

# BMJ Open Influence of psychological factors on the prognosis of chronic shoulder pain: protocol for a prospective cohort study

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## ABSTRACT

**Introduction:** Shoulder pain is a highly prevalent condition. Psychological factors could play an essential role in the prognosis of chronic shoulder pain (CSP). The aims of the study will be to analyse the level of association between psychological factors and pain-disability at baseline and prospectively to assess their prognostic role; to evaluate the association of pain catastrophising and kinesiophobia at baseline and prospectively in the relationship between pain intensity and disability, or between self-efficacy and disability in patients with CSP; to explore the association of self-efficacy at baseline and prospectively in the relationship between pain intensity and disability, in comparison with kinesiophobia and pain catastrophising.

**Methods and analysis:** The study is a longitudinal, prospective cohort study with a 12-month follow-up. It will be conducted in 4 primary-care centres and one hospital of the province of Malaga, Spain. 307 participants aged between 18 and 70 years suffering from CSP (3 months or more) will be included. Primary outcomes will include pain, disability and self-efficacy, whereas kinesiophobia, pain-related fear, pain catastrophising, anxiety, depression, patient expectations of recovery, age, gender, duration/intensity of symptoms, educational level and other factors will be predictive measures. Follow-up: baseline, 3, 6 and 12 months.

**Ethics and dissemination:** The local ethics committee (The Costa del Sol Ethics Committee, Malaga, 28042016) has approved this protocol. Dissemination will occur through presentations at National and International conferences and publications in international peer-reviewed journals.

**Trial registration number:** NCT02738372; pre-results



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## INTRODUCTION

Shoulder pain is the third most common musculoskeletal condition presenting to physicians or physiotherapists<sup>1</sup> in primary health-care after low back and neck pain,<sup>2 3</sup> being a significant cause of morbidity,<sup>4</sup> and

## Strengths and limitations of this study

- The inclusion of a long battery of psychological factors evaluating their role in the prognosis of chronic shoulder pain.
- The exploration of the mediating power of self-efficacy, kinesiophobia and pain catastrophising in chronic shoulder pain.
- The inclusion of self-efficacy as an outcome measure.
- Some psychological factors such as pain acceptance and psychological distress will be not included in this study.
- Another limitation could be that some psychological factors are quite broad in definition, increasing the risk on finding conflicting evidence on their relationship with outcomes.

functional disability in both working<sup>5 6</sup> and general population.<sup>6–8</sup> It affects one in three adults,<sup>7 9 10</sup> accounting 1% of general practitioners' (GPs) consultations in primary care.<sup>11</sup>

Incidence rates range from 11.2 to 29.5 per 1000 person-years,<sup>11–14</sup> and the reported prevalence rates range from 4.7 to 46.7 per 1000 person-years.<sup>10 14 15</sup> Incidence and prevalence rates tend to increase with age,<sup>16</sup> in women,<sup>10 16 17</sup> in persons from lower socioeconomic groups, and in psychologically stressed populations.<sup>18</sup>

Despite the large group of individuals seeking for primary-care services, about 50% of patients with shoulder pain still report persistent pain after 12 months.<sup>9 16 18 19</sup> As a result, socioeconomic burdens are considerable due to extensive use of health care services, sickness absence, disability pension and loss of productivity,<sup>20–24</sup> as well as patient's suffering.

That is why there is a consensus in the field that research efforts need to be focused on obtaining insight into which prognostic factors play the most important roles in

chronic shoulder pain (CSP), and how those factors impact on pain and function, as this understanding is crucial to acquire a clear comprehension of all the process involved in CSP and to underline pain-treatment effects in seeking to improve the poor prognosis of this entity.

CSP is a complex syndrome, and pain chronicity often cannot be explained (solely) by an obvious anatomic defect or tissue damage.<sup>25</sup> A recent review<sup>26</sup> exposed that the effective management of shoulder pain relies on a detailed knowledge of peripheral pathology (ie, adhesive capsulitis, SLAP lesion or rotator cuff tendinopathy), as well as on a comprehensive understanding of how pain can be generated, propagated and modified. In this sense, there has been a growing recognition that the degree of chronic pain is influenced by the beliefs, attitudes and expectations of individuals.<sup>27–29</sup>

