Oplæg - Fagforskningsdag 25/4-24

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Lungemedicinsk Forskningsenhed, Medicinsk Afdeling, Vejle Sygehus – En del af Sygehus Lillebælt

Telephone follow-up as a substitute for standard out-clinic follow-up in CPAP therapy for obstructive sleep apnea patients: A randomized controlled trial

- Sov trygt med Telemedicin – En undersøgelse af obstruktiv søvnapnø patienters adherence af CPAP-behandling ved brug af telemedicinsk kontrol: Et randomiseret kontrolleret studie

Præsentation af resultater fra forskningsprojekt udført i Søvnambulatoriet, Vejle Sygehus

Agenda

- Kort om mig

- Søvnapnø behandling

- Telemedicin

- Projektets formål

- Projektets opbygning

- Projektets resultater

- Det større perspektiv
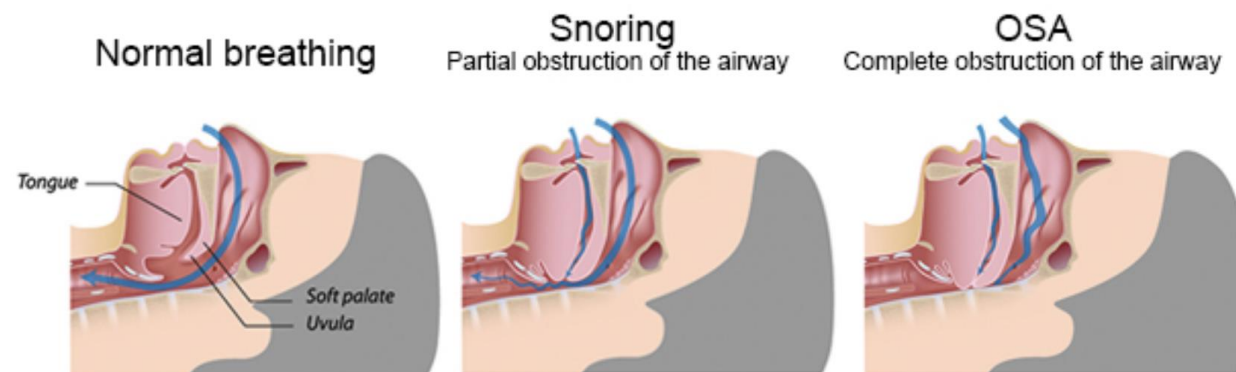
- Bornholms sundheds- og sygeplejeskole 2016-2020

- Medicinsk sengeafsnit, Vejle Sygehus 2020

- Akut Visitationsafsnit, Vejle Sygehus 2020-2022

- Den sundhedsfaglige kandidat, SDU 2021-2023

- Medicinsk Afdeling og Psykiatrisk Afdeling 2023 – Forskningssygeplejerske

- Lungemedicinsk Forskningsenhed, Medicinsk Afdeling dec. 2023 - Ph.d.-studerende

Hvad er søvnapnø?

Obstruktiv søvnapnø er når personen holder vejrtrækningspauser(apnø) under søvn.

- En apnøperiode defineres som en vejrtrækningspause på 10 sekunder eller mere under søvn.

- En hypopnøperiode er en reduktion af vejrtrækningen i 10 sekunder eller længere, hvilket fører til en reduktion i iltmætning på 3% eller mere.

- AHI = apnø-hypopnø-index

- Normal: <5 AHI

- Mild: 5-14 AHI

- Moderat: 15-29 AHI

- Svær: >=30 AHI

Normal breathing

Tongue

Soft palate

Uvula

Snoring
Partial obstruction of the airway

OSA
Complete obstruction of the airway

Stamford Sleep Solutions Dr. Edward Shukovsky. Sleep Loss Health Risks [Internet]. Stamford Sleep Solutions Dr. Edward Shukovsky. 2023 [cited 2023 Apr 3]. Available from: https://www.sleepbetterct.com/health-concerns/

Hvad er søvnapnø?

Prævalens:

- Den estimerede prævalens af symptomatisk OSA bestående af søvnighed i dagtimerne og snorken er 4 % for mænd og 2 % for kvinder i Danmark.

Risikofaktorer:

- Mandligt køn, stigende alder, etnicitet, genetisk disposition, og fedme (ca. 70 % af OSA populationen)
- Forværres af rygning, alkoholforbrug og brug af beroligende medicin

Mortalitet og morbiditet:

- Hjerte-kar-sygdomme, slagtilfælde, type 2-diabetes, depression, kognitiv svækkelse og risikoen for bilulykker under kørslen.
- Der er en højere dødelighedsrisiko, når OSA er ubehandlet.

Guldstandard behandlingen er CPAP

Det anslås, at 30-80 % af OSA-patienterne har utilstrækkelig brug eller helt undlader at følge deres CPAP-behandling, primært på grund af ubehag ved brug af apparatet eller manglende oplevet effekt.

Det generelle accepterede adherence mål er minimum 4 timers brug pr nat i minimum 70 % af en periode over 3 måneder.

Bivirkninger:
Irritation af slimhinder
Tryk på huden fra masken der forårsager sårdannelse
eller hudallergi
Refluks
Hovedpine
Smerter i bihuler og mellemøre.

Ambulatoriebehandling

Udredning

Ikke motiveret for at bruge CPAP apparatet

Føler ikke effekt

Opstart af behandling

Glemmer at møde

Glemmer at melde afbud

Årlig opfølgning

Lang ventetid på opfølgning

I Danmark anslås det, at næsten halvdelen af de patienter, der påbegynder CPAP-behandling, afbryder behandlingen inden for det første år.

