WEBVTT

NOTE duration:"00:18:27"

NOTE recognizability:0.908

NOTE language:en-us

NOTE Confidence: 0.803823993548387

00:00:00.000 --> 00:00:01.836 To introduce sleep smart,

NOTE Confidence: 0.803823993548387

00:00:01.836 --> 00:00:04.131 Smart is a randomized clinical

NOTE Confidence: 0.803823993548387

00:00:04.131 --> 00:00:06.247 trial assessing whether treatment

NOTE Confidence: 0.803823993548387

00:00:06.247 --> 00:00:08.877 of obstructive sleep apnea shortly

NOTE Confidence: 0.803823993548387

00:00:08.877 --> 00:00:11.605 after an acute ischemic stroke or

NOTE Confidence: 0.803823993548387

00:00:11.605 --> 00:00:14.230 high risk TE reduces the risk of

NOTE Confidence: 0.803823993548387

00:00:14.230 --> 00:00:16.262 cardiovascular events and improves

NOTE Confidence: 0.803823993548387

00:00:16.262 --> 00:00:18.294 functional outcomes representing sleep.

NOTE Confidence: 0.803823993548387

00:00:18.300 --> 00:00:20.455 Smart today are Doctor Devin

NOTE Confidence: 0.803823993548387

00:00:20.455 --> 00:00:21.874 Brown and Doctor Sherman.

NOTE Confidence: 0.803823993548387

00:00:21.874 --> 00:00:23.842 Dr Brown is a professor of

NOTE Confidence: 0.803823993548387

00:00:23.842 --> 00:00:25.874 neurology at University of Michigan

NOTE Confidence: 0.803823993548387

00:00:25.874 --> 00:00:27.514 Medical School Doctor Sherman,

NOTE Confidence: 0.803823993548387

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00:00:27.520 --> 00:00:29.296 who is also a professor for

NOTE Confidence: 0.803823993548387

00:00:29.296 --> 00:00:30.480 Alaji and a director.

NOTE Confidence: 0.803823993548387

00:00:30.480 --> 00:00:32.112 Sleep Medicine at University

NOTE Confidence: 0.803823993548387

00:00:32.112 --> 00:00:33.744 of Michigan Medical school.

NOTE Confidence: 0.803823993548387

00:00:33.750 --> 00:00:35.318 Thank you very much for joining us today.

NOTE Confidence: 0.893322629642857

00:00:36.830 --> 00:00:39.098 Thank you so much for the invitation

NOTE Confidence: 0.893322629642857

00:00:39.098 --> 00:00:40.946 and it's really wonderful to be

NOTE Confidence: 0.893322629642857

00:00:40.946 --> 00:00:43.577 able to stop by for a visit and talk

NOTE Confidence: 0.893322629642857

00:00:43.577 --> 00:00:45.635 with you briefly about sleep smart.

NOTE Confidence: 0.893322629642857

00:00:45.640 --> 00:00:47.112 As we already said,

NOTE Confidence: 0.893322629642857

00:00:47.112 --> 00:00:49.810 Ron Sherman is also on the line,

NOTE Confidence: 0.893322629642857

00:00:49.810 --> 00:00:52.426 and so I'm sure he's happy to answer

NOTE Confidence: 0.893322629642857

00:00:52.426 --> 00:00:54.891 any of your most difficult questions

NOTE Confidence: 0.893322629642857

00:00:54.891 --> 00:00:58.410 will save those for him for at the end,

NOTE Confidence: 0.893322629642857

00:00:58.410 --> 00:01:00.250 Sharon's presentation was was very

NOTE Confidence: 0.893322629642857

00:01:00.250 --> 00:01:02.464 heartwarming at and her house is

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NOTE Confidence: 0.893322629642857

00:01:02.464 --> 00:01:04.336 also quite lovely compared to mine,

NOTE Confidence: 0.893322629642857

00:01:04.340 --> 00:01:06.580 so apologies for the background.

NOTE Confidence: 0.893322629642857

00:01:06.580 --> 00:01:11.005 And perhaps for the less

NOTE Confidence: 0.893322629642857

00:01:11.005 --> 00:01:12.775 heartwarming presentation.

NOTE Confidence: 0.893322629642857

00:01:12.780 --> 00:01:15.292 And so let's start just by talking a

NOTE Confidence: 0.893322629642857

00:01:15.292 --> 00:01:17.562 little bit about why in the context

NOTE Confidence: 0.893322629642857

00:01:17.562 --> 00:01:19.740 of caring for a stroke patient,

NOTE Confidence: 0.893322629642857

00:01:19.740 --> 00:01:21.288 you would want to even care

NOTE Confidence: 0.893322629642857

00:01:21.288 --> 00:01:22.320 about obstructive sleep apnea.

NOTE Confidence: 0.893322629642857

00:01:22.320 --> 00:01:24.441 There are so many other things to

NOTE Confidence: 0.893322629642857

00:01:24.441 --> 00:01:26.478 consider to worry about to focus on.

NOTE Confidence: 0.893322629642857

00:01:26.480 --> 00:01:28.720 Why are we obsessed with

NOTE Confidence: 0.893322629642857

00:01:28.720 --> 00:01:30.064 obstructive sleep apnea,

NOTE Confidence: 0.893322629642857

00:01:30.070 --> 00:01:31.658 well, obstructive sleep apnea

NOTE Confidence: 0.893322629642857

00:01:31.658 --> 00:01:33.643 is very common post stroke.

NOTE Confidence: 0.893322629642857

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00:01:33.650 --> 00:01:36.176 It is approaching the prevalence of

NOTE Confidence: 0.893322629642857

00:01:36.176 --> 00:01:38.778 hypertension, so it's up in the 70s.

NOTE Confidence: 0.893322629642857

00:01:38.780 --> 00:01:41.146 So when you see a stroke patient,

NOTE Confidence: 0.893322629642857

00:01:41.150 --> 00:01:42.480 the chances of that person.

NOTE Confidence: 0.893322629642857

00:01:42.480 --> 00:01:45.636 Obstructive sleep apnea are extremely common.

NOTE Confidence: 0.893322629642857

00:01:45.640 --> 00:01:47.944 We know that obstructive sleep apnea

NOTE Confidence: 0.893322629642857

00:01:47.944 --> 00:01:50.841 is an independent risk factor for both

NOTE Confidence: 0.893322629642857

00:01:50.841 --> 00:01:52.996 incident stroke and recurrent stroke,

NOTE Confidence: 0.893322629642857

00:01:53.000 --> 00:01:55.436 and it's also an independent risk factor

NOTE Confidence: 0.893322629642857

00:01:55.436 --> 00:01:58.100 for poor outcomes following ischemic stroke,

NOTE Confidence: 0.893322629642857

00:01:58.100 --> 00:02:00.488 including both functional

NOTE Confidence: 0.893322629642857

00:02:00.488 --> 00:02:02.876 and cognitive outcomes.

NOTE Confidence: 0.893322629642857

00:02:02.880 --> 00:02:04.596 So what are the links there?

NOTE Confidence: 0.893322629642857

00:02:04.600 --> 00:02:06.460 How does obstructive sleep

NOTE Confidence: 0.893322629642857

00:02:06.460 --> 00:02:08.320 apnea potentially cause stroke?

NOTE Confidence: 0.893322629642857

00:02:08.320 --> 00:02:10.260 How does it potentially cause

NOTE Confidence: 0.893322629642857

00:02:10.260 --> 00:02:11.812 poor outcomes after stroke?

NOTE Confidence: 0.893322629642857

00:02:11.820 --> 00:02:13.470 Well, there are lots of different.

