Universidad Rey Juan Carlos

Rectorado

Dña. Elisabet Huertas Hoyas, secretaria del Comité de Ética de la Investigación de la Universidad Rey Juan Carlos,

CERTIFICA

Que este Comité ha evaluado el proyecto de investigación titulado:

EFECTO DE UN PROGRAMA DE MINDFULNESS EN PACIENTES CON CEFALEA TENSIONAL Y MIGRAÑA CRÓNICAS

Con número de registro interno: 2209202333823

y considera que:

- Se cumplen los requisitos éticos necesarios del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles para sus participantes.

- La capacidad del investigador y los medios disponibles son apropiados para llevar a cabo el estudio.

Por lo que ha decidido emitir un dictamen **FAVORABLE** para la realización de dicho proyecto, cuyo investigador principal es Don **JOSÉ ANGEL DEL BLANCO MUÑIZ**.

Lo que firmó en Móstoles fecha indicada en la firma electrónica.

Firmado: Dña. Elisabet Huertas Hoyas.

- Este informe sólo tiene validez para el proyecto o procedimiento propuesto y en las condiciones en ellos descritas. Cualquier cambio que afecte a las implicaciones éticas y/o de seguridad del mismo y de los participantes, invalida este informe y deberá ser puesto en conocimiento de este Comité de Ética para su valoración.

- El Comité de Ética de la Investigación puede instar a las autoridades autonómicas para que proceda a la suspensión cautelar de la investigación autorizada en los casos en los que no se hayan observado los requisitos que establece la legislación vigente y sea necesaria para proteger los derechos de los ciudadanos.

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CONSORT

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No.	Checklist item	Reported on page No.
Title and abstract	1a	Identification as a randomized trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5 (The original statistical analysis plan specified repeated-measures ANOVA. Following completion of the study, an additional baseline-adjusted ANCOVA was performed in response to a reviewer's recommendation because of a marked baseline imbalance in migraine frequency.)
Participants	4a	Eligibility criteria for participants	5-6
	4b	Settings and locations where the data were collected	6 and 9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome	8-9-10-11

		measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	6
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A — Not Applicable
Randomization: Sequence generation	8a	Method used to generate the random allocation sequence	5-6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6

Section/Topic	Item No.	Checklist item	Reported on page No.
Randomization: Allocation concealment mechanism	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	5-6 (The randomization sequence was generated by an independent researcher and was not accessible to the researcher responsible for participant enrollment. After eligibility confirmation and informed consent, a third independent researcher assigned participants according to the pre-generated sequence. No formal allocation-concealment mechanism was implemented.)
Randomisation: Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	5 (statistician-blinded)
	11b	If relevant, description of the similarity of interventions	N/A — Not Applicable
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11-12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11-12
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12
	13b	For each group, losses and exclusions after randomisation, together with reasons	6
Recruitment	14a	Dates defining the periods of recruitment and follow-up	12
	14b	Why the trial ended or was stopped	12
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1 (Pages 13-14)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 1 (Pages 13-14)
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 2 (Pages 14-15)
	17b	For binary outcomes, presentation of both absolute	N/A

		and relative effect sizes is recommended	
Section/Topic	**Item No.**	**Checklist item**	**Reported on page No.**
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Table 2 (Pages 14-15)
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	14
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17-18-19
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	16-17
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15-16
Other information			
Registration	23	Registration number and name of trial registry	Reported on pages 2, 5, 20
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Reported on page 20

* We strongly recommend reading this statement in conjunction with the CONSORT 2010 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.

SUBJECT	Group (0 = Control; 1 = Intervention	Body Mass	Screen time (hours/da	Vigorous P	Moderate F
1	0	19,56	3	0	0
2	1	23,88	3	0	0
3	1	29,63	13	0	280
4	1	19,03	2	90	90
5	1	22,23	8	0	0
6	1	25,28	3	0	30
7	1	27,22	3	0	0
8	1	27,99	11	0	0
9	1	23,04	10	0	0
10	1	25,56	4	0	0
11	1	18,82	3	0	0
12	0	25,85	10	0	0
13	1	19,38	5	0	420
14	0	27,68	12	0	0
15	1	23,71	10	0	0
16	1	28,09	5	60	60
17	0	24,91	2	0	0
18	1	25,24	5	0	0
19	1	20,20	4	40	0
20	1	28,03	4	90	300
21	0	22,66	6	0	0
22	0	28,96	12	0	0
23	1	29,38	9	0	80
24	0	18,75	8	0	0
25	0	19,78	9	0	0
26	0	24,22	8	80	120
27	0	21,30	2	120	120
28	0	20,76	12	0	0
29	0	23,03	3	0	200
30	0	17,56	10	0	300
31	0	22,05	3	0	0
32	1	29,38	5	30	60
33	0	19,13	12	0	0
34	1	18,36	12	60	60
35	0	25,34	3	0	300
36	1	24,39	12	60	180
37	0	22,91	8	60	200
38	0	22,07	6	30	120
39	0	20,90	8	60	120
40	0	24,69	8	30	300

