The effect of parental group sleep education in young children with Down syndrome: The REST-Ed study

RESTED STUDY REPORT

Full title of study:	The effect of parental group sleep education in young children with Down syndrome: the REST-Ed Study.
IRAS ID:	227772
Name of main REC:	East of Scotland Research Ethics Committee
REC reference number:	19/ES/0058
Date of favourable ethical opinion:	25 July 2019
ISRCTN	ISRCTN65197569 https://doi.org/10.1186/ISRCTN65197569
Sponsor:	NHS Lothian

LEGEND

AHI – Apnoe/Hypopnoea Index

CAHI – Central Apnoea/Hypopnoea Index

CAI – Central Apnoea Index

OAHI – Obstructive Apnoea/Hypopnoea Index

ODI – Oxygen desaturation index

OSA – Obstructive Sleep Apnoea

SpO2 – Oxygen saturations

RESTED STUDY TEAM

CI – Dr Florian Gahleitner
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PARTICIPANT FLOW

Notes of Interest	Consented for study	Completed screening sleep study	Eligible to continue post sleep study	Randomization	Completion of study
52	16 (31%)	13/16 (81%)[1]	10/13 (77%)[2]	7/10 (70%)[3]	7/7 (100%)
		[1] Two (2) participants awaiting sleep study at time when decision taken to close trial early	[2] One (1) participant unable to tolerate sleep study equipment, agreed to withdraw from study	[3] One (1) participant no longer contactable	
		[1] One (1) participant not contactable to arrange sleep study post consent	[2] One (1) participant diagnosed with severe obstructive sleep apnoea (exclusion criterion)	[3] Two (2) participants did not proceed due to decision taken to close trial early	
			[2] One (1) participant had low baseline SpO2 of 89% and awaiting surgery		

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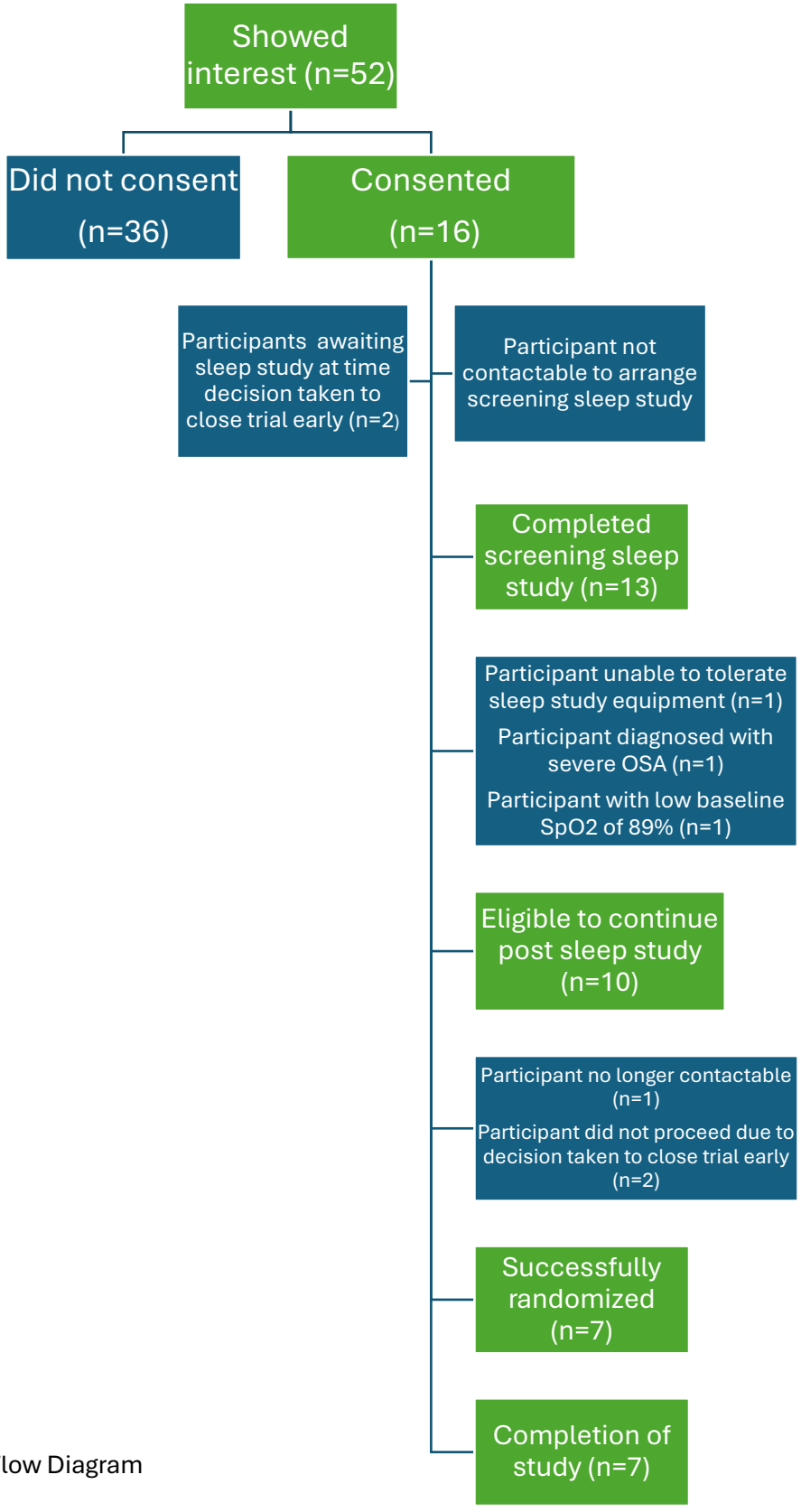