NOTE Confidence: 0.893322629642857

00:02:13.470 --> 00:02:14.902 Possibilities first.

NOTE Confidence: 0.893322629642857

00:02:14.902 --> 00:02:18.482 Sleep apnea causes elaboration of

NOTE Confidence: 0.893322629642857

00:02:18.482 --> 00:02:22.649 free radicals of khyle 6 E selected.

NOTE Confidence: 0.893322629642857

00:02:22.650 --> 00:02:25.050 These things can promote Atheros sclerosis.

NOTE Confidence: 0.893322629642857

00:02:25.050 --> 00:02:26.978 It promotes deleterious cerebral

NOTE Confidence: 0.893322629642857

00:02:26.978 --> 00:02:28.424 hemodynamics and through

NOTE Confidence: 0.893322629642857

00:02:28.424 --> 00:02:29.870 multiple different mechanisms,

NOTE Confidence: 0.893322629642857

00:02:29.870 --> 00:02:31.778 including platelet activation

NOTE Confidence: 0.893322629642857

00:02:31.778 --> 00:02:33.686 and increased EPO,

NOTE Confidence: 0.893322629642857

00:02:33.690 --> 00:02:35.634 and decreased fibrinogen increases

NOTE Confidence: 0.893322629642857

00:02:35.634 --> 00:02:38.064 hypercoagulability and any of these

NOTE Confidence: 0.893322629642857

00:02:38.064 --> 00:02:40.666 three factors alone or in combination,

NOTE Confidence: 0.893322629642857

00:02:40.670 --> 00:02:42.310 can increase the risk of

NOTE Confidence: 0.893322629642857

00:02:42.310 --> 00:02:43.622 both incident and recurrent.

NOTE Confidence: 0.893322629642857

00:02:43.630 --> 00:02:45.380 Stroke and then following a

NOTE Confidence: 0.893322629642857

00:02:45.380 --> 00:02:47.730 little bit of a different pathway.

NOTE Confidence: 0.893322629642857

00:02:47.730 --> 00:02:49.705 Sleep apnea again through all

NOTE Confidence: 0.893322629642857

00:02:49.705 --> 00:02:51.285 of the different physiologic

NOTE Confidence: 0.893322629642857

00:02:51.285 --> 00:02:52.818 changes that it can cause.

NOTE Confidence: 0.893322629642857

00:02:52.820 --> 00:02:55.490 May end up producing angiogenesis,

NOTE Confidence: 0.893322629642857

00:02:55.490 --> 00:02:57.308 dendritic and axonal

NOTE Confidence: 0.893322629642857

00:02:57.308 --> 00:02:59.126 sprouting and synaptogenesis,

NOTE Confidence: 0.893322629642857

00:02:59.130 --> 00:03:02.220 and these factors can result

NOTE Confidence: 0.893322629642857

00:03:02.220 --> 00:03:04.692 in poorer stroke recovery.

NOTE Confidence: 0.893322629642857

00:03:04.700 --> 00:03:04.989 So,

NOTE Confidence: 0.893322629642857

00:03:04.989 --> 00:03:07.301 given that we have both of these two

NOTE Confidence: 0.893322629642857

00:03:07.301 --> 00:03:09.519 very important potential outcomes,

NOTE Confidence: 0.893322629642857

00:03:09.520 --> 00:03:12.180 recurrent stroke and stroke recovery,

NOTE Confidence: 0.893322629642857

00:03:12.180 --> 00:03:14.982 which should we target in a

NOTE Confidence: 0.893322629642857

00:03:14.982 --> 00:03:17.374 trial looking at treatment of

NOTE Confidence: 0.893322629642857

00:03:17.374 --> 00:03:19.298 obstructive sleep apnea poststroke?

NOTE Confidence: 0.893322629642857

00:03:19.300 --> 00:03:19.592 Well,

NOTE Confidence: 0.893322629642857

00:03:19.592 --> 00:03:21.636 our approach was really that we wanted

NOTE Confidence: 0.893322629642857

00:03:21.636 --> 00:03:23.630 to have our cake and eat it too,

NOTE Confidence: 0.893322629642857

00:03:23.630 --> 00:03:25.232 and so this says you can't

NOTE Confidence: 0.893322629642857

00:03:25.232 --> 00:03:27.020 have your cake and eat it too.

NOTE Confidence: 0.893322629642857

00:03:27.020 --> 00:03:28.580 That's obviously being stated by

NOTE Confidence: 0.893322629642857

00:03:28.580 --> 00:03:30.140 somebody who doesn't understand what

NOTE Confidence: 0.893322629642857

00:03:30.191 --> 00:03:31.637 you're supposed to do with cake,

NOTE Confidence: 0.893322629642857

00:03:31.640 --> 00:03:35.528 so we took this approach that we wanted to.

NOTE Confidence: 0.893322629642857

00:03:35.530 --> 00:03:38.379 Test both of our hypotheses that CPAP

NOTE Confidence: 0.893322629642857

00:03:38.379 --> 00:03:40.816 could improve prevention and it could

NOTE Confidence: 0.893322629642857

00:03:40.816 --> 00:03:42.522 improve recovery and within sleep.

NOTE Confidence: 0.893322629642857

00:03:42.522 --> 00:03:44.720 Smart participants are enrolled as if it

NOTE Confidence: 0.893322629642857

00:03:44.774 --> 00:03:46.937 is a single trial they've taken through.

NOTE Confidence: 0.893322629642857

00:03:46.940 --> 00:03:48.916 The protocol is if it's a single trial,

NOTE Confidence: 0.893322629642857

00:03:48.920 --> 00:03:51.090 but then at the time of analysis,

NOTE Confidence: 0.893322629642857

00:03:51.090 --> 00:03:52.720 which hopefully will come at

NOTE Confidence: 0.893322629642857

00:03:52.720 --> 00:03:54.790 some point in in several years.

NOTE Confidence: 0.938253303333333

00:03:54.790 --> 00:03:56.645 It then breaks down into

NOTE Confidence: 0.938253303333333

00:03:56.645 --> 00:03:58.129 really two separate trials,

NOTE Confidence: 0.938253303333333

00:03:58.130 --> 00:04:00.758 one where all participants are contributing

NOTE Confidence: 0.938253303333333

00:04:00.758 --> 00:04:03.180 their data to the prevention outcome,

NOTE Confidence: 0.938253303333333

00:04:03.180 --> 00:04:06.160 and those include both the high risk Tia.

NOTE Confidence: 0.938253303333333

00:04:06.160 --> 00:04:07.678 Of which there are very few,

NOTE Confidence: 0.938253303333333

00:04:07.680 --> 00:04:09.920 and the ischemic stroke patients,

NOTE Confidence: 0.938253303333333

00:04:09.920 --> 00:04:11.558 and they have to be enrolled

NOTE Confidence: 0.938253303333333

00:04:11.558 --> 00:04:13.549 within 14 days of symptom onset.

NOTE Confidence: 0.938253303333333

00:04:13.550 --> 00:04:15.944 But then to answer the recovery aim,

NOTE Confidence: 0.938253303333333

00:04:15.950 --> 00:04:18.170 we use only a subset of

NOTE Confidence: 0.938253303333333

00:04:18.170 --> 00:04:19.280 the enrolled participants.

