

Sleep SMART Scripts for Site Coordinators to use with Potential Participants/Participants/LARs

Italics font with brackets = *[instructions to coordinator]*

Recruitment:

Thank you for taking time to speak with me.

I know that this can be a tough time, with everyone pushing information at you and asking more and more of you.

I really appreciate your openness to speaking with me about this study.

The study is simple.

We think that there are certain aspects of your sleep that could get in the way of your recovery from stroke, and might contribute to another stroke, but we're not certain.

We're conducting a study to determine whether it is better to treat or not treat a condition called obstructive sleep apnea after someone has a stroke or TIA.

In this study, everyone will get a close examination of their breathing during sleep using a sleep apnea test.

Obstructive sleep apnea is a condition where your throat closes off over and over again during sleep, and you stop breathing until your brain wakes you up to breathe again.

This can happen many times during the night, even if you're completely unaware of it.

In this study, if you're found to have obstructive sleep apnea, you'll get a chance to try a therapy that treats the problem, called CPAP.

CPAP is a device that pumps air through a tube to a mask that you wear while you sleep.

The air from the machine helps to hold your throat open, so your breathing doesn't stop while you're asleep.

Of course, this only works when you use CPAP.

After one night with CPAP, if you qualify, you'll be randomized to one of two groups: one, where you continue with CPAP treatment and another where you do not.

The intention, again, is to determine whether using CPAP – hopefully every night -- improves your recovery from stroke, or keeps you from having another stroke in the future.

We simply do not know if this will help.

The study will last 6 months, and, after that, you'll be free to pursue or continue treatment for sleep apnea with your own physicians, as part of your regular clinical care if you'd like to.

Does that make sense?

Prior to the Nox T3 sleep apnea test:

Thank you for taking time to speak with me again.

Last time we spoke, I mentioned that the first part of this study would be an examination of your breathing during sleep.

This is called a sleep apnea test and it's what we'll be doing tonight, while you sleep.

We'll connect you to the sleep testing device that monitors how you breathe while sleeping.

Your cooperation in this study will help us determine whether using CPAP after a stroke helps recovery or prevents a future stroke.

This study will help your doctors treat you and people like you in the future.

We really appreciate your willingness to help us in this good cause.

So, tonight we'll monitor your breathing during sleep and we'll give you more information tomorrow.

After the Sleep Study:

Positive results (eligible for aCPAP run-in night):

Yesterday we studied your breathing during sleep, and we did find that you had periods where you stopped breathing, called obstructive sleep apnea.

Of course, your brain reacted, and you began to breathe again, but these episodes suggest your breathing during sleep could be improved with CPAP.

CPAP helps keep your throat open during sleep, so that you don't stop breathing.

Now, you should know that many people in your situation, and many people in general, suffer from obstructive sleep apnea.

It's generally thought that *not* breathing at night isn't good for you, so tonight we'll try CPAP to see how you react.

We'll give you more information as we go along, so please don't worry.

How does that sound to you?

After CPAP run-in night:

Used 4 hours or more and eligible to be randomized to CPAP vs care as usual:

It looks like you were able to use CPAP for much of the night last night.

How did that go for you? *[Do reflective listening – I see, so you felt. . .]*

You're now eligible to move onto the next phase of the study where you could be assigned to receive CPAP or not receive CPAP for the next 6 months.

Now that you've experienced one night of CPAP, would you be comfortable if you were assigned to the no-CPAP group? *[Wait for answer].*

Would you be comfortable if you were assigned to the CPAP group?

If you are assigned to the CPAP group, it will be very important that you use the machine.

Are you willing to give this a shot with our support? *[If yes, to both, then still eligible for randomization].*

Then I'll update the information in the computer and we'll see which group you are assigned to. I'll be back soon to let you know.

1. Randomized to aCPAP:

You've been randomly assigned to receive CPAP treatment for the next 6 months.

If it's alright, I'd like to tell you more now about your sleep apnea test results and about how CPAP worked for you.

You used CPAP for **xx** hours last night.

The night before CPAP, you stopped, or nearly stopped breathing, at least **10** times per hour.

This means that, on average, your breathing dropped off at least every 6 minutes.

Each episode lasted 10 seconds or more.

Most of these episodes likely made your blood oxygen levels go down, which means that your body was not getting the oxygen it needs multiple times throughout the night.

The good news is that CPAP was effective for you.

[Read next sentence only if AHI from machine on run-in-night was <10:] You stopped breathing only **xx** times per hour when you used CPAP, so we know that it works for you.

You'll be able to use CPAP from now on, during this study.

It's yours to take with you wherever you go so that you can sleep with it every night.

You can think of CPAP as a part of the healthy lifestyle you're committing to during your recovery.

I want to assure you that this CPAP device is FDA approved for the treatment of obstructive sleep apnea and you may even know people who have used one.

The CPAP can only help you when you use it. I have every confidence, based on last night's use, that you can do this. How do you feel about it? *[Do reflective listening.]*

We also have a team of experienced coaches who can help you along the way because doing something new can sometimes be difficult.

Don't get down on yourself if it is hard at first, just use the support team's help at any time.

We're here to help you every step of the way. How does that sound to you?

So, as your first task in this arm of the study, I'd like to make sure that you and anyone you think will help you in your recovery have the telephone number for your coach.

Let's put that number into your phone or your family member's phone now.

You can call them anytime and they'll be reaching out to you as well.

They're there to help you with problems, but also just to sit and chat a bit about how things are going, so you do not have to have a problem to take their call.

Most people find taking the time out with a coach to be very useful.

Also, the coaches will have more information than I do about your sleep study and they can go into a bit more detail, which you may find useful.

Just remember, we're here to help and you'll never be turned away.

Some time before you leave the hospital, we'll try to help connect you, via the telephone, with a sleep coach just to make an introduction.

If you have a second call within the first week after your discharge, we'll be able to provide you with a \$10 Amazon gift card as a thank you, because we believe this is a really important step to helping you use CPAP.

How do you feel about working with a coach like this?

We have a 5-minute video that will introduce you to the sleep coaching process.

Would it be ok if I played it for you now? *[If yes, play Care Management video. If no, return at a later time to see if ok to play the video.]*

[After video]: How do you feel after watching the video? *[Do Reflective Listening here].*

If you are someone who likes to keep track of your progress, there is an app that can show you your CPAP use information anytime you want.

The app, or if you prefer, the website, is free for you to use.

It's operated by the manufacturer of your CPAP machine.

You can see the information from each night's CPAP use, including a nightly score that tells you how well you did with CPAP, and you can even get some feedback over email or texts.

Is this something you would like to learn more about?

[If yes, can pull up website on participant's phone (myair.resmed.com)]

[If no, remind the participant that the information is on the Sleep SMART website if the participant would like to learn more later.]

2. Randomized to control group:

You've been randomly assigned to not receive CPAP for the next 6 months.

You can focus your recovery on other things, and we'll follow you over that period of time.

After the 6 months, we'll give you more information about your breathing during sleep, and you'll have the option to follow up with your doctors about your sleep if you'd like to do that.

How does this sound to you?