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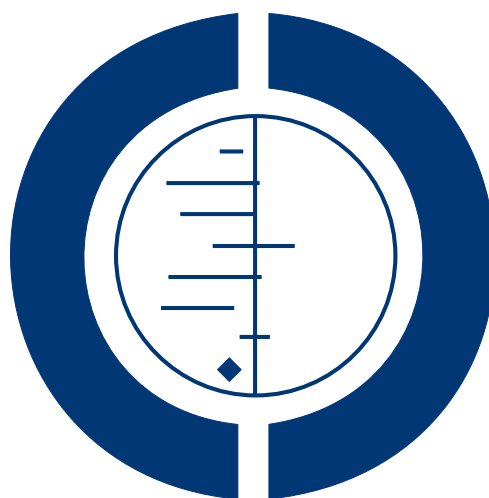
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[Intervention Protocol]

Psychosocial interventions for improving quality of life outcomes in adults undergoing strabismus surgery

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To investigate the effects of psychosocial interventions versus no intervention on quality of life and psychosocial outcomes in adults undergoing strabismus surgery. The primary objective is to assess whether patients who have taken part in a psychosocial intervention prior to their strabismus surgery report significantly improved quality of life compared to those who receive standard care, i.e. strabismus surgery alone. The secondary outcome measures will include anxiety, depression, social anxiety and social avoidance, as well as degree of success in terms of surgical outcome.

BACKGROUND

Description of the condition

Strabismus, or squint, is a condition where the eyes are not in alignment; it can be caused by a broad range of pathologies. Strabismus may be present constantly or intermittently, where the eyes are straight for some of the time. Whether the patient has binocular functions (using both eyes together as a pair), or is able to suppress the image from the squinting eye, determines whether they will experience diplopia (double vision). In cases of constant squint that occur before the age of seven, the brain usually inhibits the visual sensations of one eye in favour of the other and thus it

is unusual before this age to experience double vision, however if the strabismus develops in adulthood diplopia is frequently experienced. The majority of squints can further be divided into esotropia (inward deviation) or exotropia (outward deviation). Less frequently there may be a hypertropia (upward deviation) or hypotropia (downward deviation) or rarely a cyclodeviation where the eye is rotated.

Strabismus is estimated to occur in approximately 4% of the adult population (Beauchamp 2003). There is significant evidence to show that having a squint is associated with negative psychosocial effects and impacts on all aspects of the patients' lives (Wen 2011). Even in cases where the squint is intermittent, patients report reduced health-related quality of life outcomes, such as negative feel-

ings, general disability and problems with eye contact and interpersonal relationships, compared to the normal population (Hatt 2010). Patients with strabismus have been found to experience significantly lower quality of life overall and in terms of functional and psychosocial subscales compared to visually normal adults and patients with other eye conditions (Hatt 2009). Poorer quality of life in strabismus patients has been associated with being female, of a lower socio-economic status (Durnian 2010), increased feelings of social anxiety and participating in more socially avoidant coping strategies (Durnian 2009).

Given the effect strabismus has on a person's appearance and visual function the impact on psychological functioning is not surprising. Adults with strabismus experience higher levels of anxiety compared to the general population (Jackson 2006; Klauer 2000) and a number of studies have identified negative attitudes towards people with strabismus (Paysse 2001). These prejudices have a negative effect on socialisation (Olitsky 1999) and employability, particularly for women (Coats 2000). Satterfield et al (Satterfield 1993) found living with strabismus to affect friendships, school and work. Strabismus sufferers can also experience ridicule or abuse during childhood which may have a negative effect on self image and lead to some adults using adaptive techniques to hide their strabismus.

