

Supplementary table 3

Details of the risk of bias assessment

Risk of bias assessment of cross-sectional studies

The Appraisal Tool for Cross-Sectional Studies (AXIS tool) comprises 20 items in 5 domains, evaluating various aspects of methodological quality (Downes MJ, Brennan ML, Williams HC, Dean RS. Development of a critical appraisal tool to assess the quality of cross-sectional studies (AXIS). *BMJ Open* 2016;6:e011458). Each item has three rating options: “Yes” - met the description of a particular evaluation criterion, “No” - did not meet a particular criterion or “Don't know” - insufficient information to evaluate a particular criterion.

Risk of bias questions (AXIS)

Introduction

1. Were the aims/objectives of the study clear?

Methods

2. Was the study design appropriate for the stated aim(s)?
3. Was the sample size justified?
4. Was the target/reference population clearly defined? (Is it clear who the research was about?)
5. Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?
6. Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?
7. Were measures undertaken to address and categorise non-responders?
8. Were the risk factor and outcome variables measured appropriate to the aims of the study?
9. Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?
10. Is it clear what was used to determine statistical significance and/or precision estimates? (e.g. p-values, confidence intervals)
11. Were the methods (including statistical methods) sufficiently described to enable them to be repeated?

Results

12. Were the basic data adequately described?

13. Does the response rate raise concerns about non-response bias?
14. If appropriate, was information about non-responders described?
15. Were the results internally consistent?
16. Were the results presented for all the analyses described in the methods?

Discussion

17. Were the authors' discussions and conclusions justified by the results?
18. Were the limitations of the study discussed?

Other

19. Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?
20. Was ethical approval or consent of participants attained?

Table. Risk of bias assessment of cross-sectional studies (AXIS tool)

Author, year	Introduction	Methods										Results				Discussion		Other		
		1	2	3	4	5	6	7	8	9	10	11	12	13*	14	15	16	17	18	19*
Balint et al., 2002	Y	Y	N ¹	Y	DK ²	DK ²	Y	Y	Y	Y	Y	Y	N	N/A ³	Y	Y	Y	N ⁴	NI ⁵	NI ⁶
Chang et al., 2015	N ⁷	N ⁷	N ⁸	Y	DK ²	DK ²	N/A ³	N ⁷	DK ⁹	Y	Y	N ¹⁰	N/A ³	N/A ³	Y	Y	N ¹¹	Y	NI ⁵	Y
Bossert et al., 2016	Y	Y	N ¹²	Y	DK ²	DK ²	Y	Y	DK ¹³	Y	Y	Y	N	N/A ³	Y	Y	Y	Y	NI ⁵	Y
Resnick et al., 2017	N ¹⁴	Y	N ¹	Y	N ¹⁵	N ¹⁵	Y	Y	Y	Y	Y	Y	N	N ¹⁶	Y	Y	Y	Y	NI ⁵	Y

Y=yes; N=no; DK= don't know; NI= no information; N/A=not applicable;*Item is reverse scored (i.e., no is a positive) ¹no information on sample size; ²no information why exactly these patients were chosen; ³not applicable for this study design; ⁴limitations of the study are not discussed; ⁵no information on funding; ⁶no information on ethical approval or consent of participants; ⁷aims/objectives/methods of the study are not clear; ⁸no information why Authors has chosen the period 2002-2011; ⁹scarce information on the reference and index test; ¹⁰baseline data for each group are missing; ¹¹discussions and conclusions seem not be justified by the results; ¹²no information about the reason of the patients number; ¹³questionable whether "how strong was your severe impairment" is actually a validated tool; ¹⁴not clear imaging procedures used in the image-guided group; ¹⁵several subtypes of JIA; ¹⁶information about non-responders are not described.

Risk of bias assessment of non-randomised studies

The Risk Of Bias In Non-randomised Studies - of Interventions tool (ROBINS-I tool) comprises 34 items in 7 domains, evaluating various aspects of methodological quality (Sterne JAC et al, ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ* 2016;355:i4919). Each domain has five rating options: “Low risk of bias” - the study is comparable to a well performed randomised trial; “Moderate risk of bias” - the study provides sound evidence for a non-randomised study but cannot be considered comparable to a well performed randomised trial; “Serious risk of bias” - the study has some important problems; “Critical risk of bias” - the study is too problematic to provide any useful evidence and should not be included in any synthesis; “No information” - No information on which to base a judgement about risk of bias.