Given the importance of pain as a mechanism of survival, it is perhaps unsurprising that pain perception is clearly influenced by conscious and unconscious memory, cognitive and emotional functioning and contextual factors that are explicitly included in a biopsychosocial formulation of pain.<sup>30</sup> Inside of the biopsychosocial understanding of chronic pain, there is a growing interest, and acceptance in hypothesising that the association between physical impairment, pain intensity and pain-related disability is only moderate and that psychological factors may influence the experience of pain and its impact and hence may play a crucial role in the maintenance of pain-related problems.<sup>27 31</sup> Currently, some evidence has shown how psychological factors could be associated with the prognosis of CSP.<sup>32–34</sup> Reilingh *et al*<sup>32</sup> investigated the course and prognosis of shoulder pain in the 6 first months after presentation to the GP. Predictors of a better outcome for CSP were lower scores on pain catastrophising and higher baseline pain intensity (explained variance 21%). Gill *et al*<sup>33</sup> examined which factors are predictive of incident, recurrent or resolved shoulder pain in a community-based sample from the general population. Findings showed how recurrent shoulder pain was associated with depressive symptoms. Chester *et al*<sup>34</sup> aimed to identify which baseline patient and clinical characteristics are associated with a better outcome, 6 weeks and 6 months after starting a course of physiotherapy for shoulder pain. In this study, higher patient expectation of complete recovery compared to slight improvement because of physiotherapy and higher pain self-efficacy were associated with patient-rated outcomes.

Therefore, it seems presumable that psychological factors could play a role in people with shoulder pain and favour the perpetuation of CSP. Self-efficacy has been proposed to predict pain, pain behaviour, physical functioning and disability in chronic musculoskeletal pain.<sup>35 36</sup> Furthermore, self-efficacy is considered to be a stronger mediator of the relationship between pain behaviour, pain intensity and disability than psychological factors such as kinesiophobia and pain

catastrophising.<sup>37–39</sup> However, the role of self-efficacy as an outcome measure and as mediator in CSP has not been studied yet. Knowing and understanding which psychological factors are specifically involved in the prognosis of CSP is challenging to facilitate clinical decision-making and, if necessary, timely, and specific consultation with—or referral to—other healthcare providers.<sup>40</sup>

There are four hypotheses in the present study. First, higher levels of psychological factors at baseline and prospectively such as kinesiophobia, pain-related fear, depression, anxiety, patient expectations of recovery and pain catastrophising are associated with a higher level of pain intensity, and disability, and lower level of self-efficacy. Second, pain catastrophising and/or kinesiophobia mediate the relationship between pain intensity and disability, or between self-efficacy and disability at baseline. Third, changes in pain catastrophising and/or changes in kinesiophobia mediate the relationship between changes in pain intensity and changes in disability, or changes in self-efficacy and changes in disability after 12 month follow-ups. Fourth, self-efficacy is the strongest mediator in the relationship between pain intensity and disability at baseline and prospectively. Hence, the aims of the present study will be: (1) to analyse the level of association between psychological factors and pain-disability at baseline and prospectively to assess their prognostic role; (2) to evaluate the association of pain catastrophising and kinesiophobia at baseline and prospectively in the relationship between pain intensity and disability or between self-efficacy and disability in patients with CSP; (3) to explore the association of self-efficacy at baseline and prospectively in the relationship between pain intensity and disability, in comparison with kinesiophobia and pain catastrophising.

## METHODS AND ANALYSIS

### Study design and setting

The present study will be a 12 month multicentre, prospective, cohort study that will be carried out between May 2016 and April 2017 in four primary-care centres and one hospital of the province of Malaga, Spain. Several questionnaires assessing different psychological factors will be administrated to these participants. The outcomes will be assessed at baseline (t1) and at 3 follow-ups times (after 3 (t2), 6 (t3) and 12 months (t4)). Ethical approval has been obtained from Costal del Sol Ethics Committee, Malaga, Spain (28042016). The study will be implemented and reported in line with the SPIRIT statement.

