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## A core outcome set for three ophthalmic conditions: a healthcare professional and patient consensus on Core Outcome Sets for Amblyopia, Ocular Motility and Strabismus (COSAMS study)

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## A core outcome set for three ophthalmic conditions: a healthcare professional and patient consensus on Core Outcome Sets for Amblyopia, Ocular Motility and Strabismus (COSAMS study)

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**Author contributions:** FR and JJK contributed to conceptualising and designing the study. SJ was responsible for the day-to-day running of the project. All authors contributed to the review of the study design and to the review and analysis of study data. JJK drafted the manuscript. FR and SJ made major revisions. Due to the strong involvement of JJK and FR at several different stages of the study, all authors agreed to consider them joint senior. All authors read and approved the final manuscript.

## Abstract

**Objectives:** Amblyopia, strabismus and ocular motility disorders are common conditions with significant impact on visual function, appearance and quality of life. The aim of this study is to establish a core set of outcomes for all treatment interventions for each of the three conditions for use in clinical trials and routine clinical practice.

Design: Prospective 3-stage core outcome set process.

Setting: UK-wide consultation.

Participants: Researchers, clinicians, patients and carers.

**Methods and analysis:** A comprehensive databank of outcomes was developed from a systematic review of the literature, and a series of focus groups with healthcare professionals, researchers, patients and carers. The databank of outcomes was then scored in a two-round Delphi survey completed by two stakeholder groups; healthcare professionals/ researchers and patients/carers. The results to the online Delphi were discussed at a face-to-face consensus meeting where the core outcome sets were finalised.

**Results:** For amblyopia, strabismus and ocular motility (40/42/33) participants contributed to both rounds of the Delphi and (6/9/7) voting members attended the consensus meetings respectively. Consensus was reached on ten core outcomes for both amblyopia and ocular motility and nine for strabismus. The core outcomes ocular alignment, vision-related quality-of-life, adverse events and cost were common to all three conditions.

**Conclusions:** The study used robust consensus methods to develop a core outcome set for three ophthalmic conditions. The implementation of these core outcome sets in

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> clinical trials and routine clinical practice will ensure that the outcomes that are being measured and reported are relevant to all stakeholders. This will enhance the relevance of study findings and enable results from different studies to be compared.

## Keywords:

Core outcome set; Amblyopia; Strabismus; Ocular motility; Consensus; Delphi

## Article summary:

## Strengths and limitations of this study:

- We targeted amblyopia, strabismus and ocular motility disorders which are common ophthalmic conditions.
- We have developed three core outcome sets; one for each condition.
- The study included key stakeholders including researchers, clinicians, patients and carers.
- Use of these core outcome sets in future studies has the potential to enable comparison of the results across studies.
- Although developed in the UK, there is potential for these COS to be further developed and used more widely.

## Introduction

Amblyopia (lazy eye) and strabismus (squint) occur in up to 5% of the general population [1,2]. It is unknown how prevalent ocular motility disorders (abnormal eye movements) are in the general population. These conditions often present in children and can lead to long-term problems for children and young adults such as blurred vision, double vision, low esteem and even blindness if not treated [3]. There are several approaches to the management of these conditions including occlusion, penalisation, spectacles, prisms, drugs, surgery, botulinum toxin, exercises, watchful waiting, or a combination of two or more of the above [4-20].

Interventional systematic reviews in this field of research have identified that there is considerable variation in the outcomes being measured and reported in primary research

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studies, which impacts on the ability to compare and synthesise outcome results across studies. Moreover, it was noted that there is a paucity of outcome data available on important patient outcomes such as quality of life, long-term outcome as well as the cost of treatment [4-20]. To mitigate these issues and to increase the relevance of research, a core outcome set (COS) can be developed which represents an agreed standardised set of outcomes that should be measured and reporting in all studies for a specific area of health or healthcare. A search of the COMET (Core Outcome Measures in Effectiveness Trials) database revealed that there are several studies that have investigated important outcomes for eyes and vision disease; examples include cataracts and glaucoma but none have specifically looked at amblyopia, strabismus or ocular motility disorders [21].

The aim of this study was to develop core outcome sets for use in clinical trials and routine practice for all intervention types for the treatment of amblyopia, strabismus and ocular motility disorders in children and adults that includes input from all stakeholders. While we aim to develop three separate COS for each of the ophthalmic conditions, we anticipate that there could be considerable overlap in the importance of certain outcomes across these conditions.

## Methods

The development of the COS study involved three stages (Figure 1): (1) the generation of a long list of outcomes; (2) a two- round online Delphi survey and (3) face- to- face consensus meetings to discuss the results of the Delphi survey and agree on the COS. The process considered the minimum standards for the design of a COS study (COS-STAD), which included careful consideration of the scope, stakeholders and the consensus process [22].

## **Outcome list generation**

A databank of outcomes was generated from two sources: a systematic review of outcomes reported by researchers and clinicians in studies for the treatment of the conditions under evaluation, and, secondly using three separate focus groups (one for each condition) containing a mix of healthcare professionals, researchers, patients and

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carers. The detailed search strategy, methods and results for the systematic review have been published elsewhere [23]. Outcomes from the systematic review and suggested outcomes from the recorded focus group meetings were extracted verbatim and grouped into suitable domains to facilitate easy classification. The final list was checked by experts in all three clinical conditions (SJ, FR), who also had the opportunity to use their clinical expertise to add additional outcomes to the list. In preparation for the Delphi survey, clinical assessment outcomes used only by healthcare professionals were either separated out (not to be scored by patients) or combined into a simplified outcome for patients to score. Each outcome was written using plain language and feedback sought from four researchers from the Health Service Research department, University of Liverpool and a clinician from a local hospital on the acceptability and their understanding of the wording used. The databank of outcomes can be found in Supplementary Table 1.

## Online Delphi survey

The databank of outcomes was used to populate an online Delphi survey, which was administered using DelphiManager [24]. Participants were invited from two key stakeholder groups. The first group consisted of healthcare professionals involved in the care for people with one of the three conditions or researchers working within this field. Invitations to participate were sent by email flyers to national professional organisations including the British and Irish Orthoptic Society, Paediatric Ophthalmology networks, and local groups linked with the University of Liverpool. The second group included patients or carers of patients affected by at least one of the three conditions of interest. Patients and carers were invited to participate into the survey using flyers distributed on the University of Liverpool noticeboards, newsletters (via the professional Society), social media (twitter) and in ophthalmology departments in local hospitals including Aintree University Hospital, The Royal Liverpool University Hospital and Southport and Ormskirk hospitals. Through routine clinical practice, the study authors (SJ, FR) and healthcare professionals were also encouraged to distribute the patient survey links to their relevant patients if they showed an interest in the study.

Four surveys were set up, one for the healthcare professionals and researchers that contained the outcomes to be scored for all three conditions, and, three separate surveys

containing only the outcomes relevant to patients and carers associated with each individual condition. The Delphi process was completed using two rounds (hereafter referred to R1 and R2). In each round participants were presented with the list of outcomes and asked to score each outcome on how important it was to include in the COS, using a 9-point Likert scale, with 1-3 labelled 'not important', 4-6 labelled 'important but not critical', and 7-9 labelled as 'critically important' [25]. Participants had the option to indicate 'unable to score' on any outcome they felt unable to score, and at the end of R1, participants were invited to submit additional outcomes they thought were missing from the list. These outcomes were reviewed by the study authors (SJ, FR) and any outcomes that represented a new relevant outcome were added to the list to be scored in R2. Irrespective of participants scoring, no outcomes were removed from the list between R1 and R2. During R2, participants were shown the distribution of scores for both stakeholder groups for each outcome along with their own score from R1 and asked to score the outcome again, using the same scale, taking this extra information into account.

## Consensus meeting

Separate face-to-face consensus meetings were held at the University of Liverpool, UK for each of the three conditions. Participants who either had an active role in the focus groups and/or completed both rounds of the Delphi survey were invited to attend, although others with an interest in the project were invited to ensure each meeting had a balanced mix of participants from both stakeholder groups. In advance of the meeting, participants received a copy of their scores from the online survey (if appropriate) and a consensus matrix (Supplementary Table 1) detailing the results of R1 and R2 by stakeholder group, and which outcomes had reached the a priori definition of consensus in, consensus out or no consensus (Table 1). The consensus definition is similar to that used in other COS development studies.

The meeting for amblyopia was chaired by a non-clinical researcher with expertise in COS development methodology (JJK) while the meeting for strabismus and ocular motility was chaired by a student investigator with a clinical background (SJ).

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In order to facilitate the discussion all outcomes that had reached consensus 'in' after R2 for both stakeholder groups were presented first, followed by outcomes that reached consensus 'in' for only one stakeholder group. All outcomes that scored critical for inclusion for 50-69% of the participants for either both or one of the stakeholder groups in R2 were presented next followed by all other outcomes that were scored by both stakeholder groups. Outcomes that were only scored by healthcare professionals and researchers were discussed last. Results for each outcome from the Delphi were shown to the participants with more time allocated to discussing outcomes where there was more uncertainty on whether the outcome should be included in the COS or not. Views for and against inclusion in the COS were sought by the meeting chair, who also ensured that participants had equal opportunity to comment prior to voting. Voting was undertaken anonymously using Poll Everywhere [26] software which was linked to mobile and tablet devices. The definition of consensus used in the Delphi survey (Table 1) was applied to the consensus meeting. The final COS was presented at the end of the meetings.

## Study registration, ethics and reporting guidance

The study was prospectively registered with the COMET Initiative (Core Outcome Measures in Effectiveness Trials) [27]. Ethical approval was obtained from the University of Liverpool institutional research ethics committee for the focus groups, online survey and the consensus meetings to be undertaken with healthcare professionals and patients (Ref. Nos. 2063 and 2260). Informed consent was obtained from participants. The study is reported in line with the Core Outcome Set – Standards for Reporting (COS-STAR) guidance [28].

## **Patient and Public Involvement**

The study was supported by a patient advisory group which provided input to this research study. The patient advisory group met on a regular basis for the duration of the study. Patients contributed to the design of the study and were involved at all stages of the survey and consensus meetings.

#### Results

 A summary of the COS development process is shown in Figure 1. The final COS contains ten, nine and ten outcomes across seven, six and seven domains for amblyopia, strabismus and ocular motility respectively (Table 2). Ocular alignment, vision-related quality-of-life, adverse events and cost were common to all three conditions.

## Development of the databank of outcomes

The systematic review and focus groups of health care professionals, researchers, patients and carers identified 31, 61, and 78 individual outcomes for amblyopia, strabismus and ocular motility respectively. These were combined with a list of outcomes suggested by professional experts (SJ, FR) resulting in a total of 40, 70 and 106 outcomes for amblyopia, strabismus and ocular motility respectively. The outcomes were classified into 12 domains, (symptoms, visual function, refraction, oculomotor function, quality-of-life, treatment dependency, signs, investigations, long-term outcome, compliance, adverse events, cost) and outcomes that were not considered to be patient relevant were separated out or combined. As an example, 'refractive status', 'spherical and cylindrical refraction' and 'median spherical equivalence' were combined into a single outcome 'refractive status' for patients as they all have a similar meaning, but are often referred to separately by healthcare professionals. Details of all outcomes including domain classification, combined outcomes and plain language descriptions of outcomes is provided in Supplementary Table 1.

#### Online Delphi

Thirty three healthcare professionals / researchers scored all outcomes for both R1 and R2 of the amblyopia component of the online survey while 29 completed for strabismus and ocular motility. Three patients/carers completed both rounds for amblyopia while nine completed both rounds for strabismus and five for ocular motility (Figure 1). At the end of R1, five outcomes for amblyopia, 12 for strabismus and 23 for ocular motility reached consensus 'in' for both stakeholder groups. After a review of all additional outcomes suggested by participants in R1, three new outcomes were added to the strabismus survey in R2 (improvement in angle by a set amount (suggested by a

healthcare professional) and, immediate result post-surgery and long-term discomfort from scar tissue (both suggested by a patient)).

On completion of R2, ten outcomes reached consensus 'in' for amblyopia across both stakeholder groups while 17 and 32 outcomes reached the same criteria for strabismus and ocular motility respectively.

## Consensus meeting

Six, nine and seven voting participants attended the consensus meeting for amblyopia, strabismus and ocular motility respectively with an even balance of healthcare professional/researchers and patients present (Figure 1).

## Amblyopia

 For amblyopia, future functionality/long-term impact and adverse events reached the consensus 'in' criteria for both stakeholder groups in both rounds of the Delphi and remained in the COS. Despite reaching consensus 'in' for both rounds of the Delphi for both stakeholder groups, intolerable diplopia and occlusion amblyopia (both adverse events) were not included in the final COS as it was felt that these could be captured under 'adverse events' and therefore were not critical for separate inclusion in the COS. Long-term outcome was also excluded following discussion as the group felt that there was currently no agreed set time for measuring long-term objective outcomes. Best corrected visual acuity and compliance marginally did not reach consensus 'in' during R2 of the Delphi but made the final COS after discussion. Following a discussion on the other visual function outcomes, near visual acuity was also added because it was noted that it was a good marker of early improvement for the treatment of amblyopia and important for children as it is important to their education. Refractive status reached consensus for both groups in R2 but following discussion this was replaced by *spherical* and cylindrical refraction (scored only by health care professionals in the Delphi) because it was successfully argued that this was a more precise measurement of refractive status. The list of outcomes within the quality of life domain were discussed simultaneously. While this was not listed specifically as an outcome in the Delphi, participants agreed to include visual-related quality of life in the core set as it was felt that a generic healthrelated guality of life outcome was not sensitive enough. Psychological impact of

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 treatment was scored only by healthcare professionals in the Delphi but reached consensus 'in' during R2. Following discussion led by a parent participant, the panel derived a new outcome to include *treatment-related impact* into the final COS in order to capture the effect of treatment, such as patching on children, which could be long lasting. For both Delphi rounds, cost outcomes did not reach consensus 'in' by either stakeholder groups, however, the consensus panellists successfully advocated for its inclusion as a core outcome as *cost* outcome data is vital information for contemporary health systems.