Fig.1. Flow Diagram

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BASELINE CHARACTERISTICS

DEMOGRAPHICS OF PARTICIPANTS HAVING SCREENING SLEEP STUDY

PARTICIPANT	GENDER	AGE (months)[1]
1	M	11
2	F	52
3	M	15
4	M	29
5	M	19
6	M	8
7	F	22
8	M	8
9	M	68
10	M	39
11	F	13
12	M	23
13	M	47

[1] age at time of sleep study

Total number of participants: 13

Gender: 10 male / 3 female

Median age 22 months (8 – 68 months)

OUTCOME MEASURES

Summary of sleep study / results

	Normal study	Abnormal study	AHI	OAHI	CAHI	Mean SpO2	Min SpO2	ODI
1	1	0	0.4	0	0.4	97	92	1
2	1	0	0	0	0	96	92	0.4
3	1	0	1.8	0.3	1.5	94	84	3.6
4	1	0	1.3	0	1.3	96	88	1.4
5	1	0	0.9	0.8	0.2	98	93	0.9
6	0	1*	8.3	**2**	6.3	96	86	11.6
7	1	0	0.6	0.1	0.4	98	93	0.7
8	1	0	0.7	0.6	0.1	98	91	1.1
9	1	0	0.7	0.2	0.4	97	89	1.2
10	unable to tolerate sleep study equipment							
11	0	1	3.2	**1.8**	1.4	98	90	2
12	0	1	13.7	**13.6**	0.1	95	77	17.8
13	0	1	1.1	0	1.1	**89**	83	1.1

* raised total AHI but CAI at upper limit of normal and patient was able to be included

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Median AHI = 1

Median OAHI = 0.25

Median CAHI = 0.4

Median baseline SpO2 = 96.5%

Median minimum SpO2 = 89.5%

Abnormal sleep studies:

Mild OSA (n=2) – Of note, mild OSA was no contraindication for proceeding with trial

Moderate OSA (n=0)

Severe OSA (n=1)

Low baseline SpO2 (n=1)

Participants 1-7 completed the trial

Participants 8-13 did not complete the trial

Participant	Reason for not completing the study
8	Participant did not proceed due to decision taken to close trial early
9	Participant did not proceed due to decision taken to close trial early
10	Participant was unable to tolerate sleep study equipment
11	Participant no longer contactable
12	Participant diagnosed with severe OSA (exclusion criterion)
13	Participant with low baseline SpO2 of 89%

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Summary of actigraphy / results

Participants eligible for being enrolled and randomized post sleep study, underwent actigraphy at baseline, and 4 weeks, 6 months and 12 months post intervention/control.