NOTE Confidence: 0.938253303333333

00:04:19.280 --> 00:04:21.398 Those who had an ischemic stroke

NOTE Confidence: 0.938253303333333

00:04:21.398 --> 00:04:23.410 within seven days of consent,

NOTE Confidence: 0.938253303333333

00:04:23.410 --> 00:04:25.522 and those who also have to have had

NOTE Confidence: 0.938253303333333

00:04:25.522 --> 00:04:27.467 an NIH stroke scale of at least

NOTE Confidence: 0.938253303333333

00:04:27.467 --> 00:04:29.580 one at the time of enrollment,

NOTE Confidence: 0.938253303333333

00:04:29.580 --> 00:04:30.150 because, otherwise,

NOTE Confidence: 0.938253303333333

00:04:30.150 --> 00:04:32.145 how are you going to be able

NOTE Confidence: 0.938253303333333

00:04:32.145 --> 00:04:34.355 to note that there has been an

NOTE Confidence: 0.938253303333333

00:04:34.355 --> 00:04:37.150 improvement in in their recovery?

NOTE Confidence: 0.938253303333333

00:04:37.150 --> 00:04:39.486 So the design of sleep smart is that

NOTE Confidence: 0.938253303333333

00:04:39.486 --> 00:04:42.298 it is a late phase multicenter trial.

NOTE Confidence: 0.938253303333333

00:04:42.300 --> 00:04:45.348 The control group is usual care,

NOTE Confidence: 0.938253303333333

00:04:45.350 --> 00:04:47.094 so it's usual care.

NOTE Confidence: 0.938253303333333

00:04:47.094 --> 00:04:48.402 Plus automatically adjusting

NOTE Confidence: 0.938253303333333

00:04:48.402 --> 00:04:50.510 CPAP versus usual care alone.

NOTE Confidence: 0.938253303333333

00:04:50.510 --> 00:04:53.134 We could have designed this to have an

NOTE Confidence: 0.938253303333333

00:04:53.134 --> 00:04:55.349 active control will not active control,

NOTE Confidence: 0.938253303333333

00:04:55.350 --> 00:04:57.102 but a placebo control using sham

NOTE Confidence: 0.938253303333333

00:04:57.102 --> 00:04:58.646 CPAP and it's something with

NOTE Confidence: 0.938253303333333

00:04:58.646 --> 00:04:59.938 which we have experienced.

NOTE Confidence: 0.938253303333333

00:04:59.940 --> 00:05:02.622 But it really would have complicated

NOTE Confidence: 0.938253303333333

00:05:02.622 --> 00:05:04.525 our design substantially and

NOTE Confidence: 0.938253303333333

00:05:04.525 --> 00:05:07.300 it would have advocated the.

NOTE Confidence: 0.938253303333333

00:05:07.300 --> 00:05:09.316 Possibility of are using a run at night,

NOTE Confidence: 0.938253303333333

00:05:09.320 --> 00:05:12.254 which is a key part of our protocol design,

NOTE Confidence: 0.938253303333333

00:05:12.260 --> 00:05:14.156 and so in the face of knowing that

NOTE Confidence: 0.938253303333333

00:05:14.156 --> 00:05:16.259 we are using open label treatment,

NOTE Confidence: 0.938253303333333

00:05:16.260 --> 00:05:19.109 we used a probe design where the

NOTE Confidence: 0.938253303333333

00:05:19.109 --> 00:05:21.687 outcome assessors are masked to

NOTE Confidence: 0.938253303333333

00:05:21.687 --> 00:05:23.164 randomization assignment and

NOTE Confidence: 0.938253303333333

00:05:23.164 --> 00:05:24.328 then again as I said before,

NOTE Confidence: 0.938253303333333

00:05:24.330 --> 00:05:26.670 this is really a secondary prevention

NOTE Confidence: 0.938253303333333

00:05:26.670 --> 00:05:29.269 trial with an embedded recovery trial.

NOTE Confidence: 0.910098293333333

00:05:32.410 --> 00:05:34.025 This shows how a participant

NOTE Confidence: 0.910098293333333

00:05:34.025 --> 00:05:35.317 goes through the protocol.

NOTE Confidence: 0.910098293333333

00:05:35.320 --> 00:05:36.860 So after consent and

NOTE Confidence: 0.910098293333333

00:05:36.860 --> 00:05:38.015 baseline data collection,

NOTE Confidence: 0.910098293333333

00:05:38.020 --> 00:05:40.714 the first night is allocated to

NOTE Confidence: 0.910098293333333

00:05:40.714 --> 00:05:43.677 sleep apnea testing with an ox T3

NOTE Confidence: 0.910098293333333

00:05:43.677 --> 00:05:46.248 sleep apnea device and then to have

NOTE Confidence: 0.910098293333333

00:05:46.248 --> 00:05:47.736 qualifying obstructive sleep apnea.

NOTE Confidence: 0.910098293333333

00:05:47.740 --> 00:05:49.720 The Respiratory Event index has to

NOTE Confidence: 0.910098293333333

00:05:49.720 --> 00:05:52.463 be at least 10 and half of those

NOTE Confidence: 0.910098293333333

00:05:52.463 --> 00:05:54.485 events cannot be no greater than

NOTE Confidence: 0.910098293333333

00:05:54.557 --> 00:05:56.916 half of them can be central events,

NOTE Confidence: 0.910098293333333

00:05:56.920 --> 00:05:58.733 and then the person moves on to

NOTE Confidence: 0.910098293333333

00:05:58.733 --> 00:06:00.430 the second night where he or she.

NOTE Confidence: 0.910098293333333

00:06:00.430 --> 00:06:01.810 Essentially gets a taste of C.

NOTE Confidence: 0.910098293333333

00:06:01.810 --> 00:06:04.700 Pap gets to try it out in the run and night,

NOTE Confidence: 0.910098293333333

00:06:04.700 --> 00:06:07.367 and if that subject uses C PAP

NOTE Confidence: 0.910098293333333

00:06:07.367 --> 00:06:09.281 for release cumulatively 4 hours

NOTE Confidence: 0.910098293333333

00:06:09.281 --> 00:06:11.363 during that night and also does

NOTE Confidence: 0.910098293333333

00:06:11.363 --> 00:06:13.403 not exceed 10 for the central

NOTE Confidence: 0.910098293333333

00:06:13.403 --> 00:06:15.693 apnea index read off of the device.

NOTE Confidence: 0.910098293333333

00:06:15.693 --> 00:06:17.931 So meaning therefore the person did

NOTE Confidence: 0.910098293333333

00:06:17.931 --> 00:06:20.168 not have treatment induced central

NOTE Confidence: 0.910098293333333

00:06:20.168 --> 00:06:22.512 sleep apnea and the participant is

NOTE Confidence: 0.910098293333333

00:06:22.512 --> 00:06:24.540 willing after that one night of

NOTE Confidence: 0.910098293333333

00:06:24.604 --> 00:06:26.804 exposure to see PAP to have a 5050

NOTE Confidence: 0.910098293333333

00:06:26.804 --> 00:06:29.549 chance of intervention versus control group,

NOTE Confidence: 0.910098293333333

00:06:29.550 --> 00:06:30.831 then that person.

NOTE Confidence: 0.910098293333333

00:06:30.831 --> 00:06:32.966 Is eligible for randomization and

NOTE Confidence: 0.910098293333333

00:06:32.966 --> 00:06:34.831 receives again either automatically

NOTE Confidence: 0.910098293333333

00:06:34.831 --> 00:06:37.191 adjusting CPAP plus best medical

NOTE Confidence: 0.910098293333333

00:06:37.191 --> 00:06:39.517 therapy versus just best medical

NOTE Confidence: 0.910098293333333

00:06:39.517 --> 00:06:41.712 therapy alone and then we follow

NOTE Confidence: 0.910098293333333

00:06:41.712 --> 00:06:43.740 the subjects for three months for

NOTE Confidence: 0.910098293333333

00:06:43.811 --> 00:06:46.151 the recovery outcomes and then six

NOTE Confidence: 0.910098293333333

00:06:46.151 --> 00:06:48.370 months for the prevention outcomes.