Risk of bias questions (ROBINS-I)

Bias due to confounding

1.1 Is there potential for confounding of the effect of intervention in this study?

If N/PN to 1.1: the study can be considered to be at low risk of bias due to confounding and no further signalling questions need be considered.

If Y/PY to 1.1: determine whether there is a need to assess time-varying confounding: 1.2. Was the analysis based on splitting participants' follow up time according to intervention received?

If N/PN, answer questions relating to baseline confounding (1.4 to 1.6)

If Y/PY, proceed to question 1.3.

1.3. Were intervention discontinuations or switches likely to be related to factors that are prognostic for the outcome?

If N/PN, answer questions relating to baseline confounding (1.4 to 1.6)

If Y/PY, answer questions relating to both baseline and time-varying confounding (1.7 and 1.8)

1.4. Did the authors use an appropriate analysis method that controlled for all the important confounding domains?

1.5. If Y/PY to 1.4: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?

1.6. Did the authors control for any post-intervention variables that could have been affected by the intervention?

1.7. Did the authors use an appropriate analysis method that adjusted for all the important confounding domains and for time-varying confounding?

1.8. If Y/PY to 1.7: Were confounding domains that were adjusted for measured validly and reliably by the variables available in this study?

Optional: What is the predicted direction of bias due to confounding?

Bias in selection of participants into the study

2.1. Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of intervention? If N/PN to 2.1: go to 2.4

2.2. If Y/PY to 2.1: Were the postintervention variables that influenced selection likely to be associated with intervention?

2.3 If Y/PY to 2.2: Were the postintervention variables that influenced selection likely to be influenced by the outcome or a cause of the outcome?

2.4. Do start of follow-up and start of intervention coincide for most participants?

2.5. If Y/PY to 2.2 and 2.3, or N/PN to 2.4: Were adjustment techniques used that are likely to correct for the presence of selection biases?

Optional: What is the predicted direction of bias due to selection of participants into the study?

Bias in classification of interventions

3.1 Were intervention groups clearly defined?

3.2 Was the information used to define intervention groups recorded at the start of the intervention?

3.3 Could classification of intervention status have been affected by knowledge of the outcome or risk of the outcome?

Optional: What is the predicted direction of bias due to measurement of outcomes or interventions?

Bias due to deviations from intended interventions

4.1. Were there deviations from the intended intervention beyond what would be expected in usual practice?

4.2. If Y/PY to 4.1: Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?

4.3. Were important co-interventions balanced across intervention groups?

4.4. Was the intervention implemented successfully for most participants?

4.5. Did study participants adhere to the assigned intervention regimen?

4.6. If N/PN to 4.3, 4.4 or 4.5: Was an appropriate analysis used to estimate the effect of starting and adhering to the intervention?

Optional: What is the predicted direction of bias due to deviations from the intended interventions?

Bias due to missing data

5.1 Were outcome data available for all, or nearly all, participants?

5.2 Were participants excluded due to missing data on intervention status?

5.3 Were participants excluded due to missing data on other variables needed for the analysis?

5.4 If PN/N to 5.1, or Y/PY to 5.2 or 5.3: Are the proportion of participants and reasons for missing data similar across interventions?

5.5 If PN/N to 5.1, or Y/PY to 5.2 or 5.3: Is there evidence that results were robust to the presence of missing data?

Optional: What is the predicted direction of bias due to missing data?

Bias in measurement of outcomes

6.1 Could the outcome measure have been influenced by knowledge of the intervention received?

6.2 Were outcome assessors aware of the intervention received by study participants?

6.3 Were the methods of outcome assessment comparable across intervention groups?

6.4 Were any systematic errors in measurement of the outcome related to intervention received?

Optional: What is the predicted direction of bias due to measurement of outcomes?