### Participants

A consecutive sample comprised participants with CSP will be recruited. GPs will carry out the recruitment. Then, the research assistants who will be previously instructed by the research team will assess the

participants for eligibility. If the participants satisfy the eligibility criteria, they will be invited to participate in this study, and then they will be evaluated at baseline and 3, 6 and 12 months' follow-up. The inclusion criteria as follows: (1) men/women aged over 18 years and (2) participants suffering from shoulder pain (pain intensity of 3 or more on a 0–10 numerical pain rating scale) will be included in this study, among all these following shoulder pain conditions: non-specific shoulder pain, subacromial pain syndrome, rotator cuff tendinopathy, adhesive capsulitis, instability without trauma, SLAP lesion, acromioclavicular pathology and/or shoulder osteoarthritis. Diagnosis will be carried out by clinical testing based on the recommendations of McClure *et al.*<sup>41</sup> and radiological test through MRI and/or ultrasound imaging; (3) duration of symptoms: more than 3 months. The exclusion criteria as follows: (1) recent shoulder dislocation (1 year prior) and/or systemic diseases such as rheumatoid arthritis, fibromyalgia and/or polymyalgia rheumatic; (2) shoulder pain considered to be originated from the cervical region, and other traumas, or if there is a neurological dysfunction (ie, multiple sclerosis or stroke), osteoporosis, haemophilia and/or cancer; (3) participants receiving shoulder surgery; (4) participants with shoulder pain after post fracture; and (5) inability to provide informed consent and/or complete written questionnaires.

## Procedures

### Recruitment

Anonymised age and gender details will be collected for those participants who decline to take part in the project, to assess the external validity of the recruited sample of participants.

Eligible participants who will be interested in the study will be asked to provide written informed consent to participate. Participants will then complete several questionnaires at baseline, 3, 6 and 12 months after the beginning of the study.

Participant data files will be stored in numerical order and in a secure and accessible place and manner. Participant files will be maintained in storage for a period of 3 years after completion of the study.

### Outcomes measures

Outcome measures and some of the potential prognostic factors will be measured at baseline and prospectively, with the aim of observing possible associations between potential prognostic factors and pain disability, and self-efficacy at baseline, and prospectively to assess their prognostic role, and if some of them appear as confounding factors.

### Primary outcome

#### *Pain and function*

1. The Shoulder Pain and Disability Index (SPADI) is a self-administered index consisting of 13 items divided into two subscales: pain and disability.<sup>42</sup> It grades a normal shoulder as 0 and maximally affected as 130,

and an 11-point numerical pain rating scale with 0 as normal and 10 as maximal pain.

### Secondary outcome

#### *Self-efficacy*

2. Pain Self-Efficacy Questionnaire (PSEQ) contains 10 questions that will measure the patient's confidence in performing certain activities despite pain. Items are scored on a scale from 0 to 6, with a maximum possible score of 60 points. Lower scores indicate less self-efficacy.<sup>43</sup>

### Potential prognostic factors

Psychological factors will be assessed through four questionnaires at baseline, 3, 6 and 12 months follow-up.

#### *Kinesiophobia, pain-related fear, pain catastrophising, anxiety, depression and patient expectations of recovery*

1. The Fear-avoidance Components Scale (FACS) is a new patient-reported measure designed to evaluate pain-related fear and kinesiophobia in patients with painful medical conditions. It consists of 20 items that are scored on a 5-point scale.<sup>44</sup>
2. The Pain Catastrophising Scale (PCS) will be included to assess catastrophic thinking about pain. It consists of 13 items describing different thoughts and feelings that individuals may have when experiencing pain. Items are scored on a 5-point scale. A general score and scores on three subscales (ie, helplessness, magnification and rumination) will be obtained; higher scores indicate more severe catastrophic thoughts about pain.<sup>45</sup>
3. The Hospital Anxiety and Depression Scale (HADS) is a 14-item scale designed to detect anxiety and depression, independent of somatic symptoms. It consists of two 7-item subscales measuring depression (HADS-D) and anxiety (HADS-A). It uses a 4-point response scale that ranges from 0 (absence of symptoms) to 3 (maximum symptoms), with possible scores for each subscale ranging from 0 to 21.<sup>46</sup> Higher scores indicate higher levels of disorder. The HADS has been widely used as a screening instrument for the detection of comorbid depressive and anxiety disorders in patients with musculoskeletal disorders.<sup>47–49</sup>
4. Patient expectations of recovery will be measured by asking the participants to rate the likelihood that they would resume some form of recovery at 3, 6 and 12 months' follow-up ("How likely is it that within the next 3 months you will have resumed some form of recovery?"). Participants will indicate their response on a scale with the end points (0%) not at all likely to (100%) extremely likely.<sup>50</sup>