NOTE Confidence: 0.899225460714286

00:06:50.700 --> 00:06:53.300 We were asked to cover a couple of

NOTE Confidence: 0.899225460714286

00:06:53.300 --> 00:06:55.489 different topics during this brief talk,

NOTE Confidence: 0.899225460714286

00:06:55.490 --> 00:06:58.577 and so I'm going to move on to enrollment

NOTE Confidence: 0.899225460714286

00:06:58.577 --> 00:07:01.328 criteria and how we we conceptualize those.

NOTE Confidence: 0.899225460714286

00:07:01.330 --> 00:07:03.386 And we're going to try to highlight some

NOTE Confidence: 0.899225460714286

00:07:03.386 --> 00:07:05.710 of the questions that were asked of us.

NOTE Confidence: 0.899225460714286

00:07:05.710 --> 00:07:07.520 So the enrollment criteria really

NOTE Confidence: 0.899225460714286

00:07:07.520 --> 00:07:09.330 quite broad in sleep smart.

NOTE Confidence: 0.899225460714286

00:07:09.330 --> 00:07:11.486 We're trying to have a generalizable trial.

NOTE Confidence: 0.899225460714286

00:07:11.490 --> 00:07:13.416 We're trying to have a treatment

NOTE Confidence: 0.899225460714286

00:07:13.416 --> 00:07:15.112 that potentially can help the

NOTE Confidence: 0.899225460714286

00:07:15.112 --> 00:07:16.528 most number of participants.

NOTE Confidence: 0.899225460714286

00:07:16.530 --> 00:07:19.484 So there the inclusion criteria are really.

NOTE Confidence: 0.899225460714286

00:07:19.490 --> 00:07:20.040 Very broad.

NOTE Confidence: 0.899225460714286

00:07:20.040 --> 00:07:22.240 If you've had an ischemic stroke or high

NOTE Confidence: 0.899225460714286

00:07:22.298 --> 00:07:24.358 risk TA in the prior 14 days in year,

NOTE Confidence: 0.899225460714286

00:07:24.360 --> 00:07:26.984 at least 18, and you're asleep smart site,

NOTE Confidence: 0.899225460714286

00:07:26.990 --> 00:07:30.240 you're essentially eligible from the

NOTE Confidence: 0.899225460714286

00:07:30.240 --> 00:07:32.660 inclusion side of things we have.

NOTE Confidence: 0.899225460714286

00:07:32.660 --> 00:07:35.236 For what I'm going to describe is 4

NOTE Confidence: 0.899225460714286

00:07:35.236 --> 00:07:37.200 categories of exclusion criteria.

NOTE Confidence: 0.899225460714286

00:07:37.200 --> 00:07:39.104 The first are really the general ones,

NOTE Confidence: 0.899225460714286

00:07:39.110 --> 00:07:41.504 so if you have somebody who's a

14

NOTE Confidence: 0.899225460714286

00:07:41.504 --> 00:07:42.890 pregnant woman incarcerated and

NOTE Confidence: 0.899225460714286

00:07:42.890 --> 00:07:44.385 can't sign our own consent,

NOTE Confidence: 0.899225460714286

00:07:44.390 --> 00:07:45.562 that somebody who you're

NOTE Confidence: 0.899225460714286

00:07:45.562 --> 00:07:47.027 going to want to exclude,

NOTE Confidence: 0.899225460714286

00:07:47.030 --> 00:07:48.566 and if it's somebody who could

NOTE Confidence: 0.899225460714286

00:07:48.566 --> 00:07:50.218 not perform all of his or her.

NOTE Confidence: 0.899225460714286

00:07:50.220 --> 00:07:51.864 Activities of daily living

NOTE Confidence: 0.899225460714286

00:07:51.864 --> 00:07:53.508 prior to the stroke.

NOTE Confidence: 0.899225460714286

00:07:53.510 --> 00:07:55.374 Then that's also someone

NOTE Confidence: 0.899225460714286

00:07:55.374 --> 00:07:57.238 who would be excluded.

NOTE Confidence: 0.899225460714286

00:07:57.240 --> 00:07:59.060 The next category are the

NOTE Confidence: 0.899225460714286

00:07:59.060 --> 00:08:00.516 CPAP specific related issues.

NOTE Confidence: 0.899225460714286

00:08:00.520 --> 00:08:03.336 So if you are on currently on mechanical

NOTE Confidence: 0.899225460714286

00:08:03.336 --> 00:08:05.839 ventilation or if you have a tracheostomy,

NOTE Confidence: 0.899225460714286

00:08:05.840 --> 00:08:07.376 you're not going to benefit from

NOTE Confidence: 0.899225460714286

00:08:07.376 --> 00:08:09.380 C PAP and so you're excluded.

NOTE Confidence: 0.899225460714286

00:08:09.380 --> 00:08:11.361 And then if you've used C PAP

NOTE Confidence: 0.899225460714286

00:08:11.361 --> 00:08:12.700 in the last month,

NOTE Confidence: 0.899225460714286

00:08:12.700 --> 00:08:14.072 we have a concern that if your

NOTE Confidence: 0.899225460714286

00:08:14.072 --> 00:08:15.109 randomized so the control group

NOTE Confidence: 0.899225460714286

00:08:15.109 --> 00:08:16.741 you're going to go home and use your

NOTE Confidence: 0.899225460714286

00:08:16.783 --> 00:08:18.088 see PAP and therefore crossover,

NOTE Confidence: 0.899225460714286

00:08:18.090 --> 00:08:20.645 so you're excluded for that as well.

NOTE Confidence: 0.899225460714286

00:08:20.650 --> 00:08:23.702 The third category are things that we

NOTE Confidence: 0.899225460714286

00:08:23.702 --> 00:08:26.370 think potentially could make CPAP riskier.

NOTE Confidence: 0.899225460714286

00:08:26.370 --> 00:08:27.726 It's very low.

NOTE Confidence: 0.899225460714286

00:08:27.726 --> 00:08:28.630 Risk treatment,

NOTE Confidence: 0.899225460714286

00:08:28.630 --> 00:08:31.402 but there there are some factors that

NOTE Confidence: 0.899225460714286

00:08:31.402 --> 00:08:34.277 may increase risks and so those include

NOTE Confidence: 0.899225460714286

00:08:34.277 --> 00:08:36.695 things such as bullous lung disease,

NOTE Confidence: 0.899225460714286

00:08:36.700 --> 00:08:38.532 pneumothorax having hypo tension

NOTE Confidence: 0.899225460714286

00:08:38.532 --> 00:08:40.822 that's so significant that you're

NOTE Confidence: 0.899225460714286

00:08:40.822 --> 00:08:42.667 requiring pressers at that time.

NOTE Confidence: 0.899225460714286

00:08:42.670 --> 00:08:45.540 If you've had massive epistaxis.

NOTE Confidence: 0.899225460714286

00:08:45.540 --> 00:08:47.676 If you have a possible CSF

NOTE Confidence: 0.899225460714286

00:08:47.676 --> 00:08:49.100 leak or Numa cephalus,

NOTE Confidence: 0.899225460714286

00:08:49.100 --> 00:08:51.316 or if you've had any kind of bone

NOTE Confidence: 0.899225460714286

00:08:51.316 --> 00:08:53.091 off procedure where the bone has

NOTE Confidence: 0.899225460714286

00:08:53.091 --> 00:08:54.825 not been replaced on the head,

NOTE Confidence: 0.899225460714286

00:08:54.830 --> 00:08:57.629 then C Pap maybe a little bit more risky.