Bias in selection of the reported results

Is the reported effect estimate likely to be selected, on the basis of the results, from...

7.1 ... multiple outcome measurements within the outcome domain?

7.2 ... multiple analyses of the interventionoutcome relationship?

7.3 ... different subgroups?

Optional: What is the predicted direction of bias due to selection of the reported result?

Table. Risk of bias assessment of non-randomised studies of the effects of interventions (ROBINS-I tool).

Author, year	Bias due to confounding	Bias in selection of participants into the study	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported results	Overall Bias
Hartung et al., 2010	NI ¹	Serious ²	Moderate ³	Low	Low	Low	Low	Serious
Park et al., 2015	Moderate ⁴	Low	Serious ⁵	Low	Low	Serious ⁶	Serious ⁷	Serious
Althoff et al., 2015	Low	Low	Moderate ⁸	Low	Low	Serious ⁹	Moderate ¹⁰	Serious
Petscavage-Thomas and Gustas, 2016	Low	Low	Moderate ⁸	Low	Low	Serious ⁹	Moderate ¹⁰	Serious
Just et al., 2018	Moderate ¹¹	Moderate ¹²	Moderate ¹³	Low	Low	NI ¹⁴	Moderate ¹⁵	Moderate
Omar et al., 2018	Serious ¹⁶	Moderate ¹²	Serious ¹⁷	Low	Low	NI ¹⁸	Low	Serious
Hsu et al., 2018	Serious ¹⁶	Serious ¹⁹	Moderate ²⁰	Serious ²¹	Serious ²²	Low	Low	Serious
Humby et al., 2018	Critical ²³	Low	Low	Low	NI ²⁴	Low	Moderate ¹⁰	Critical
Lundstrom et al., 2019	Serious ²⁵	Low	Serious ²⁶	Moderate ²⁷	Low	Moderate ²⁸	Low	Serious
Gershkovich et al., 2019	Serious ¹⁶	Low	Moderate ²⁹	Low	Low	Serious ³⁰	Serious ³¹	Serious
Diffre et al., 2020	Serious ¹⁶	Low	Moderate ²⁹	Moderate ²⁷	Low	Serious ³⁰	Moderate ⁷	Serious

McKee et al., 2020	Serious ¹⁶	Low	Moderate ²⁹	Moderate ²⁷	Low	Serious ³⁰	Moderate ⁷	Serious
Henne et al., 2020	Serious ¹⁶	Moderate ¹²	Moderate ²⁹	Moderate ²⁷	NI ²⁴	Serious ³⁰	Serious ³¹	Serious

NI= no information; ¹no information on confounding; ²selection into the study is related to intervention and outcome and intervention group is classified after outcome assessment; ³some aspects of the assignment of intervention status are determined retrospectively; ⁴no clear confounding found, no methods for protecting for confounding; ⁵the stratification is at high risk for bias (patients chose procedure after information on costs and pros and cons); ⁶few information on the process of outcome measurement, no blinding is done, retrospective study; ⁷conclusions are drawn from a small part of the results; ⁸intervention groups are only partially clearly defined; ⁹minimal information available on outcomes measurement; ¹⁰results derive from one domain of the outcomes; ¹¹reliability and validity of measurement of important domains are sufficient, so we do not expect serious residual confounding; ¹²no information on patients selection; ¹³intervention status is partially affected by knowledge of the outcome; ¹⁴no information on outcome assessment, retrospective study; ¹⁵no selection of reported outcomes; ¹⁶at least one important domain is not appropriately measured, or not controlled for confounding; ¹⁷the lack of adequate reasoning why a patient is classified in the respective group leads to the possible bias; ¹⁸no information on outcome assessment; ¹⁹selection into the study is related to intervention and outcome; ²⁰some aspects of the assignment of intervention status are determined retrospectively; ²¹some patients do not adhere to the assigned intervention regimen, and an appropriate analysis used to estimate the effect of starting and adhering to the intervention is not performed; ²²no evidence that results are robust due to the presence of missing data; ²³several domains are not protected for confounding (e.g. different study centres, different people performing the intervention, different diseases); ²⁴no information on missing data; ²⁵at least one important domain is not appropriately measured, or not controlled for confounding (e.g. confounding risk for exact injection point); ²⁶the lack of adequate reasoning why a patient is classified in the respective group leads to the possible bias; ²⁷no information on co-interventions; ²⁸the methods of outcome assessment are probably similar between groups, the knowledge of the intervention can change the outcome, retrospective study; ²⁹no information if the data used to define intervention groups are recorded at the start of the intervention; ³⁰no or only minimal information available on outcomes measurement; ³¹the reported effect estimates likely to be selected.