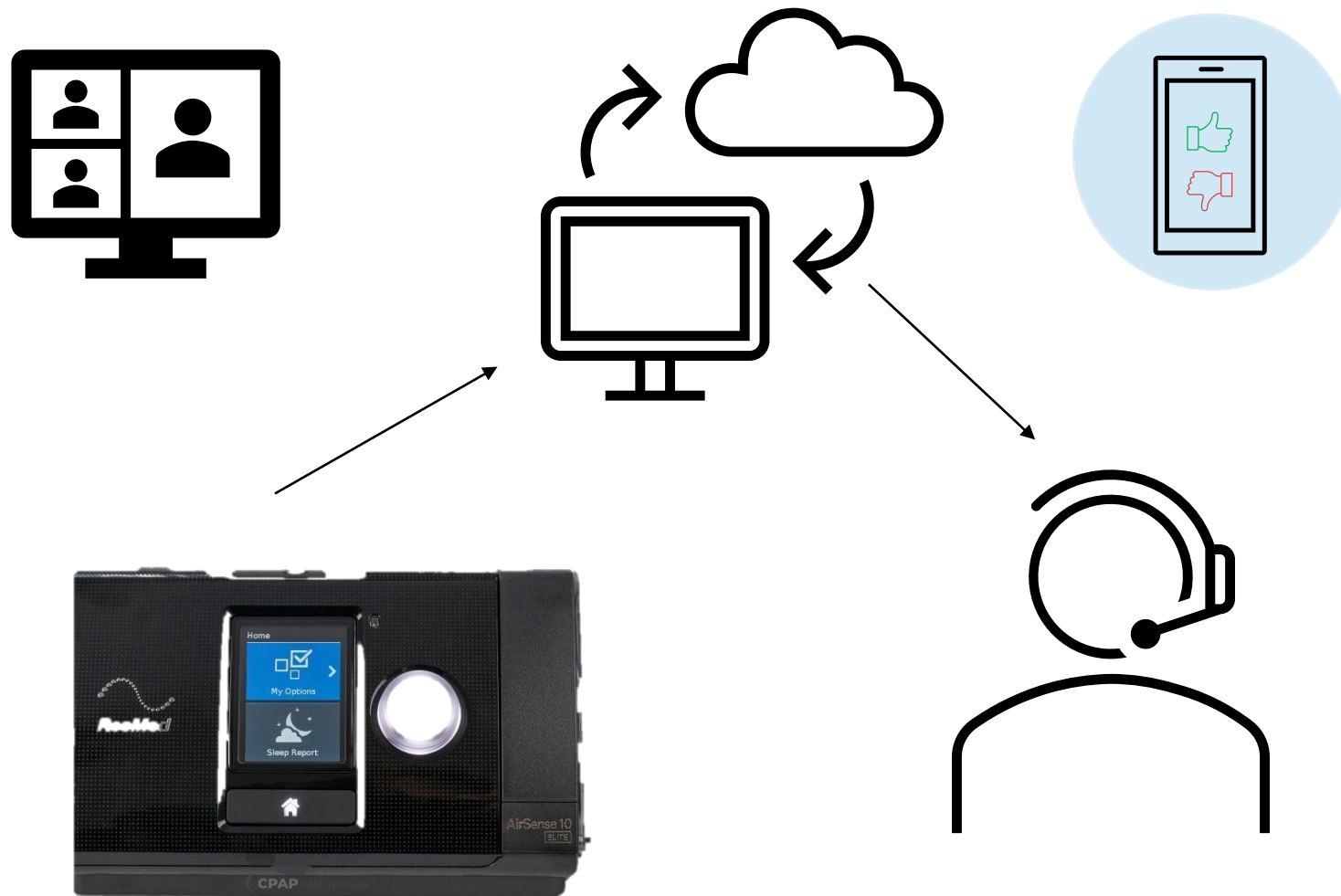Hvordan får vi patienterne til at bruge deres CPAP apparat?

Hvordan mindsker vi presset på ambulatorierne og sikrer større effektivitet i konsultationerne?

Telemedicin

Fra forskningen

- Automatisk feedback mekanisme
- Online e-learning programmer
- Daglige beskeder
- Monitorering med/uden telefonopkald
- Telekonsultationer (video)

Table 1 – Summery of literature on telemedicine solutions for OSA patients starting CPAP therapy

First author, year, country	Study design	Number of participants	Population	Intervention	Follow-up (months)	Main outcomes	Results
Contal et al., 2021 [29], Switzerland	RCT	120 participants. Allocated 1:1	OSA patient	Teleconsultations	3 and 12 months	Mean CPAP use over 12 months.	20 participants stopped CPAP therapy in the UC group compared to 14 in the TC group. There was no difference of CPAP use between the two groups (279 minutes).
Kosky et al., 2022 [30], Australia	Prospective intervention study	Urban: 130. Distant: 56.	OSA patients.	Telemedicine combining video consultations, telephone calls, and telemonitoring.	Trial duration was individual, and follow-up was in the final week of CPAP use.	Mean nightly CPAP use in the final week of the CPAP trial.	There was no difference of CPAP use between the two groups (4,7 hours). In both groups 70 % continued CPAP after the trial.
Nilius et al., 2019 [26], Germany	RCT	Intervention: 38 Control: 37	Stroke patients with AHI >15.	Telemonitoring and phone calls.	6 months	PAP adherence after 6 months in minutes use per day	An average 4.7 phone calls were required to obtain CPAP adherence in the telemedicine group. Adherence was significantly higher in the TC group compared to the SC group.
Hwang et al., 2017 [11], USA	Four-armed, randomized, factorial design clinical trial	1.455 patients randomized 1:1:1:1.	Patients with suspected OSA.	Web-based education programs, or telemonitored automated feedback messaging, or both.	90 days	CPAP usage in 90 days	In patients with OSA, the use of CPAP telemonitoring with automated feedback message increased 90-day adherence. Although telemedicine-based education increased clinic attendance for OSA examination, it did not significantly enhance CPAP adherence.
Turino et al., 2017 [27], Spain	RCT	100 participants randomized	OSA patients	Telemonitoring and teleconsultations when	3 months	The efficacy and cost-effectiveness of telemonitoring for	Telemonitoring did not increase CPAP therapy adherence significantly and decreased patient satisfaction. Nevertheless, it