### Other potential prognostic factors

1. Side of shoulder problem (right, left and both) will be coded into three levels: (i) right; (ii) left and (iii) both.

2. Shoulder dominance (right, left and ambidexterity) will be coded into three levels: (i) right; (ii) left and (iii) ambidexterity.
3. History of previous shoulder problems will be measured with a yes/no question.
4. Current treatment will be evaluated through a checklist divided in five groups: (i) no treatment; (ii) pharmacological treatment; (iii) injections; (iv) physical therapy and (v) other treatments (massage, reflexology, acupuncture).
5. Being convinced of this pathology will be measured with a yes/no question.
6. Active shoulder ROM-free of pain will be measured with a manual inclinometer placed in the affected shoulder.
7. Comorbidities will be tested with the Self-Administered Comorbidity Questionnaire (SCQ).<sup>51</sup> Patients will be asked if they had one or more medical conditions (from a list of 15 diagnoses). If they gave a positive response, they will be asked whether the condition limited their activity.
8. Recurrence of shoulder problem was dichotomised to those patients who had a recurrent episode within the past 12 weeks and those who had a recurrent episode more than 12 weeks. With a simple answer: yes/no.
9. The Numerical Rating Scale (NRS) was used to assess each patient's pain intensity at baseline and follow-ups. The NRS scores range from 0 to 10, with 0 representing no pain and 10 representing the worst pain imaginable. The NRS has been shown to have good same-day test-retest reliability.<sup>52</sup>
10. Work status will be coded into five categories of work: (i) unemployment; (ii) sick leave; (iii) retirement; (iv) housewife and (v) active worker.
11. Work absenteeism will be measured by the following sentence: how many days (if any) within the previous 4 weeks' care workers had not attended work due to feeling ill and unfit for work. Respondents answered by number of days. Numbers were then grouped into three categories (0=0 days, 1=1–2 days, 2=3 or more days).<sup>53</sup>
12. Work performance will be measured by the Word Health Organization Health and Work Performance Questionnaire (HPQ) through the following sentence: How would you rate your overall job performance on the days you worked during the past 4 weeks (28 days)?; responses used a scale ranging from 0 to 10, with higher scores indicating higher work performance in the previous 4 weeks.<sup>54</sup>
13. Educational level will be coded into five educational levels: (i) university/college  $\geq 4$  years; (ii) university/college 4 years; (iii) upper secondary; (iv) elementary secondary and (v) no studies.<sup>55</sup>
14. Gender, age, height and weight will be reported by self-reported questionnaire.

The summary of potential prognostic factors and outcome measures is presented in [table 1](#).

### Sample size estimation

To contrast the null hypothesis that six potential prognostic factors (kinesiophobia, pain-related fear, pain catastrophising, anxiety-depression, age and gender) included in the estimation does not explain the primary outcome, ANOVA-test in a multiple linear regression model will be used, considering a significance level of 0.05, and a statistical power of 0.9, assuming that one variable (anxiety-depression<sup>34</sup>) provides a coefficient of determination of 0.31, and for a higher coefficient of 0.36, a sample of 230 patients will be needed. Assuming an expected drop-out rate of 25%, a total number of 307 patients will be needed.

### Statistical analysis

Data set will be carried out using SPSS for Windows (V.22; SPSS, Chicago, IL). There will be four measurements in the study, T1=at baseline, T2=3 months, T3=6 months, T4=12 months' follow-up. Kolmogorov-Smirnov test will be used to analyse the normal distribution of the variables ( $p > 0.05$ ). Continuous variables will be presented through centrality measures (mean, median), and dispersion (SD and IQR), and categorical variables through frequencies and percentages. Rank sums, Wilcoxon signed Rank test, Mann-Whitney U test and Friedman's test will be used depending on the comparisons to be made, in case of non-normal distribution of variables. For the identification of potential prognostic factors, the psychological variables (kinesiophobia, pain-related fear, pain catastrophising, anxiety, depression and patient expectations of recovery) and sociodemographic characteristics (age, gender, height, weight, shoulder problems, work status, work absenteeism, work performance, intensity of pain, active shoulder ROM-free of pain, educational level, treatments received and comorbidities) will be introduced as predictors in a multiple linear regression analysis, taking SPADI as continuous dependent variable.