Risk of bias assessment of randomised clinical trials

The risk-of-bias tool for randomized trials (RoB 2) is structured into five domains through which bias might be introduced into the result (Sterne JAC, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ* 2019;366:l4898). The response options for the signalling questions are: “Yes”; “Probably yes”; “Probably no”; “No”; “No information”. To maximize the signalling questions’ simplicity and clarity, they are phrased so that a response of “Yes” may be indicative of either a low or high risk of bias, depending on the most natural way to ask the question. The tool includes algorithms that map responses to signalling questions onto a proposed risk-of-bias judgement for each domain, and then reaching an overall risk-of-bias judgement for a specific outcome. The possible risk-of-bias judgements are: “Low risk of bias” - the study is judged to have a low risk of bias for all domains for this result.; “Some concerns” - the study is judged to raise some concerns in at least one domain for this result, but not to have a high risk of bias for any domain.; “High risk of bias” - the study is judged to have a high risk of bias in at least one domain for this result, Or the study is judged to have some concerns for multiple domains in a way that substantially lowers confidence in the result.

Risk of bias questions (RoB 2)

Bias arising from the randomization process

- 1.1 Was the allocation sequence random?
 - 1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?
 - 1.3 Did baseline differences between intervention groups suggest a problem with the randomisation process?
- Optional: What is the predicted direction of bias arising from the randomization process?

Bias due to deviations from intended interventions

- 2.1 Were participants aware of their assigned intervention during the trial?
- 2.2 Were carers and people delivering the interventions aware of participants’ assigned intervention during the trial?
- 2.3. If Y/PY/NI to 2.1 or 2.2: Were important co-interventions balanced across intervention groups?
- 2.4. Was the intervention implemented successfully?
- 2.5. Did study participants adhere to the assigned intervention regimen?
- 2.6. If N/PN/NI to 2.3, 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of starting and adhering to the intervention?

Optional: What is the predicted direction of bias due to deviations from intended interventions?

Bias due to missing outcome data

3.1 Were data for this outcome available for all, or nearly all, participants randomised?

3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?

3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?

3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?

Optional: What is the predicted direction of bias due to missing outcome data?

Bias in measurement of the outcome

4.1 Was the method of measuring the outcome inappropriate?

4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?

4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?

4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?

4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?

Optional: What is the predicted direction of bias in measurement of the outcome?

Bias in selection of the reported result

5.1 Were the data that produced this result analysed in accordance with a prespecified analysis plan that was finalised before unblinded outcome data were available for analysis?

Is the numerical result being assessed likely to have been selected, on the basis of the results, from:

5.2 ... multiple eligible outcome measurements (eg, scales, definitions, time points) within the outcome domain?

5.3 ... multiple eligible analyses of the data? N/PN Y/PY NI

Optional: What is the predicted direction bias due to selection of the reported results?

Table. Risk of bias assessment of randomised clinical trials (RoB 2).

