TITLE PAGE

Title of project:

The efficacy of self-management programs for chronic pain: A Preliminary Review

Course title: Writing a Proposal for a Scientific Study, PHPR 862

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Faculty advisor(s): Marion Slack

Student(s): Kim Azari, Kelsey Garlick, Taness BIllington

ABSTRACT

Specific Aims: To identify studies that have been conducted on pain self-management interventions to describe the strategies used in the treatment of pain.

Subjects: Adults 18 years of age or older with chronic pain.

Methods: Eligible studies were determined using a study inclusion-screening tool. Once determined to be eligible, selected studies were analyzed by two investigators using a full article data extraction form which collected data on the study characteristics, patient characteristics, self-management strategies and relevant study outcomes.

Main Results: The chronic pain management strategies from the 14 randomized controlled trials used in this study included: acupuncture, mobile based intervention, yoga, meditation/relaxation techniques, cupping therapy, musical therapy, cognitive behavioral therapy, physical therapy and self-management therapies. Using different scales, every RCT resulted with a statistically significant reduction in pain from baseline.

Conclusions Pain level appears to be significantly reduced when using any of the alternative management strategies.

INTRODUCTION

A. Problem statement

Pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage."[1] Pain is subjective, meaning it feels different for each individual and is very difficult to verbalize. Because it is a sensation within the body that is always unpleasant, if someone experiences a similar sensation but it is not unpleasant then it is not considered to be pain. This unpleasant feeling causes an emotional experience at the same time. Duration is the differentiating factor between chronic and acute pain. Chronic pain, by definition, cannot be cured but rather the pain may be managed to an acceptable level with specific alleviating methods and tools.[1,2]

Chronic pain is a problem that is estimated to affect 1 in 10 adults and is a common cause of distress and disability. Up to 64% of chronic pain is idiopathic in nature and has no definite tissue pathology. Chronic pain that is not properly managed can lead to feelings of hopelessness and depression and can cause major interferences in individual and family functioning. Chronic pain causes a considerable cost to society and the health care system. There is a major need for interventions that are low-cost, accessible and effective at treating chronic pain.[3] Self-management strategies have become an important part of the management of chronic illnesses in general and teach patients about health promoting activities, how to limit the impact of the disease on daily activities and how to monitor the illness and acclimate to changes.[4]

There are no other meta-analyses or systemic reviews comparing the different interventions of chronic pain relief from randomized controlled trials dated 2010 until now. Since chronic pain is such a prevalent issue and there are different pharmacologic and non-pharmacologic strategies for treatment, there should be a study showing the strengths of each of those. This study will be able to compare each of the interventions for self-management of pain found in these recent studies.

C. Purpose

The purpose of this study was to conduct a preliminary review of self-management interventions for management of chronic pain to provide an overview of the types of strategies used and the effectiveness of these strategies.

D. Specific Aims/Working Hypotheses

Our primary working hypothesis is self-management strategies in the treatment of pain are more effective when added to usual care than just the use of usual care alone. The specific aim of the study is to examine the efficacy of self-management programs as reported in randomized controlled trials.

METHODS

Project Design

This study will be a preliminary review.

Subjects

Population will be adults with chronic pain, which is defined as persistent or pain that has progressed over a long period time. Intervention is a self-management intervention compared to usual care. The outcomes will include pain intensity as measured by a scale. The study design has to be a randomized controlled trial. Any studies involving patients below the age of 18 will be excluded from the study. Studies will also be excluded if published before 2010. A study-screening tool was used to select eligible studies. Two investigators independently identified studies that meet inclusion criteria and reviewed each other's selections and resolve differences by consensus. Refer to Appendix A to view the study-screening tool.

Treatment

Intervention is a self-management intervention compared to usual care. The independent variable was self-management intervention in addition to usual care for pain versus the usual care for pain itself.

Measures

A data extraction form was used which is found in Appendix B. The data extraction form included study characteristics such as the purpose of the study, study design, study setting, baseline pain intensity and definition of chronic pain according to the study investigators. The data extraction form also included the patient characteristics of the study, description of the self-management intervention and a summary of the selected outcomes of the study.