NOTE Confidence: 0.899225460714286

00:08:57.630 --> 00:08:58.500 In those participants,

NOTE Confidence: 0.899225460714286

00:08:58.500 --> 00:08:59.950 and therefore they are excluded.

NOTE Confidence: 0.899225460714286

00:08:59.950 --> 00:09:02.110 We also have a category for the site P.

NOTE Confidence: 0.899225460714286

00:09:02.110 --> 00:09:04.288 I feeling like there's some other

NOTE Confidence: 0.899225460714286

00:09:04.288 --> 00:09:06.027 entity that increases the risk

NOTE Confidence: 0.899225460714286

00:09:06.027 --> 00:09:08.016 of C PAP and so we allow for of

NOTE Confidence: 0.899225460714286

00:09:08.085 --> 00:09:10.041 course the judgment of the local

NOTE Confidence: 0.899225460714286

00:09:10.041 --> 00:09:12.798 teams to decide this is not a good

NOTE Confidence: 0.899225460714286

00:09:12.798 --> 00:09:14.970 idea for our for our patient.

NOTE Confidence: 0.899225460714286

00:09:14.970 --> 00:09:17.287 And then the 4th category really is

NOTE Confidence: 0.899225460714286

00:09:17.287 --> 00:09:19.588 something that makes it really unfeasible.

NOTE Confidence: 0.899225460714286

00:09:19.590 --> 00:09:20.418 So for instance,

NOTE Confidence: 0.899225460714286

00:09:20.418 --> 00:09:23.130 if the participant or if the sort of the

NOTE Confidence: 0.899225460714286

00:09:23.130 --> 00:09:24.925 patient is using oxygen supplementations

NOTE Confidence: 0.899225460714286

00:09:24.925 --> 00:09:27.060 greater than four liters per minute,

NOTE Confidence: 0.899225460714286

00:09:27.060 --> 00:09:27.876 you can't believe.

NOTE Confidence: 0.899225460714286

00:09:27.876 --> 00:09:29.236 That into our CPAP machines,

NOTE Confidence: 0.899225460714286

00:09:29.240 --> 00:09:30.950 and therefore it's really unfeasible

NOTE Confidence: 0.899225460714286

00:09:30.950 --> 00:09:33.897 and then if that person is on some type

NOTE Confidence: 0.899225460714286

00:09:33.897 --> 00:09:35.506 of precautions, contact precaution,

NOTE Confidence: 0.899225460714286

00:09:35.506 --> 00:09:36.522 respiratory precautions,

NOTE Confidence: 0.899225460714286

00:09:36.522 --> 00:09:39.570 we don't want to cross contaminate

NOTE Confidence: 0.899225460714286

00:09:39.641 --> 00:09:41.636 with our equipment and infect

NOTE Confidence: 0.899225460714286

00:09:41.636 --> 00:09:43.631 another participant so it really

NOTE Confidence: 0.907452343636363

00:09:43.697 --> 00:09:44.919 becomes unfeasible.

NOTE Confidence: 0.907452343636363

00:09:44.920 --> 00:09:46.820 Switching gears a little bit,

NOTE Confidence: 0.907452343636363

00:09:46.820 --> 00:09:49.158 we were asked to talk a little

NOTE Confidence: 0.907452343636363

00:09:49.158 --> 00:09:51.033 bit about the stroke physicians

NOTE Confidence: 0.907452343636363

00:09:51.033 --> 00:09:53.038 versus the sleep positions and

NOTE Confidence: 0.907452343636363

00:09:53.038 --> 00:09:55.140 how those interactions occur.

NOTE Confidence: 0.907452343636363

00:09:55.140 --> 00:09:58.857 We've had some comments from potential

NOTE Confidence: 0.907452343636363

00:09:58.857 --> 00:10:01.496 sites where they have said is CPAP

NOTE Confidence: 0.907452343636363

00:10:01.496 --> 00:10:03.669 really safe for stroke patients?

NOTE Confidence: 0.907452343636363

00:10:03.670 --> 00:10:05.252 So I'm concerned that if my person

NOTE Confidence: 0.907452343636363

00:10:05.252 --> 00:10:07.245 if my patient is enrolled and then

NOTE Confidence: 0.907452343636363

00:10:07.245 --> 00:10:08.513 randomize the intervention group,

NOTE Confidence: 0.907452343636363

00:10:08.520 --> 00:10:11.034 that CPAP could potentially cause harm

NOTE Confidence: 0.907452343636363

00:10:11.034 --> 00:10:13.898 that is most commonly said by a sleep.

NOTE Confidence: 0.907452343636363

00:10:13.900 --> 00:10:14.868 I started a stroke.

NOTE Confidence: 0.907452343636363

00:10:14.868 --> 00:10:15.836 Position if it is,

NOTE Confidence: 0.907452343636363

00:10:15.840 --> 00:10:18.200 if it said and on the flip side,

NOTE Confidence: 0.907452343636363

00:10:18.200 --> 00:10:19.550 there are some sites where they'll

NOTE Confidence: 0.907452343636363

00:10:19.550 --> 00:10:21.149 come back to us and say how

NOTE Confidence: 0.907452343636363

00:10:21.149 --> 00:10:22.445 can you withhold CPAP after you

NOTE Confidence: 0.907452343636363

00:10:22.445 --> 00:10:24.152 know that the patient has been

NOTE Confidence: 0.907452343636363

00:10:24.152 --> 00:10:25.304 diagnosed with obstructive sleep

NOTE Confidence: 0.907452343636363

00:10:25.304 --> 00:10:27.244 apnea by randomizing that person

NOTE Confidence: 0.907452343636363

00:10:27.244 --> 00:10:30.215 to the control group that is more

NOTE Confidence: 0.907452343636363

00:10:30.215 --> 00:10:32.777 commonly said by a sleep physician.

NOTE Confidence: 0.907452343636363

00:10:32.780 --> 00:10:33.581 And so overall,

NOTE Confidence: 0.907452343636363

00:10:33.581 --> 00:10:35.836 we really feel that we are in a

NOTE Confidence: 0.907452343636363

00:10:35.836 --> 00:10:37.466 position of clinical equipoised with

NOTE Confidence: 0.907452343636363

00:10:37.466 --> 00:10:40.018 respect to C PAP for stroke patients.

NOTE Confidence: 0.907452343636363

00:10:40.020 --> 00:10:42.642 We don't know whether CPAP will

NOTE Confidence: 0.907452343636363

00:10:42.642 --> 00:10:44.923 help harm or essentially do

NOTE Confidence: 0.907452343636363

00:10:44.923 --> 00:10:47.198 neither for our stroke patients.

NOTE Confidence: 0.907452343636363

00:10:47.200 --> 00:10:49.230 There have been no definitive

NOTE Confidence: 0.907452343636363

00:10:49.230 --> 00:10:51.260 randomized controlled trials for stroke

NOTE Confidence: 0.907452343636363

00:10:51.322 --> 00:10:53.614 patients for stroke outcomes that have

NOTE Confidence: 0.907452343636363

00:10:53.614 --> 00:10:55.679 shown anything is improved by CPAP.