Monthly Days (days/month) – Baseline	Monthly Days (days/month) – Post-inter
30	
25	9
15	15
10	15
25	18
30	30
30	30
4	4
20	
18	18
28	15
16	22
20	24
23	20
20	25
20	9
5	5
30	24
30	30
13	30
7	5
5	5
20	15
10	15
10	6
25	7
6	5
14	14
4	2
15	15
5	5
15	15
3	1
5	6
2	2
30	30
7	13
8	5
7	15
1	5

Episode Duration (hours) – Baselin	Episode Duration (hours) – Post	Pain Intensity (0–10) – Baseline
24		7
24	24	10
2	3	7
12	11	8
	30	7
24	48	6
16	20	7
48	48	8
24		7
20	20	10
24	24	9
8	8	7
24	20	9
8	6	7
5	3	7
6	6	6
6	6	9
10	20	8
12	20	7
2	2	8
24	24	6
24	48	9
5	5	7
6	3	7
24	4	10
4	20	7
3	4	7
4	3	6
4	8	7
24	20	8
7	24	7
1	2	5
48	8	8
24	20	5
3	3	5
4	24	6
4	7	8
24	24	7
4	4	7
6	3	8

Pain Intensity (0–10) – Post-intervention	HIT-6 – Baseline	HIT-6 – Po	ASI-3 Phys
	67		13
9	73	60	5
6	72	65	0
8	62	64	6
7	74	62	7
6	68	68	3
5	64	65	6
8	73	57	5
	68		2
9	72	68	3
9	72	66	12
7	64	57	18
7	67	68	7
6	74	70	22
6	65	66	11
7	65	64	12
8	64	64	7
8	65	63	3
8	74	78	10
7	56	60	2
7	60	61	5
10	70	65	3
6	63	63	5
7	65	66	1
7	62	55	0
7	65	62	15
4	55	50	2
7	58	62	5
5	61	46	13
8	67	61	5
7	60	65	6
6	52	59	6
4	67	46	3
6	65	63	5
5	57	57	9
6	53	50	5
8	64	64	0
8	62	60	1
7	61	62	15
7	64	63	2

ASI-3 Physical Concerns – Post-inter	ASI-3 Cogn	ASI-3 Cognitiv	ASI-3 Socia	ASI-3 Sc	TSK-11–
	20		12		20
6	8	5	23	18	17
1	6	6	2	5	27
6	4	6	6	6	11
0	5	1	6	5	32
1	3	3	2	1	20
1	9	5	9	4	32
9	5	4	7	5	20
	12		3		15
1	19	16	15	16	32
7	11	10	12	12	26
8	17	7	19	11	27
3	8	3	8	6	29
23	9	13	8	14	40
10	17	11	10	10	31
7	8	4	1	3	18
6	14	9	17	9	26
5	0	0	3	5	30
7	17	13	9	8	29
4	0	4	4	3	16
6	1	2	3	3	23
1	1	2	10	10	20
2	3	1	3	2	20
0	3	4	10	5	18
2	0	0	15	10	14
21	12	17	12	16	20
0	1	0	4	2	21
9	2	8	5	10	19
6	13	2	11	7	18
4	7	4	12	11	19
6	6	13	3	7	16
2	1	0	3	4	16
1	1	3	3	1	20
6	4	3	8	10	19
9	3	3	7	6	28
4	7	4	8	5	20
2	1	2	4	4	20
1	3	4	15	14	20
8	1	1	4	3	19
6	1	6	2	9	17

TSK-11 – Post-intervention	Athens Insomnia Scale (AIS) – Baselir	Athens Insomnia Scale (AIS) – Post-ir
	6	
23	14	16
25	11	10
11	9	9
23	13	8
15	3	2
35	9	7
25	12	13
	13	
30	9	10
28	12	7
28	5	3
23	13	10
30	14	11
27	14	16
17	9	9
30	8	16
29	10	11
20	7	8
17	16	14
24	3	1
19	12	10
24	12	11
20	8	6
13	5	5
19	14	16
16	8	4
18	13	13
12	8	4
22	11	8
18	3	1
18	4	7
13	7	1
19	7	6
27	5	7
16	7	7
21	4	7
22	4	3
18	3	3
20	15	15