Data Collection

The study investigators independently reviewed the eligible studies identified using the data extraction form found in Appendix. The investigators reviewed each other's analysis and resolved any differences by consensus.

Data Analysis

We estimated a sample size of at least 10-15 research reports that would meet eligibility criteria. To analyze the data, a table was constructed displaying the characteristics of each study report. For studies with adequate data, an effect size (the difference between the means divided by the SD) was calculated for the reduction in pain for the treatment group compared to the control group.

Risk of bias was assessed using a 9-item rating tool (see Appendix C). The tool was specifically designed for assessing risk of bias in RCT's and assessed selection bias (3 items), attrition (1 item), detection bias (1 item), performance bias (2 items), reporting bias (1 item) and independence from sponsor influence (1 item). The likelihood of each type of bias was rated as low, unclear, or high.

Each investigator independently assessed risk of bias for their assigned studies and then met with another investigator who assessed the same trial to compare data. There were at least two investigators assessing the risk of bias for each trial. Any disagreements were resolved through consensus.

RESULTS

A total of 14 studies were analyzed using the data extraction tool. Eight of those studies

were conducted in the United States, three in China, one in Australia, one in the Netherlands and one in England. The sample sizes of the studies ranged from a total of 55 participants to 598 total participants. The percent of male subjects ranged from 8 percent to 58.2 percent. The mean age in years for the studies ranged from 42 years to 75 years of age. There were seven studies that focused on chronic low back pain, two on shoulder pain, four on chronic non-malignant pain and one on chronic neck and shoulder pain. Of all 14 studies, numerous types of management strategies were compared. The array of management strategies included were acupuncture, mobile based intervention, yoga, meditation/relaxation techniques, cupping therapy and musical therapy. Other management strategies were cognitive behavioral therapy, physical therapy and self-management therapies.

Baseline and post-treatment pain intensity levels are shown on the right side of Table 1. The studies used a variety of scales to assess pain including the VAS, 11 point numeric rating scale, the BPI 4-item scale, and several other scales. Effect sizes for the reduction of pain varied between 2.2 a very large effect size for an acupuncture intervention, to 0.02, a very small effect size for an intervention that included relaxation and cognitive behavioral therapy combined in a web-based format. However, the effect sizes for the other studies ranged from 0.18 to 0.42 which are small to moderate effects. The two smallest effect sizes (0.02 and 0.18) were for interventions that included multiple components. [The last observation could be discussed in the discussion section—one would think the effects of multiple interventions should be additive (i.e. more effective) than a single intervention.]

The risk of bias assessment was assessed for all 14 studies using the risk of bias assessment tool found in Appendix C. There were twelve studies that were found to have a low risk of bias. A total of two studies were determined to be unclear when assessing the risk of bias

by the investigators.

DISCUSSION

The primary finding of this study is that there are a variety of different types of pain self-management strategies that can be effective in managing chronic pain in adults greater than 18 years of age. These self-management strategies can be used for different types of chronic pain such as low back pain, shoulder pain and neck pain. The studies combining multiple components surprisingly had the lowest effect size. Normally, one would think the effects of multiple interventions should be additive but these studies showed otherwise. The variety of pain self-management strategies included in this preliminary review indicates that more studies are needed that focus on these therapies and compare them to usual care for pain in order to determine if they should be incorporated into the routine management of chronic pain.

A study by Furlan et al. was conducted comparing various studies on complementary and alternative medicine for chronic pain.[1] What made this study similar to ours was the research and data extraction methods while also having similar results. Although the methods were similar, this study had a more narrow topic of just complementary and alternative medicine while our study broadly focused on nonpharmacological options for pain. Even with the narrow scope, this study concluded that there were inconsistencies in the results because of methodological and clinical diversity, comparable to our results since we had various types of outcome measures with the different intervention types. Another comparable study conducted by Jadad AR and Browman GP investigated different trials evaluating the effectiveness of the World Health Organization (WHO) analgesic ladder for treating cancer pain.[2] We modeled our methods after this study making our study designs very similar. Overall, it is very difficult to compare our

results with other similar studies because of the diverse outcomes measures among all of the randomized controlled trials.