Contal O, Poncin W, Vaudan S, De Lys A, Takahashi H, Bochet S, Grandin S, Kehrer P, Charbonnier F. One-Year Adherence to Continuous Positive Airway Pressure With Telemonitor- ing in Sleep Apnea Hypopnea Syndrome: A Randomized Controlled Trial. Front Med. 2021 Apr 20;8:626361.

Kosky C, Madeira N, Boulton K, Hunter MT, Ling I, Reynor A, Sturdy G, Walsh J, Dhaliwal S, Singh B, Eastwood PR, McArdle N. Telemedicine compared to standard face-to-face care for continuous positive airway pressure treatment: real-world Australian experience. Sleep. 2022 Oct 10;45(10):zsac157.

Nilius G, Schroeder M, Domanski U, Tietze A, Schäfer T, Franke KJ. Telemedicine Improves Continuous Positive Airway Pressure Adherence in Stroke Patients with Obstructive Sleep Apnea in a Randomized Trial. Respiration. 2019;98(5):410–20.

Hwang D, Chang JW, Benjafield AV, Crocker ME, Kelly C, Becker KA, Kim JB, Woodrum RR, Liang J, Derose SF. Effect of Telemedicine Education and Telemonitoring on Con- tinuous Positive Airway Pressure Adherence. The Tele-OSA Randomized Trial. Am J Respir Crit Care Med. 2018 Jan 1;197(1):117–26.

Turino C, de Batlle J, Woehrle H, Mayoral A, Castro-Grattoni AL, Gómez S, Dalmases M, Sánchez-de-la-Torre M, Barbé F. Management of continuous positive airway pressure treatment compliance using telemonitoring in obstructive sleep apnoea. Eur Respir J. 2017 Feb;49(2):1601128.

Tabel lånt fra eget kandidatspeciale

Region Syddanmark

Sygehus Lillebælt
Syddansk Universitetshospital

				nonadherent to treatment.		improving CPAP adherence.	was less expensive than standard follow-up.
Munafo et al., 2016 [1], USA	Non-blinded, multi-center, prospective study	140 participants randomized 1:1	OSA patients	Telemonitoring.	90 days	CPAP adherence after 90 days.	The difference of CPAP use between the two groups was non-significant. The telehealth group had 83 % daily (5.1 hours) adherence whereas the standard of care group had 73 % (4.7 hours).
Kotzian et al., 2019 [25], Austria	RCT	33 participants Standard: 16 Telemedicine: 17	Stroke patients with OSA	Telemedicine monitoring.	3 months and 12 months	PAP adherence after three months and 12 months (min of use per day)	Telemonitored patients used the PAP machine for 76 minutes longer each night after three months, which were a significant difference. However, after one year, there was no significant difference.
Fox et al., 2012 [28], Canada	RCT	75 participants Standard: 36 Telemedicine: 39	OSA patients	Telemonitoring and phone calls	3 months	PAP adherence after three months (min used per day)	Telemedicine monitoring improved PAP adherence at 3 months with 87 minutes, significantly.
Tamisier et al., 2020 [31], France	RCT	206 participants Standard: 104 Telemonitoring (TM): 102	OSA patients	Telemonitoring.	6 months	CPAP adherence (hours per night).	CPAP adherence was similar in both groups. In the TM group 64 % reached 4 hours of CPAP vs. 72 % in the standard group. The difference was nonsignificant. The TM group had an average of 4.73 h usage per night vs an average of 5.08 h usage per night in the standard group.

Munafo D, Hevener W, Crocker M, Willes L, Sridasome S, Muhsin M. A telehealth program for CPAP adherence reduces labor and yields similar adherence and efficacy when compared to standard of care. Sleep Breath. 2016 May;20(2):777–85.

Kotzian ST, Saletu MT, Schwarzinger A, Haider S, Spatt J, Kranz G, Saletu B. Proac- tive telemedicine monitoring of sleep apnea treatment improves adherence in people with stroke– a randomized controlled trial (HOPES study). Sleep Medicine. 2019 Dec;64:48–55.

Fox N, Hirsch-Allen A, Goodfellow E, Wenner J, Fleetham J, Ryan CF, Kwiatkowska M, Ayas NT. The Impact of a Telemedicine Monitoring System on Positive Airway Pressure Adher- ence in Patients with Obstructive Sleep Apnea: A Randomized Controlled Trial. Sleep. 2012 Apr;35(4):477–81.

Tamisier R, Treptow E, Joyeux-Faure M, Levy P, Sapene M, Benmerad M, Bailly S, Grillet Y, Stach B, Muir JF, Pegliasco H, Pépin JL. Impact of a Multimodal Telemonitoring Inter- vention on CPAP Adherence in Symptomatic OSA and Low Cardiovascular Risk. Chest. 2020 Nov;158(5):2136–45.