There are both surgical and non-surgical treatment options for some types of strabismus, including optical correction such as glasses and prisms as well as pharmacological therapies such as botulinum toxin. In cases where patients' squints are not associated with double vision, surgical correction has less impact on visual function and is performed in order to put the eye back in correct alignment and improve patient appearance. In other cases patients may experience debilitating double vision, meaning that they have mixed functional and cosmetic aspects to their strabismus, both of which may be corrected by surgery. Assessment of surgical success has been traditionally measured clinically by objective measures of ocular deviation and functional improvements. However, this fails to acknowledge the impact on a person's quality of life and the impact strabismus can have on psychological well being. For those patients who are successfully aligned post surgery, quality of life has shown to be improved (Hatt 2010) and this is particularly so for those without double vision before surgery (Jackson 2006). These post surgical gains have also been shown to rise continually for up to one year post surgery (Hatt 2012). A recent review provides a comparison of the main health-related quality of life measures used in this field (Carlton 2011). However, in all of these studies, although the quality of life of strabismus patients is lower than the general population, the data show considerable variation with some patients doing better than others. In fact there are a group of patients for whom surgery does not improve quality of life despite surgery being clinically successful. This variation would suggest that factors other than clinical measurements play a role in improving outcomes for patients undergoing strabismus surgery. Hence, psychosocial interventions in these individuals in addition

to surgery maybe a potentially useful tool to improve quality of life post surgery and patient satisfaction with surgical intervention.

Description of the intervention

Psychosocial interventions have been implemented with success in a number of conditions including cancer (Rehse 2003), chronic lower back pain (Hoffman 2007), diabetes (Steed 2003) and coronary artery disease (Linden 1996), with statistically and clinically significant improvements in quality of life reported in all reviews. Although structured psychosocial interventions for patients prior to surgery have been the focus of less research, some early work has shown improvements in psychological well being postoperatively (Johnston 1993). Psychosocial interventions have been defined as any programme that incorporates techniques that aim to reduce psychosocial distress. Due to this broad definition the content of these interventions is extremely diverse and can include anything from basic education through to self management, cognitive behavioural therapy (CBT) and social support. These interventions are wide ranging in their theoretical background, complexity, content and mode of delivery.

How the intervention might work

As psychosocial interventions differ in their theoretical underpinnings the proposed mechanisms through which these interventions work differ. Patient education programmes typically provide information about the disease, treatment and what to expect after surgery, and provide advice about what the patient needs to do to manage the outcomes of their surgery effectively. The main reason for providing education has been to reduce anxiety by decreasing uncertainty about aspects of the condition and feelings of helplessness by giving patients control over aspects of the procedure and recovery. It is more common, however, for patient education to be incorporated into other types of interventions as the provision of information alone is not usually sufficient to bring about significant long-term benefits for the patient (Gibson 2002). Self management interventions provide patients with the information they need to manage the situation but rather than using a didactic approach to delivering the information a more patient-centred approach is used, where the patient's beliefs about the illness are elicited first. This helps to understand the patient's perspective and any barriers which may be preventing them from putting the advice into practice. In CBT cognitive processes are thought to mediate the relationship between emotions and behaviour, therefore clinicians will work with clients on either a group or individual basis to understand the link between their thoughts, feelings and how they behave. The primary aim is to identify current maladaptive cognitions, challenge them and reformulate thoughts to generate new balanced and adaptive strategies. By using cognitive restructuring exercises, individuals increasingly recognise how their

emotions, cognitions and interpretations modulate their view of their condition in positive and negative directions. As a result, it is hoped that individuals will be better able to manage their behaviour and thoughts as related to their condition.

Effective social support from family and friends can be an integral part of improving outcomes for patients. This may be by enabling them to understand the link between the patient's thoughts, feelings and behaviour or by attending to their own perceptions and misperceptions of the situation. Negative support can be just as detrimental as no support, therefore social support interventions may work to either intervene in current relationships and networks in order to improve their responsiveness or introduce the individual to new social ties which may be able to provide more appropriate support.