## Strabismus

For strabismus, symptoms and patient satisfaction reached the consensus 'in' criteria for both stakeholder groups in both rounds of the Delphi and remained in the COS. Best corrected visual acuity also reached consensus 'in' for both rounds and groups in the Delphi although the consensus panel argued that any change in vision and/or loss of vision as an adverse event would be very significant and reportable as per the Royal College of Ophthalmology guidelines [29]. At the consensus meeting, participants noted that strabismus interventions aim to change the strabismus angle and visual acuity should not be affected by the intervention unless an adverse event occurred. Thus a change in visual acuity would be captured within adverse events. On this basis a decision was taken to exclude visual acuity from the core set. All remaining visual acuity tests were discussed simultaneously, and while the post-op diplopia test reached consensus 'in' during the Delphi exercise, the consensus panel voted in favour of including *binocular vision* as core, as it was more representative of a group of visual function related outcomes. Oculomotor function outcomes were discussed simultaneously and it was highlighted that ocular movement was critical to be reported in all strabismus types as a change caused by the intervention would be significant. Quantifying both the ocular alignment and deviation were also seen to be critical in the context of any strabismus type and were included as core outcomes. Visual-related quality-of life, adverse events and cost were also included in the COS for reasons discussed for amblyopia.

## Ocular Motility

The discussions for ocular motility closely followed those of strabismus with the addition of clinical signs being added as an extra core outcome. Similar to adverse events, this outcome was a catch all for all clinical signs which were scored individually in the Delphi Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

exercise. This strategy was seen favourable by the meeting participants as many subconditions of ocular motility have specific signs associated with them. An example includes corneal exposure in the ocular motility condition of Thyroid Eye Disease but which is not relevant in other ocular motility disorders.

## Discussion

 This study has developed a set of core outcomes for the treatment of three ophthalmic conditions using a robust consensus process involving healthcare professionals, researchers, patients and carers. We recommend that, as a minimum, these core outcomes are used in future trials of interventions to treat amblyopia, strabismus and ocular motility disorders. We also advocate that these outcomes are recorded in routine clinical practice to ensure that the outcome data collected is meaningful and important. While these three core outcome sets were developed independently within the same study, there exists some parallels, and as a consequence, four outcomes (ocular alignment, vision-related quality-of-life, adverse events and cost) were common to all three conditions.

A strength of this study is that it was prospectively registered with the COMET Initiative and it was developed using the COS- STAD (Core Outcome Set - STAndards for Development) recommendations [22]. Engagement with patient participants was particularly challenging and we sought to improve patient input by offering paper copies of the Delphi survey with pre-paid return envelopes in orthoptic clinics, although this was later abandoned after a number of sessions when there was no uptake. As a consequence of a relatively low number of patients responding to the Delphi and attrition between the two rounds, there was concern that consensus was not being achieved at the end of the final round given the number of outcomes reaching consensus for both stakeholder groups had increased dramatically from R1. While measures were taken to ensure survey participation and retention was maximised (including sending reminders and extending deadlines for completion), it was felt that after several months of keeping the survey open our efforts became futile. In order to compensate for this we ensured that the consensus meetings where the final COS were ratified contained a good balance of healthcare professionals and patients. The main limitation of this study was that the consensus process was based using only participant's in the UK. However, as a starting

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point, we have reason to believe that this COS could also be useful in other countries and settings.

Further consensus work is needed to establish the best measurement instruments to measure these core outcomes. To assist this process, the systematic review for generating the databank of outcomes also recorded the measurement instruments associated with each outcome [23]. The generalisability of the COS also needs to be reviewed in healthcare settings outside the UK. While the review of outcomes identified studies from around the world (with prominence from the United States, United Kingdom, China and other European countries), the formal consensus process was undertaken using only participants from the UK, and those attending the consensus meeting were mostly localised to the North West of England.

There are few reported COS in the literature that relate to the three conditions in this study. An attempt to utilise a COS is evident for the National Strabismus Data Set project (29). However, the choice of outcomes largely reflects routine clinical practice and there are no 'core' outcomes specified within the full outline of assessments that are specified for strabismic conditions. Chiu and colleagues recommended four outcomes for reporting results of surgery for intermittent exotropia (30). Their study aimed to explore the extent of standardisation of outcomes reported in surgical studies for the condition. However the study was limited by the extent of literature review (10-year literature search period) and lack of external consensus. A short narrative review of outcome measurements for size of deviation showed considerable variability across the tests available and the recommendations for their use. They suggested four core outcomes for all future studies: alignment, near stereoacuity, control score, and quality of life score. If assigning near stereoacuity and control score to 'binocular vision', their outcomes map to those reported in our COS for strabismus. Most recently a study aiming to define successful outcomes for strabismus surgery was published by Serafino et al (31). Although this study did not state an intention to develop a COS, there are a lot of similarities and overlap in the objectives and methodology used. A Delphi process was used to identify areas of consensus and disagreement among experts for the definition of success post strabismus surgery. The panel of experts in their study represented wide international geographic areas and included experts who were chosen based on their peer-reviewed publications, participation at international meetings and their surgical experience. The

study concluded the following: they achieved consensus on which strabismus types need their separate set of outcome criteria. They also identified the importance of "stereopsis" and "the range of single vision" for inclusion of success definition in some strabismus types. The study also found that there was no consensus on the length of time after surgery for determination of success, magnitude of deviation consistent with success, and whether manifest or latent deviation should be considered to define success. Limitations of the study were that their survey did not involve scoring of outcomes, there was no systematic search of literature of reported outcomes prior to survey construction, and patients or service users were not consulted in the process. A further study to evaluate outcome measures for use in clinical trials involving subjects with nystagmus is in the planning stage and registered within the COMET initiative database (32). This study aims to investigate the intra and inter-subject variability in a variety of putative outcome measures in children over time in order to evaluate the most suitable and robust outcome measures for future trials.

A search in the COMET initiative database in April 2020 did not reveal registration of Serafino's study (31) or any further additions of similar studies in the database. Duplication of efforts and waste of research can result from failure to register COS studies of similar scopes and objectives.

## Conclusion

The three COS developed from this study can be applied to future trials and routine data collection for all intervention types to treat the three ophthalmic conditions considered. There use will allow the comparison of outcome data to be made across studies and to better inform treatment decisions. Future work will include seeking consensus on how these outcomes should be measured and to evaluate the acceptability of the current COS to patients and professionals in other countries, particularly where healthcare systems differ from the UK.

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Figure 1 Study flowchart

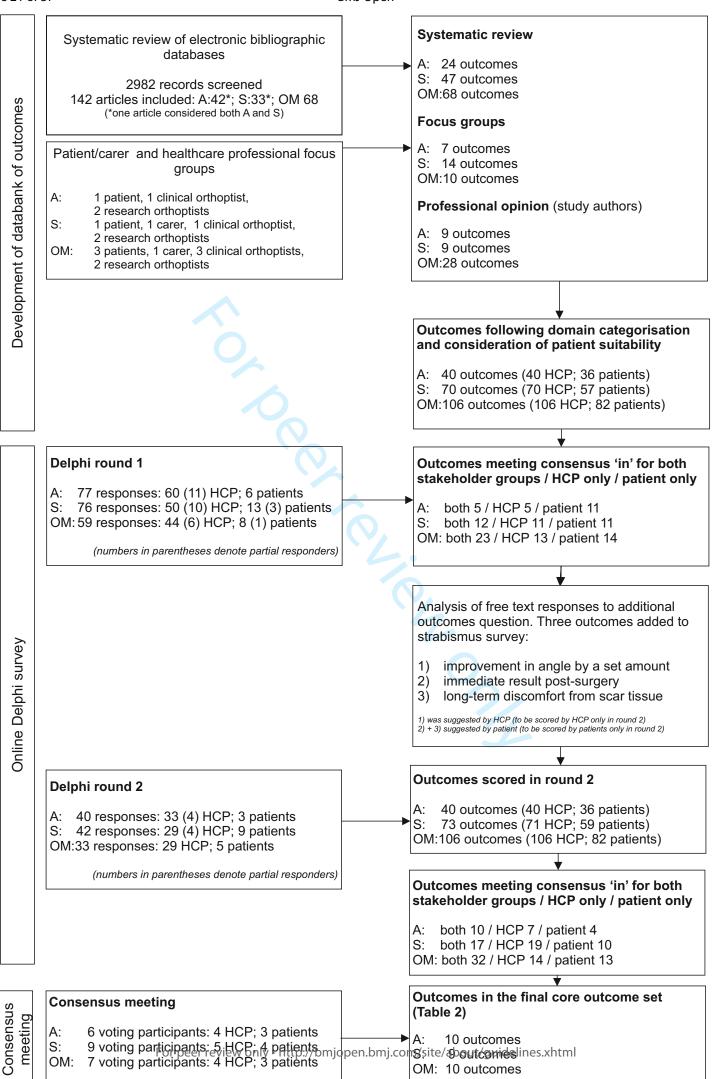
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Consensus	Description	Definition of consensus	by copyright, including
classification			
Consensus in	Consensus that the outcome	$\geq$ 70% of participants scoring the outc as '7–9' (critically important)	ome
	should be included in the core set	as '7–9' (critically important)	es relate
Consensus out	Consensus that the outcome	≥70% of participants scoring the outc	ome
	should not be included in the	as '1–3' (not important)	ext ar
	core set		nd da
No consensus	Uncertainty about the	Anything else	ma mi
	importance of the outcomes	St h	ping
		erien on	Ai training, and similar technologies.

Outcome	Domain	Amblyopia	Strabismus	Ocular
				Motility
Best corrected visual acuity	Visual function	Х		for us
Near visual acuity	Visual function	Х		ses re
Binocular vision	Visual function		Х	X slated
Spherical and cylindrical	Refractive status	Х		1 to te
refraction	Ur.			ext ar
Ocular alignment	Oculomotor function	Х	Х	X da
Deviation	Oculomotor function		Х	X m
Ocular movement	Oculomotor function	h	Х	X ning,
Symptoms	Symptoms	10,	X	X Altra
Clinical signs	Signs		6	X X X
Vision-related quality of life	Quality of life	Х	X	g, and X
Treatment-related impact	Quality of life	Х		
Future functionality / long term	Quality of life	Х	C	llar t
impact				echn
Patient satisfaction	Quality of life		Х	x Notes
Compliance	Compliance	Х		s.
Adverse events	Adverse events	Х	Х	Х
Cost	Cost	Х	Х	Х

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Supplementa	y Table 1:	Long list of outcomes u	used in the Delphi survey and critical sco	ring in bo	th rounds	r, in 0-04 of the Del	phi surve	ey by stal	keholder g	roup	
Outcomes ide	entified fro	m: systematic review (S	R), focus groups (FG) and professional op	inion (PO)	)].	J3 on ⊴ing f					
ercentages h	ighlighted i	in red denote outcomes	that reached the consensus 'in' criteria.			orus Srus					
I/A: not score	ed by stakel	holder group (HCPs or p	atients)			ay 20 inseig ies re					
mblyopia	·		used in the Delphi survey and critical sco R), focus groups (FG) and professional op that reached the consensus 'in' criteria. Datients)			21. Down gnement plated to					
Domain	Source	Outcome	Lay-term summary	Delphi	results	nload Supe text a					
			Deer			om http://bm (ABES) . ≀ta mining, <i>⊭</i>					
			01.		Rour				Rour	nd 2	
			10	H	CPs	in Patie	nts	H	CPs	Pat	ients
				n	% (7-9)	, and similar technologies.	% (7-9)	n	% (7-9)	n	% (7-9)
Symptoms	FG	1. Patient symptoms	Symptoms or complaints related to vision or eyes	67	34.3	on June similar te	50.0	37	37.8	3	66.7
Visual function	SR	2. Best corrected visual acuity	Vision measured at distance corrected with glasses	70	98.6	lune ar <del>tæ</del> c	66.7	37	100.0	3	66.7
	SR	3. Near visual acuity	Close up or reading vision	70	65.7	다 태 3	50.0	37	78.4	3	66.7
	PO	4. Habitual visual acuity	Vision measured in the usual preferred state for a person	62	58.1	2025 ologi	80.0	37	67.6	3	100.0
	SR	5. Uncorrected visual acuity	Vision without glasses or contact lenses	70	4.3	5 at gies.	40.0	37	5.4	3	0.0
	FG	6. Suppression	Testing if the person has developed "suppression" of one image to improve double vision which usually happens in childhood as a coping mechanism from the brain to improve visual development	70	42.9	Agence Bit	75.0	36	47.2	2	100.0
	FG	7. Fixation	Testing if the person is using the central part of the retina to see with or alternatively using an eccentric part of the retina	70	52.9	Bibliographique de l	33.3	36	50.0	3	33.3

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	FG	8.	Contrast sensitivity	Objects of varying brightness	66	12.1	inet	60.0	34	5.9	3	0.0
	SR	9.	Visual evoked potentials	Testing vision signals from the eyes to the brain with electrodiagnostics (visual evoked potentials/VEP)	56	8.9	-042403 on inchuding f	33.3	33	3.0	2	0.0
	SR	10.	Binocularity	to check if the eyes are working together to give any level of 3D vision or depth appreciation	70	47.1	111 May 2 Ense forwasesor	80.0	36	63.9	2	50.0
	SR	11.	Stereoacuity	Fine 3D vision or depth appreciation with both eyes or "stereo vision"	70	37.1	lay 2 nse sesor	80.0	35	34.3	2	100.
	PO	12.	Simultaneous perception	Testing lower levels of 3D vision	70	30.0	021. ignei elatie	60.0	35	25.7	2	0.0
	PO	13.	Retinal correspondence		70	31.4	äng N¢∕∰ v	N/A	35	11.4	N/A	N/A
Refraction	SR	14.	Refractive status		69	84.1	e Siy	66.7	35	94.3	3	100.
	SR	15.	Spherical & cylindrical refraction	Testing the amount of prescription of glasses or	69	79.7	1 May 2021. Downloaded Enseignement Superie moisescretated by text and	N/A	35	91.4	N/A	N/A
	SR	16.	Median spherical equivalent	contact lenses	64	26.6	deid NaA⊊ (	N/A	33	21.2	N/A	N/A
Oculomotor unction	SR	17.	Ocular alignment /deviation	Assessing if the eyes are straight or deviated and measuring the amount of eye deviation	68	63.2	A BE	66.7	35	71.4	3	100.
	PO	18.	Abnormal head posture	The presence of a compensatory head posture to avoid double vision	68	33.8	l from http://bu eur (ABES) . Ispataconinicog,	66.7	34	32.4	3	66.7
Quality of life	SR	19.	Quality of life measures (in general)	Health related quality of life (all relevant aspects)	69	53.6	, Aldrainiong,	100.0	35	62.9	3	100.
	FG	20.	Psychological impact of the disorder	Negative impact of lazy eye (amblyopia) on emotions and/or behaviour	69	55.1	n.brr indong	83.3	34	67.6	3	100.
	SR	21.	Psychological impact of treatment of disorder	The psychological impact of treatment of lazy eye (amblyopia) on emotions and/or behaviour	69	62.3	NBA G	N/A	34	73.5	N/A	N/A
	PO	22.	Self-esteem	Negative impact of lazy eye (amblyopia) on self- esteem & confidence	69	59.4	sippil.	100.0	34	70.6	3	100.
	SR	23.	Social anxiety and social avoidance due to the disorder	Negative impact of lazy eye (amblyopia) on social interaction or causing social stigma	69	55.1	June 13, Iar techn	83.3	34	67.6	3	100.
	SR	24.	Academic/ occupation achievement in relation to the condition or its treatment	Academic/ occupation achievement in relation to the condition or its treatment	69	60.9	2025 at <i>i</i> ologies.	83.3	34	76.5	3	66.7
	SR	25.	Activity of daily living (ADL)	Negative impact of lazy eye (amblyopia) on normal daily activities	68	52.9	Agence 6	100.0	33	72.7	3	100.
	SR	26.	Patient satisfaction from treatment	Patient satisfaction from treatment	68	61.8			34	76.5	3	100.
	FG	27.	Future functionality/long- term impact	Future functionality/long-term impact (patient- reEOrted)	69	78.3	6 6 6 6 6 html	100	34	91.2	3	100.

