EXTRACTION DATA GUIDELINE

1. BIBLIOMETRIC INFORMATION		**REVIEWER 1**
Code		
Author		
Title		
Year publication		
Journal		
journal category	TM/no specialist	
Article reference		
b) Study characteristics		
Country of the setting of the study		
Setting	uni/ multicentric/ unclear	
N of participants		
Recruitment period	copy/paste	perído que duró el reclutamiento,

Patient's origin	hospitalised/ outpatient/ academic enviroment/ unclear	Outpatient se considerará siempre que la intervención no sea con pacientes hospitalizados (incluye: clínicas, consultas,) Academic enviroment: universidades, centros académicos, o de investigación donde no se realizaría normalemente la intervención
Co-interventions	YES/NO/ UNCLEAR	SI: se permite que los participantes puedan realizar otras terapias/mediación mientras dura el estudio NO: se especifica no realizar ninguna terapia/intervención mientras dura el estudio
Number of sesions	listado hasta 40 y opción:individual	Introducir el número de sesiones que se realizan, si es un tratamiento individualizado y se adapta el número de sesiones a cada paciente escoger opción "individual"
Lenght of complete treatment		Si se realizan 2 sesiones en 2 meses, en una semana o en 1 día (el follow-up se recoge después). si se puede ponerlo en semanas, si es un día poner un día
Additional training of care-givers	YES/NO/ UNCLEAR	Si: se realizó una formación adicional a los profesionales que realizaban la intervención. NO: si no está esta información no se considera additional training si es para garantizar la mejor realización del estuido
Staff expertise	YES/NO/ UNCLEAR	SI: Se reportan los años de experiencia de los profesionales que realizan la intervención como dato importante. o el hecho de tenera una formación especializada acorde con la intervención NO: si se interpreta que no es importante la experiencia del personal o se declara que los profesionales tenían diferentes grados de experiencia UNCLEAR: si no se puede interpretar

Extra staff	YES/NO/ UNCLEAR	SI: para realizar la intervención se requiere incorporar más personal que el que se utilizaría en un usual care NO: si aunque no se especifica se entiende que no se aumenta el personal para realizar el estudio UNCLEAR: si no está la información
Nombre intervención control	copy/paste	
Follow up	copy/paste	
Blinding	YES/NO/ UNCLEAR	
Participants		
Therapists		
External assessors		si son distintos al terapeuta
Statistician		si no está reportado es un no
Primary outcome	PROMS/ physiological usual care/ physiological external expertise/ unclear/mixed	PROMS: cuestionarios, escalas, todo lo que sea reportado por el paciente Physiological usual care: BP, HR, RR, nistagmus, Physiological external expertise: blood test, glucose, MRI.., specific devices mixed: PROMS y physiological
Stadistical analysis (ITT)	YES/NO/ unclear	YES: si se realizó o no se produjeron pérdidas NO: no se realizó ITT
Is there a description of the pragmatic attitude of the article: the intent of the trial	YES/NO/ UNCLEAR	párrafo donde se describa la intención de diseñar un estudio lo más parecido al usual care. puede estar en el abstract/intro/ métodos/discusión. Y puede estar tanto en estudios pragmáticos como de efectividada
(Copy and paste)		copiar el fragmento que justifique vuestra decisión
Does the article use any design or reporting tool?	design/ reporting/ both/no	tiene que estar especificado en el texto, o flow chart

Spirit	YES/NO	
Precis or Precis-2	YES/NO	
Consort	YES/NO	
Tidier	YES/NO	
Does the study have any funding?	YES/NO/ UNCLEAR	si describe que no tiene, responder no unclear si no se raporta

2. INTENT OF THE TRIAL	**ALL REVIEWERS**
Assessed by using the following three qualitative categories pre-established by the reviewer's team:	I) aimed to clinical informing for decision-making
	II) aimed to resemble clinical practice,
	III) aimed both to resemble clinical practice and to clinical inform for decision-making.

3. RATIONALE OF THE INTERVENTION GIVEN BY THE AUTHORS	**ALL REVIEWERS**
It refers to the proof-of-concept information existing in the literature that the study's author reports answering the research question in the introduction section. Reviewers pre-established 3 types of rationale:	I) report the existence of mechanistic experiments explaining the mechanisms of action of the intervention
	II) report the existence of sham-controlled studies testing the intervention against a placebo,
	III) report comparative effectiveness data trials about the intervention.