The use of self-management programs for chronic pain has shown to be helpful for patients and reducing overall pain intensity. It should become incorporated in usual practice for the treatment of chronic pain. By incorporating self-management programs into usual practice, it can help reduce the amount of medications patients have to take for chronic pain, therefore reducing adverse effects to medications. Further research should be conducted combining multiple self-management programs, and assessing if the combination results in better management of pain. This will allow for a better assessment of what would be the best programs for management of chronic pain.

For this study there were a few limitations. First, since this was a preliminary review of RCT's, it was difficult to make an extraction tool that incorporated everything for all the studies, since different studies reported information and results differently. Also, many published studies are for chronic pain from cancer, which was not included in our study, so it was difficult to find multiple studies that completely excluded cancer pain. Finally, the risk of bias for blinding of outcome assessment was high in all of the studies that were reviewed. This was because the interventions in the study were difficult to conceal to the participants since it was not just a medication that could be disguised.

CONCLUSIONS

The men and women of all the studies reviewed seemed to have the same levels of pain intensity prior to receiving any self-management programs. Chronic pain levels appear to be significantly reduced when using any of the described pain management strategies, showing that these

strategies can provide great alternative therapy options. Disability has the potential to improve but may not always be a significant reduction. With the incorporation of self-management programs into usual practice of treatment for chronic pain, pain intensity can be significantly reduced. Overall, the addition of self-management programs to usual care have shown to help reduce pain intensity in patients with chronic pain compared to just receiving usual care.

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Table 1.

Characteristics of Identified Studies

Study/ Year/ Location	Management Strategy	Total N	Gender (% Male)	Age (years, mean, SD)	Type of Pain	Pain Intensity: Baseline	Pain Intensity: Post	Other Outcomes
Zhang, 2016/ China	Acupuncture	80	38%	45 ± 7.4	Shoulder pain	C: 64±1.4[a] I: 63.7±10.2[a]	C: 51.7±17.2[a] I: 10.8±19.8[a]	Pain interference: + Activities of daily living: + Disability: + DASH scores: +
Vong, 2011/ U.S.	Motivational enhancement therapy + Physical therapy	76	I: 42.1% C: 31.6%	Not reported	Low back pain	C: 5.3 ± 2.0[b] I: 5.3 ± 2.3[b]	C: 3.9 ± 2.5[b] I: 3.1 ± 2.1[b]	Disability : -
Fersum, 2013/ Norway	Cognitive behavioral/cognitive functional therapy	121	I: 47.1% C: 51.2%	I: 41 ± 10.3 C: 42.9 ± 12.5	Low back pain	I: 4.9[c] C: 5.2[c]	I: 2.3[c] C: 3.8[c]	Oswestry Disability Index: + Hopkins symptom checklist: + Fear-avoidance physical: + Fear-avoidance work: + Sick days leave: +
Nicholas, 2013/ Australia	Outpatient cognitive behavioral pain self management program	141	I: 35% C_1: 30% C_2: 48%	I: 74.59 ± 5.98 C_1: 72.40 ± 5.5 C_2: 74.95 ± 6.6	Non cancer pain	I: 5.32 ± 2.05[d] C_1: 5.48 ± 2.07[d] C_2: 5.67 ± 2.26[d]	I: 0.6 ± 1.7[e] C_1: -0.1 ± 1.6[e]	RMDQ Pain related disability (I vs C_1) : + RMDQ Pain related disability (C_1 vs C_2): + Pain related distress (I vs C_1): +
Irvine, 2015/ U.S.	Mobile web intervention	597	I: 41.7% C: 37.2%	Not reported	Low back pain	I: 0.96 ± 1.26[f] C: 1.09 ± 1.34[f]	I: 0.56 ± 1.00[f] C: 0.98 ± 1.43[f]	Quality of life (I vs C): + Attitudes toward pain (I vs C): +
Wetherell, 2011/U.S.	Acceptance and Commitment therapy	114	49.1%	54.9	Chronic nonmalignant pain of any type	I: 6.0 ± 1.2[g] C: 5.8 ± 1.4[g]	I: 5.6 ± 1.8[g] C: 4.9 ± 1.9[g]	No significant secondary results
Morone, 2016/ U.S.	Meditation and Relaxation techniques	282	I: 33.6% C: 37.2% Total overall: 33.7%	I: 75 ± 7.2 C: 74 ± 6.0	Chronic lower back pain	I: 11±4[h] C: 10.5±4.2[h]	I: 9.5±5.1[h] C: 10.6±4.7[h]	RMDQ Pain related disability (I vs C) : +
Cherkin, 2016/ U.S.	Relaxation techniques, CBT, yoga, and MBSR	341	34.3%	49.3 ± 12.2	Chronic lower back pain	I_{MBSR}: 6.1±1.6[d] I_{CBT}: 6.0±1.5[d] C: 6.0±1.6[d]	I_{MBSR}: 4.15[d] I_{CBT}: 4.24[d] C: 4.9[d]	Roland disability questionnaire: + Pain bothersomeness: +
Lambeek, 2010/ Netherlands	Physical therapy and integrated care and workplace intervention	134	58.2%	I: 45.5 ± 8.9 C: 46.8 ± 9.2	Chronic lower back pain	I: 5.7±2.2[d] C: 6.3±2.1[d]	I: 4.06±1.85[d] C: 4.45±1.74[d]	Functional status: +
Ruehlman, 2012/ U.S	Relaxation techniques, CBT, physical	305	36%	44.93	Overall chronic pain	I: 24.47±3.11[i] C:	I: 22.41±4.31[i] C: 22.34±4.6[i]	Pain knowledge: + Catastrophizing:

	therapy, and web based intervention					23.93±3.49[i]		+ Psychological outcomes: +
Lamb, 2010/ England	Cognitive behavioral therapy	598	I: 41% C: 39%	I:53±14.6 C: 54± 14.9	Chronic lower back pain	I: 59± 19.2[j] C: 59±19.5[j]	I_1:12.2% ± 2.37[k] I_2:13.7% ±2.45[k] I_3:13.4%± 2.59[k] C_1: 5.4% ±2.95[k] C_2: 5.7% ± 3.29[k] C_3: 6.4% ± 3.26[k]	Roland Morris disability: + Fear avoidance beliefs: + Pain- self efficacy: +
Zhang, 2016/China	Contralateral manual acupuncture	80	I: 29% C: 45%	I: 44.3 ± 7.2 C: 45.6± 7.6	Chronic shoulder pain	I: 63.7±10.2[b] C:64.0±1.4[b]	I_1:39.2±13.4[l] I_2:10.8±17.0[l] I_3:10.8±15.1[l] I_4:10.8±19.8[l] C_1:58.6±8.7[l] C_2:51.2±15.5[l] C_3:51.9±17.8[l] C_4:51.7±17.2[l]	Activities of daily living: + Disabilities in arm, shoulder and hand (DASH): +
Chi, 2016/China	Cupping	60	8%	I:43.6±8.0 C:42.5±7.4	Chronic neck and shoulder pain	I_1:9.7±1.6[b] I_2:8.5±0.9[b] C_1:9.7±1.6[b] C_2:8.5±0.9[b]	I_1:3.6[b] I_2:2.6[b] C_1:9.5[b] C_2:7.9[b]	Blood pressure decrease: +
Bradt, 2016/ US	Music therapy	55	I:17.9% C:3.7%	I: 54.5±13 C:53±12.8	Chronic pain	I:28.6±15.0[m] C:34.2±13.6[m]	I: 32.5±15.2[m] C:27.7±12.7[m]	Pain interference (MPI): + General activity (MPI): + Anxiety (HADS): + Depression (HADS): + Treatment satisfaction: -
Nicholas, 2017/ Australia	CBT-based self management program	75	32%	73.9±6.5	Chronic pain	I:5.3±2.06[d] C:5.48±2.08[d]	I:4.64±2.22[d] C:5.44±2.15[d]	Pain related disability: + Pain related distress: + Depression: + Fear avoidance: + Pain self-efficacy: +