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	SR	28.	Fear of losing better		69	71.0	20-042403 or ht, including	66.7	33	84.8	3	66.7
Compliance	SR	29	eye Compliance	How well the treatment is done	69	95.7		66.7	33	97.0	3	66.7
Adverse events	SR		Adverse effects from treatment (any)	Adverse effects from treatment (any)	69	73.9	20-042403 on 11 ht, including hor	80.0	33	87.9	2	100.
events	SR	31.	Intolerable diplopia	Intolerable double vision as a side effect from treatment	69	89.9		83.3	33	100.0	3	100.
	SR		Occlusion amblyopia	Development of lazy eye (amblyopia) in the better eye as a result of patching/penalisation treatment	69	76.8	May 2021. Downloaded from Enseignement Superieur (A usces rectated too texct and data	100.0	33	87.9	3	100.
	SR	33.	Visual disorientation	Visual disorientation due to treatment with occlusion of better eye	64	45.3	nent dee	66.7	32	56.3	3	100.
	PO	34.	Disturbed distance estimation	Disturbed distance estimation due to treatment with occlusion of better eye	64	39.1	nloa text	66.7	32	46.9	3	33.3
	SR	35.	Skin irritation or allergy to patches	Skin irritation or allergy from eye patches used to occlude the eye	69	50.7	ded ancol	33.3	33	51.5	3	33.3
	PO	36.	Atropine eye drops side effects	Side effects of the eye drops used regularly at home for treatment of lazy eye (amblyopia)	69	65.2	from dada	33.3	33	69.7	3	66.7
Cost	SR	37.	Economic data (in general)	Economic data (in general) including services and families/individuals	54	24.1	ABES). ABES).	16.7	30	20.0	3	0.0
	PO	38.	Cost of treatment on services	Cost of treatment on services	55	25.5	ing:	16.7	31	32.3	3	0.0
	PO	39.	Cost of treatment on families/individuals	Cost of treatment on families/individuals	54	37.0	.//bmjope  ngg Aktra	33.3	30	50.0	3	0.0
	50											
Long-term	FG	40.	Long-term outcomes	Long-term outcomes (clinical outcomes)	59	84.7	en.bmj.com/ aiping, and si	100.0	33	93.9	3	100
Long-term	FG	40.	Long-term outcomes	Long-term outcomes (clinical outcomes)	59	84.7	njopen.bmj.com/ on June 13, 2025 at Agence Bibliographique de l Aktraining, and similar technologies.	100.0	33	93.9	3	100.0

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<u>Strabismu</u>	<u>s</u>					including	142403 o				
Domain	Source	Outcome	Lay-term summary	Delphi	results	g for uses relate	n 11 May				
					Roun	d 1 eign	2021		Round	12	
				нс	CPs	Patient	Г. "Соч	HCPs	;	Patie	ents
			0r	n	% (7-9)	t Superi text and n	vnloade(7-9)	n	% (7-9)	n	% (7-9
Symptoms	FG	1. Patient symptoms	Symptoms or complaints related to vision or eyes	60	91.7	16 data		33	100.0	9	77.
	FG	2. Diplopia	Improvement in double vision in general	60	95.0		<b>285.7</b>	33	100.0	8	62.
	FG	3. Appearance of strabismus	Appearance of the squint	60	85.0	14 mining, 15 g	46.7	33	87.9	9	33.
	FG	<ul> <li>4. Eye aesthetics as the patient perceives</li> </ul>	Appearance of the squint as the patient perceives	60	80.0	15 training, 15 g,	<b>1</b> <b>6</b> <b>6</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b>	33	84.8	9	44.
	FG	5. Eye aesthetics as relatives and friends perceive	Appearance of the squint as the relatives and friends perceive	60	58.3	ning,	46.7	33	63.6	9	33.
Visual function	SR	6. Best corrected visual acuity	Vision measured at distance corrected with glasses	60	71.7	and 11 d s	272.7	33	90.9	7	100
	PO	7. Near visual acuity	Close up or reading vision	60	45.0	12 3	<sup>9</sup> 75.0	33	63.6	7	71.
	PO	8. Habitual visual acuity	Vision measured in the usual preferred state for a person	53	41.5	12 milar 10 tec	ung70.0	32	59.4	7	100
	PO	9. Uncorrected visual acuity	Vision without glasses or contact lenses	60	8.3	12 🖁	<u>.</u> <del>2</del> 583	33	3.0	7	71.
	FG	10. Suppression	Testing if the person has developed "suppression" of one image to improve double vision which usually happens in childhood as a coping mechanism from the brain to improve visual development	60	65.0		2025 at A	32	75.0	8	75.
	PO	11. Fixation	Testing if the person is using the central part of the retina to see with or alternatively using an eccentric part of the retina	60	46.7	9	gence 33.3	32	46.9	7	42.
	PO	12. Contrast sensitivity	Objects of varying brightness	59	6.8	8	<b>Bi</b> 37.5	32	0.0	8	37.
	SR	13. Binocularity	Testing "binocularity" which is to check if the eyes are working together to give any level of 3D vision or depth appreciation	60	76.7	12	Bibliographique	32	75.0	8	87.

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	SR	14.	Stereoacuity at near	Fine 3D vision or depth appreciation with both eyes measured for near	60	60.0	, in 12 lud	<b>-042</b> 58.3 <b>203</b>	32	62.5	8	87.5
	SR	15.	Stereoacuity at near and distance (any strabismus type)	Fine 3D vision or depth appreciation with both eyes measured for both near and distance	59	44.1	12 luding for us	<b>9</b> ,58.3	32	46.9	8	75.0
	SR	16.	Stereoacuity at near and distance (for certain strabismus types? please specify)	Fine 3D vision or depth appreciation with both eyes measured for both near and distance for certain types of squint	54	53.7	or uses related to text and N/A	lay 2021. Down	30	56.7	N/A	N/A
	SR	17.	Field of binocular single vision	Testing the extent of area of vision where there is no double vision while looking around with both eyes open	60	46.7	12 and	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	32	53.1	8	62.5
	FG	18.	Post op diplopia test	Testing if a person is likely to get double vision after correcting the eye deviation with surgery	59	81.4	11 ត្ល ទ	<b>381.8</b>	32	93.8	9	77.8
	SR	19.	Simultaneous perception	Testing lower levels of 3D vision	59	37.3		50.0	32	25.0	8	62.5
	PO	20.	Retinal correspondence	Testing lower levels of 3D vision	60	43.3	N/Ang.	N/A	32	37.5	N/A	N/A
	PO	21.	Refractive status	Testing the amount of prescription of glasses or contact lenses	60	61.7	11 <b>≥</b>	<b>5</b> 4.5	32	75.0	8	50.0
Oculomotor function	SR	22.	Ocular alignment /deviation	Assessing if the eyes are straight or deviated and measuring the amount of eye deviation	60	86.7	12 <b>a</b> i.	<b>91.7</b>	32	100.0	8	50.0
	SR	23.	Abnormal head posture	The presence of a compensatory head EOsture to avoid double vision	60	66.7	م 11 پې ۵	<b>2</b> 63.6	32	84.4	9	77.8
	FG	24.	Ocular motor alignment at various positions especially where the deviation is greatest	Assessing if the eyes are straight or deviated and measuring the amount of eye deviation at different EOsitions	60	75.0	and similar teo	om/ on June	32	87.5	N/A	N/A
	SR	25.	Presence of incomitance (any strabismus type)	Testing if there is variation of the eye deviation in different EOsitions when looking around	59	71.2	N/Aologies	13, 2025	32	78.1	N/A	N/A
	SR	26.	Presence of incomitance (for certain strabismus types? please specify)	Testing if there is variation of the eye deviation in different EOsitions when looking around	58	75.9		at Agence	31	80.6	N/A	N/A
	SR	27.	Control of deviation (any strabismus type)	Measuring how well the person can control the eye turn	59	79.7	12	Bibliographi	32	96.9	9	55.6
	SR	28.	Control of deviation (for	Measuring how well the person can control the eye turn	58	81.0	N/A	graph N/A	31	93.5	N/A	N/A

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		certain strabismus types? please				by copyright, including	bmjopen-2020-042403 on				
SR	29.	specify) Ocular movement	How well eyes move as a person is looking around	60	66.7	40 0		32	71.9	9	77.
SR	30.	Presence of latent nystagmus (any strabismus type)	Checking if there are involuntary rapid movements of the eyes when one eye is covered	58	46.6	uses rela	May 2021	32	53.1	9	44
SR	31.	Presence of latent nystagmus (for certain strabismus types? please specify)	Checking if there are involuntary rapid movements of the eyes when one eye is covered	57	54.4	N/A	1.5 1 May 2021. Downloaded fi	32	71.9	N/A	N/
SR	32.	Presence of dissociated vertical deviation (DVD) (any strabismus type)	Testing if there is tendency for the eye to move up and out +/- rotates when covered	58	51.7	<u>a</u> -	12	32	53.1	8	37
SR	33.	Presence of dissociated vertical deviation (DVD) (for certain strabismus types? please specify)	Testing if there is tendency for the eye to move up and out +/- rotates when covered	56	64.3	ng, Al training, N/A N/A	m 54.5 M http://bmjopen.bmj.com/	31	71.0	N/A	N/
SR	34.	A or V pattern deviation	Testing if there is a deviation that increases either on looking up or looking down	60	60.0	N/And	§N/A	32	81.3	N/A	N
SR	35.	Fusional vergence at near and distance /fusion amplitudes/prism fusion range	Testing how well the eyes can control a deviation induced with prisms in clinic	60	68.3	similar technologies, 11 13	on June 13,	32	81.3	9	55
SR	36.	Near point of convergence (for any strabismus type)	Testing if the eyes can normally look inwards to see a near object to an acceptable amount	60	31.7	13 13 13	202 <mark>5</mark> at A	32	43.8	9	66
SR	37.	Near point of convergence (for certain strabismus types? please specify)	Testing if the eyes can normally look inwards to see a near object to an acceptable amount	58	51.7	N/A	Agence Bibliographique de l	32	62.5	N/A	N

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	FG	38.	Accommodation (for any strabismus type)	Testing if the eyes can change their focus appropriately to see objects at varying distances	60	23.3	, including	0-042 403 61.5	32	18.8	9	44.4
	FG	39.		Testing if the eyes can change their focus appropriately to see objects at varying distances	58	60.3	g for uses	on 11 May	31	61.3	N/A	N/A
	SR	40.		Testing the ratio between the ability of the eyes to look inwards and their ability to focus	59	30.5	13 13	246.2	32	28.1	9	33.3
	SR	41.		Testing the ratio between the ability of the eyes to look inwards and their ability to focus	58	65.5	N/At and	n N/A	31	67.7	N/A	N/A
	CLIN PART	42.	Improvement in angle by a set amount e.g. >10^	000	N/A	N/A	data N/Ata m	from N/A	31	51.6	N/A	N/A
	PT PART	43.	Immediate result EOst-surgery**		N/A	N/A	N/Ang	N/A	N/A	N/A	8	12.5
uality of life	SR	44.	U	Health related quality of life (all relevant aspects)	53	81.1	13 Al training,	<b>0</b> 69.2	31	93.5	9	66.7
	SR	45.	0 /	Negative impact of squint (strabismus) on emotions and/or behaviour	53	88.7	13 ng	<b>1</b> 69.2	30	100.0	9	77.8
	SR	46.		EOsitive impact of treatment on emotions and/or behaviour	53	75.5	and similar	84.6 9	30	80.0	9	77.8
	SR	47.	Social anxiety and social avoidance due to the disorder	Negative impact of squint (strabismus) on social interaction or causing social stigma	53	84.9	ar technol	June 71.4	30	90.0	9	66.7
	FG	48.	Academic/ occupation achievement in relation to the condition or its treatment	Academic/ occupation achievement in relation to the condition or its treatment	52	69.2	ogies. 13 -	2025 at Agenc	30	76.7	9	66.7
	FG	49.		Activity of daily living (ADL) such as driving	52	67.3	14	<sup>6</sup> 78.6	29	86.2	9	77.8
	SR	50.		Patient satisfaction from treatment	53	83.0	14	ce 78.6 Biblio92.9 Graphique de L	29	96.6	9	88.9