Tabel lånt fra eget kandidatspeciale

Studiet undersøger om telefonkonsultationer kan bruges som substitut for ambulatoriekonsultationer uden at påvirke adherence til CPAP-behandlingen.

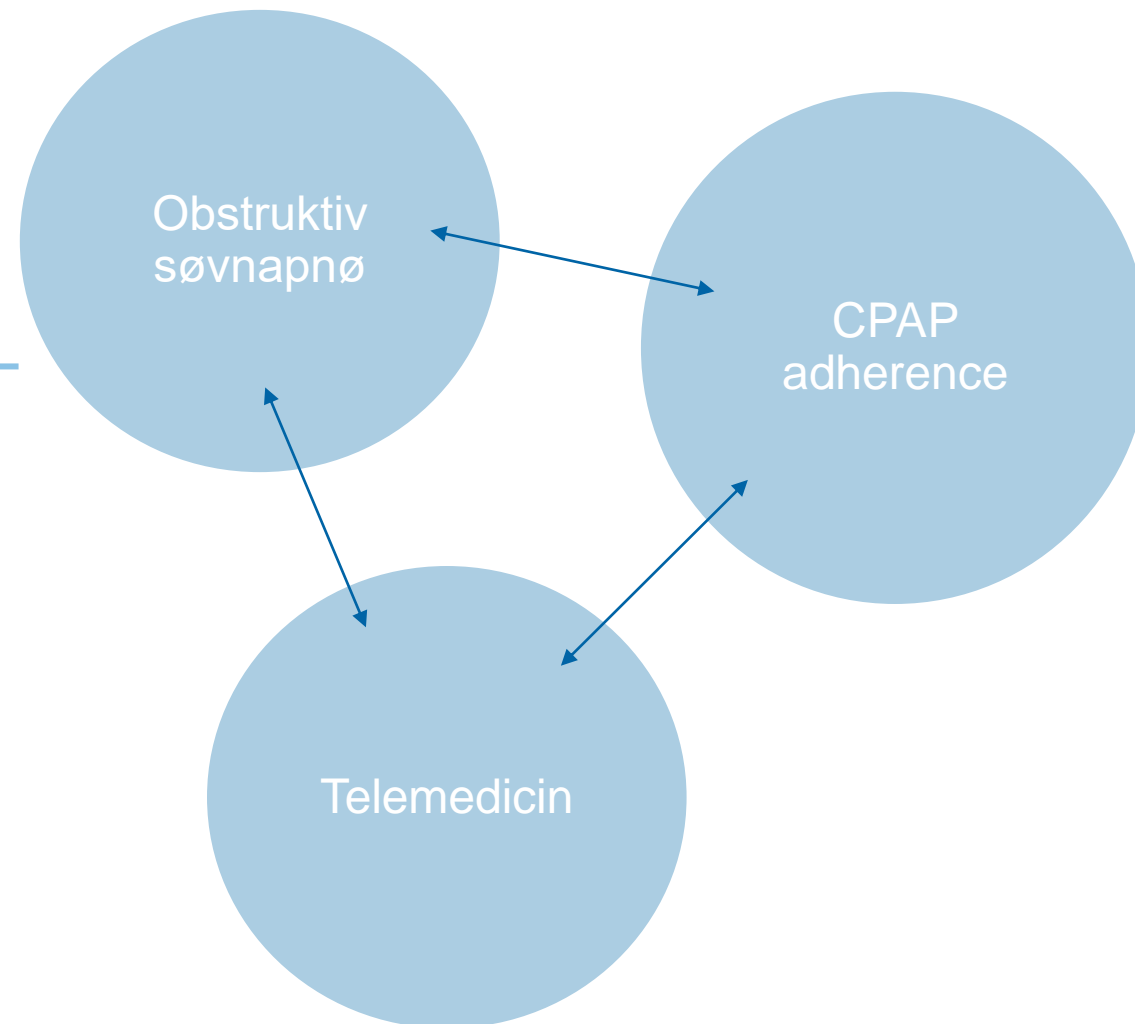*Assess the feasibility of Telephone Follow-Up Consultations (TC) as alternatives to Standard Out-Clinic Follow-Up Consultations (SC) without compromising CPAP Adherence.*