Why it is important to do this review

The psychosocial impact of strabismus has gathered increasing recognition and interest in the last decade. There is evidence in the literature to suggest that the presence of a squint lowers quality of life and self esteem and increases levels of anxiety, depression, social avoidance and social anxiety. In addition, strabismus can also adversely affect employment opportunities, friendships and partner selection. Many adopt behavioural techniques to conceal their strabismus, such as wearing glasses and assuming certain head positions. Although studies have identified the psychological and social impact of strabismus and shown that quality of life can improve following surgery, this does not happen for all. It frequently does not reach the level of the general population and some of the negative consequences of the squint remain. There has been minimal research looking at which factors contribute to these adjustment difficulties and hence the development of suitable interventions to address these issues is minimal. Therefore a systematic review in this area will help assimilate what work has been done and provide a useful platform to identify further research needed to expand our knowledge in this area.

OBJECTIVES

To investigate the effects of psychosocial interventions versus no intervention on quality of life and psychosocial outcomes in adults undergoing strabismus surgery. The primary objective is to assess whether patients who have taken part in a psychosocial intervention prior to their strabismus surgery report significantly improved quality of life compared to those who receive standard care, i.e. strabismus surgery alone. The secondary outcome measures will include anxiety, depression, social anxiety and social avoidance, as well as degree of success in terms of surgical outcome.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) including cluster-RCTs.

Types of participants

Any adult patient with strabismus from 18 years or over with no upper age limit. The strabismus can be of any cause and include congenital, infantile, childhood onset, acquired in later life or secondary to other causes.

There is no restriction on the time frame from onset of strabismus to time of intervention.

We will exclude those patients with psychological problems from other causes or patients who have previously undergone psychosocial intervention.

Types of interventions

Any intervention that attempts to address the negative psychosocial effects known to be associated with strabismus versus no intervention.

Types of outcome measures

Primary outcomes

Improvement in quality of life, as measured by self administered quality of life questionnaires, between three to six months following surgery, and one year or more where available. Tools that will be used include vision-specific instruments such as VFQ-25, NEI-VFQ and VF 14, strabismus-specific such as AS-20 and A&SQ, and generic measures such as SF8, 12 and 36 and EQ5D. Preference will be for those questionnaires that have been validated as published, showing construct validity and that are widely used.

Secondary outcomes

Anxiety, depression, social anxiety and social avoidance at the same time point, as assessed by self completed patient questionnaires in addition to degree of success in terms of desired surgical outcome, as determined by size of angle of ocular deviation following surgery. This would be considered as successful if within 10 prism dioptres of emmetropia and absence of diplopia in the primary position and in downgaze/reading.

Search methods for identification of studies

Electronic searches

We will search the Cochrane Central Register of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Group Trials Register) (The Cochrane Library), MEDLINE, EMBASE, Latin American and Caribbean Literature on Health Sciences (LILACS), PsycINFO, the *meta*Register of Controlled Trials (*m*RCT) (www.controlled-trials.com), ClinicalTrials.gov (www.clinicaltrials.gov) and the WHO International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/search/en). We will not use any date or language restrictions in the electronic search for trials.

See: Appendices for details of search strategies for CENTRAL (Appendix 1), MEDLINE (Appendix 2), EMBASE (Appendix 3), LILACS (Appendix 4), PsycINFO (Appendix 5), *m*RCT (Appendix 6), ClinicalTrials.gov (Appendix 7) and the ICTRP (Appendix 8).

Searching other resources

We will search the reference lists of included studies to identify further potentially relevant studies for inclusion in the review. We will manually search the *British Orthoptic Journal*, proceedings of the European Strabismological Association (ESA), International Strabismological Association (ISA) and published transactions from the meetings of European Strabismus Association (ESA) and American Association for Pediatric Ophthalmology and Strabismus (AAPOS). We will search these resources from 1980 to present. We will also carry out handsearches of *Psychology and Health*, *British Journal of Health Psychology*, *Health Psychology* and *Annals of Behavioral Medicine*. We will contact researchers who are active in the field for information about further published or unpublished studies.

Data collection and analysis

Selection of studies

Two review authors will independently assess study abstracts identified from electronic and manual searches to establish whether they met the criteria and define them as include, exclude and unsure. Included papers will encompass RCTs; excluded papers will encompass cases reports. In cases where the two review authors do not agree following discussion, a majority decision will be reached with all review authors. Following this we will obtain full copies of definitely or potentially relevant studies. Where information is unclear we will contact the study authors.