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	FG	51.	Future functionality/long- term impact	Future functionality/long-term impact (patient- reEOrted)	52	92.3	in 11 ding 12 fo	÷.	29	96.6	9	88
Compliance	PO	52.	Compliance	How well the treatment is done	52	63.5	12 <b>'g</b>	<sup>9</sup> <u>9</u> 1.7	29	62.1	8	87
Freatment dependency	SR	53.	Successful discontinuation of lens therapy or "special glasses" (for any strabismus type)	Successful discontinuation of lens therapy or "special glasses" such as bifocals or minus lenses	49	40.8	r uses related to text and d 4 2	1 May 2021. D	28	46.4	6	83
	SR	54.		Successful discontinuation of lens therapy or "special glasses" such as bifocals or minus lenses	49	51.0	ר פו	o 1	28	64.3	N/A	N/
	PO	55.	Successful discontinuation of prism therapy	Successful discontinuation of prism therapy	52	46.2	ta mining, 4	00.0	29	51.7	6	83.3
Adverse events	SR	56.	Adverse effects from treatment (any)	Adverse effects from treatment (any)	53	83.0	10 A tra	<b>5</b> 60.0	29	93.1	9	55
	FG	57.	Adverse effect on vision from patches or prisms used to treat diplopia	Adverse effect on vision from patches or prisms used to treat diplopia such as vision degradation or psychosocial effects	53	67.9	and	.bm 42.9	29	75.9	6	83
	SR	58.	Intolerable diplopia	Intolerable double vision	53	98.1	11 <u>si</u>	<b><u>9</u>81.8</b>	29	96.6	9	77
	SR	59.	Induced ptosis (post toxin injection)	Appearance of transient droopy eye lid as a result of using toxin injection to treat squint	52	51.9	11 11 7 9 9	<b>Մա</b> 57.1 1	29	55.2	8	N/A
	SR	60.		Appearance of a bleed in the surface of the eye after squint surgery or injection	52	32.7	9 9	<b>3</b> 233.3 25	29	20.7	8	37
	SR	61.	Discomfort or abnormal sensation	Discomfort or pain during/after treatment of squint	53	28.3	9 <mark>%</mark>	at 44.4	29	17.2	8	37
	SR	62.	Overcorrection or under correction of the deviation with surgery or injection	Persistence of the squint at a lesser extent or appearance of deviation in the opEOsite direction	52	71.2	9	gence Bibliographique de l	29	79.3	9	66
	SR	63.	Recurrence of deviation	Reappearance of the squint after treatment	53	66.0	9	grap	29	75.9	9	88

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	SR	64.	Induced vertical	Appearance of a vertical squint after treatment of a	53	69.8	8 (L	275.0	29	82.8	9	77.8
	SR	CF.	deviation	horizontal deviation				ŧ.				
			Induced A or V pattern	Appearance of a deviation that increases either on looking up or looking down	53	54.7	<sup>9</sup> gf	<b>9</b> 66.7	29	65.5	8	75.0
	SR	66.	Development of DVD	Appearance of a tendency for the eye to move up and out when covered	50	46.0	6 <b>o</b> r u	⊐16.7	29	34.5	8	37.5
	SR	67.	Induced incomitance	Development of variation of the eye deviation in different EOsitions when looking around	53	56.6	7 Ses	020-04275.0 0666.7 116.7 May 71.4	29	62.1	7	71.4
	SR	68.	Number of operations/proce dures needed	Number of operations/procedures needed	53	66.0	related 9	202.66.7 Downloaded from 90.9	29	65.5	8	62.5
Cost	SR	69.	Economic data (in general)	Economic data (in general) including services and families/individuals	45	44.4	11 6	<b>§</b> 36.4	27	37.0	9	33.3
	SR	70.	Cost of treatment on services	Cost of treatment on services	45	46.7	11 Xt	<b>0</b> 18.2	27	44.4	9	33.3
	SR	71.	Cost of treatment on families/ individuals	Cost of treatment on families/individuals	45	40.0	11 dat	45.5	26	38.5	9	22.2
Long-term outcomes	SR	72.	Long-term outcomes	Long-term outcomes (clinical outcomes)	50	88.0	ג מ 11 א פיין דיין	<b>90.9</b>	29	96.6	9	88.9
Guidelinee	PT PART	73.	Long term discomfort from scar tissue **	The second se	N/A	N/A	N/A@e••	<mark>∂</mark> N/A	N/A	N/A	9	55.6
							training, and s	spen.bmj.com/				
							Al training, and similar technologies.	mjopen.bmj.com/ on June 13, 2025 at Agence Biblio				

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## Ocular motility disorders

ocular moti	lity disord	<u>ers</u>				by copyright, including for uses related to te					
Domain	Source	Outcome	Lay-term summary			ay ∠u es re	Delphi r	esults			
					Ro	und 🛱 🛱 🖸	2		Ro	und 2	
					HCPs	nen d to	Patients		HCPs	Pat	tients
			r .	n	% (7-9)	nt Superieur (ABES) . o texٍt and data mining o texٍt and data mining	%	n	% (7-9)	n	% (7-9)
Symptoms	SR	1. Patient symptoms	Symptoms or complaints related to vision or eyes	50	92.0	a froi eur ( d_gat	88.9	29	96.6	5	100.0
	SR	2. Improvement in diplopia (in general)	Improvement in double vision in general	50	90.0	a 8 mi	100.0	29	100.0	5	100.0
	SR	3. Improvement of diplopia in primary gaze	Improvement of double vision when looking straight ahead	50	94.0	ning,	87.5	29	100.0	5	100.0
	SR	4. Improvement in diplopia in primary and down gaze	Improvement in double vision when looking straight ahead and down (reading position)	50	88.0	Al tra	85.7	29	100.0	5	100.0
	SR	5. Improvement in diplopia in primary and down gaze with prisms	Improvement in double vision when looking straight ahead and down with prisms	50	86.0	nipg,	75.0	29	96.6	5	100.0
	SR	<ol> <li>Severity and duration of visual symptoms/eye deviation</li> </ol>	Severity and duration of visual symptoms/eye deviation	50	78.0	ang simijar	-	29	79.3	5	100.0
	SR	7. Appearance of the eye deviation	Appearance of the eye deviation	50	74.0	n Ju nijar	33.3	29	79.3	5	60.0
	SR	<ol> <li>Reduction in pain (for certain types of ocular motility disorders? please specify)</li> </ol>	Reduction in pain	49	75.5	ne 13, 2023 at technologies		29	89.7	4	100.0
	SR	<ol> <li>Improvement in oscillopsia/blur and vertigo in adults (in nystagmus)</li> </ol>	Improvement in oscillopsia/blur and vertigo in adults (in nystagmus)	50	92.0		66.7	29	100.0	5	100.0
	FG	10. Improvement in headaches (for certain types of ocular motility disorders? please specify)	Improvement in headaches	50	80.0	6 6	50.0	29	79.3	4	40.0
Visual function	SR	11. Best corrected visual acuity	Vision measured at distance for one eye at a time corrected with glasses	50	60.0	7 7 7	42.9	29	69.0	5	60.0

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SR	12. Near visual acuity	Close up or reading vision	50	44.0	ncluo	62.5	29	48.3	5	6
PO	13. Habitual visual acuity	Vision measured in the usual preferred state for a person	44	50.0		6 /1.4	29	69.0	5	8
PO	14. Uncorrected visual acuity	Vision without glasses or contact lenses	50	6.0	1/2r	28.6	29	0.0	5	20
SR	15. Binocular BCVA	Vision measured at distance with both eyes open at the same time corrected with glasses	49	57.1	Ses I	80.0	28	71.4	5	10
SR	16. Suppression	Testing if the person has developed "suppression" of one image to improve double vision which usually happens in childhood as a coping mechanism from the brain to improve visual development	50	46.0	for uses related to text and	33.3	29	48.3	3	6
PO	17. Fixation	Testing "fixation" which is if the person is using the central part of the retina to see with or alternatively using an eccentric part of the retina	50	32.0	superio ext <sub>4</sub> anc	25.0	29	24.1	4	2
PO	18. Contrast sensitivity	Testing "contrast sensitivity" which is objects of varying brightness Contrast sensitivity	49	6.1	eur (AE 1 gata i	<b>o</b> 33.3	28	0.0	3	2
PO	19. Colour vision test (for any type of ocular motility disorder)	Colour vision test	50	8.0	ABES) . a mjining,	60.0	29	0.0	5	2
PO	20. Colour vision test (for certain types of ocular motility disorders? please specify)	re.	49	36.7	ng, Ad training, ⊗,	N/A	29	31.0	N/A	N
PO	21. Visual field test (for certain types of ocular motility disorders? please specify)	Visual field test	48	37.5	ining, an	50.0	29	24.1	5	6
SR	22. Broadening of the null region (in nystagmus)	Broadening of the null region (in nystagmus)	48	58.3	d sin	100.0	29	69.0	4	10
SR	23. Reduce the amplitude of nystagmus (in nystagmus)	Reduce the amplitude of nystagmus (in nystagmus)	48	60.4	and similar technologies	100.0	29	69.0	3	10
SR	24. Stereo acuity	Fine 3D vision or depth appreciation with both eyes or "stereo vision"	50	62.0	ංගී <b>ං</b>	ພີ່ 87.5 N	29	75.9	5	10
SR	25. Field of binocular single vision	Testing the extent of area of vision where there is no double vision while looking around with both eyes open	50	70.0	logies	025 71.4 at	29	86.2	5	8
PO	26. Post op diplopia test	Testing if a person is likely to get double vision after correcting the eye deviation with surgery	50	68.0	7	A 100.0	29	82.8	5	10
SR	27. Simultaneous perception	Testing lower levels of 3D vision	50	48.0	7	<b>6</b> 42.9	29	41.4	5	6
SR	28. Retinal correspondence		50	38.0		B N/A	29	24.1	N/A	N
SR	29. Refractive status (for any type of ocular motility disorder)	Testing the amount of prescription of glasses or contact lenses	50	46.0	6	ographique	29	37.9	5	4

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	SR	30.	Refractive status (for certain types of ocular motility disorders? please specify)		47	48.9	inclusting f	N/A	29	51.7	N/A	N/
Oculomotor function	SR	31.	Ocular alignment / deviation	Assessing if the eyes are straight or deviated and measuring the amount of eye deviation	47	91.5		71.4	29	100.0	5	80.
	SR	32.	Abnormal head posture	The presence of a compensatory head posture to avoid double vision	47	76.6	Ense Ses I	66.7	29	89.7	5	80.
	FG	33.	Ocular motor alignment at various positions specially where the deviation is greatest	Assessing if the eyes are straight or deviated and measuring the amount of eye deviation at different positions	47	80.9	s related to	N/A	29	89.7	N/A	N/
	SR	34.	Presence of incomitance (for any type of ocular motility disorder)	Variation of angle of deviation at different positions of gaze	47	63.8	thioadec t Superio text and	66.7	29	79.3	3	N/A 66.7 N/A 100.
	SR	35.	Presence of incomitance (for certain types of ocular motility disorders? please specify)	Deer	44	72.7	i trom http://bn eur (ABES). I data(mining, / Z	N/A	28	75.0	N/A	
	PO	36.	• • • •	Measuring how well the person can control the eye turn	47	83.0	Page Al	83.3	29	89.7	5	100
	PO	37.	Control of deviation (for certain types of ocular motility disorders? please specify)	CL:	43	83.7	open.bmj.con I tratning, and ∑	N/A	29	96.6	N/A	N/
	SR	38.	Ocular movement	How well eyes move as a person is looking	47	85.1	l, and		29	93.1	5	100
	SR	39.	Forced duction test (for any type of ocular motility disorder)	A test done to check eye muscle action passively using forceps	45	31.1	d sitnilar N∕milar	N/A	29	24.1	N/A	N/
	SR	40.	Forced duction test (for certain types of ocular motility disorders? please specify)		44	65.9	ne 13, Z/hn		27	66.7	N/A	N/
	SR	41.	Three step/head tilt test (for any type of ocular motility disorder)	A test to check eye deviation with head tilt and head turn in addition to the straight-ahead EOsition	44	20.5	ologies. N	N/A	29	10.3	N/A	N/
	SR	42.	Three step/head tilt test (for certain types of ocular motility disorders? please specify)		45	66.7	Agence N/A	N/A	28	60.7	N/A	N/
	PO	43.	Presence of dissociated vertical deviation (DVD)	Presence of a tendency for the eye to move up and out when covered	47	46.8	N/A N/A	N/A	29	44.8	N/A	N/
	SR	44.	A or V pattern deviation	Testing if the deviation increases on looking up or looking down	47	55.3	grapi	57.1	29	62.1	5	40

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PO	45.	Fusional vergence at near and distance /fusion amplitudes/prism fusion range	Testing how well the eyes can control a deviation induced with prisms in clinic	47	53.2	including fo	042403 57.1 01 1	29	62.1	4	
SR	46.	Reading eye movements (for any type of ocular motility disorders)	Checking if eye movements are normal during reading	45	22.2	use En	May 71.4	29	20.7	5	
SR	47.	Reading eye movements (for certain types of ocular motility disorders? please specify)		42	42.9	seignement Superieu s related text and o Z	21. Downlo	29	48.3	N/A	
SR	48.	Presence of a phoria (for any type of ocular motility disorders)	A test done to check if there is a hidden small eye alignment problem	46	54.3	perieu t and d	aded 12.9	29	58.6	5	
SR	49.	Presence of a phoria (for certain types of ocular motility disorders? please specify)	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	41	56.1	eur (ABEŜ). d data r≪ining, Z	om http://t	28	71.4	N/A	
SR	50.	Objective extortion (for any type of ocular motility disorders)	Checking if the eye is rotated outwards due to a muscle problem (tested in clinic without the need of patient response)	43	25.6		42.9	28	25.0	5	
SR	51.	Objective extortion (for certain types of ocular motility disorders? please specify)		41	58.5	inina, and	n.bm.N/A	27	66.7	N/A	
SR	52.	Subjective extortion (for any type of ocular motility disorders)	Check if the eye is rotated outward due to a muscle problem (tested in clinic and results depend on patient response)	44	50.0	and similar	42.9	28	60.7	4	
SR	53.	Subjective extortion (for certain types of ocular motility disorders? please specify)		41	73.2	N/66.	June 13,-2	27	92.6	N/A	
SR	54.	Near point of convergence (for any type of ocular motility disorders)	Testing if the eyes can normally look inwards to see a near object to an acceptable amount	47	34.0	-	<b>2025</b> at A	29	34.5	5	
SR	55.	Near point of convergence (for certain types of ocular motility disorders? please specify)		41	63.4	N/A	igence N/A	28	78.6	N/A	
SR	56.	Accommodation (for any type of ocular motility disorders)	Testing if the eyes can change their focus appropriately to see objects at varying distances	46	15.2	8	Bibliographique de l	29	13.8	5	