NOTE Confidence: 0.907452343636363

00:10:55.680 --> 00:10:57.150 So we feel comfortable with

NOTE Confidence: 0.907452343636363

00:10:57.150 --> 00:10:59.000 holding it from the control group,

NOTE Confidence: 0.907452343636363

00:10:59.000 --> 00:11:00.878 and there there's precedence for this.

NOTE Confidence: 0.907452343636363

00:11:00.880 --> 00:11:02.560 There have been numerous.

NOTE Confidence: 0.907452343636363

00:11:02.560 --> 00:11:04.240 Randomized controlled trials that

NOTE Confidence: 0.907452343636363

00:11:04.240 --> 00:11:06.150 have enrolled either patients

NOTE Confidence: 0.907452343636363

00:11:06.150 --> 00:11:07.668 with cardiovascular disease,

NOTE Confidence: 0.907452343636363

00:11:07.670 --> 00:11:11.149 such as Save Rick Ads or SIRKAS,

NOTE Confidence: 0.907452343636363

00:11:11.150 --> 00:11:13.760 or that have enrolled lots of

NOTE Confidence: 0.907452343636363

00:11:13.760 --> 00:11:16.010 participants with severe sleep apnea,

NOTE Confidence: 0.907452343636363

00:11:16.010 --> 00:11:18.290 such as apples where patients are

NOTE Confidence: 0.907452343636363

00:11:18.290 --> 00:11:20.480 randomized to a control group or,

NOTE Confidence: 0.907452343636363

00:11:20.480 --> 00:11:25.014 in the case of apples, to a sham control.

NOTE Confidence: 0.907452343636363

00:11:25.014 --> 00:11:28.278 So other investigative teams,

NOTE Confidence: 0.907452343636363

00:11:28.280 --> 00:11:29.561 other funding agencies,

NOTE Confidence: 0.907452343636363

00:11:29.561 --> 00:11:32.123 other peer review panels have found

NOTE Confidence: 0.907452343636363

00:11:32.123 --> 00:11:34.010 this to be completely ethical

NOTE Confidence: 0.907452343636363

00:11:34.010 --> 00:11:36.660 and not have any concern.

NOTE Confidence: 0.907452343636363

00:11:36.660 --> 00:11:38.720 There's also the 2017 U.

NOTE Confidence: 0.907452343636363

00:11:38.720 --> 00:11:41.405 S Preventive Taskforce report that

NOTE Confidence: 0.907452343636363

00:11:41.405 --> 00:11:44.596 helped inform our our decision making

NOTE Confidence: 0.907452343636363

00:11:44.596 --> 00:11:47.557 at the time that we were designing

NOTE Confidence: 0.907452343636363

00:11:47.560 --> 00:11:49.684 sleep smart and and proposing it

NOTE Confidence: 0.907452343636363

00:11:49.684 --> 00:11:51.805 for the first time that states that

NOTE Confidence: 0.907452343636363

00:11:51.805 --> 00:11:52.980 there is no established benefit

NOTE Confidence: 0.907452343636363

00:11:52.980 --> 00:11:54.700 of C PAP for any health outcome.

NOTE Confidence: 0.907452343636363

00:11:54.700 --> 00:11:55.351 This is just.

NOTE Confidence: 0.907452343636363

00:11:55.351 --> 00:11:56.219 In the general population,

NOTE Confidence: 0.907452343636363

00:11:56.220 --> 00:11:58.608 not even specific to stroke aside

NOTE Confidence: 0.907452343636363

00:11:58.608 --> 00:12:00.632 from the modest improvement in

NOTE Confidence: 0.907452343636363

00:12:00.632 --> 00:12:02.427 sleep related quality of life,

NOTE Confidence: 0.907452343636363

00:12:02.430 --> 00:12:03.400 and the more recent U.

NOTE Confidence: 0.907452343636363

00:12:03.400 --> 00:12:05.650 S preventive taskforce doesn't say

NOTE Confidence: 0.907452343636363

00:12:05.650 --> 00:12:08.841 anything that would compel us not to

NOTE Confidence: 0.907452343636363

00:12:08.841 --> 00:12:11.427 randomize participants to a control group.

NOTE Confidence: 0.907452343636363

00:12:11.430 --> 00:12:13.430 We were also asked to talk a little

NOTE Confidence: 0.907452343636363

00:12:13.430 --> 00:12:14.974 bit about crossover so crossovers

NOTE Confidence: 0.907452343636363

00:12:14.974 --> 00:12:17.270 where you have a control person who

NOTE Confidence: 0.907452343636363

00:12:17.330 --> 00:12:19.334 someone who's randomized to the control

NOTE Confidence: 0.907452343636363

23

00:12:19.334 --> 00:12:21.402 group who then wants to use CPAP.

NOTE Confidence: 0.907452343636363

00:12:21.402 --> 00:12:23.110 So when that does occur and it's

NOTE Confidence: 0.907452343636363

00:12:23.174 --> 00:12:24.714 not something that we thought

NOTE Confidence: 0.907452343636363

00:12:24.714 --> 00:12:25.946 would be very common.

NOTE Confidence: 0.907452343636363

00:12:25.950 --> 00:12:27.755 Based on our preliminary work

NOTE Confidence: 0.907452343636363

00:12:27.755 --> 00:12:30.110 and based on prior CPAP trials,

NOTE Confidence: 0.907452343636363

00:12:30.110 --> 00:12:32.462 pilot trials among stroke

NOTE Confidence: 0.907452343636363

00:12:32.462 --> 00:12:34.482 patients if that does occur,

NOTE Confidence: 0.907452343636363

00:12:34.482 --> 00:12:36.630 then the clinical team should absolutely

NOTE Confidence: 0.907452343636363

00:12:36.691 --> 00:12:38.767 feel free to refer the participant

NOTE Confidence: 0.907452343636363

00:12:38.767 --> 00:12:40.809 for sleep apnea testing for sleep.

NOTE Confidence: 0.907452343636363

00:12:40.810 --> 00:12:43.258 Get me a treatment in the clinical realm,

NOTE Confidence: 0.907452343636363

00:12:43.260 --> 00:12:45.332 it usually takes some time for that

NOTE Confidence: 0.907452343636363

00:12:45.332 --> 00:12:47.389 to be available to the participant,

NOTE Confidence: 0.907452343636363

00:12:47.390 --> 00:12:49.890 so it may actually.

NOTE Confidence: 0.863257626

00:12:49.890 --> 00:12:52.046 Push the see PAP treatment for clinical

NOTE Confidence: 0.863257626

00:12:52.046 --> 00:12:54.486 care outside of the even six month window.

NOTE Confidence: 0.863257626

00:12:54.490 --> 00:12:56.436 By the time the person is able

NOTE Confidence: 0.863257626

00:12:56.436 --> 00:12:58.055 to get tested and treated and

NOTE Confidence: 0.863257626

00:12:58.055 --> 00:13:00.369 have a C Pap in his or her home,

NOTE Confidence: 0.863257626

00:13:00.370 --> 00:13:02.904 but the research team, we would suggest

NOTE Confidence: 0.863257626

00:13:02.904 --> 00:13:04.850 not help facilitate that process.

NOTE Confidence: 0.863257626

00:13:04.850 --> 00:13:06.999 It is a protocol violation for a

NOTE Confidence: 0.863257626

00:13:06.999 --> 00:13:08.449 control participant to start using

NOTE Confidence: 0.863257626

00:13:08.449 --> 00:13:10.321 C PAP so it has to be reported

NOTE Confidence: 0.863257626

00:13:10.385 --> 00:13:11.945 as such and in the analysis,

NOTE Confidence: 0.863257626

00:13:11.950 --> 00:13:13.812 at least in the intent to treat

NOTE Confidence: 0.863257626

00:13:13.812 --> 00:13:15.779 component which is our primary analysis.