Author, year	Randomisation process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall Bias
Naredo et al., 2004	Some concerns ¹	Low	Low	Low/High ²	Low	Some concerns/ High
Luz et al., 2008	Some concerns ³	Low	Low	Some concerns ⁴	Low	Some concerns
Sibbitt et al., 2009	Some concerns ¹	Low	Low	Some concerns ⁵	Low	Some concerns
Im et al., 2009	Some concerns ⁶	Low	Low	Some concerns ⁷	Low	Some concerns
Lee et al., 2009	Some concerns ¹	Low	Low	Low	Low	Some concerns
Cunnington et al., 2010	Some concerns ¹	Low	Low	Low	Low	Some concerns
Hashiuchi et al., 2011	Some concerns ¹	Low	Low	Low	Low	Some concerns
Zhang et al., 2011	High ⁸	Low	Some concerns ⁹	Some concerns ¹⁰	Some concerns ¹¹	High
Park et al., 2011	Some concerns ¹	Low	Low	Low	Low	Some concerns
Sibbitt Jr et al., A randomized controlled trial evaluating the cost-effectiveness of sonographic guidance for intra-articular injection of the osteoarthritic knee, 2011	Some concerns ¹	Low	Low	Some concerns ⁵	Low	Some concerns
Sibbitt Jr et al., A randomized controlled trial of the cost-effectiveness of ultrasound-guided intraarticular injection of inflammatory arthritis, 2011	Some concerns ¹	Low	Low	Some concerns ⁵	Low	Some concerns
Sibbitt et al., 2012	Some concerns ¹²	Low	Low	Some concerns ⁵	Low	Some concerns
Bum Park et al., 2012	Some concerns ¹	Low	Low	Low	Low	Some concerns
Jang et al., 2013	Some concerns ¹	Low	Low	Some concerns ⁵	Low	Some concerns
Sabeti-Aschraf et al., 2013	Low	Low	Low	Low	Some concerns ¹³	Low

Makhlouf et al., 2014	Low	Low	Low	High ¹⁴	Some concerns ¹⁵	High
Park et al., 2013	Some concerns ¹	Low	Low	Low	Low	Some concerns
Ustun et al., 2013	Some concerns ¹	Low	Low	Low	Some concerns ¹⁶	Some concerns
Kim et al., 2013	Some concerns ¹	Low	Low	Low	Low	Some concerns
Chang et al., 2014	Some concerns ¹	Low	Low	Low	Low	Some concerns
Fowler et al., 2014	High ¹²	Low	Low	Some concerns ⁵	Low	High
Saeed et al., 2014	Low	Low	High ¹⁷	Low	Low	High
Jee et al., 2014	Some concerns ¹	Low	Low	Some concerns/High ¹⁸	Low	High
Cecen et al., 2015	High ²⁰	Low	Low	Low	Low	High
Soneji et al., 2016	Some concerns ¹	Low	Low	Some concerns ⁵	Low	Some concerns
Shinomiya et al., 2016	Some concerns ²¹	Low	Low/High ²²	Some concerns ²³	Low	Some concerns/High
Cho et al., 2016	Low	Low	Low	Low	Low	Low
Raeissadat et al., 2017	High ²⁴	Low	Low	Some concerns ²⁵	Low	High
Eslamian et al., 2017	Some concerns ¹	Low	Low	Low	Low	Some concerns
Orlandi et al., 2017	Some concerns ¹	Low	Some concerns ²⁶	Some concerns ²⁷	Low	Some concerns
Mardani-Kivi et al., 2018	Some concerns ¹	Low	Low	Low	Low	Some concerns
Mitchell et al., 2018	Some concerns ¹	Low	Low	High ¹⁴	Some concerns ¹⁵	High
Nordberg et al., 2018	Some concerns ²⁸	Low	Low	Low	Some concerns ²⁹	Some concerns
Lee et al., 2018	Some concerns ¹	Low	Low	Some concerns ⁵	Low	Some concerns
Babaei-Ghazani et al., 2018	Some concerns ¹	Low	Low	Some concerns ⁵	Low	Some concerns
Khallaf et al., 2018	High ³⁰	High ³¹	Low	Low	Low	High
Chen et al., 2018	Some concerns ³²	Low	Low	Some concerns ⁵	Low	Some concerns
Pan et al., 2019	Some concerns ³³	Low	High ³⁴	High ³⁵	High ³⁶	High
Kim et al., 2019	Some concerns ¹	Low	Low	Some concerns ⁵	Low	Some concerns
Hak Roh et al., 2019	Some concerns ¹	Low	Low	Some concerns ⁵	Low	Some concerns