Finally, analysis through COX regression will be conducted to determine the HRs of the aforementioned factors with the presence of pain and disability (using SPADI values to determine this state), through proportional hazard models. A  $p$ -value  $< 0.05$  will be considered statistically significant.

### Data collection and management

To ensure accurate, complete and reliable data, all study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with limited access. A coded ID number will identify reports, data collection, process and administrative forms only to maintain participant confidentiality.

### Modification of the protocol

Any modifications to the protocol that may affect the conduct of the study, potential benefit of the patient or may affect patient safety, including changes of study

**Table 1** Overview of measurement instruments and time of assessment

Construct	Type	Staff member	Baseline (T1)	3 months (T2)	6 months (T3)	12 months (T4)
Outcome measures						
Pain and function	SPADI	Interviewer	X	X	X	X
Self-efficacy	PSEQ	Interviewer	X	X	X	X
Shoulder problems						
Side of shoulder problem (i) right; (ii) left; (iii) both.	Self-reported questionnaire	Interviewer	X			
Shoulder dominance (i) right; (ii) left; (iii) ambidexterity	Self-reported questionnaire	Interviewer	X			
History of previous shoulder problems	Self-reported questionnaire (yes/no)	Interviewer	X			
What modality of treatment? ((i) no treatment; (ii) pharmacological treatment; (iii) injections; (iv) physical therapy; (v) other treatments (massage, reflexology, acupuncture)	Self-reported questionnaire	Interviewer	X	X	X	X
Have you been convinced of this pathology?	Self-reported questionnaire (yes/no)	Interviewer	X	X	X	X
Potential prognostic factors						
Pain-related fear and kinesiophobia	FACS	Interviewer	X	X	X	X
Pain catastrophising	PSC	Interviewer	X	X	X	X
Active shoulder ROM-free of pain	Manual Inclinator	Interviewer	X	X	X	X
Anxiety and depression	HADS	Interviewer	X	X	X	X
Patient expectations of recovery	Self-reported question (0–100)	Interviewer	X	X	X	X
Comorbidities						
Recurrence of shoulder pain	SCQ	Interviewer	X	X	X	X
	Self-reported questionnaire (yes/no)	Interviewer	X			
Intensity of pain	NRS	Interviewer	X	X	X	X
Work status ((i) unemployment; (ii) sick leave; (iii) retirement; (iv) housewife; (v) active worker)	Self-reported questionnaire	Interviewer	X	X	X	X
Work absenteeism	Self-reported questionnaire	Interviewer	X	X	X	X
Work performance	Question obtaining of HPQ	Interviewer	X	X	X	X
Age, gender	Self-reported questionnaire	Interviewer	X			
Height, weight	Self-reported questionnaire	Interviewer	X			
Educational level: (i) university/college $\geq 4$ years; (ii) university/college 4 years; (iii) upper secondary; (iv) elementary secondary; (v) no studies	Self-reported questionnaire	Interviewer	X			

FACS, Fear-avoidance Components Scale; HADS, Hospital Anxiety and Depression Scale; NRS, Numerical Rating Scale; PCS, Pain Catastrophising Scale; PSEQ, Pain Self-Efficacy Questionnaire; SCQ, Self-Administered Comorbidity Questionnaire.

objectives, study design, patient population, sample sizes and study procedures, or significant administrative aspects will require a formal amendment to the protocol.

Such amendment will be agreed on by this research group and approved by Costa del Sol Ethics Committee, Malaga, Spain, prior to implementation and notified to the health authorities in accordance with local regulations.

### Dissemination

The trial is registered in Clinicaltrials.gov: NCT02738372.

The results of the study will be disseminated at several research conferences and as published articles in peer-reviewed journals.