NOTE Confidence: 0.863257626

00:13:15.780 --> 00:13:17.760 The control participant who starts

NOTE Confidence: 0.863257626

00:13:17.760 --> 00:13:20.480 using C PAP will be analyzed.

NOTE Confidence: 0.863257626

00:13:20.480 --> 00:13:23.288 As a control participant.

NOTE Confidence: 0.863257626

00:13:23.290 --> 00:13:24.481 Crossovers from control.

NOTE Confidence: 0.863257626

00:13:24.481 --> 00:13:27.260 Two intervention or to to CPAP use

NOTE Confidence: 0.863257626

00:13:27.327 --> 00:13:29.588 have been very uncommon in in sleep

NOTE Confidence: 0.863257626

00:13:29.588 --> 00:13:31.968 smart so far it's been around 2%.

NOTE Confidence: 0.962847176

00:13:34.900 --> 00:13:37.590 So what about anticipated challenges?

NOTE Confidence: 0.962847176

00:13:37.590 --> 00:13:38.965 Well, we knew that recruitment

NOTE Confidence: 0.962847176

00:13:38.965 --> 00:13:40.065 would be an issue.

NOTE Confidence: 0.962847176

00:13:40.070 --> 00:13:42.662 Recruitment is an issue for every

NOTE Confidence: 0.962847176

00:13:42.662 --> 00:13:43.958 randomized controlled trial.

NOTE Confidence: 0.962847176

00:13:43.960 --> 00:13:46.400 CPAP adherence is an issue

NOTE Confidence: 0.962847176

00:13:46.400 --> 00:13:48.840 for every CPAP related trial,

NOTE Confidence: 0.962847176

00:13:48.840 --> 00:13:50.968 but some of the things that we did

NOTE Confidence: 0.962847176

00:13:50.968 --> 00:13:52.406 not anticipate having difficulty

NOTE Confidence: 0.962847176

00:13:52.406 --> 00:13:54.570 with included a global pandemic.

NOTE Confidence: 0.962847176

00:13:54.570 --> 00:13:56.994 We did not presage that,

NOTE Confidence: 0.962847176

00:13:56.994 --> 00:13:59.202 and having difficulty achieving

NOTE Confidence: 0.962847176

00:13:59.202 --> 00:14:01.410 in window outcome assessments

NOTE Confidence: 0.962847176

00:14:01.487 --> 00:14:03.767 has been much more challenging.

NOTE Confidence: 0.962847176

00:14:03.770 --> 00:14:05.726 Then we had anticipated we have

NOTE Confidence: 0.962847176

00:14:05.726 --> 00:14:07.829 more missing data at the three

NOTE Confidence: 0.962847176

00:14:07.829 --> 00:14:09.649 month TIMEPOINT for the modified

NOTE Confidence: 0.962847176

00:14:09.649 --> 00:14:11.836 Rankin which is our primary for

NOTE Confidence: 0.962847176

00:14:11.836 --> 00:14:13.888 that aim than we had anticipated.

NOTE Confidence: 0.962847176

00:14:13.890 --> 00:14:16.842 We did try in the design of sleep smart

NOTE Confidence: 0.962847176

00:14:16.842 --> 00:14:20.147 to prepare for some of these challenges.

NOTE Confidence: 0.962847176

00:14:20.150 --> 00:14:23.062 So for instance we built in telephone

NOTE Confidence: 0.962847176

00:14:23.062 --> 00:14:25.131 outcome assessments from the onset

NOTE Confidence: 0.962847176

00:14:25.131 --> 00:14:27.387 that was always allowable and sleep

NOTE Confidence: 0.962847176

00:14:27.387 --> 00:14:30.098 smart even pre COVID and most of our

NOTE Confidence: 0.962847176

00:14:30.098 --> 00:14:32.030 outcomes can be assessed by telephone.

NOTE Confidence: 0.962847176

00:14:32.030 --> 00:14:34.130 There are only a few secondary outcomes.

NOTE Confidence: 0.962847176

00:14:34.130 --> 00:14:35.594 Exploratory outcomes that cannot,

NOTE Confidence: 0.962847176

00:14:35.594 --> 00:14:37.424 but most of them can.

NOTE Confidence: 0.962847176

00:14:37.430 --> 00:14:40.342 We really tried to be very careful and

NOTE Confidence: 0.962847176

00:14:40.342 --> 00:14:42.591 intentional about the selection of our

NOTE Confidence: 0.962847176

00:14:42.591 --> 00:14:44.775 outcome assessments to make them as

NOTE Confidence: 0.962847176

00:14:44.840 --> 00:14:47.180 short as possible and when possible,

NOTE Confidence: 0.962847176

00:14:47.180 --> 00:14:51.460 to allow something to be conducted by phone.

NOTE Confidence: 0.962847176

00:14:51.460 --> 00:14:53.652 We also created a lot of tools for

NOTE Confidence: 0.962847176

00:14:53.652 --> 00:14:56.270 site teams to be able to reach out to

NOTE Confidence: 0.962847176

00:14:56.270 --> 00:14:58.416 participants in case there were any

NOTE Confidence: 0.962847176

00:14:58.416 --> 00:15:00.852 issues trying to achieve outcome assessments.

NOTE Confidence: 0.962847176

00:15:00.860 --> 00:15:02.732 So we built in a place in the

NOTE Confidence: 0.962847176

00:15:02.732 --> 00:15:04.338 back of the consent form.

NOTE Confidence: 0.962847176

00:15:04.340 --> 00:15:05.122 For instance,

NOTE Confidence: 0.962847176

00:15:05.122 --> 00:15:07.077 where lots of contact information,

NOTE Confidence: 0.962847176

00:15:07.080 --> 00:15:08.349 alternative contact information

28

NOTE Confidence: 0.962847176

00:15:08.349 --> 00:15:09.618 for the subject,

NOTE Confidence: 0.962847176

00:15:09.620 --> 00:15:12.450 alternative contact information for partners,

NOTE Confidence: 0.962847176

00:15:12.450 --> 00:15:12.785 friends,

NOTE Confidence: 0.962847176

00:15:12.785 --> 00:15:14.125 family members could be

NOTE Confidence: 0.962847176

00:15:14.125 --> 00:15:15.800 documented and then referred to.

NOTE Confidence: 0.962847176

00:15:15.800 --> 00:15:17.595 We created several letter templates

NOTE Confidence: 0.962847176

00:15:17.595 --> 00:15:20.892 for sites to use to reach out to

NOTE Confidence: 0.962847176

00:15:20.892 --> 00:15:22.796 subjects about scheduled appointments.

NOTE Confidence: 0.962847176

00:15:22.800 --> 00:15:25.340 Missed appointments unable to reach

NOTE Confidence: 0.962847176

00:15:25.340 --> 00:15:27.698 those types of things we've developed.

NOTE Confidence: 0.962847176

00:15:27.700 --> 00:15:30.892 A slide set that sites can

NOTE Confidence: 0.962847176

00:15:30.892 --> 00:15:33.726 use to help educate teams.