Data extraction and management

The two review authors will independently extract information relating to outcomes using paper data collection forms developed by the Cochrane Eyes and Vision Group. We will resolve discrepancies by discussion. In cases where there is still a discrepancy this will be resolved by discussion with the rest of the group.

We will extract the following details from the studies.

- Methods: inclusion, exclusion criteria, follow-up period
- Participants: age, type of strabismus, size of strabismus, previous treatment
- Interventions: type of psychological intervention, period of intervention
- Outcomes: quality of life, success of surgery in reducing ocular deviation
- Adverse events: such as complications associated with surgery, including unintentional over or under correction of the deviation, diplopia, slipped muscle and visual loss

If questionnaires have different methods for scoring, we will standardise these before comparison from 0% to 100%.

Assessment of risk of bias in included studies

We will assess study quality according to the methods set out in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will use The Cochrane Collaboration's tool for assessing risk of bias.

When examining studies we will assess allocation bias by looking at sequence generation and allocation concealment. It will not be possible for participants or personnel to be masked to the psychological treatment modality, however other sources of bias such as incomplete outcome data and selective reporting will be looked for.

Outcome measures, in terms of quality of life, as measured by validated quality of life questionnaires (as detailed above), should be self completed by patients and not with the assistance of staff as this may induce detection bias if staff have knowledge of which group patients are in.

Outcome measure in terms of improvement in eye position and absence of diplopia, as assessed by standard orthoptic clinical measurements, should be assessed by an individual not involved directly in the surgery to reduce bias.

Measures of treatment effect

For assessment of psychological treatment effect in terms of reported quality of life measures on validated questionnaires we will use standardised mean difference for continuous data, following assessment of normality using normal quartile plots.

For assessment of surgical treatment effect we will consider odds ratio or risk ratio for dichotomous data relating to presence or absence of diplopia and standardised mean difference for continuous

data relating to change in size of angle of ocular deviation. We will stratify trials according to preoperative diplopia.

Unit of analysis issues

We expect that studies of parallel-group design will be included. We will exclude cross-over trials. When analysing the outcome measures of studies this will be on a group and not an individual basis. Where individual results are reported we will derive appropriate summary statistics to allow data comparison before analysis. The surgical outcome measure is the change in ocular alignment and is not affected by whether one or two eyes have been operated upon. The quality of life measures are also not related to whether one or both eyes are affected.

Dealing with missing data

We will contact the primary authors to obtain missing data. If there is no response after one month they will be contacted again. A total of three months will be allowed for a response. If no response occurs we will record this as missing data.

Assessment of heterogeneity

We do not expect there to be significant heterogeneity in data synthesis for a given outcome measure. We will use the I^2 statistic to quantify inconsistency in study population, type of strabismus and type of psychological intervention and the impact on meta-analysis. We will assess heterogeneity as specified in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011):

- 0% to 40%: might not be important
- 30% to 60%: may represent moderate heterogeneity
- 50% to 90%: may represent substantial heterogeneity
- 75% to 100%: considerable heterogeneity

Assessment of reporting biases

If sufficient studies are identified (10 or more), we will use a funnel plot to assess for reporting bias.

Data synthesis

If there is no evidence of heterogeneity we will use the fixed-effect model. If significant heterogeneity is found a descriptive summary of the results will be given.

Subgroup analysis and investigation of heterogeneity

If enough studies are available we will undertake a subgroup analysis of the effects of different psychological interventions and their effect on strabismus.

Sensitivity analysis

If appropriate, we will undertake a sensitivity analysis to assess the effect on the review of the trials excluded as a result of having missing data.