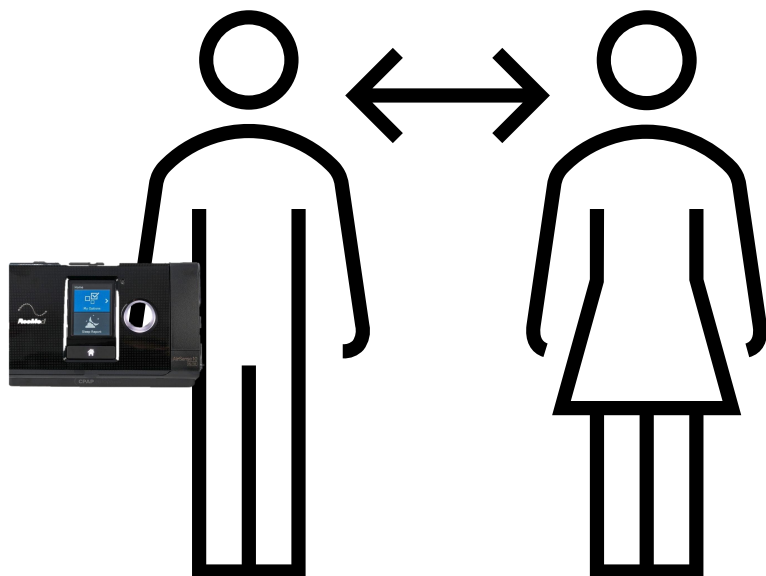FORKORTELSER

Telefon konsultation **(TC)**
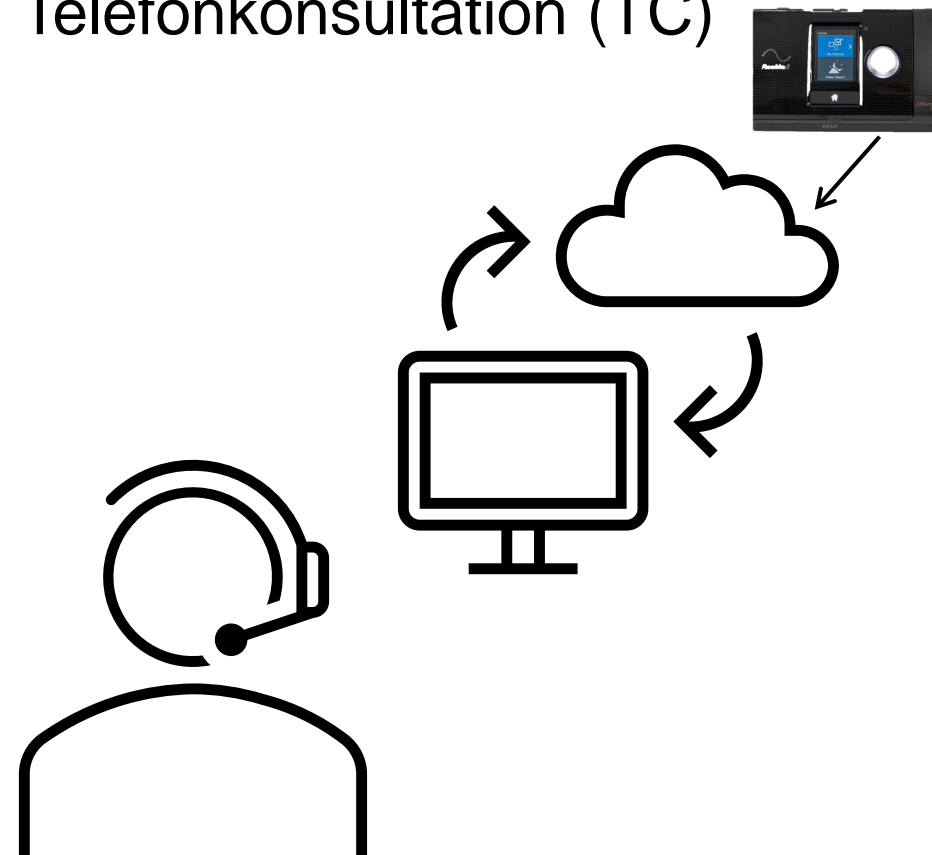
Standard ambulatorie konsultation **(SC)**

Obstruktiv søvnapnø

CPAP adherence

Telemedicin

Standard ambulatoriekonsultation (SC)

Telefonkonsultation (TC)

Follow-up periode: 1 måned og 12 måneder

Enkelt-center, prospektivt, assessorblindet, randomiseret (1:1) kontrolleret studie, initieret og udført hos Søvnambulatoriet, Vejle Sygehus.
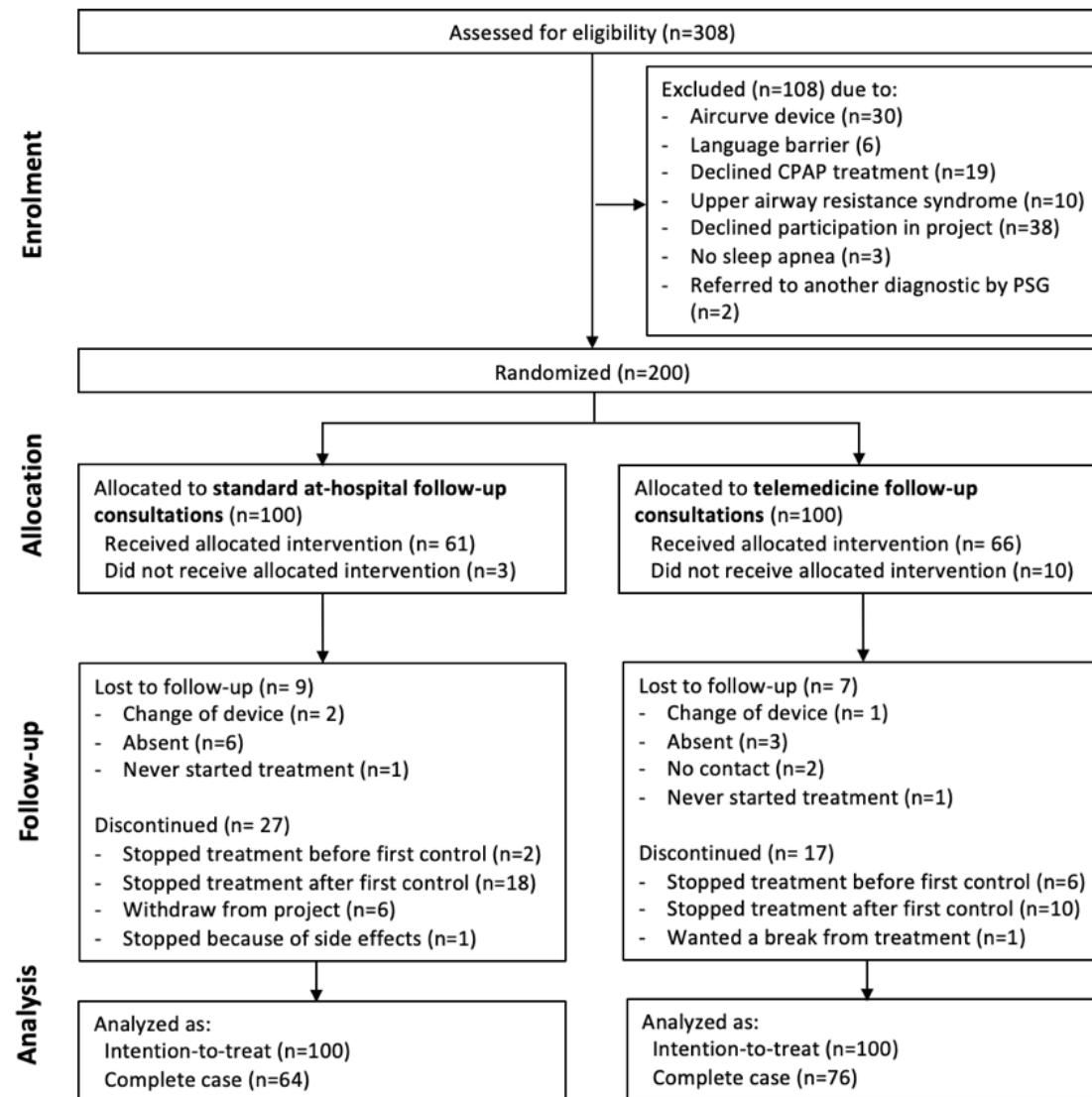
Inklusion i perioden Nov. 2018 – Aug. 2019