a: Questionnaire values 2 weeks, 4 weeks, 8 weeks, and 16 weeks after therapy initiations
b: A 10 cm VAS labeled "no pain" at the left end and "pain as bad as it can be" on the right side was used and subjects marked their present level of pain intensity.
c: The PINRS measures pain severity by asking the patient to select a number (from 0 to 10) to represent how severe the pain had been over the last 2 weeks.
d: Numerical rating scale using an 11 point scale where 0 indicated "no pain" and 10 indicates "pain as bad as it could be"
e: Reported as crude mean differences from pretreatment to post treatment with no C_2 since it did not change.
f: set of back pain measures asked about intensity of back pain
g: BPI 4-item subscale for pain severity
h: NRS scale, Scores range from 0 to 20, with higher scores indicating worse pain
i: The 15-item PCP-S provides a multidimensional assessment of the individual's pain problem with scales that measure pain severity and interference, as well as the emotional burden of pain.
j: Von Korff: scale that measures pain and disability from 0-100
k: Questionnaire value percent change from baseline data at 3 months, 6 months and 12 months after initiation
l: Questionnaire values 2 weeks, 4 weeks, 8 weeks, and 16 weeks after therapy initiations
m: Pain Self-Efficacy Questionnaire: range from 0 to 60 with higher scores representing greater self-efficacy

Table 2.

Risk of Bias Assessment

Study/ Year	Allocation sequence generation	Concealment of Allocation	Equivalence of groups at baseline	Attrition, drop outs, experimental mortality	Blinding to allocated interventi on	Blinding of outcome assessment	Adherence to protocol is adequate	Selective reporting	Independence from sponsor influence	Other sources of bias	Overall assessm nt
Irvine/ 2015	Unclear	High	Low	Low	Unclear	High	Low	Unclear	High	None	Unclear
Morone/ 2016	Low	Low	Low	Low	Low	High	Unclear	Low	Low	None	Low
Nicholas /2013	Low	Low	Low	High	Low	High	Low	High	Low	None	Low
Wetherel l/2010	Low	Low	Unclear	Low	Low	High	Low	Low	Low	None	Low
Vong/ 2011	Low	Unclear	Low	High	Low	High	Low	Low	Low	None	Low
Zhang/ 2016	Low	Unclear	Low	Low	Low	High	Unclear	Low	Low	None	Low
Fersum/ 2016	Low	Low	High	High	High	High	Low	Low	Low	None	Unclear
Cherkin/ 2016	Low	Low	Low	High	Unclear	Unclear	Low	Low	Low	None	Low
Lambeek /2010	Low	Low	Low	Low	High	High	Low	Low	Low	None	Low
Ruehlma n/2012	Unclear	Unclear	Low	Low	Unclear	Unclear	Unclear	Low	Low	None	Low
Lamb/20 10	Low	Low	Low	Low	High	Low	Low	Low	Low	None	Low
Nicholas /2017	Low	Low	Low	High	Low	High	Low	High	High	None	Low
Chi/2016	Low	Low	Low	Low	Unclear	High	Unclear	Low	Low	None	Low
Bradt/ 2016	Low	Low	Low	High	High	High	Low	Low	Low	None	Low

APPENDICES

Appendix A

Title

Study Inclusion Screening Tool

Date of review: _____ Initials of reviewer: _____

Unique Identifier: _____
Study Citation: _____

Review the abstract and answer the following questions for inclusion.
(If unable to determine the answers from the abstract or no abstract is available, use the full article for review.)

