrf , https://wiki.sleep.ru.is/doku.php?id=esada_instructions:redcap_instructions#add_edit_a_record_-_for_ecrf_project)

- Configure the device (A1S)
- Complete the clinical measurements (height, weight, blood pressure).
- Briefly demonstrate the device to the participant and show where instructions may be found (both the laminated sheet and the QR code for the video instructions)
- Show the login credentials (as previously pointed out it is suggested that the username and password for the participant is printed before handing the device over)
- Assist with the set-up of the Scanwatch
- Assist with downloading and configuring the App
- If needed, show how to access the website
- Send questionnaires via RedCap (The maximum number of reminders to be send to the participant needs to be determined)
- Assure that the participant understands that there are two separate questionnaires, one on RedCap and one on the SleepRevolution web platform
- Inform the patient and arrange for the return of the device

c. AFTER THE DAY OF THE STUDY

- Monitor responses on the RedCap platform
- Monitor responses on the platform (ESQ)
- Download and upload the sleep studies

3. Clinical routine diagnostic arm at the study site

- Please follow the routines of the diagnostic procedures practiced at your clinic (e.g. in-lab PSG or polygraphy)
- . Please use the sleep diagnostic test usually applied for your local diagnostic pathway.
- Prepare the diagnostic test
- Perform diagnostic test
- Analysis of the diagnostic test

4. Meeting between sleep doctor and patient

- Review of questionnaires and sleep diagnostic report by the doctor
- Physical examinatio.
- Meeting of doctor and patient, clinical interview, information related to diagnosis and treatment
- Medical files: Hospital IT system as a medical note

STUDY TIME PROTOCOL (PRIMARY STUDY OUTCOME VARIABLE)

Study Site:

Patient Study ID:

Patient Initials:

Randomized to (mark correct field)
Sleep Revolution first: Standard care first:

Date of study start:

Procedure	**Time (5 minutes intervals only like 5, 10, 15 .. etc)**	**Initials**
SLEEP REVOLUTION PROCEDURE Date of start:		
Preparation of the sleep study and digital methodology, initiation of the App and the platform		
Patient instruction and handing over of A1S to the patient		
Trouble shooting and monitoring of the patient during home sleep studies		
Patient contact at return of equipment		
Upload of data and transfer to data to the medical records		
Final scoring of the sleep recordings		
Bring all data together for the patient-doctor consultation		
Additional activities not listed above		
Sum of activities in the SR pathway		
STANDARD CARE PROCEDURE Date of start:		
Preparation of the sleep study		
<u>Ambulatory sleep study (if applicable):</u> All procedures from welcome at the first day prior the sleep test and to the discharge after successful sleep test procedure (see also explanation text)		
In-house sleep study (if applicable): All procedures from welcome in the evening and discharge in the morning		
Upload of data and transfer to data to the medical records (see also explanation text)		
Scoring of the sleep recordings		

Assemble all data for the patient consultation with sleep doctor		
Additional activities not listed above		
Sum of activities in the routine pathway		
Communication between sleep doctor and patient		
Patient consultation with the sleep-doctor including final diagnosis and treatment decision if applicable, documentation in the medical record		
Any activity not listed above		
Sum of all activities in the study		