Participant 1	Baseline	4 weeks post	6mths post	12mths post
Sleep onset time	19:50	20:06	20:08	20:26
Sleep latency hr:min	Not available	Not available	Not available	Not available
Total sleep time hr:min	09:07	09:00	09:04	08:59
Wake after sleep onset hr:min	02:01	01:45	01:59	00:55
Sleep efficiency%	81.7	83.8	80.9	90.7
Age	1Years,2Months	1Years,3Months	1Years,8Months	2Years,2Months

Participant 2	Baseline	4 weeks post	6mths post	12mths post
Sleep onset time	19:59	19:54	20:06	19:57
Sleep latency hr:min	Not available	00:16	00:12	Not available
Total sleep time hr:min	09:14	08:38	08:26	08:10
Wake after sleep onset hr:min	01:24	01:35	02:08	02:09
Sleep efficiency%	85.2	82.3	78.2	78.6
Age	4Years,6Months	4Years,8Months	5Years,3Months	5Years,7Months

Participant 3*	Baseline	4 weeks post	6mths post	12mths post
Sleep onset time	19:38	19:28	19:13	19:12
Sleep latency hr:min	Not available	00:15	Not available	Not available
Total sleep time hr:min	07:00	07:41	07:12	07:02
Wake after sleep onset hr:min	03:25	03:14	02:51	02:54
Sleep efficiency%	67.4	68.8	71.6	70.7
Age	1Years,6Months	1Years,8Months	2Years,1Months	2Years,7Months

Participant 4*	Baseline	4 weeks post	6mths post	12mths post
Sleep onset time	19:04	19:16	19:13	19:09
Sleep latency hr:min	00:02	Not available	00:04	00:08
Total sleep time hr:min	08:59	08:32	08:16	08:31
Wake after sleep onset hr:min	02:12	02:03	02:27	02:21
Sleep efficiency%	79.9	80.2	76.5	77.3
Age	2Years,7Months	2Years,9Months	3Years,2Months	3Years,8Months

Participant 5	Baseline	4 weeks post	6mths post	12mths post
Sleep onset time	21:23	21:16	21:01	21:24
Sleep latency hr:min	00:15	00:07	00:31	00:28
Total sleep time hr:min	06:14	06:44	06:48	06:47
Wake after sleep onset hr:min	03:07	02:44	02:45	02:46
Sleep efficiency%	64.9	70.2	67.5	67.4
Age	1Years,10Months	1Years,11Months	2Years,4Months	2Years,11Months

Participant 6	Baseline	4 weeks post	6mths post	12mths post
Sleep onset time	21:22	21:16	21:07	19:43
Sleep latency hr:min	00:30	00:32	00:42	00:16
Total sleep time hr:min	07:13	07:17	06:50	07:30
Wake after sleep onset hr:min	03:04	02:48	03:12	02:59
Sleep efficiency%	66.9	68.7	63.6	69.6
Age	0Years,9Months	0Years,11Months	1Years,4Months	1Years,10Months

Participant 7*	Baseline	4 weeks post	6mths post	12mths post
Sleep onset time	20:36	20:50	20:32	20:09
Sleep latency hr:min	00:59	00:36	00:22	00:15
Total sleep time hr:min	07:20	08:03	07:31	08:08
Wake after sleep onset hr:min	02:55	02:59	02:41	02:21
Sleep efficiency%	65.3	69.4	71.3	75.7
Age	2Years,1Months	2Years,2Months	2Years,7Months	3Years,1Months

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Summary narrative of questionnaires / results

As part of the REST-ED Study protocol, participants / parents were asked to complete the following validated questionnaires:

Composite Sleep Disturbance Score (CSDS)

Infant and Toddler Quality of Life Questionnaire (ITQOL SF-47)

Child Behaviour Checklist (CBCL 1 ½-5 years)

Pictorial Epworth Sleepiness Scale (pESS)

Short General Health Questionnaire; GHQ (exploring parental mental health)

Questionnaires were issued at visits 2, 4, 5, and 6.

Questionnaires issued at visits 2, 4, 5 and 6 to all 7 included participants. Data was missing in part, for 3 participants at visit 4, one participant at visit 5 and two participants at visit 6.

The GHQ questionnaire explored parental mental health symptoms. For any participant's parent who scored positively, therefore indicating concern regarding their mental health, the parent was contacted and advised to discuss this with their GP. GHQ follow up occurred at the following frequency: n=2 at visit 2, n=3 at visit 4, n=1 at visit 5 and n=1 at visit 6.

5 of 7 participant parents' scored positively; with two participants parents' scoring positively on two occasions (visits 2 and 4 and 4 and 6 respectively). The highest frequency scoring positively was visit 4 with 3/7.

Parental mental health will continue to be considered in any future research and screened for using validated tools.

Acceptability of online educational program

After each session parents had an opportunity to clarify information and received the appropriate information leaflet online (sleep or AHP input). They were asked how clear the information was for them and there were no concerns expressed by parents verbally. All confirmed they had found the educational presentations clear.

ADVERSE EVENTS

There were no adverse events associated with this study. The study was closed early in view of lack of interest / recruitment.