Inklusionskriterier:

- OSA (ICD-10 kode Dg47.32)
- Min. 18 år
- Opstarter CPAP behandling

Eksklusionskriterier:

- Kronisk obstruktiv lungesygdom
- Behov for Aircurve maskine
- UARS
- LTNIV
- Forstår og snakker ikke dansk

Enrolment

Assessed for eligibility (n=308)

Excluded (n=108) due to:
- Aircurve device (n=30)
- Language barrier (6)
- Declined CPAP treatment (n=19)
- Upper airway resistance syndrome (n=10)
- Declined participation in project (n=38)
- No sleep apnea (n=3)
- Referred to another diagnostic by PSG (n=2)

Randomized (n=200)

Allocation

Allocated to **standard at-hospital follow-up consultations** (n=100)
 Received allocated intervention (n= 61)
 Did not receive allocated intervention (n=3)

Allocated to **telemedicine follow-up consultations** (n=100)
 Received allocated intervention (n= 66)
 Did not receive allocated intervention (n=10)

Follow-up

Lost to follow-up (n= 9)
- Change of device (n= 2)
- Absent (n=6)
- Never started treatment (n=1)

Discontinued (n= 27)
- Stopped treatment before first control (n=2)
- Stopped treatment after first control (n=18)
- Withdraw from project (n=6)
- Stopped because of side effects (n=1)

Lost to follow-up (n= 7)
- Change of device (n= 1)
- Absent (n=3)
- No contact (n=2)
- Never started treatment (n=1)

Discontinued (n= 17)
- Stopped treatment before first control (n=6)
- Stopped treatment after first control (n=10)
- Wanted a break from treatment (n=1)

Analysis

Analyzed as:
 Intention-to-treat (n=100)
 Complete case (n=64)

Analyzed as:
 Intention-to-treat (n=100)
 Complete case (n=76)

Baseline karakteristik

Table 1 Baseline demographics and sleep data for participants allocated to TC or SC, and for participants in the TC or SC group in the complete case <u>analysis</u>

	Allocated to treatment population		Complete case population	Population der gennemførte studiet
	SC	TC	SC	TC
n (%)	100 (50.0)	100 (50.0)	64 (45.7)	76 (54.3)
Sex (female)	28 (28)	25 (25.0)	16 (25.0)	17 (22.4)
Age (years)	56.1 (12.4)	54.4 (12.2)	57.7 (12.3)	54.9 (11.8)
BMI (kg/m^2)	31.7 (5.2)	31.6 (5.6)	32.3 (5.3)	31.6 (5.6)
Distance to hospital (km)	27 (20 – 38)	27 (14 – 36)	28 (23 – 43)	25 (13 – 36)
Missing	1 (0.5)	1 (0.5)	1 (1.6)	0 (0)
AHI (events/hours)	32.5 (19.5 – 43)	25 (15 – 44.5)	34.5 (29 – 48)	31 (19 – 51)
ESS score	9.0 (4 – 12)	9.0 (5 – 13)	9.0 (5.5 – 12)	9.0 (5 – 12)
Missing	0 (0)	1(1)	0 (0)	1 (1.3)

Continuous variables are mean (SD) or median (25th-75th percentiles), categorical variables and missing are n (%)

Abbreviation: SC (standard out-clinic follow-up consultation); TC (telephone follow-up consultation); AHI (apnea-hypopnea-index); ESS (Epworth sleepiness scale).

KAN TELEFONKONSULTATIONER SUBSTITUERE AMBULATORIEKONSULTATION UDEN AT PÅVIRKE ADHERENCE TIL CPAP BEHANDLING?