1. Does the study involve an intervention for teaching pain self-management?
   Yes No
2. Is the study a randomized controlled trial?
   Yes No
3. Are patient-related outcomes reported? (Outcomes may include pain intensity, activity level, quality of life, etc.)
   Yes No

If you answered "yes" to all three questions, the study will be included in the systematic review.

_____

If you answered "no" to any questions, note the reason(s) for exclusion below.
(check all that apply):

☐ No pain management intervention
☐ Not a randomized controlled trial
☐ Does not report any relevant target outcomes
☐ Editorial/Letter
☐ Commentary
☐ Case study
☐ Not English language

Date of review team meeting: _____

Decision: Include _____ Exclude _____ Arbitration Needed _____

Date of Arbitration: _____

Decision: Include _____ Exclude _____

Appendix B

Full Article Data Extraction Tool
Systematic Review of Patient Self Pain Management

- Unique Identifier: _____ Reviewer Initials: _____
- Study Citation: _____ Data Extraction Date:_____
-

STUDY CHARACTERISTICS	
1. Purpose of study	Purpose:_____
2. Type of pain	❑ Chronic ❑ Acute ❑ Not defined
3. Baseline pain Intensity	❑ Yes ❑ No Notes:
4. Location	❑ Yes ❑ No Notes:
5. Cause	❑Yes ❑No Notes:
6. Study Design	❑ Randomized controlled trial
7. Study Setting *(country where study was conducted)*	U.S. ❑ Other _____
8. Source population	❑Older adult ≥65 ❑Adult ≥ 18 ≤65 ❑Other____
9. Definition of chronic pain	
PATIENT CHARACTERISTICS	
11. Number of patients	Total # _____ Intervention group: Control group:
12. Age *(report means if available)*	(1) <18 yrs ❑ (2) 18-55 yrs ❑ (3) ≥55yrs ❑ (4) Mean age ($\bar{x}$): _____ Standard Deviation (SD): ±____ (5) Median age: ____ (6) Age not reported ❑
13. Comorbidities	❑ Yes_____ ❑ No
14. Gender	(1) # of Males: _____ % _____ (2) # of Females: _____ % _____ (3) Not reported ❑

15. Employment Status	❑ Full time ❑ Part time ❑ other:_____ ❑ Not reported	
16. Education	❑ High school diploma or less ❑ Bachelor's degree ❑ Graduate degree or higher ❑ Other _____ ❑ Not reported	
SELF-MANAGEMENT STRATEGIES		
22. Type of Intervention	❑ cognitive-behavioral ❑ Musical ❑ Relaxation techniques ❑ Diaghragmatic breathing ❑ EMDR	❑ Physical therapy ❑ Web-based ❑ Tai-chi ❑ visualization techniques ❑ Other _____
23. Intervention Time	_____ hours	
24. Duration of Intervention	_____ weeks	
25. Providers	❑ Psychologist ❑ MD ❑ RPH ❑ Chiropractor ❑ Other _____	❑ Physical therapy ❑ RN ❑ Chinese medicine
OUTCOMES		
	Intervention Group	**Control Group**
26. Pain intensity- Pre **27. Pain intensity -Post**	Mean=_____ SD=_____ Mean=_____ SD=_____	Mean=_____ SD=_____ Mean=_____ SD=_____
28. Work days lost	Mean=_____ SD=_____	Mean=_____ SD=_____
29. Pain interference with daily activities	Qt=_____ %=_____	Qt=_____ %=_____
30. Disability	Qt=_____ %=_____	Qt=_____ %=_____
31. Rate overall satisfaction with treatment	Mean=_____ SD=_____	Mean=_____ SD=_____

- **Notes:** *(Record any notes here, e.g. contact of study authors.)*

Appendix C

Risk of Bias Assessment for Reviews of RCTs

A separate assessment is required for each outcome variable. (Adapted from the Cochrane Collaboration, 2011)