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	SR	57.	Accommodation (for certain types of ocular motility disorders? please specify)		42	42.9	ncluding t N		28	46.4	N/A	
	SR	58.	Dynamic retinoscopy (for certain types of ocular motility disorders? please specify)	Changing refractive power of the eye with varying focus	42	19.0	N/ses	N/A	27	37.0	N/A	
	SR	59.		Testing a specific tracking slow movement of the eye for an object	45	64.4		42.9	28	60.7	5	
	SR	60.	Saccades (for certain types of ocular motility disorders? please specify)	Testing a specific rapid tracking eye movement for an object	45	62.2	to text and di	57.1	28	67.9	5	
	SR	61.		Special tracking eye movement using a striped drum	46	34.8	N/\$ (5)	N/A	29	31.0	N/A	
Additional clinical signs	SR	62.	Eye movement recordings (for certain types of ocular motility disorders? please specify)	Eye movement recordings	40	27.5	http://bmjop BES) . mining, Al tr	42.9	28	32.1	5	
	SR	63.	Palpebral fissure size/lid position (for certain types of ocular motility disorders? please specify)	Checking eye lid position - whether it is droopy or elevated compared to normal	44	63.6	njopen.bmj.com Al trainiŋg, and		29	65.5	5	
	SR	64.	Facial asymmetry (for	Checking if the sides of the face are		00.0		50.0	00	00.7	4	ſ

SR	63.	disorders? please specify) Palpebral fissure size/lid position (for certain types of ocular motility disorders?	Checking eye lid position - whether it is droopy or elevated compared to normal	44	63.6	ainiŋg,	40.0	29	65.5	5	40.0
		please specify)				anc	<u>6</u>				
SR	64.	Facial asymmetry (for 4th n palsy)	Checking if the sides of the face are symmetrical or not to help diagnose some congenital motility disorders	45	33.3	d simila	50.0	29	20.7	4	25.0
SR	65.	Pupil examination (for any type of ocular motility disorders)	To check pupil size; reaction etc	44	45.5	ar tech	une 50.0	29	41.4	5	20.0
SR	66.			43	74.4		3,-2025 at	29	79.3	N/A	N/A
SR	67.		Checking if the eyes are protruding out of their position	44	79.5		Agence B	29	86.2	5	60.0
SR	68.	Intraocular pressure (for certain types of ocular motility disorders? please specify)	Check eye pressure	43	48.8	5	Bibliograp	28	42.9	4	100.0

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	SR	69.	Corneal exposure (for certain types of ocular motility disorders?	Checking for corneal changes resulting from incomplete eyelid closure	42	76.2	ht, including	<b>75.0</b>	28	96.4	5	80.0
	SR	70.	please specify) Corneal sensitivity (for certain types of ocular motility disorders? please specify)	Checking if corneal nerve supply is intact	39	66.7	for Uses I	75.0	28	67.9	5	100.0
	SR	71.	Canthal displacement (for certain types of ocular motility disorders? please specify)	Change in position of the eye contour	32	28.1	related to to N	N/A	23	21.7	N/A	N/A
	SR	72.	Oculocardiac reflex (for certain types of ocular motility disorders? please specify)	Slowing of the heart rate due to entrapped eye muscle	28	32.1	ivaded i Superieu N∕Nd d	N/A	22	36.4	N/A	N/A
	SR	73.	Globe dystopia (for certain types of ocular motility disorders? please specify)	Check the position of the eyeball in relation to the other eye and other parts of the face	33	39.4	r (ABES) ata_minir	60.0	22	36.4	4	50.0
	SR	74.	Enophthalmos (for certain types of ocular motility disorders? please specify)	Checking if the eyes are sinking in from their normal position	42	66.7	ng, Дl tra	75.0	29	82.8	5	80.0
linical ivestigations	SR	75.	Assessment for fractures and soft-tissue herniation for example inferior rectus muscle; fat; or connective tissue radiographically (for certain types of ocular motility disorders? please specify)	Assessment for fractures and soft-tissue herniation for example inferior rectus muscle; fat; or connective tissue radiographically	41	87.8	שוויטעפור-בסבט-ע-ב-אסט טון או איז	66.7	29	96.6	4	75.0
	SR	76.	Assessment for muscle atrophy or absent nerve radiographically (for certain types of ocular motility disorders? please specify)	Assessment for muscle atrophy or absent nerve radiographically	35	65.7	chnologies.	<b>60.0</b>	26	69.2	4	75.0
	SR	77.	Histologic examination of excised tissue (for certain types of ocular motility disorders? please specify)	Histologic examination of excised tissue	26	57.7	N/A Environmente	N/A	24	75.0	N/A	N/A
Quality of life	SR	78.	Quality of life measures (in general)	Health related quality of life (all relevant aspects)	45	82.2	8 9	87.5	29	93.1	5	100.0

	FG	79.	, , ,	Negative impact of eye motility problem on	45	84.4	by copyright, includie کالله دولانین	100.0	29	96.6	5	100.0
	FG	80.	the disorder Psychological impact of	emotions and/or behaviour Positive impact of treatment on emotions and/or	45	77.8	N/A d	N/A	29	93.1	N/A	N/A
	FG	81.	treatment of disorder Social anxiety and social avoidance due to	behaviour Negative impact of eye motility problem on social interaction or causing social stigma	45	77.8	for <sub>o</sub> uses	100.0	29	89.7	5	100.0
	FG	82.	the disorder Academic/ occupation achievement in relation to the condition or its treatment	Academic/ occupation achievement in relation to the condition or its treatment	44	72.7	es related	87.5	29	79.3	5	80.0
	FG		Activity of daily living (ADL)	Activity of daily living (ADL) such as driving	45	80.0	80 te	100.0	29	93.1	5	100.
	SR		treatment	Patient satisfaction from treatment	45	82.2	with an	87.5	29	93.1	5	80.0
	FG	85.	Future functionality/long-term impact	Future functionality/long-term impact (patient- reported)	44	86.4	ieur ( <i>F</i> Id data	100.0	29	96.6	5	100.0
Compliance	SR	86.	Compliance	How well the treatment is done	42	54.8	7 mii	71.4	29	65.5	5	80.0
Treatment dependency	PO	87.	Successful discontinuation of glucocorticoids (in orbital inflammatory conditions such as thyroid eye disease)	Successful discontinuation of lens therapy or glucocorticoids (in orbital inflammatory conditions such as thyroid eye disease)	34	64.7	eignement Superieur (ABES) . Regated t& tex and gata mining, AJ training, and simjjar بواعد الله المعني المعني المعني المعني المعني المعني الم	66.7	25	76.0	4	50.0
	PO	88.	Successful discontinuation of lens therapy or "special glasses"	Successful discontinuation of lens therapy or "special glasses" such as bifocals or minus lenses	43	51.2	ng, <sub>4</sub> nd s	50.0	29	58.6	4	50.0
	PO	89.	Successful discontinuation of prism therapy	Successful discontinuation of prism therapy	44	56.8	sinjjar	66.7	29	69.0		66.7
Adverse events	SR	90.	Adverse effects from treatment (any)	Adverse effects from treatment (any)	44	79.5	techi techi	7 10010	29	82.8	5	100.
	FG	91.	Adverse effect on vision from patches or prisms used to treat diplopia	Adverse effect on vision from patches or prisms used to treat diplopia such as vision degradation or psychosocial effects	44	56.8	technqlogies		29	82.8	5	80.0
	PO	92.	Intolerable diplopia	Intolerable double vision	44	97.7		100.0	29	100.0	5	100.
	PO	93.	Induced ptosis (Post toxin injection)	Appearance of transient droopy eye lid as a result of using toxin injection to treat squint	43	48.8	5	80.0	29	62.1	5	80.0
	PO	94.	Induced subconjunctival haemorrhage	Appearance of a bleed in the surface of the eye after squint surgery or injection	44	34.1	7	57.1	28	32.1	5	80.0
	PO	95.	Discomfort or abnormal sensation	Discomfort or pain during/after treatment of squint	43	39.5	7 bianographic	85.7	29	48.3	5	100.

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PO96.Overcorrection or under correction of the deviation with surgery or injectionPersistence of the squint at a lesser extent or appearance of deviation in the opposite direction4472.766PO97.Recurrence of deviationReappearance of the squint after treatment deviation4470.586PO97.Recurrence of deviationReappearance of a vertical squint after treatment deviation4450.566PO98.Induced vertical deviationAppearance of a vertical squint after treatment of a horizontal deviation4459.166PO99.Induced A or V pattern appearance of a tendency for the eye to move up and out when covered4459.166PO100.Development of DVD neededAppearance of a tendency for the eye to move up and out when covered4456.866PO101.Induced incomitance neededDevelopment of variation of the eye deviation in different positions/procedures needed4468.280CostPO103.Economic data (in general)Economic data (in general) including services and families/individuals3948.788PO104.Cost of treatment on servicesCost of treatment on families/individualsCost of treatment on families/individuals3941.086Long-termSR106.Long-term outcomesLong-term outcomesLong-term outcomesLong-term outcomes4488.6	PO96.Overcorrection or under correction of the deviation with surgery or injectionPersistence of the squint at a lesser extent or appearance of deviation in the opposite direction4472.7For the squint at a lesser extent or appearance of deviation in the opposite directionPO97.Recurrence of deviationReappearance of the squint after treatment4470.5SecPO98.Induced vertical deviationAppearance of a vertical squint after treatment4459.1SecPO99.Induced vertical deviationAppearance of a vertical in that increases either up and out when covered4459.1SecPO100.Development of DVD up and out when covered up and out when covered4456.8SecPO101.Induced incomitance general)Development of variation of the eye deviation in different positions when looking around4468.2SecPO102.Number of operations general)Number of operations/procedures needed4468.2SecPO103.Economic data (in general)Economic data (in general) including services and families/individuals3946.2SecPO104.Cost of treatment on fermilies/individualsCost of treatment on families/individuals3941.0SecPO104.Long-term outcomesLong-term outcomes (clinical outcomes)4488.6Sec	PO         96.         Overcorrection or under correction of the deviation with surgery or injection         Persistence of the squint at a lesser extent or appearance of deviation in the opposite direction         44         72.7         66 (Figure 1)           PO         97.         Recurrence of deviation         Reappearance of a vertical squint after treatment         44         70.5         86 (Figure 2)           PO         98.         Induced vertical deviation         Appearance of a vertical squint after treatment of a horizontal deviation         44         59.1         6 (Figure 2)           PO         98.         Induced vertical deviation         Appearance of a vertical squint after treatment of a horizontal deviation         44         59.1         6 (Figure 2)           PO         98.         Induced N or V pattern on looking up or looking down         44         59.1         6 (Figure 2)           PO         100.         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## A core outcome set for three ophthalmic conditions: a healthcare professional and patient consensus on Core Outcome Sets for Amblyopia, Ocular Motility and Strabismus (COSAMS study)

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## A core outcome set for three ophthalmic conditions: a healthcare professional and patient consensus on Core Outcome Sets for Amblyopia, Ocular Motility and Strabismus (COSAMS study)

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## Abstract

**Objectives:** Amblyopia, strabismus and ocular motility disorders are common conditions with significant impact on visual function, appearance and quality of life. We aimed to

establish a core set of outcomes for each of the three conditions for use in clinical trials and routine clinical practice.

**Design:** A comprehensive databank of outcomes was developed from a systematic review of the literature and a series of focus groups with healthcare professionals, researchers, patients and carers. The databank of outcomes was scored in a two-round Delphi survey completed by two stakeholder groups; healthcare professionals / researchers and patients / carers. Results of the online Delphi were discussed at a face-to-face consensus meeting where the core outcome sets were finalised.

Setting: UK-wide consultation.

Participants: Researchers, clinicians, patients and carers.

Outcome measures: Core Outcome Sets.

**Results:** For amblyopia, strabismus and ocular motility, 40/42/33 participants contributed to both rounds of the Delphi; 6/9/7 members attended consensus meetings, respectively. Consensus was reached on ten core outcomes for both amblyopia and ocular motility and nine for strabismus. All three conditions shared the core outcomes: *adverse events, cost, vision-related quality of life, and ocular alignment*. The strabismus and ocular motility disorder core sets included, in addition, *measuring the deviation, binocular vision, ocular movement, patient satisfaction and symptoms*. The amblyopia set, distinct from the sets for the other two conditions, included *best corrected distance and near visual acuity, spherical and cylindrical refraction, compliance, and treatment-related and functionality / long-term impacts*.

**Conclusions:** The study used robust consensus methods to develop a core outcome set for three ophthalmic conditions. Implementation of these core outcome sets in clinical trials and routine clinical practice will ensure that the outcomes being measured and reported are relevant to all stakeholders. This will enhance the relevance of study findings and enable comparison of results from different studies.

## Keywords:

Core outcome set; Amblyopia; Strabismus; Ocular motility; Consensus; Delphi

## Article summary:

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## Strengths and limitations of this study:

- This study followed robust methodology as guided by the Core Outcome Measures in Effectiveness Trials (COMET) Initiative.
- We targeted amblyopia, strabismus and ocular motility disorders which are common ophthalmic conditions.
- The study included key stakeholders including researchers, clinicians, patients and carers.
- Attrition rates in the Delphi process were moderate but similar to other COS studies.
- Larger response numbers, including international participants, would be preferrable for wider generalisability.