Minimumskrav for adherence nået? – Ja/nej

Table 2 Odds Ratio and 95% confidence interval for obtaining adherence goal[a] over 12 months in the intention-to-treat analysis

	SC (n=100)	TC (n=100)	Crude OR (95 % CI)	P-value	Adjusted[b] OR (95 % CI)	P-value
Adherence goal (%)[c]	36 (36)	30 (30)	0.76 (0.42 – 1.38)	0.38	0.84 (0.45 – 1.58)	0.59
Adherence goal (min)	47 (47)[d]	46 (46)	0.96 (0.55 – 1.67)	0.89	1.08 (0.59 – 1.96)	0.81

Numbers are n (%)

[a] Adherence goal measured as ≥4 hours of CPAP use in 70 % of 365 days.

[b] Adjusted for sex, age, baseline ESS, BMI, baseline AHI, distance from home to hospital in kilometers

[c] Days of adherence goal obtained in percentage

[d] One value missing in the SC group for minutes (total n=99)

Abbreviations: SC (standard out clinic follow-up consultation); TC (telephone follow-up consultation); CI (confidence interval)

Ingen signifikant forskel

* Loss to follow-up og dropouts er defineret som non-adherent

Resultater – primært outcome for subpopulation

Table 3 Median difference and 95% confidence interval for CPAP use over 12 months in the complete case analysis

	SC (n=64)[a]	TC (n=76)	Crude median difference (95 % CI)	P-value	Adjusted[b] median difference (95 % CI)	P-value
CPAP use (%)[c]	77.5 (29.5 – 93)	53 (11 – 87.4)	-25.0 (-49.4 – -0.6)	0.045	-21.96 (-43.76 – -0.15)	0.048
CPAP use (min)	324 (131 – 402)	235 (52 – 374.5)	-89.0 (-187.7 – 9.7)	0.077	-107.7 (-193.2 – -22.1)	0.014

Numbers are median (25th-75th percentiles)

[a]One value missing in the SC group for minutes (total n=63)

[b] Adjusted for sex, age, baseline ESS, BMI, baseline AHI, distance from home to hospital in km

[c] Days of adherence goal obtained in percentage

Abbreviations: SC (standard out-clinic follow-up consultation); TC (telephone follow-up consultation); CI (confidence interval)

Table 3 Median difference and 95% confidence interval for CPAP use over 12 months in the complete case analysis

	SC	TC (n=76)	Crude median difference (95 % CI)	P-value	Adjusted[b] median difference (95 % CI)	P-value
CPAP use (%)[c]	77.5 (29...		-25.0 (-49.4 – -0.6)	0.045	-21.96 (-43.76 – -0.15)	0.048
CPAP use (min)	324 (131 – 402)	235 (52 – 37...		0.077	-107.7 (-193.2 – -22.1)	0.014

Numbers are median (25th-75th percentiles)

[a]One value missing in the SC group for minutes (total n=63)

[b] Adjusted for sex, age, baseline ESS, BMI, baseline AHI, distance from home to hospital...

[c] Days of adherence goal obtained in percentage

Abbreviations: SC (standard out-clinic follow-up consultation); TC (telephone follow-up consultation); CI (confidence interval)

HVAD FORTÆLLER DET OS?

> ➢ Forskel mellem antallet af dropouts og loss to follow-up mellem TC og SC = højere compliance til den ambulante opfølgning i TC

Table 3 Median difference and 95% confidence interval for CPAP use over 12 months in the complete case analysis

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Numbers are median (25th-75th percentiles)

[a] One value missing in the SC

[b] Adjusted for sex, age, baseli...

[c] Days of adherence goal obtained in percentage

Abbreviations: SC (standard out-clinic follow-up consultation); TC (telephone follow-up consultation); CI (confidence interval)

Vær OBS på skævhed i populationen og husk at indtænke ydre faktorer til diskussionen

Fx COVID-19 og motivation for at melde afbud til årskontrollen, grupperne imellem

ER DER FORSKEL MELLEM DEM SOM ER DROPPET UD OG DEM SOM HAR GENNEMFØRT STUDIET?

Table 5 Influence of age and distance to hospital on the dropout rate

	Complete case	Dropped out	Median difference (95 % CI)	P-value
n (%)	140 (70.0)	60 (30.0)		
SC group	64 (64)	36 (36)		
TC group	76 (76)	24 (24)		
Age	56.5 (48 – 64.5)	54.5 (44 – 61.5)	-2.0 (-6.44 – 2.44)	0.38
SC group	59 (50 – 65.5)	54 (44 – 61.5)	-5.0 (-11.28 – 1.28)	0.12
TC group	54.5 (47 – 62)	55 (44 – 61.5)	0.0 (-7.19 – 7.19)	0.99
Distance to hospital (km)	27 (18 – 37)	27 (15 – 34)	0.0 (-5.38 – 5.38)	0.99
SC group	28 (23 – 43)	25.5 (14 – 33.5)	-3.00 (-10.58 – 4.58)	0.43
TC group	25 (13 – 36)	29 (15 – 38)	4.00 (-6.59 – 14.59)	0.46

Numbers are n (%) and median (25th-75th percentiles)

Abbreviations: km (kilometers); CI (confidence interval); SC (standard out-clinic follow-up consultation); TC (telephone follow-up consultation)

Resultater – Bortfalds analyse

Supplementary document 1 Dropout analysis presenting baseline demographics and sleep data for participants who completed the study and dropped out during the study

	Completed study	Dropped out	P-value
n (%)	140 (70.0)	60 (30.0)	
Groups			0.064
SC group	64 (32)	36 (18)	
TC group	76 (38)	24 (12)	
Sex			0.152
Male	107 (76.4)	40 (66.7)	
Female	33 (23.6)	20 (33.3)	
Age	56.2 (12.1)	53.1 (12.6)	0.103
BMI	31.92 (5.45)	31.03 (5.17)	0.287
Distance to hospital (km)	27 (18-37)	27 (15-34)	0.515
Missing	1 (0.7)	1 (1.67)	
Baseline AHI	33 (21-49.5)	18.5 (13.5-33.5)	<0.001
Baseline ESS	9 (5-12)	8 (4-12)	0.45
Missing	1 (0.5)	0 (0)	

Categorical variables are n (%) and continuous variable are mean (SD) for parametric data and median (25th-75th percentiles) for non-parametric data.