Author/date_____ **Date of Assessment_____**

Study Design_____

1. Allocation sequence generation (Selection bias)
   Low: Random process is used; e.g. computer generated, random numbers table, dice, etc.
   Unclear: The process used is not described. Rate 'unclear' if states 'were randomized' with no description of the process.
   High: Any procedure that does not include a random process, e.g. chart numbers, alphabet, time of day, order of entrance, etc.
   Rationale:

2. Concealment of allocation (Selection bias)
   Low: The allocation sequence was concealed; e.g. assignment was obtained from a computer program, or central randomization office, or coded containers and/or drugs prepared in pharmacy was used, or similar methods were described.
   Unclear: Concealment process was not described.
   High: Some type of process is described that is not adequate, e.g. allocation list was available, allocation was performed at the time participant was admitted to study, etc.
   Rationale:

3. Equivalence of groups at baseline (Selection bias)
   Low: Analysis of baseline characteristics shows no statistical differences OR differences were controlled in the statistical analysis; if baseline measures were possible on the dependent variable, comparisons indicated no difference.
   Unclear: No statistical comparison of comparison groups.
   High: Differences in baseline characteristics were reported and not controlled in the analysis or no data on baseline characteristics reported
   Rationale:

4. Attrition, drop outs, experimental mortality
   Low: Number of subjects randomized matches the number used to report findings. (Verify from tables/text and flowchart.)
   Unclear: No mention of loss to follow-up; no data provided on follow-up.
   High: Reported loss of participants or participants appear to have been lost to follow-up based on the data reported in the flowchart and/or tables/text.
   Rationale:

5. Blinding to allocated intervention (Detection bias)

Low: Assessment of target outcome variables was blinded, i.e. providers performing the outcome assessment were blinded to group assignment.
Unclear: Not described; rate unclear if study is described as blinded but blinding of assessor is not described.
High: The practitioner who provided services also performed the outcome assessment or information indicates assessor was not blinded.
Rationale:

6. Blinding of outcome assessment (Performance bias)

Low: Providers and participants are blind to the type of intervention that the participant is receiving. The methods used for blinding and who was blinded should be described in the methods section.
Unclear: Information on blinding is incomplete or unclear; the persons blinded are not identified and the method of blinding is not described.
High: Study is not blinded or study is described as 'blinded' but other information indicates that participants or providers could easily identify the treatment group. For example, one group received capsules and the other group, tablets.
Rationale:

7. Adherence to protocol is adequate (Performance bias)

Low: An adequate method is described for assessing adherence AND adequate adherence to the protocol is reported.
Unclear: No method to assess adherence is described and/or no adherence findings are reported.
High: The level of adherence reported is not adequate; e.g. average number of tablets dispensed was 50%.

8. Selective reporting (Reporting bias)

Low: The primary outcome measure identified in the methods section is also the primary outcome measure reported.
Unclear: Not clear what the primary measure of the study was or if primary outcome measure of the study was a secondary measure of the study.
High: Primary outcome measure identified in the methods section was reported as an incidental measure in the results section or is buried in a list of several outcome measures.
Rationale:

9. Independence from sponsor influence

Low: Authors report no conflicts of interest; there is no indication that sponsor was involved in the study except in a minor role (e.g. providing medications and placebo).
Unclear: No information is provided on funding or conflicts of interest.
High: Information is provided that indicates there may be conflicts of interest or that sponsor was involved in the study, e.g. provided funding, assistance writing the manuscript, etc.
Rationale:

10. Other sources of bias

Assess any additional sources of bias that might be relevant to a particular study. For example, special methods to conceal the odor of a medication.

Overall assessment: The risk for bias appears [low, unclear, high]. State rationale.

Notes:

Selection Bias: Selection bias affects the equivalence of the comparison groups at baseline. The risk of bias can be assessed by checking the methods section for a description of the random process that was used to generate the group assignments. Random process is defined as a process that gives every member of the sample an equal chance to be assigned to any of the treatment groups (e.g. a process derived from gambling).

To verify that the comparison groups are indeed equivalent, check the table reporting the baseline characteristics. If baseline are characteristics show no meaningful differences between the groups then the likelihood of bias is low.