## Introduction

Amblyopia (lazy eye) and strabismus (squint) occur in up to 5% of the general population <sup>12</sup>. It is unknown how prevalent ocular motility disorders (abnormal eye movements) are in the general population. These conditions often present in children and can lead to long-term problems for children and young adults such as blurred vision, double vision, low esteem and even blindness if not treated <sup>3</sup>. There are several approaches to the management of these conditions including occlusion, penalisation, spectacles, prisms, drugs, surgery, botulinum toxin, exercises, watchful waiting, or a combination of two or more of the above <sup>4-20</sup>.

Interventional systematic reviews in this field of research have identified that there is considerable variation in the outcomes being measured and reported in primary research studies, which impacts on the ability to compare and synthesise outcome results across studies. Moreover, it was noted that there is a paucity of outcome data available on important patient outcomes such as quality of life, long-term outcome as well as the cost of treatment <sup>4-20</sup>. To mitigate these issues and to increase the relevance of research, a core outcome set (COS) can be developed which represents an agreed standardised set of outcomes that should be measured and reporting in all studies for a specific area of health or healthcare. A search of the COMET (Core Outcome Measures in Effectiveness Trials) database revealed that there are several studies that have investigated important

outcomes for eyes and vision disease; examples include cataract <sup>21 22</sup> ,glaucoma <sup>23</sup> and age-related macular degeneration <sup>24</sup> but none have specifically looked at amblyopia, strabismus or ocular motility disorders <sup>25</sup>.

The aim of this study was to develop core outcome sets for use in clinical trials and routine practice for all intervention types for the treatment of amblyopia, strabismus and ocular motility disorders in children and adults that includes input from all stakeholders. While we aim to develop three separate COS for each of the ophthalmic conditions, we anticipate that there could be considerable overlap in the importance of certain outcomes across these conditions. This is due to the fact that the three conditions often overlap and co-exist in patients, are frequently targeted within the same research studies, and are usually managed by the same group of health care professionals.

## Methods

The development of the COS study involved three stages (Figure 1): (1) the generation of a long list of outcomes; (2) a two- round online Delphi survey and (3) face- to- face consensus meetings to discuss the results of the Delphi survey and agree on the COS. The process considered the minimum standards for the design of a COS study (COS-STAD), which included careful consideration of the scope, stakeholders and the consensus process <sup>26</sup>.

## **Outcome list generation**

A databank of outcomes was generated from two sources: a systematic review of outcomes reported by researchers and clinicians in studies for the treatment of the conditions under evaluation, and, secondly using three separate focus groups (one for each condition) containing a mix of healthcare professionals, researchers, patients and carers. The detailed search strategy, methods and results for the systematic review have been published elsewhere <sup>27</sup>. Outcomes from the systematic review and suggested outcomes from the recorded focus group meetings were extracted verbatim and grouped into suitable domains to facilitate easy classification. The final list was checked by experts in all three clinical conditions (SJ, FR), who also had the opportunity to use their clinical expertise to add additional outcomes to the list. In preparation for the Delphi

survey, clinical assessment outcomes used only by healthcare professionals were either separated out (not to be scored by patients) or combined into a simplified outcome for patients to score. Each outcome was written using plain language and feedback sought from four researchers from the Health Service Research department, University of Liverpool and a clinician from a local hospital on the acceptability and their understanding of the wording used. The databank of outcomes can be found in Supplementary Table 1.

## **Online Delphi survey**

 The databank of outcomes was used to populate an online Delphi survey, which was administered using DelphiManager <sup>28</sup>. Participants were invited from two key stakeholder groups. The first group consisted of healthcare professionals involved in the care for people with one of the three conditions or researchers working within this field. Invitations to participate were sent by email flyers to national professional organisations including the British and Irish Orthoptic Society, Paediatric Ophthalmology networks, and local groups linked with the University of Liverpool. The second group included patients or carers of patients affected by at least one of the three conditions of interest. Patients and carers were invited to participate into the survey using flyers distributed on the University of Liverpool noticeboards, newsletters (via the professional Society), social media (twitter) and in ophthalmology departments in local hospitals including Aintree University Hospital, The Royal Liverpool University Hospital and Southport and Ormskirk hospitals. Through routine clinical practice, the study authors (SJ, FR) and healthcare professionals were also encouraged to distribute the patient survey links to their relevant patients if they showed an interest in the study.

Four surveys were set up, one for the healthcare professionals and researchers that contained the outcomes to be scored for all three conditions, and, three separate surveys containing only the outcomes relevant to patients and carers associated with each individual condition. The Delphi process was completed using two rounds (hereafter referred to R1 and R2). In each round participants were presented with the list of outcomes and asked to score each outcome on how important it was to include in the COS, using a 9-point Likert scale, with 1-3 labelled 'not important', 4-6 labelled 'important but not critical', and 7-9 labelled as 'critically important' <sup>29</sup>. Participants had the option to indicate 'unable to score' on any outcome they felt unable to score, and at the end of R1,

 participants were invited to submit additional outcomes they thought were missing from the list. These outcomes were reviewed by the study authors (SJ, FR) and any outcomes that represented a new relevant outcome were added to the list to be scored in R2. Irrespective of participant scoring, no outcomes were removed from the list between R1 and R2. During R2, participants were shown the distribution of scores for both stakeholder groups for each outcome along with their own score from R1 and asked to score the outcome again, using the same scale, taking this extra information into account.

## Consensus meeting

Separate face-to-face consensus meetings were held at the University of Liverpool, UK for each of the three conditions. Participants who either had an active role in the focus groups and/or completed both rounds of the Delphi survey were invited to attend, although others with an interest in the project were invited to ensure each meeting had a balanced mix of participants from both stakeholder groups. In advance of the meeting, participants received a copy of their scores from the online survey (if appropriate) and a consensus matrix (Supplementary Table 1) detailing the results of R1 and R2 by stakeholder group, and which outcomes had reached a priori definition of consensus in, consensus out or no consensus (Table 1). The consensus definition is similar to that used in other COS development studies.

The meeting for amblyopia was chaired by a non-clinical researcher with expertise in COS development methodology (JJK) while the meeting for strabismus and ocular motility was chaired by a student investigator with a clinical background (SJ).

In order to facilitate the discussion all outcomes that had reached consensus 'in' after R2 for both stakeholder groups were presented first, followed by outcomes that reached consensus 'in' for only one stakeholder group. All outcomes that scored critical for inclusion for 50-69% of the participants for either both or one of the stakeholder groups in R2 were presented next followed by all other outcomes that were scored by both stakeholder groups. Outcomes that were only scored by healthcare professionals and researchers were discussed last. Results for each outcome from the Delphi were shown to the participants with more time allocated to discussing outcomes where there was

more uncertainty on whether the outcome should be included in the COS or not. Views for and against inclusion in the COS were sought by the meeting chair, who also ensured that participants had equal opportunity to comment prior to voting. Voting was undertaken anonymously using Poll Everywhere <sup>30</sup> software which was linked to mobile and tablet devices. The definition of consensus used in the Delphi survey (Table 1) was applied to the consensus meeting. The final COS was presented at the end of the meetings.

## Study registration, ethics and reporting guidance

The study was prospectively registered with the COMET Initiative (Core Outcome Measures in Effectiveness Trials)<sup>31</sup>. Ethical approval was obtained from the University of Liverpool institutional research ethics committee for the focus groups, online survey and the consensus meetings to be undertaken with healthcare professionals and patients (Ref. Nos. 2063 and 2260). Informed consent was obtained from participants. The study is reported in line with the Core Outcome Set – Standards for Reporting (COS-STAR) guidance <sup>32</sup>.

## **Patient and Public Involvement**

The study was supported by a patient advisory group which provided input to this research study. The patient advisory group met on a regular basis for the duration of the study. Patients contributed to the design of the study and were involved at all stages of the survey and consensus meetings.

### Results

A summary of the COS development process is shown in Figure 1. The final COS contains ten, nine and ten outcomes across seven, six and seven domains for amblyopia, strabismus and ocular motility respectively (Tables 2-4). Ocular alignment, vision-related quality-of-life, adverse events and cost were common to all three conditions.

## Development of the databank of outcomes

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The systematic review and focus groups of health care professionals, researchers, patients and carers identified 31, 61, and 78 individual outcomes for amblyopia, strabismus and ocular motility respectively. These were combined with a list of outcomes suggested by professional experts (SJ, FR) resulting in a total of 40, 70 and 106 outcomes for amblyopia, strabismus and ocular motility respectively. The outcomes were classified into 12 domains, (symptoms, visual function, refraction, oculomotor function, quality-of-life, treatment dependency, signs, investigations, long-term outcome, compliance, adverse events, cost) and outcomes that were not considered to be patient relevant were separated out or combined. As an example, 'refractive status', 'spherical and cylindrical refraction' and 'median spherical equivalence' were combined into a single outcome 'refractive status' for patients as they all have a similar meaning, but are often referred to separately by healthcare professionals. Details of all outcomes including domain classification, combined outcomes and plain language descriptions of outcomes is provided in Supplementary Table 1.

## Online Delphi

Thirty three healthcare professionals / researchers scored all outcomes for both R1 and R2 of the amblyopia component of the online survey while 29 completed for strabismus and ocular motility. Three patients/carers completed both rounds for amblyopia while nine completed both rounds for strabismus and five for ocular motility (Figure 1). At the end of R1, five outcomes for amblyopia, 12 for strabismus and 23 for ocular motility reached consensus 'in' for both stakeholder groups. After a review of all additional outcomes suggested by participants in R1, three new outcomes were added to the strabismus survey in R2 (improvement in angle by a set amount (suggested by a healthcare professional) and, immediate result post-surgery and long-term discomfort from scar tissue (both suggested by a patient)).

On completion of R2, ten outcomes reached consensus 'in' for amblyopia across both stakeholder groups while 17 and 32 outcomes reached the same criteria for strabismus and ocular motility respectively.

## Consensus meeting

Six, nine and seven voting participants attended the consensus meeting for amblyopia, strabismus and ocular motility respectively with an even balance of healthcare professional/researchers and patients present (Figure 1).

#### Amblyopia

For amblyopia, future functionality/long-term impact and adverse events reached the consensus 'in' criteria for both stakeholder groups in both rounds of the Delphi and remained in the COS. Despite reaching consensus 'in' for both rounds of the Delphi for both stakeholder groups, intolerable diplopia and occlusion amblyopia (both adverse events) were not included in the final COS as it was felt that these could be captured under 'adverse events' and therefore were not critical for separate inclusion in the COS. Long-term outcome was also excluded following discussion as the group felt that there was currently no agreed set time for measuring long-term objective outcomes. Best corrected visual acuity and compliance marginally did not reach consensus 'in' during R2 of the Delphi but made the final COS after discussion. Following a discussion on the other visual function outcomes, near visual acuity was also added because it was noted that it was a good marker of early improvement for the treatment of amblyopia and important for children as it is important to their education. Refractive status reached consensus for both groups in R2 but following discussion this was replaced by *spherical* and cylindrical refraction (scored only by health care professionals in the Delphi) because it was successfully argued that this was a more precise measurement of refractive status. The list of outcomes within the quality of life domain were discussed simultaneously. While this was not listed specifically as an outcome in the Delphi, participants agreed to include visual-related quality of life in the core set as it was felt that a generic healthrelated quality of life outcome was not sensitive enough. Psychological impact of treatment was scored only by healthcare professionals in the Delphi but reached consensus 'in' during R2. Following discussion led by a parent participant, the panel derived a new outcome to include *treatment-related impact* into the final COS in order to capture the effect of treatment, such as patching on children, which could be long lasting. For both Delphi rounds, cost outcomes did not reach consensus 'in' by either stakeholder groups, however, the consensus panellists successfully advocated for its inclusion as a core outcome as *cost* outcome data is vital information for contemporary health systems.

## Strabismus

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For strabismus, symptoms and patient satisfaction reached the consensus 'in' criteria for both stakeholder groups in both rounds of the Delphi and remained in the COS. Best corrected visual acuity also reached consensus 'in' for both rounds and groups in the Delphi although the consensus panel argued that any change in vision and/or loss of vision as an adverse event would be very significant and reportable as per standard healthcare safety procedures <sup>33</sup>. At the consensus meeting, participants noted that strabismus interventions aim to change the strabismus angle and visual acuity should not be affected by the intervention unless an adverse event occurred. Thus a change in visual acuity would be captured within adverse events. On this basis a decision was taken to exclude visual acuity from the core set. All remaining visual function outcomes were discussed simultaneously, and while the post-op diplopia test reached consensus 'in' during the Delphi exercise, the consensus panel voted in favour of including *binocular* vision as core, as it was more representative of a group of visual function related outcomes. Oculomotor function outcomes were discussed simultaneously and it was highlighted that ocular movement was critical to be reported in all strabismus types as a change caused by the intervention would be significant. Quantifying both the ocular alignment and deviation were also seen to be critical in the context of any strabismus type and were included as core outcomes. *Visual-related quality-of life, adverse events* and *cost* were also included in the COS for reasons discussed for amblyopia.

## Ocular Motility

The discussions for ocular motility closely followed those of strabismus with the addition of clinical signs being added as an extra core outcome. Similar to adverse events, this outcome was a catch all for all clinical signs which were scored individually in the Delphi exercise. This strategy was seen favourably by the meeting participants as many sub-conditions of ocular motility have specific signs associated with them. One example for this is corneal exposure in the ocular motility condition of Thyroid Eye Disease but which is not relevant in other ocular motility disorders.

## Discussion

This study has developed a set of core outcomes for the treatment of three ophthalmic conditions using a robust consensus process involving healthcare professionals, researchers, patients and carers. Consensus was reached on what should be measured

in each of the three COS. They consisted of nine to ten outcomes distributed across six to seven domains to cover all important aspects related to treatment (objective clinical, adverse events, subjective or patient-reported outcomes, and health economics). While these three core outcome sets were developed independently, there are some parallels, and as a consequence, four outcomes (*ocular alignment, vision-related quality-of-life, adverse events and cost*) were common to all three conditions. The amblyopia COS captures the condition's unique features by reporting additionally on '*best corrected visual acuity', 'near visual acuity', 'compliance', 'spherical and cylindrical refraction', 'treatment-related impact' and 'future functionality/long-term impact', keeping in mind that children are the predominantly affected population. The COS for strabismus and ocular motility disorders, on the other hand, include '<i>binocular vision', 'ocular movement', 'measuring the deviation', 'symptoms' and 'patient satisfaction'*. The ocular motility disorder COS was unique in additionally reporting '*clinical signs'* related to the relevant conditions.