Abbreviation: SC (standard out-clinic follow-up consultation); TC (telephone follow-up consultation); OSA (obstructive sleep apnea); AHI (apnea-hypopnea-index); ESS (Epworth sleepiness scale).
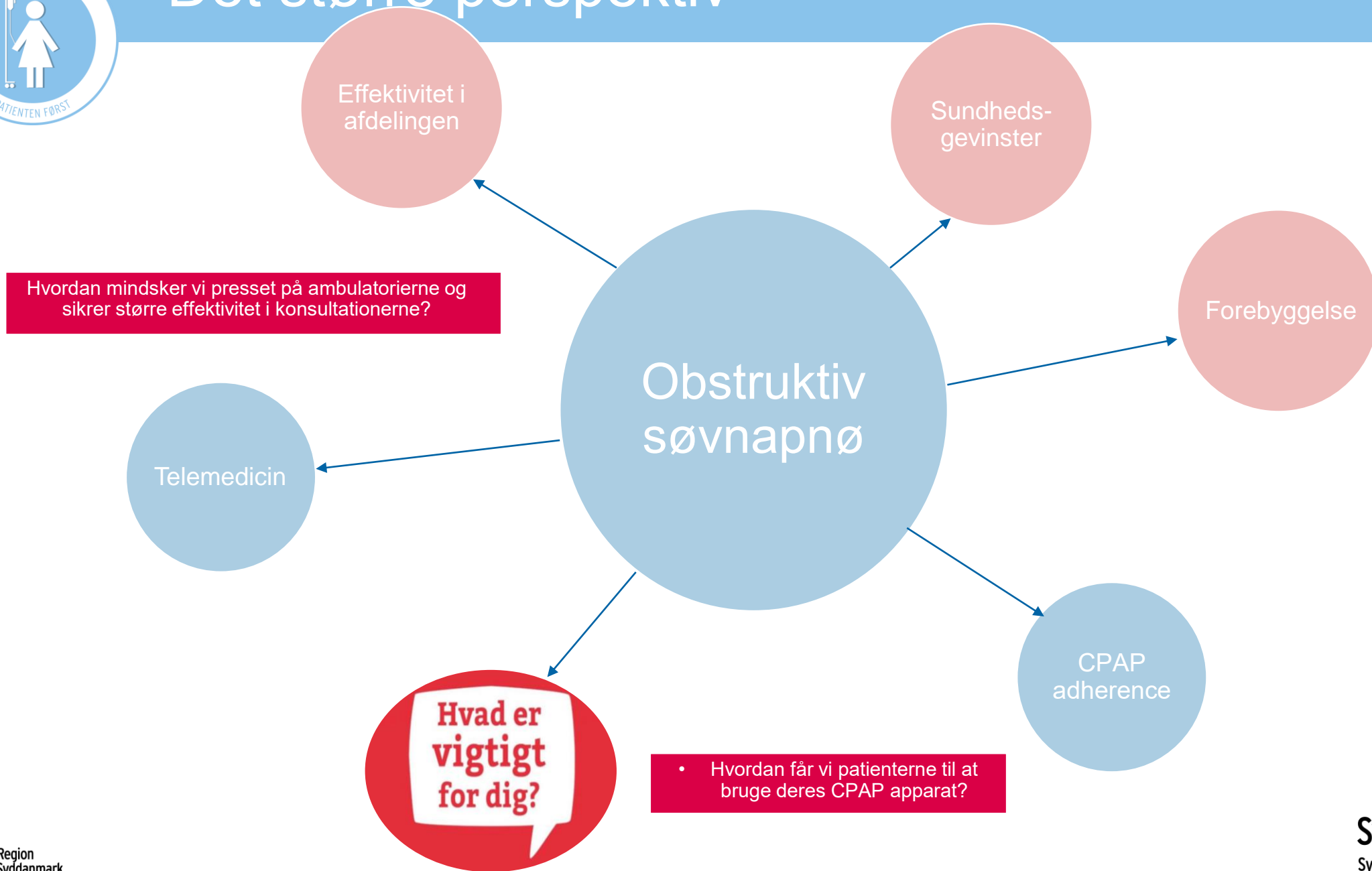
- Studiet viste, at TC ikke havde nogen signifikant effekt på adherence til CPAP-behandling sammenlignet med SC, og at TC derfor til en vis grad kan betragtes som et alternativ til ambulatorie konsultationer.

- Vi fandt en højere compliance-rate for opfølgende konsultationer blandt deltagerne i TC-gruppen. Det tyder på, at man ved at erstatte SC med TC kan fastholde patienterne i ambulatorierne, hvilket kan danne grundlag for at tilbyde yderligere interventioner til patienterne, som understøtter en bedre overholdelse af CPAP-behandlingen.

- Desuden var den eneste påvirkende faktor, der blev fundet, en højere baseline AHI blandt deltagere, der gennemførte undersøgelsen sammenlignet med dropouts, hvilket indikerer, at en høj AHI kan øge sandsynligheden for, at patienten overholder behandlingen.

Spørgsmål?