4. EXPERIMENTAL AND CONTROL INTERVENTIONS	REVIEWER 1
EXPERIMENTAL INTERVENTION	
Combination of techniques no standardized	a combination of MT techniques chosen by the practitioner based on patient's needs
Isolated technique no standardized	a single MT technique chosen by the therapist based on patient's needs
Combination of techniques protocol	a combination of MT techniques standardised by the trial protocol
Combination of therapies no standardized	a combination of different modalities of treatment based on patient's needs, pe; MT combined with exercises
Isolated technique protocol	a single MT technique standardized by the trial protocol
Combination of therapies protocol	a combination of therapies standardized to all the patients by the trial protocol
CONTROL INTERVENTION	
other intervention	other active intervention
placebo	an inactive intervention that looks like the drug or treatment being tested
usual care	an intervention that is the care the targeted patient population would be expected to receive as part of the normal practice
no intervention	another group that is not receiving any intervention

5. LIMITATIONS REPORTED BY THE AUTHORS	ALL REVIEWERS
The extraction data was based on the 12 limitations categories proposed by Alvarez et al. (Alvarez et al. 2021)	Randomization and/or concealment
	Blinding
	Lost to follow-up/dropout
	Sample Size
	Inadequate control
	Funding
	Type of setting/care providers
	Inadequate subjects
	Study length and follow up
	Intervention
	Outcome measures
	Comprimised generalization of the results

6. PRECIS- 2 TOOL ASSESSMENT: consists of 9 domains, including eligibility, recruitment, setting, organisation, flexibility (delivery), flexibility (adherence), follow-up, primary outcome, and primary analysis. Mean values were calculated, including all reported domains. For this study, reviewers rated the non-reported domains " blank " and excluded them from score. Score of three will be used when a domain is as pragmatic as explanatory.	SCORE (1-5)
DOMAIN 1: ELIGIBILITY	los criterios de inclusión deben incluir aquellos participantes relacionados con la pregunta de investigación y con el primary outcome TENER en cuenta también si el sistema sanitario que se plantea se parece a la realidad o si usa muchos tests para seleccionar
DOMAIN 2: RECRUITMENT	penalizar cuando se realizen esfuerzos para reclutar pacientes de forma distinta a la práctica habitual. Altamente pragmático cuando se recluta de más de un sitio
DOMAIN 3: SETTING	aunque haya varios centros si no hay más de un país no poner un 5, a no ser que el objetivo del estudio sea ver los efectos de la intervención específicamente en un país, o la intervención es fácilmente aplicable en otros países (tener en cuenta situación económica y sanitaria). También si se compara con usual care este puede variar entre países.
DOMAIN 4: ORGANIZATION	Si la formación adicional se realiza para garantizar el funcionamiento del estudio o se considera parte de la intervención no se considerará explicativo. Penalizar el caso que la formación adicional sea para mejorar los efectos de la intervención

DOMAIN 5: FLEXIBILITY DELIVERY	si hay un protocolo ver hasta qué punto se parece a la práctica habitual
DOMAIN 6: FLEXIBILITY ADHERENCE	Aunque habitualmente no se raporta, a veces se puede intuir mirando las justificaciones de la pérdidas en el flow chart
DOMAIN 7: FOLLOW UP	penalizan follow-up muy cortos, con más sesiones de lo habitual o con mucha recolección de datos y/o más personal para realizarlo
DOMAIN 8: PRIMARY OUTCOME	aunque no sea PROMS, puede ser relevante para el paciente (no penalizar)
DOMAIN 9: PRIMARY ANALYSIS	Aunque el texto no especifique si hay ITT o no revisar el flow chart o las tablas de resultados para entender como se han tratado las pérdidas
REVIEWER OPINION QUESTIONS: opinión personal del REVIEWER (subjetiva), se ha añadido una pregunta más	
Is there anything that suggests that the trial not resemble usual clinical practice (copy and paste)	YES/NO/ UNCLEAR
are the results applicable to other usual care settings	YES/NO/ UNCLEAR
If not, how could you improve the similiarity of the study with usual clinical practice?	write

7. CONSORT 2010 ASSESSMENT: all items from the extension for pragmatic trials and non-pharmacological interventions were included (Moher et al. 2010; Zwarenstein et al. 2008; Boutron et al. 2017).
Se ha añadido la opción not applicable en algunas preguntas. los ítems con ** solo son aplicables si el estudio se autodenomina pragmático. Los ítems * son para todos los artículos ya que es la extensión para intervenciones no-farmacológicas

Title and abstract
1a.Identification as a randomized trial in the title
1b.Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)
Introduction
2a.Scientific background and explanation of the rationale **Describe the health or health service problem that the intervention is intended to address and other interventions that may commonly be aimed at this problem
2b.Specific objectives or hypotheses
Methods
Trial design
3a.Description of trial design (such as parallel, factorial) including allocation ratio *When applicable, how care providers were allocated to each trial group
3b.Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants
4a.Eligibility criteria for participants *When applicable, eligibility criteria for centres and for care providers **Eligibility criteria should be explicitly framed to show the degree to which they include typical participants and/or, where applicable, typical providers (eg, nurses), institutions (eg, hospitals), communities (or localities eg, towns) and settings of care (eg, different healthcare financing systems)