We recommend that, as a minimum, these core outcomes are used in future trials of interventions to treat amblyopia, strabismus and ocular motility disorders. We also advocate that these outcomes are recorded in routine clinical practice to ensure that the outcome data collected is meaningful and important.

A strength of this study is that it was prospectively registered with the COMET Initiative and it was developed using the COS- STAD (Core Outcome Set - STAndards for Development) recommendations <sup>26</sup>. Engagement with patient participants was particularly challenging and we sought to improve patient input by offering paper copies of the Delphi survey with pre-paid return envelopes in orthoptic clinics, although this was later abandoned after a number of sessions when there was no uptake. As a consequence of a relatively low number of patients responding to the Delphi and attrition between the two rounds, there was concern that consensus was not being achieved at the end of the final round given the number of outcomes reaching consensus for both stakeholder groups had increased dramatically from R1. While measures were taken to ensure survey participation and retention was maximised (including sending reminders and extending deadlines for completion), it was felt that after several months of keeping the survey open, our efforts became futile. In order to compensate for this, we ensured that the consensus meetings where the final COS were ratified, contained a good Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

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balance of healthcare professionals and patients. The main limitation of this study was that the consensus process was based using only participants in the UK. However, as a starting point, we have reason to believe that this COS could also be useful in other countries and settings.

Further consensus work is needed to refine and establish the best measurement instruments and time points for when to measure these core outcomes. To assist this process, the systematic review for generating the databank of outcomes also recorded the measurement instruments and timings associated with each outcome <sup>27</sup>.Moreover, for some outcomes, the metric (e.g. change from baseline or inter-ocular difference (IOD) of BCVA), and method of aggregation (e.g. mean or median) <sup>22</sup> would need to be determined. Defining success criteria (e.g. 8 or 10 dioptres from orthophoria for alignment, for distance and/or near) is another aspect of outcome refining and definition to be done by further work. The generalisability of the COS also needs to be reviewed in healthcare settings outside the UK. While the review of outcomes identified studies from around the world (with prominence from the United States, United Kingdom, China and various European countries), the formal consensus process was undertaken using only participants from the UK, and those attending the consensus meeting were mostly localised to the North West of England.

There are few reported COS in the literature that relate to the three conditions in this study. Chiu et al. recommended four outcomes for reporting results of surgery for intermittent exotropia <sup>34</sup>. Their study aimed to explore the extent of standardisation of outcomes reported in surgical studies for the condition. However, the study was limited by the extent of literature review for this specific condition (10-year literature search period) and lack of external consensus. A short narrative review of outcome measurements for size of deviation showed considerable variability across the tests available and the recommendations for their use. They suggested four core outcomes for all future studies: alignment, near stereoacuity, control score, and quality of life score. If assigning near stereoacuity and control score to 'binocular vision', their outcomes map to those reported in our COS for strabismus.

Moreover, two recently published studies attempted to define criteria for success in treatment, one for amblyopia and the other for strabismus surgery, which could be

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considered complementary to the COS and not alternatives because they essentially give more definitions of primary outcomes rather than suggesting a set of specific outcomes to be measured in research.

A report was published by Shoshany et al. <sup>35</sup> stating that the IRIS measures for amblyopia developed by the American Academy of Ophthalmology (IRIS7 <sup>36</sup>, modified in 2019 to IRIS50 <sup>35</sup>) provide uniform criteria for defining amblyopia treatment success. Treatment was defined as 'successful' if corrected IOD was less than 0.23 logMAR 12–18 months after first diagnosis. IRIS50 considers improvement in VA, which may be relevant to patients who had dense amblyopia at baseline but nevertheless improved. Thus, IRIS50 may be a more practical reporting measure than IRIS7. In general, Shoshany et al. propose that these measures will allow more efficient reporting of quality metrics and rapid and objective assessment of new amblyopia treatments <sup>35</sup>.

In addition, a study aiming to define successful outcomes for strabismus surgery was published by Serafino et al. <sup>37</sup>. Although this study did not state an intention to develop a COS, there are a lot of similarities and overlap in the objectives and methodology used. A Delphi process was used to identify areas of consensus and disagreement among experts for the definition of success post strabismus surgery. The panel of experts in their study represented wide international geographic areas and included experts who were chosen based on their peer-reviewed publications, participation at international meetings and their surgical experience. The study concluded the following: they achieved consensus on which strabismus types need their separate set of outcome criteria. They also identified the importance of 'stereopsis' and 'the range of single vision' for inclusion of success definition in some strabismus types, which interestingly could be mapped to 'binocular vision' in our strabismus COS. The study also found that there was no consensus on the length of time after surgery for determination of success, magnitude of deviation consistent with success, and whether manifest or latent deviation should be considered to define success, which the review of our study <sup>27</sup> has also found, and which we are advocating to define, by future work. Differences from our study is that their survey did not involve scoring of outcomes, there was no systematic search of literature

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of reported outcomes prior to survey construction, and patients or service users were not consulted in the process.

A search in the COMET initiative database in April 2020 did not reveal registration of any further additions of similar studies in the database. It is advantageous to register COS studies in the database to facilitate collaborative work of similar scope, and to avoid duplication of efforts and waste of research.

## Conclusion

The three COS developed from this study can be applied to future trials and routine data collection for all intervention types to treat the three ophthalmic conditions considered. Their use will allow the comparison of outcome data to be made across studies and to better inform treatment decisions. Future work will include seeking consensus on how these outcomes should be measured and to evaluate the acceptability of the current COS to patients and professionals in other countries, particularly where healthcare systems differ from the UK.

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**Author contributions:** FR and JJK contributed to conceptualising and designing the study. SJ was responsible for the day-to-day running of the project. All authors contributed to the review of the study design and to the review and analysis of study data. JJK drafted the manuscript. FR and SJ made major revisions. Due to the strong involvement of JJK and FR at several different stages of the study, all authors agreed to consider them joint senior. All authors read and approved the final manuscript.

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## Figure 1 Study flowchart

## Table 1 Definition of consensus

Consensus	Description	Definition of consensus
classification		
Consensus in	Consensus that the outcome	≥70% of participants scoring
	should be included in the core	the outcome as '7–9' (critically
	set	important)
Consensus out	Consensus that the outcome	≥70% of participants scoring
	should not be included in the	the outcome as '1–3' (not
	core set	important)
No consensus	Uncertainty about the	Anything else
	importance of the outcomes	

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## Table 2 Final COS for amblyopia

Domain	Outcome
Visual function	1. Best corrected visual acuity
	2. Near visual acuity
Refractive status	3. Spherical and cylindrical refraction
Oculomotor function	4. Ocular alignment (is there an ocular deviation?)
Quality of life	5. Vision-related quality of life (for example, activities of
	daily living)
	6. Treatment-related impact (for example, negative
	effects of patching on children during treatment)
	7. Future functionality / long-term impact
Compliance	8. Compliance
Adverse events	9. Any adverse events (for example, intolerable diplopia,
	occlusion amblyopia)
Cost	10. Cost (for example, cost to services, families, and
	individuals)
	4.

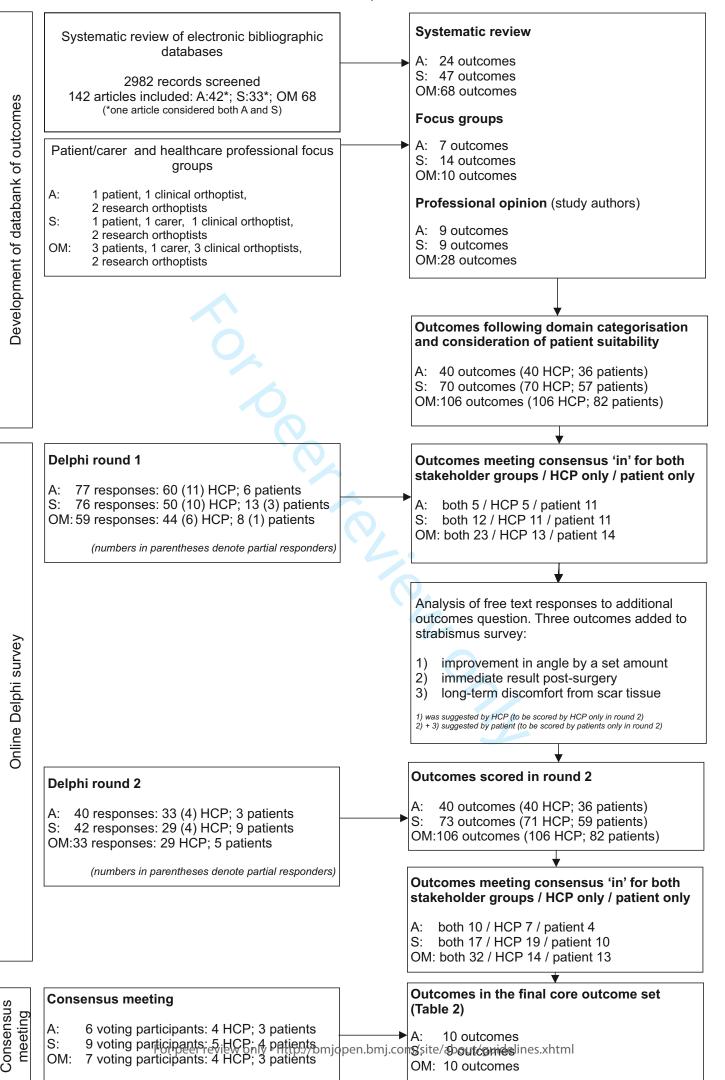
## Table 3 Final COS for strabismus

Domain	Outcome
Symptoms	1. Symptoms (for example, diplopia and appearance of th strabismus)
Visual function	2. Binocular vision (for example, stereoacuity and binocula single vision)
Oculomotor function	<ol> <li>Ocular alignment (are the eyes straight?)</li> <li>Measurement of deviation (what is the amount of deviation?)</li> <li>Ocular movement (specifically incomitance, later nystagmus, DVD and A&amp;V pattern)</li> </ol>
Quality of life	<ul> <li>6. Vision-related quality of life; psychosocial aspects (such a self-esteem, confidence, behaviour, social interaction) an functional aspects (such as activities of daily living)</li> <li>7. Patient satisfaction</li> </ul>
Adverse events	8. Any adverse events (for example, intolerable diplopia recurrence of the deviation, overcorrection or under-correctio of the deviation)
Cost	9. Cost (for example, cost to services, families, and individuals

## Table 4 Final COS for ocular motility disorders

Domain	Outcome
Compations	1 Comptons (for everyla dialogic and every
Symptoms	1. Symptoms (for example, diplopia and appearance of
	the eye deviation)
Visual function	2. Binocular vision (for example, stereoacuity, field of
	binocular single vision, and post-op diplopia test)
Oculomotor function	3. Ocular alignment (are the eyes straight?)
	4. Measurement of deviation (what is the amount of
	deviation?)
	5. Ocular movement (specifically incomitance, latent
	nystagmus, DVD and A&V pattern)
Quality of life	6. Vision-related quality of life; psychosocial aspects (such
	as self-esteem, confidence, behaviour, social interaction) and
	functional aspects (such as activities of daily living)
	7. Patient satisfaction
Adverse events	8. Any adverse events (for example, intolerable diplopia
	recurrence of the deviation, and adverse effects from patches
	or prisms)
Cost	9. Cost (for example, cost to services, families, and
	individuals)
Clinical signs	10. Clinical signs (for example, corneal exposure, proptosis /
	exophthalmos, enophthalmos)

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ong list of outcomes u : systematic review (SF red denote outcomes older group (HCPs or pa Outcome	BMJ Open used in the Delphi survey and critical score R), focus groups (FG) and professional op s that reached the consensus 'in' criteria. Datients)			nttp://on 3ES) . mining, A	iphi surve	y by stal		roup	
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	C	n	% (7-9)	, and s	% (7-9)	n	% (7-9)	n	% (7-9)
1. Patient symptoms	Symptoms or complaints related to vision or eyes	67	34.3	singila on c	50.0	37	37.8	3	66.7
<ol> <li>Best corrected visual acuity</li> </ol>	Vision measured at distance corrected with	70	98.6	inciar de l		37	100.0	3	66.7
3. Near visual acuity	Close up or reading vision	70	65.7	्रीष्ठा ,	50.0	37	78.4	3	66.7
4. Habitual visual acuity		62	58.1	3 opo	80.0	37	67.6	3	100.0
<ol> <li>Uncorrected visual acuity</li> </ol>	Vision without glasses or contact lenses	70	4.3	jies.	40.0	37	5.4	3	0.0
6. Suppression	Testing if the person has developed "suppression" of one image to improve double vision which usually happens in childhood as a coping mechanism from the brain to improve visual development	70	42.9			36	47.2	2	100.0
7. Fixation	Testing if the person is using the central part of the retina to see with or alternatively using an eccentric part of the retina	70	52.9	3 3	33.3	36	50.0	3	33.3
3 4 5	acuity 3. Near visual acuity 4. Habitual visual acuity 5. Uncorrected visual acuity 6. Suppression	acuity     glasses       3. Near visual acuity     Close up or reading vision       4. Habitual visual acuity     Vision measured in the usual preferred state for a person       5. Uncorrected visual acuity     Vision without glasses or contact lenses       6. Suppression     Testing if the person has developed "suppression" of one image to improve double vision which usually happens in childhood as a coping mechanism from the brain to improve visual development       7. Fixation     Testing if the person is using the central part of the retina to see with or alternatively using an	acuity       glasses       70         acuity       glasses       70         B. Near visual acuity       Close up or reading vision       70         4. Habitual visual acuity       Vision measured in the usual preferred state for a person       62         5. Uncorrected visual acuity       Vision without glasses or contact lenses       70         6. Suppression       Testing if the person has developed       70         7. Suppression       Testing if the person is using the central part of the retina to see with or alternatively using an       70	acuityglasses7090.03. Near visual acuityClose up or reading vision7065.74. Habitual visual acuityVision measured in the usual preferred state for a person6258.15. Uncorrected visual acuityVision without glasses or contact lenses ruppression704.36. SuppressionTesting if the person has developed "suppression" of one image to improve double vision which usually happens in childhood as a coping mechanism from the brain to improve visual development7042.97. FixationTesting if the person is using the central part of the retina to see with or alternatively using an7052.9	B.       Near visual acuity       Close up or reading vision       70       65.7         B.       Habitual acuity       Vision measured in the usual preferred state for a person       62       58.1         I.       Habitual visual acuity       Vision measured in the usual preferred state for a person       62       58.1         I.       Uncorrected visual acuity       Vision without glasses or contact lenses       70       4.3       Image: acuity         I.       Suppression       Testing if the person has developed       70       4.3       Image: acuity happens in childhood as a provision which usually happens in childhood as a provision which usually happens in childhood as a provision       70       42.9       4	ActuryTesting if the person has developed "suppression" of one image to improve double vision which usually happens in childhood as a coping mechanism from the brain to improve visual development7042.9475.07. FixationTesting if the person is using the central part of the retina to see with or alternatively using an7052.93933.3	5. Suppression Testing if the person has developed "suppression" of one image to improve double vision which usually happens in childhood as a pering methodism from the brain to improve	5. Suppression Testing if the person has developed "suppression" of one image to improve double vision which usually happens in childhood as a 70 42.9 4 6 75.0 36 47.2	5. Suppression Testing if the person has developed "suppression" of one image to improve double vision which usually happens in childhood as a pering methodism from the brain to improve