Vahdatpour et al., 2019	High ²⁴	Low	Low	Low	Low	High
Roh et al., 2019	Some concerns ¹	Low	High ³⁷	Some concerns ³⁸	Low	High
Lee et al., 2019	Some concerns ³⁹	Low	Low	Low	Low	Some concerns
Rayegani et al., 2019	Some concerns ³⁹	Low	Low	Low	Low	Some concerns
Cohen et al., 2019	Low	Low	Low	Low	Low	Low
Sheth et al., 2020	Some concerns ³⁹	Low	Low	High ²⁷	Low	High
Yiannakopoulos et al., 2020	Some concerns ¹	Low	Low	High ⁴⁰	Low	High
Babaei-Ghazani et al., 2020	Some concerns ⁴¹	Low	Low	Low	Low	Some concerns
Cankurtaran et al., 2020	High ⁴²	Low	Low	Low	Low	High

¹no information when allocation is concealed; ²not well described if the ultrasound also performed the procedure (high risk of bias only for accuracy outcome); ³few information on randomization process; ⁴no description on what is measured exactly as outcomes; ⁵scarce information on outcomes measurement; ⁶no information on the randomization process; ⁷no information who assessed x-ray imaging, no information on blinding; ⁸no information on the randomization process and when allocation is concealed, unequal number of participants between groups; ⁹no information on patients lost to follow up; ¹⁰not clear who decided whether or not another injection was needed and whether this person was blinded to the group assignment; ¹¹multiple time points measured but only two time points reported (the first and the last visit) and it is unclear whether these time points are not measured; ¹²demographic data are not described; ¹³unclear in some reported results; ¹⁴no blinding of outcome assessor; no information on outcomes measurement; ¹⁵some variables are only measured at 2 week time-point; ¹⁶no adjustment for repeated measurements (but only 3 time-points: baseline-6 weeks-12 weeks); ¹⁷considerable number of patients excluded due to repeated injections/surgery; ¹⁸using ultrasound and fluoroscopy to guide an injection and then assessing the success of the procedure using fluoroscopy has a risk of leading to a measurement bias (accuracy outcome), missing information on adverse events and patient satisfaction outcome measures, Pain and Function outcomes had low risk of bias; ¹⁹the randomisation leads to a significant larger amount of females in the US group compared to the blind group, no info when allocation is concealed; ²⁰no information on the randomization process and when allocation is concealed; ²¹reason for patients lost to follow up and not integrated in the analysis is unclear (only for recurrence of symptoms outcome), for the other outcomes low risk of bias; ²²a hand surgeon not blinded to the treatment assignment performed all US studies; ²³unbalanced baseline data; ²⁴no information whether outcome assessor is blinded; ²⁵from 107 treated patients in one needle group, 7 are lost at baseline, 4 are lost at 3 months and 6 are lost at 1 year (in total 16%), 102 per group was needed according to sample size calculations, 10% of patients were lost at 1 year in the 2 needle group; ²⁶outcomes assessment is performed by the same person performing the intervention; ²⁷more female than male in one group compared to the other; ²⁸the study is most probably not designed for some type of analysis, being a secondary analysis; ²⁹differences at the baseline, before the injection, for the item "internal rotation"; ³⁰no information about intended interventions; no information about time-points; ³¹randomization is done by coin toss, leading to baseline imbalances which are not well described, no statistical testing for baseline differences; ³²no information on the randomization process, no info on age/gender; ³³>10% lost to follow up; no information on sample size calculation; ³⁴no information who assessed the outcomes; it is not clear whether this missing of blindness could have affected the outcome; ³⁵p value for grading is calculated using a t test; however, no information at which time-point it is significant and no adaption for repeated measures; ³⁶high dropouts, more than estimated in the sample size calculation; ³⁷unclear who measures outcomes; ³⁸few information on randomization process; no information when allocation is concealed; ³⁹no information on who assesses outcomes, probably it is the same one who performs the intervention; ⁴⁰no information on some baseline data (e.g. sex, comorbidities), no information on instruments for procedures; ⁴¹no information on demographic data and comorbidities.

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