

Supplementary Material

Exercise and motivational text messaging to support physical activity behaviour change in a population with obstructive sleep apnoea: a feasibility study

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CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	
	2b	Specific objectives or research questions for pilot trial	
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
	4c	How participants were identified and consented	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	
Sample size	7a	Rationale for numbers in the pilot trial	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	
Allocation concealment	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	

Supplementary File S1 contd.

mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the pilot trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
	19a	If relevant, other important unintended consequences	
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	
Protocol	24	Where the pilot trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

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	26	Ethical approval or approval by research review committee, confirmed with reference number	
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Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Supplementary File S2: Physical activity planner *RPE = rate of perceived exertion*

Physical Activity Programme (week 1 - 12) @ Unipol					
1					
2					
3					
4					
5	Participant Details				
6	Age		Cardio Exercises	Time	Effort
7			Brisk walking		RPE =
8	Gender		Rower		RPE =
9			Exercycle/cycling		RPE =
10	Height (cms)		Swimming		RPE =
11					
12	Weight (kgs)				
13			Cardio Exercises (cont)	Time/reps	Effort
14	Waist (cms)		Step ups/stair climbing		RPE =
15			Marching on spot		RPE =
16	Neck (cms)		Sit to stands		
17					
18					
19					
20			Leg Strengthening Exercises	Time/Reps	Load/intensity
21			Squats		
22			Wall sits with ball		
23			Lunges		
24			Heel raises		
25					
26					
27			Arm Strengthening Exercises	Reps	Load/intensity
28			Bicep curls		
29			Wall press ups		
30			Isometric shoulder abduction		
31			Shoulder flexion w/Theraband		
32					
33					

What are your general thoughts about physical activity?

What do you regard as barriers to you doing physical activity?

Can these be overcome? How? If....., then..... (E.g. If the weather is fine, then I will walk to the local shop)

What is your main health concern?

On a scale of 1-10, how likely are you to do more physical activity? (Likert scale)

Given everything else going on in your life, how important is doing this physical activity to you?

Why would you want to do more physical activity/strengthening? (give reasons)

Habits to assist in goal achievement

Goals (SMART)

Supplementary File S3: Confidence intervals

Table S3.1: Within groups results of secondary outcomes (95% confidence intervals) between time points

Outcome measure	T2 – T1 Mean difference (95% CI)			T3 – T1 Mean difference (95% CI)		
	Group EXE (n=10)	Group EXE+TXT (n=10)	Group TXT (n=10)	Group EXE (n=10)	Group EXE+TXT (n=10)	Group TXT (n=10)
PHQ-9*	2.4 (-2.9, 7.7)	-1.9 (-3.6, -0.2)	-2.6 (-4.7, -0.5)	1.0 (-4.0, 6.0)	-2.5 (-4.9, -0.1)	-2.0 (-4.1, 0.2)
FOSQ	0.8 (-0.6, 2.2)	-0.4 (-1.9, 1.2)	0.3 (-1.1, 1.7)	1.1 (-0.6, 2.8)	-0.6 (-2.7, 1.4)	0.6 (-1.7, 2.9)
SF-36 (GH) %	3.0 (-3.4, 9.4)	9.7 (-0.3, 19.7)	2.9 (-3.4, 9.2)	11.3 (-3.5, 26.0)	14.7 (4.6, 24.8)	6.7 (0.4, 12.9)
SEE	5.3 (-7.4, 17.9)	0.1 (-6.1, 6.3)	8.3 (1.3, 15.4)	6.8 (-15.2, 28.7)	6.1 (-1.2, 13.4)	13.1 (2.1, 24.1)
EBBS	-5.5 (-20.2, 9.2)	1.2 (-9.5, 11.9)	2.7 (-5.4, 10.8)	-1.8 (-15.7, 12.2)	7.8 (-3.5, 19.1)	4.3 (-2.9, 11.6)
RM1-FM SoC	0.6 (-0.7, 2.0)	1.2 (0.2, 2.2)	0.6 (-0.1, 1.3)	0.5 (-0.9, 1.9)	1.2 (0.4, 2.0)	1.4 (0.7, 2.2)
Grip strength (L) (kg)	-1.9 (-4.9, 1.0)	3.1 (-3.4, 9.6)	-4.2 (-9.1, 0.8)	-2.9 (-6.9, 1.2)	1.1 (-4.2, 6.4)	-3.3 (-7.3, 0.8)
Grip strength (R) (kg)	-1.8 (-3.4, 0.4)	1.1 (-2.1, 4.3)	-2.0 (-6.3, 2.3)	-2.4 (-5.3, 0.6)	-0.7 (-4.1, 2.6)	-1.9 (-6.6, 2.8)
5XSTS* (seconds)	0.3 (-0.3, 0.9)	-0.7 (-1.5, 0.1)	-0.6 (-1.4, 0.1)	-0.5 (-1.8, 0.7)	-0.6 (-1.5, 0.3)	-0.1 (-2.0, 1.9)
Gait speed (m/s)	0.1 (-0.0, 0.2)	0.3 (-0.1, 0.6)	0.1 (-0.0, 0.2)	0.1 (-0.1, 0.2)	0.3 (-0.1, 0.6)	0.1 (-0.0, 0.2)
6MWD (metres)	42.0 (-5.2, 89.2)	2.9 (-34.3, 40.1)	34.1 (0.4, 67.8)	37.9 (-4.1, 79.7)	30.4 (-1.9, 62.7)	33.7 (-1.4, 68.7)

PHQ-9 = Patient Health Questionnaire; FOSQ = Functional Outcomes of Sleep Questionnaire; SF-36 = Short Form 36; SEE = Self-efficacy for Exercise scale; EBBS = Exercise Benefits/Barriers Scale; RM1-FM SoC = Stage of change questionnaire; 5XSTS = Five times sit-to-stand; 6MWD = six minute walk distance; EXE = exercise group; EXE+TXT = exercise group plus text messaging; TXT = text messaging only group

T1 = baseline; T2 = 12 weeks post-randomisation; T3 = 24 weeks post-randomisation

****Negative values represent an improvement at T2 (12 weeks) or T3 (24 weeks) compared with baseline.***

Table S3.2: Mean 6MWD in metres at baseline and study end point by group

Group	N	Mean	Std Deviation	95% CI
6MWD_baseline Group EXE	10	456.6	98.5	374.2-538.9
6MWD_baseline Group EXE+TXT	10	492.5	81.2	434.4-550.6
6MWD_baseline Group TXT	10	497.7	95.1	429.6-565.7
6MWD_12wk Group EXE	10	498.6	77.2	434.0-563.1
6MWD_12wk Group EXE+TXT	10	495.4	94.5	427.8-563.0
6MWD_12wk Group TXT	10	531.6	108.2	454.4-609.1
6MWD_24wk Group EXE	10	494.4	78.5	428.8-560.0
6MWD_24wk Group EXE+TXT	10	522.9	115.2	440.5-605.3
6MWD_24wk Group TXT	10	517.8	111.8	451.3-611.3

6MWD = six minute walk distance (metres); EXE = exercise group; EXE+TXT = exercise group plus text messaging; TXT = text messaging only group