### DISCUSSION

The present study will be the first study analysing the role of a long battery of psychological factors (pain-related fear, kinesiophobia, anxiety, depression, patient expectations of recovery and pain catastrophising) in the prognosis of CSP. Previous studies<sup>32–34 56 57</sup> have evaluated the influence of several psychological factors on the prognosis of CSP. Macfarlane *et al*<sup>56</sup> showed how higher levels of psychological distress predicted perpetuation of CSP. Badcock *et al*<sup>57</sup> reported association between disability and psychological distress after controlling for possible confounders. Reilingh *et al*<sup>32</sup> exposed how higher levels of pain catastrophising predicted recurrence of symptoms in CSP. Gill *et al*<sup>33</sup> showed how recurrent shoulder pain was associated with depressive symptoms. Chester *et al*<sup>34</sup> reported how higher patient expectation of complete recovery compared to slight improvement as a result of physiotherapy and higher pain self-efficacy were associated with patient-rated outcomes. These previous studies support the necessity of carrying out the present study, but also the inclusion of several psychological factors, which have not been already evaluated on the prognosis of CSP, such as pain-related fear, kinesiophobia and anxiety, justifying the development of this cohort study, because it seems presumable that psychological factors may play an essential role along with biomedical and/or biomechanical factors in the perpetuation of chronicity in patients with CSP. Besides that, this will be the first study evaluating self-efficacy as an outcome measure in shoulder region. Previous studies have explored how psychological factors influence self-efficacy in chronic musculoskeletal conditions,<sup>58</sup> and how several therapeutic strategies could improve this psychological construct.<sup>59 60</sup> Therefore, the inclusion of self-efficacy as an outcome in this study could be reasonable, because this construct is based on how a person's perceived confidence in the ability of successfully carrying out daily and/or work activities or behaviour despite the pain,<sup>61</sup> and people with CSP usually have to do many tasks that implicate the

movement of their shoulders. That is why, detecting possible factors which contribute to improve or reducing effects of self-efficacy in people with CSP may give rise to benefits for this population.

### Strengths and weaknesses of the study

The strengths of this study will include a long battery of psychological factors evaluating their role in the prognosis of CSP, the exploration of the mediating power of self-efficacy, kinesiophobia and pain catastrophising in CSP, the inclusion of self-efficacy as an outcome measure and the use of the SPIRIT checklist to give more quality to the study. The limitations associated with this study must be acknowledged when interpreting the results. First, information bias could be an important limitation of this study. Some participants may have problems to deal with the questionnaires and remember any situation associated with their pain and disability at 3, 6 and 12 months' follow-up. Even so, some participants might be more likely to deny participation or abort follow-up. However, adding a drop-out rate of 20% in sample size calculation should alleviate this risk. Furthermore, some psychological factors such as pain acceptance and psychological distress will be not included in this study, because it takes too much time to carry out all the self-reported questionnaires, and participants may not respond clearly. Another limitation could be that some psychological factors are quite broad in definition, increasing the risk on finding conflicting evidence on their relationship with outcomes.

### Clinical and research implications of study findings

The early identification of which psychological factors have higher predictive value in people with CSP may assist clinicians in decision-making, and timely and specific consultations with—or referral to—other healthcare providers, and to researchers in exploring which psychological factors could be the most predictive power in shoulder region, giving rise to the possibility to steer treatments. That is why clinicians should be encouraged to identify patients with CSP who show psychological symptoms in the preliminary assessment, as this approach might increase the possibility to consider other therapeutic interventions rather than physical therapies for CSP, for example, pain neuroscience education.

### Future research

Further studies analysing prospectively the influence of psychological factors on the prognosis of CSP including several factors such as pain acceptance, psychological distress and/or coping with pain are needed. As CSP is a complex multifactorial condition, future investigations should consider the combination, and interaction of a cluster of factors to increase their predictive value, and to determine the importance of each factor. Even though the effect caused by psychological factors on the prognosis of CSP could be relevant, further research

evaluating the effects of these factors on the prognosis of CSP, and the possible mediating power of these factors in this entity, as well as their clinical usefulness is required.

## CONCLUSION

Despite the neuroanatomical and biomechanical basis of shoulder pain is interminable and not completely understood, this prospective cohort study may contribute to a new vision about the role played by pain-related fear, kinesiophobia, anxiety, depression and pain catastrophising in the prognosis of CSP, and how self-efficacy, kinesiophobia and pain catastrophising mediate the relationship between symptoms, increasing the body of knowledge in this field.

## Current study status

The recruitment of patients began in August 2016.

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**Contributors** AL-S conceived the study. AL-S and JM-C initiated the study design and FS and MM helped with the final version of this protocol. AL-S and FS provided statistical expertise in longitudinal trial design and JMM-A will be conducting the primary statistical analysis. All authors contributed to the refinement of the study protocol and approved the final manuscript.

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