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- * Indicates the major publication for the study

APPENDICES

Appendix 1. CENTRAL search strategy

- #1 MeSH descriptor Strabismus
- #2 esotrop* or exotrop*
- #3 hypertrop* or hypotrop*
- #4 strabism* or squint*
- #5 (eye* or ocular) near/3 deviat*
- #6 (eye* or ocular) near/3 disfigur*
- #7 MeSH descriptor Oculomotor Muscles
- #8 MeSH descriptor Oculomotor Nerve Diseases
- #9 MeSH descriptor Trochlear Nerve Diseases
- #10 MeSH descriptor Abducens Nerve Diseases
- #11 (third or fourth or sixth) near/2 nerve palsy
- #12 (3rd or 4th or 6th) near/2 nerve palsy
- #13 extraocular near/2 muscle near/2 surg*
- #14 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13)
- #15 MeSH descriptor Cognitive Therapy
- #16 MeSH descriptor Behavior Therapy
- #17 cognitive behavio* therapy or CBT
- #18 MeSH descriptor Psychotherapy, Group
- #19 psychotherap*
- #20 psychoeducat* or patient education
- #21 (intervention* or therap* or treat*) near/2 psychological
- #22 (intervention* or therap* or treat*) adj2 psychosocial
- #23 MeSH descriptor Counseling
- #24 counselling or counseling
- #25 MeSH descriptor Relaxation Therapy
- #26 (group or therap* or treat*) near/2 relaxation
- #27 MeSH descriptor Problem Solving
- #28 problem solving
- #29 stress management
- #30 self management
- #31 (#15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30)
- #32 (#14 AND #31)

Appendix 2. MEDLINE (OvidSP) search strategy

1. randomised controlled trial.pt.
2. (randomised or randomised).ab,ti.
3. placebo.ab,ti.
4. dt.fs.
5. randomly.ab,ti.
6. trial.ab,ti.
7. groups.ab,ti.
8. or/1-7
9. exp animals/
10. exp humans/
11. 9 not (9 and 10)
12. 8 not 11

13. exp strabismus/
14. (esotrop\$ or exotrop\$).tw.
15. (hyertrop\$ or hypotrop\$).tw.
16. (strabism\$ or squint\$).tw.
17. ((eye\$ or ocular) adj3 deviat\$).tw.
18. ((eye\$ or ocular) adj3 disfigur\$).tw.
19. oculomotor muscles/
20. oculomotor nerve diseases/
21. trochlear nerve diseases/
22. abducens nerve diseases/
23. ((third or fourth or sixth) adj2 nerve palsy).tw.
24. ((3rd or 4th or 6th) adj2 nerve palsy).tw.
25. (extraocular adj2 muscle adj2 surg\$).tw.
26. or/13-25
27. Cognitive Therapy/
28. Behavior Therapy/
29. (cognitive behavio\$ therapy or CBT).tw.
30. Psychotherapy, Group/
31. psychotherap\$.tw.
32. (psychoeducat\$ or patient education).tw.
33. ((intervention\$ or therap\$ or treat\$) adj2 psychological).tw.
34. ((intervention\$ or therap\$ or treat\$) adj2 psychosocial).tw.
35. counseling/
36. (counseling or counselling).tw.
37. Relaxation Therapy/
38. ((group or therap\$ or treat\$) adj2 relaxation).tw.
39. Problem Solving/
40. problem solving.tw.
41. stress management.tw.
42. self management.tw.
43. coping skills.tw.
44. or/27-43
45. 26 and 44
46. 12 and 45

The search filter for trials at the beginning of the MEDLINE strategy is from the published paper by Glanville et al ([Glanville 2006](#)).

Appendix 3. EMBASE (OvidSP) search strategy

1. exp randomised controlled trial/
2. exp randomization/
3. exp double blind procedure/
4. exp single blind procedure/
5. random\$.tw.
6. or/1-5
7. (animal or animal experiment).sh.
8. human.sh.
9. 7 and 8
10. 7 not 9
11. 6 not 10
12. exp clinical trial/
13. (clin\$ adj3 trial\$).tw.
14. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj3 (blind\$ or mask\$)).tw.