NOTE Confidence: 0.962847176

00:15:33.726 --> 00:15:34.962 Clinical teams,

NOTE Confidence: 0.962847176

00:15:34.962 --> 00:15:37.434 including nurses about sleep

NOTE Confidence: 0.962847176

00:15:37.434 --> 00:15:40.851 smart and we created a document

NOTE Confidence: 0.962847176

00:15:40.851 --> 00:15:43.828 that provides our sort of answers

NOTE Confidence: 0.962847176

00:15:43.828 --> 00:15:45.756 to potential difficult patient

NOTE Confidence: 0.962847176

00:15:45.756 --> 00:15:48.559 questions at the time of enrollment,

NOTE Confidence: 0.962847176

00:15:48.560 --> 00:15:49.590 and we also of course,

NOTE Confidence: 0.962847176

00:15:49.590 --> 00:15:51.930 built in Tele Med telemedicine

NOTE Confidence: 0.962847176

00:15:51.930 --> 00:15:53.334 approach to outpatient.

NOTE Confidence: 0.962847176

00:15:53.340 --> 00:15:54.963 Management of CPAP,

NOTE Confidence: 0.962847176

00:15:54.963 --> 00:15:58.750 which in COVID has been very advantageous.

NOTE Confidence: 0.938072971111111

00:16:00.900 --> 00:16:02.364 But despite the challenges,

NOTE Confidence: 0.938072971111111

00:16:02.364 --> 00:16:04.194 there remain lots of hope.

NOTE Confidence: 0.938072971111111

00:16:04.200 --> 00:16:07.126 There's hope because the of the vaccine,

NOTE Confidence: 0.938072971111111

00:16:07.130 --> 00:16:10.600 which hopefully will assist teams and

NOTE Confidence: 0.938072971111111

00:16:10.600 --> 00:16:12.700 getting back to their usual state when

NOTE Confidence: 0.938072971111111

00:16:12.758 --> 00:16:14.558 it comes to coordinator coverage.

NOTE Confidence: 0.938072971111111

00:16:14.560 --> 00:16:15.874 Respiratory therapy support,

NOTE Confidence: 0.938072971111111

00:16:15.874 --> 00:16:18.502 but mostly our hope comes from

NOTE Confidence: 0.938072971111111

00:16:18.502 --> 00:16:21.137 our sites and the sites have been

NOTE Confidence: 0.938072971111111

00:16:21.137 --> 00:16:23.356 doing a fantastic job despite the

NOTE Confidence: 0.938072971111111

00:16:23.356 --> 00:16:25.897 pandemic in the face of a pandemic,

NOTE Confidence: 0.938072971111111

00:16:25.900 --> 00:16:28.469 we are really grateful to every site.

NOTE Confidence: 0.938072971111111

00:16:28.470 --> 00:16:29.814 There are some sites,

NOTE Confidence: 0.938072971111111

00:16:29.814 --> 00:16:31.830 as you see who are randomized.

NOTE Confidence: 0.938072971111111

00:16:31.830 --> 00:16:33.666 In the 50s and the 60s,

NOTE Confidence: 0.938072971111111

00:16:33.670 --> 00:16:35.239 number of participants,

NOTE Confidence: 0.938072971111111

00:16:35.239 --> 00:16:36.808 which is fantastic.

NOTE Confidence: 0.938072971111111

00:16:36.810 --> 00:16:38.525 I would like to give a little

NOTE Confidence: 0.938072971111111

00:16:38.525 --> 00:16:40.368 shout out to two of your sites.

NOTE Confidence: 0.938072971111111

00:16:40.370 --> 00:16:44.012 North Shore with 16 and Yale

NOTE Confidence: 0.938072971111111

00:16:44.012 --> 00:16:45.833 with nine Randomizations.

NOTE Confidence: 0.938072971111111

00:16:45.840 --> 00:16:47.235 We're very grateful to you

NOTE Confidence: 0.938072971111111

00:16:47.235 --> 00:16:48.630 for all of your work.

NOTE Confidence: 0.938072971111111

00:16:48.630 --> 00:16:52.228 You also have Hartford and Staten Island,

NOTE Confidence: 0.938072971111111

00:16:52.230 --> 00:16:54.498 and we are grateful for those sites as well.

NOTE Confidence: 0.832736184615384

00:16:56.670 --> 00:16:59.470 And then just looking at by RCC

NOTE Confidence: 0.832736184615384

00:16:59.470 --> 00:17:02.356 and you see that some are CC's

NOTE Confidence: 0.832736184615384

00:17:02.356 --> 00:17:03.860 are just going gangbusters.

NOTE Confidence: 0.832736184615384

00:17:03.860 --> 00:17:06.086 Some are not participating in sleep

NOTE Confidence: 0.832736184615384

00:17:06.086 --> 00:17:08.469 smart that is very few of them.

NOTE Confidence: 0.832736184615384

00:17:08.470 --> 00:17:11.606 And then I've outlined Yale doing very

NOTE Confidence: 0.832736184615384

00:17:11.606 --> 00:17:14.108 well here somewhere in the middle.

NOTE Confidence: 0.947449361111111

00:17:16.200 --> 00:17:18.162 And so I thank you very much for again,

NOTE Confidence: 0.947449361111111

00:17:18.170 --> 00:17:22.160 the invitation and for your attention.

NOTE Confidence: 0.947449361111111

00:17:22.160 --> 00:17:24.392 And again, Ron is is available to answer

NOTE Confidence: 0.947449361111111

00:17:24.392 --> 00:17:26.448 any difficult question that that you have.

NOTE Confidence: 0.913296061428572

00:17:29.890 --> 00:17:31.689 Thank you very much for that Devin.

NOTE Confidence: 0.913296061428572

00:17:31.690 --> 00:17:35.044 Uhm, I just had a question

NOTE Confidence: 0.913296061428572

00:17:35.044 --> 00:17:37.280 about a trial powering.

NOTE Confidence: 0.913296061428572

00:17:37.280 --> 00:17:39.020 Whether it was parked for both

NOTE Confidence: 0.913296061428572

00:17:39.020 --> 00:17:40.180 the cardiovascular events as

NOTE Confidence: 0.913296061428572

00:17:40.233 --> 00:17:41.708 well as the recovery outcomes.

NOTE Confidence: 0.889589715

00:17:43.480 --> 00:17:44.620 Yeah, no, that's a good question.

NOTE Confidence: 0.889589715

00:17:44.620 --> 00:17:47.588 So we did look at power calculations

NOTE Confidence: 0.889589715

00:17:47.588 --> 00:17:50.924 for both and we anticipate that a

NOTE Confidence: 0.889589715

00:17:50.924 --> 00:17:53.882 certain percentage of the total will

NOTE Confidence: 0.889589715

00:17:53.978 --> 00:17:57.266 be available for the recovery outcome.

NOTE Confidence: 0.889589715

00:17:57.270 --> 00:17:59.791 And it turns out that we are we have a

NOTE Confidence: 0.889589715

00:17:59.791 --> 00:18:01.513 higher proportion than we had anticipated,

NOTE Confidence: 0.889589715

00:18:01.520 --> 00:18:03.584 so we we think that those two are

NOTE Confidence: 0.889589715

00:18:03.584 --> 00:18:05.937 kind of going to ride along together

NOTE Confidence: 0.889589715

00:18:05.940 --> 00:18:07.836 and that by the end we should have

NOTE Confidence: 0.889589715

00:18:07.836 --> 00:18:09.469 a sufficient number in both groups.

NOTE Confidence: 0.87751888375

00:18:10.870 --> 00:18:13.210 Fantastic in such an innovative

NOTE Confidence: 0.87751888375

00:18:13.210 --> 00:18:15.160 innovative trial design. Thank you.

NOTE Confidence: 0.742469017142857

00:18:23.540 --> 00:18:25.920 Alright, I think those are the questions.

NOTE Confidence: 0.742469017142857

00:18:25.920 --> 00:18:26.998 Well, thank you so much for joy.