4b.Settings and locations where the data were collected
Interventions
5a.The interventions for each group with sufficient details to allow replication, including how and when they were actually administered *Precise details of both the experimental treatment and comparator **Describe the comparator in similar detail to the intervention
5b.*Description of the different components of the interventions and, when applicable, description of the procedure for tailoring the interventions to individual participants.
5c.*Details of whether and how the interventions were standardized.
5d.**Describe extra resources added to (or resources removed from) usual settings in order to implement the intervention. Indicate if efforts were made to standardise the intervention or if the intervention and its delivery were allowed to vary between participants, practitioners, or study sites
5e.*Details of whether and how adherence of care providers to the protocol was assessed or enhanced
5f.*Details of whether and how adherence of participants to interventions was assessed or enhanced
Outcomes

6a.Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed **Explain why the chosen outcomes and, when relevant, the length of follow-up are considered important to those who will use the results of the trial
6b.Any changes to trial outcomes after the trial commenced, with reasons
Sample Size
7a.How sample size was determined **If calculated using the smallest difference considered important by the target decision-maker audience (the minimally important difference) then report where this difference was obtained
7b.When applicable, explanation of any interim analyses and stopping guidelines
Randomization
Sequence generation
8a.The method used to generate the random allocation sequence
8b.Type of randomisation; details of any restriction (such as blocking and block size)
Allocation concealment
9.The 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
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 *If done, who was blinded after assignment to interventions (e.g., participants, care providers, those administering co-interventions, those assessing outcomes) and how **If blinding was not done, or was not possible, explain why
11b.If relevant, a description of the similarity of interventions
11c.*If blinding was not possible, description of any attempts to limit bias
Statistical methods
12a.Statistical methods used to compare groups for primary and secondary outcomes *When applicable, details of whether and how the clustering by care providers or centres was addressed
12b. Methods for additional analyses, such as subgroup analyses and adjusted analyses
Results
Participants flow (a diagram is strongly recommended)

13a.For each group, the numbers of participants who were randomly assigned, received intended treatment and were analyzed for the primary outcome *The number of care providers or centres performing the intervention in each group and the number of patients treated by each care provider or in each centre **The number of participants or units approached to take part in the trial, the number which were eligible, and reasons for non-participation should be reported
13b.For each group, losses and exclusions after randomization, together with reasons
13c.*For each group, the delay between randomization and the initiation of the intervention
13d.Details of the experimental treatment and comparator as they were implemented
Recruitment
14a.Dates defining the periods of recruitment and follow-up
14b.Why the trial ended or was stopped
Baseline data
15.A table showing baseline demographic and clinical characteristics for each group *When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centres (volume) in each group
Numbers analysed

16. For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
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)
17b. For binary outcomes, the presentation of both absolute and relative effect sizes is recommended
Ancillary analyses
18. Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory
Harms
19.All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
Discussion
20. Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses *In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centres in each group

21. Generalizability (external validity, applicability) of the trial findings *Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centres involved in the trial **Describe key aspects of the setting which determined the trial results. Discuss possible differences in other settings where clinical traditions, health service organisation, staffing, or resources may vary from those of the trial
22. Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
23.Registration number and name of trial registry
24. Where the full trial protocol can be accessed, if available
25.Sources of funding and other support (such as supply of drugs), role of funders

8. RISK OF BIAS Cochrane tool (Higgins et al. 2011)	HIGH/ LOW/ UNCLEAR
Selection bias	
Random sequence generation	
Allocation concealment	
Performance bias Blinding participants	
Performance bias Blinding personnel	
Detection bias Blinding (outcome assessment)	
Attrition bias Incomplete outcome data	

Reporting bias	Puntuación: LOW: el artículo informa sobre el registro del protocolo y los métodos son consistentes con los resultados HIGH: no está el protocolo y los resultados no son consistentes. o está el protocolo pero los métodos del paper no son consistentes con los resultados. UNCLEAR: los métodos son consistentes pero no está el protocolo

9. GENERALISABILITY AND APPLICABILITY
we used the model proposed by Murad et al. to assess the generalisability and applicability of the results by combining information related to sample size and PRECIS-2 score (Murad et al. 2018). It was considered generalisability when having a sample > 100 and recruitment scores =/>4 in PRECIS-2 Domain 2 (recruitment). The trial was considered to have applicability of the intervention if scored =/>4 in PRECIS-2 Domains 1 and 3 (eligibility and setting).