15. exp placebo/
16. placebo\$.tw.
17. random\$.tw.
18. exp experimental design/
19. exp crossover procedure/
20. exp control group/
21. exp latin square design/
22. or/12-21
23. 22 not 10
24. 23 not 11
25. exp comparative study/
26. exp evaluation/
27. exp prospective study/
28. (control\$ or prospectiv\$ or volunteer\$).tw.
29. or/25-28
30. 29 not 10
31. 30 not (11 or 23)
32. 11 or 24 or 31
33. strabismus surgery/
34. (esotrop\$ or exotrop\$).tw.
35. (hyerptrop\$ or hypotrop\$).tw.
36. (strabism\$ or squint\$).tw.
37. ((eye\$ or ocular) adj3 deviat\$).tw.
38. ((eye\$ or ocular) adj3 disfigur\$).tw.
39. extraocular muscle/
40. oculomotor nerve disease/
41. trochlear nerve disease/
42. abducens nerve disease/
43. ((third or fourth or sixth) adj2 nerve palsy).tw.
44. ((3rd or 4th or 6th) adj2 nerve palsy).tw.
45. (extraocular adj2 muscle adj2 surg\$).tw.
46. or/33-45
47. exp psychotherapy/
48. (cognitive behavio\$ therapy or CBT).tw.
49. psychotherap\$.tw.
50. (psychoeducat\$ or patient education).tw.
51. ((intervention\$ or therap\$ or treat\$) adj2 psychological).tw.
52. ((intervention\$ or therap\$ or treat\$) adj2 psychosocial).tw.
53. counseling/
54. (counseling or counselling).tw.
55. relaxation training/
56. ((group or therap\$ or treat\$) adj2 relaxation).tw.
57. problem solving/
58. problem solving.tw.
59. stress management/
60. stress management.tw.
61. self care/
62. self management.tw.
63. coping skills.tw.
64. or/47-63
65. 46 and 64
66. 32 and 65

Appendix 4. LILACS search strategy

strabismus and psychosocial or psychotherapy or cognitive or behavioural or counselling or counseling

Appendix 5. PsycINFO search strategy

1. exp Strabismus/
2. (esotrop\$ or exotrop\$).tw.
3. (hyperptrop\$ or hypotrop\$).tw.
4. (strabism\$ or squint\$).tw.
5. ((eye\$ or ocular) adj3 deviat\$).tw.
6. ((eye\$ or ocular) adj3 disfigur\$).tw.
7. Oculomotor Muscles/
8. ((third or fourth or sixth) adj2 nerve palsy).tw.
9. ((3rd or 4th or 6th) adj2 nerve palsy).tw.
10. (extraocular adj2 muscle adj2 surg\$).tw.
11. or/1-10
12. Cognitive Techniques/
13. Cognitive Therapy/
14. Behavior Therapy/
15. (cognitive behavio\$ therapy or CBT).tw.
16. Group Psychotherapy/
17. psychotherap\$.tw.
18. (psychoeducat\$ or patient education).tw.
19. ((intervention\$ or therap\$ or treat\$) adj2 psychological).tw.
20. ((intervention\$ or therap\$ or treat\$) adj2 psychosocial).tw.
21. exp Counseling/
22. exp Psychotherapeutic Counseling/
23. (counseling or counselling).tw.
24. Relaxation Therapy/
25. ((group or therap\$ or treat\$) adj2 relaxation).tw.
26. Problem Solving/
27. problem solving.tw.
28. Stress Management/
29. stress management.tw.
30. self management.tw.
31. exp Coping Behavior/
32. coping skills.tw.
33. or/12-32
34. 11 and 33

Appendix 6. metaRegister of Controlled Trials search strategy

strabismus and (psychological or psychosocial)

Appendix 7. ClinicalTrials.gov search strategy

(Psychological OR Psychosocial) AND Strabismus

Appendix 8. ICTRP search strategy

Strabismus = Condition AND Psychological OR Psychosocial = Intervention

HISTORY

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CONTRIBUTIONS OF AUTHORS

Conceiving the review question: JH, KM, DE, HJ, GA, SN

Development of the protocol: JH, KM, HJ

Providing comments on the protocol: DE, GA, SN

Responding to peer review comments: JH, KM

Responding to comments from the editorial base: JH, KM

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None

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