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	FG	8.	Contrast sensitivity	Objects of varying brightness	66	12.1	neh	60.0	34	5.9	3	0.0
	SR	9.	Visual evoked potentials	Testing vision signals from the eyes to the brain with electrodiagnostics (visual evoked potentials/VEP)	56	8.9	-042403 on including f	33.3	33	3.0	2	0.0
	SR	10.	Binocularity	to check if the eyes are working together to give any level of 3D vision or depth appreciation	70	47.1	11 M 01.013	80.0	36	63.9	2	50.0
	SR	11.	Stereoacuity	Fine 3D vision or depth appreciation with both eyes or "stereo vision"	70	37.1	lay 2 nsei sesor	80.0	35	34.3	2	100.0
	PO	12.	Simultaneous perception	Testing lower levels of 3D vision	70	30.0	1 May 2021. Do Enseigneme noisescretated:	60.0	35	25.7	2	0.0
	PO	13.	Retinal correspondence		70	31.4	N6755 ≶	N/A	35	11.4	N/A	N/A
efraction	SR	14.	Refractive status		69	84.1	text	66.7	35	94.3	3	100.0
	SR	15.	Spherical & cylindrical refraction	Testing the amount of prescription of glasses or	69	79.7		N/A	35	91.4	N/A	N/A
	SR	16.	Median spherical equivalent	contact lenses	64	26.6	udatro Nate	N/A	33	21.2	N/A	N/A
culomotor Inction	SR	17.	Ocular alignment /deviation	Assessing if the eyes are straight or deviated and measuring the amount of eye deviation	68	63.2	aconi	66.7	35	71.4	3	100.
	PO	18.	Abnormal head posture	The presence of a compensatory head posture to avoid double vision	68	33.8	from http://b eur(ABES). 1 s⊉atacminicog,	66.7	34	32.4	3	66.7
uality of life	SR	19.	Quality of life measures (in general)	Health related quality of life (all relevant aspects)	69	53.6		100.0	35	62.9	3	100.
	FG	20.	Psychological impact of the disorder	Negative impact of lazy eye (amblyopia) on emotions and/or behaviour	69	55.1	n.bm	83.3	34	67.6	3	100.
	SR	21.	Psychological impact of treatment of disorder	The psychological impact of treatment of lazy eye (amblyopia) on emotions and/or behaviour	69	62.3	NBA S	N/A	34	73.5	N/A	N/A
	PO	22.	Self-esteem	Negative impact of lazy eye (amblyopia) on self- esteem & confidence	69	59.4	sippil	100.0	34	70.6	3	100.
	SR	23.	Social anxiety and social avoidance due to the disorder	Negative impact of lazy eye (amblyopia) on social interaction or causing social stigma	69	55.1	June 13, Iar techn	83.3	34	67.6	3	100.0
	SR	24.	Academic/ occupation achievement in relation to the condition or its treatment	Academic/ occupation achievement in relation to the condition or its treatment	69	60.9	2025 at A ologies.		34	76.5	3	66.7
	SR	25.	Activity of daily living (ADL)	Negative impact of lazy eye (amblyopia) on normal daily activities	68	52.9	6	100.0	33	72.7	3	100.0
	SR	26.	Patient satisfaction from treatment	Patient satisfaction from treatment	68	61.8	6 <b>Bib</b> i	83.3	34	76.5	3	100.0
	FG	27.	Future functionality/long- term impact	Future functionality/long-term impact (patient- reEOrted)	69	78.3	6 6	100	34	91.2	3	100.0

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	SR	28.	Fear of losing better eye		69	71.0	04240 incta	66.7	33	84.8	3	66.7
Compliance	SR	29.	Compliance	How well the treatment is done	69	95.7		66.7	33	97.0	3	66.7
Adverse events	SR	30.	Adverse effects from treatment (any)	Adverse effects from treatment (any)	69	73.9	۲ <u>آف</u>	80.0	33	87.9	2	100.0
	SR	31.	Intolerable diplopia	Intolerable double vision as a side effect from treatment	69	89.9	May Ens	83.3	33	100.0	3	100.0
	SR	32.	Occlusion amblyopia	Development of lazy eye (amblyopia) in the better eye as a result of patching/penalisation treatment	69	76.8	May 2021. Downloaded Enseignement Superie uses retated too text and	100.0	33	87.9	3	100.0
	SR	33.	Visual disorientation	Visual disorientation due to treatment with occlusion of better eye	64	45.3	Dow nent d to	66.7	32	56.3	3	100.0
	PO	34.	Disturbed distance estimation	Disturbed distance estimation due to treatment with occlusion of better eye	64	39.1	nloa Sup texet	66.7	32	46.9	3	33.3
	SR	35.	Skin irritation or allergy to patches	Skin irritation or allergy from eye patches used to occlude the eye	69	50.7	ded ancol	33.3	33	51.5	3	33.3
	PO	36.	Atropine eye drops side effects	Side effects of the eye drops used regularly at home for treatment of lazy eye (amblyopia)	69	65.2	from ur (A dada	33.3	33	69.7	3	66.7
Cost	SR	37.	Economic data (in general)	Economic data (in general) including services and families/individuals	54	24.1	http://br ABES). Incining,	16.7	30	20.0	3	0.0
	PO	38.	Cost of treatment on services	Cost of treatment on services	55	25.5	) ing	16.7	31	32.3	3	0.0
	PO	39.	Cost of treatment on families/individuals	Cost of treatment on families/individuals	54	37.0	://bmjop ) . ng; Aktra	33.3	30	50.0	3	0.0
Long-term	FG	40.	Long-term outcomes	Long-term outcomes (clinical outcomes)	59	84.7		100.0	33	93.9	3	100.0
				Long-term outcomes (clinical outcomes)			njopen.bmj.com/ on June 13, 2025 at Agence Bibliographique Aktraiping, and similar technologies.					
			For pe	er review only - http://bmjopen.bmj.com/sit	e/about/g	juidelines.xl	de					

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<u>Strabismu</u>	<u>s</u>					including	)42403 o				
Domain	Source	Outcome	Lay-term summary	Delphi	results	g for uses relate	n 11 May				
					Roun	d 1 eign	2021		Round	12	
				нс	CPs	Patient Patient	Sov	HCPs	;	Patie	ents
			0	n	% (7-9)	t Superi text and n	vnloade(7-9)	n	% (7-9)	n	% (7-9
Symptoms	FG	1. Patient symptoms	Symptoms or complaints related to vision or eyes	60	91.7	16 dat	<b>§</b> 75.0	33	100.0	9	77.
	FG	2. Diplopia	Improvement in double vision in general	60	95.0		<b>285.7</b>	33	100.0	8	62
	FG	3. Appearance of strabismus	Appearance of the squint	60	85.0	14 mining, 15 g.	<b>4</b> 6.7	33	87.9	9	33.
	FG	<ol> <li>Eye aesthetics as the patient perceives</li> </ol>	Appearance of the squint as the patient perceives	60	80.0	15 training, 15 g	<b>1</b> <b>6</b> <b>6</b> <b>6</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b>	33	84.8	9	44
	FG	5. Eye aesthetics as relatives and friends perceive	Appearance of the squint as the relatives and friends perceive	60	58.3	15 <b>.0</b>	46.7	33	63.6	9	33.
Visual function	SR	6. Best corrected visual acuity	Vision measured at distance corrected with glasses	60	71.7	and 11 d s	272.7	33	90.9	7	100
	PO	7. Near visual acuity	Close up or reading vision	60	45.0	12 3	<sup>9</sup> 75.0	33	63.6	7	71.
	PO	8. Habitual visual acuity	Vision measured in the usual preferred state for a person	53	41.5	10 <b>T</b>	царование и пределание и пре	32	59.4	7	100
	PO	9. Uncorrected visual acuity	Vision without glasses or contact lenses	60	8.3	12 🖁	<u>.</u> 	33	3.0	7	71.
	FG	10. Suppression	Testing if the person has developed "suppression" of one image to improve double vision which usually happens in childhood as a coping mechanism from the brain to improve visual development	60	65.0		2025 at A	32	75.0	8	75.
	PO	11. Fixation	Testing if the person is using the central part of the retina to see with or alternatively using an eccentric part of the retina	60	46.7	9	gence 33.3	32	46.9	7	42.
	PO	12. Contrast sensitivity	Objects of varying brightness	59	6.8	8	<b>8</b> 37.5	32	0.0	8	37
	SR	13. Binocularity	Testing "binocularity" which is to check if the eyes are working together to give any level of 3D vision or depth appreciation	60	76.7	12	Bi37.5 Bibliographique	32	75.0	8	87

				BMJ Open			by copyright,	bmjopen-2020				Page
	SR	14.	Stereoacuity at near	Fine 3D vision or depth appreciation with both eyes measured for near	60	60.0	<u>ה</u> 12 נום	<b>-042</b> 58.3 <b>403</b>	32	62.5	8	87.5
	SR	15.	Stereoacuity at near and distance (any strabismus type)	Fine 3D vision or depth appreciation with both eyes measured for both near and distance	59	44.1	, including 12 uding for u	<b>9</b> 58.3	32	46.9	8	75.0
	SR	16.	Stereoacuity at near and distance (for certain strabismus types? please specify)	Fine 3D vision or depth appreciation with both eyes measured for both near and distance for certain types of squint	54	53.7	N/A dt to text and the text	20 21 21 21 21 21 21	30	56.7	N/A	N/A
	SR	17.	Field of binocular single vision	Testing the extent of area of vision where there is no double vision while looking around with both eyes open	60	46.7	12 and	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	32	53.1	8	62.5
	FG	18.	Post op diplopia test	Testing if a person is likely to get double vision after correcting the eye deviation with surgery	59	81.4		0.100	32	93.8	9	77.8
	SR	19.	Simultaneous perception	Testing lower levels of 3D vision	59	37.3			32	25.0	8	62.5
	PO	20.	Retinal correspondence	Testing lower levels of 3D vision	60	43.3	N/An g	N/A	32	37.5	N/A	N/A
	PO	21.	Refractive status	Testing the amount of prescription of glasses or contact lenses	60	61.7	11 <b>≥</b>	<b>5</b> 4.5	32	75.0	8	50.0
Oculomotor function	SR	22.	Ocular alignment /deviation	Assessing if the eyes are straight or deviated and measuring the amount of eye deviation	60	86.7	12 nin 11 <b>9</b>	<b>91.7</b>	32	100.0	8	50.0
	SR	23.	Abnormal head posture	The presence of a compensatory head EOsture to avoid double vision	60	66.7	11 <b>9</b>	<u>3</u> 63.6	32	84.4	9	77.8
	FG	24.	Ocular motor alignment at various positions especially where the deviation is greatest	Assessing if the eyes are straight or deviated and measuring the amount of eye deviation at different EOsitions	60	75.0	and similar tec	om/ on June	32	87.5	N/A	N/A
	SR	25.	Presence of incomitance (any strabismus type)	Testing if there is variation of the eye deviation in different EOsitions when looking around	59	71.2	N/Aologie:	13, 2025	32	78.1	N/A	N/A
	SR	26.	Presence of incomitance (for certain strabismus types? please specify)	Testing if there is variation of the eye deviation in different EOsitions when looking around	58	75.9	gies. N/A	at Agence	31	80.6	N/A	N/A
	SR	27.	Control of deviation (any strabismus type)	Measuring how well the person can control the eye turn	59	79.7	12	Bibliographi	32	96.9	9	55.6
	SR	28.	Control of deviation (for	Measuring how well the person can control the eye turn	58	81.0	N/A	ap N/A	31	93.5	N/A	N/A

		certain strabismus types? please specify)				by copyright, including	bmjopen-2020-042403 on				
S	२ 29	. Ocular movement	How well eyes move as a person is looking around	60	66.7	13 <b>ද</b>		32	71.9	9	77.
S	२ 30	Presence of latent nystagmus (any strabismus type)	Checking if there are involuntary rapid movements of the eyes when one eye is covered	58	46.6	11 11 11 11 11 11 11 11 11 11 11 11 11	May 2021	32	53.1	9	44.
S	R 31	<ul> <li>Presence of latent nystagmus (for certain strabismus types? please specify)</li> </ul>	Checking if there are involuntary rapid movements of the eyes when one eye is covered	57	54.4	led to text and N/A	May 2021. Downloaded fr	32	71.9	N/A	N//
S	र 32	Presence of dissociated vertical deviation (DVD) (any strabismus type)	Testing if there is tendency for the eye to move up and out +/- rotates when covered	58	51.7		rom 54.5	32	53.1	8	37
S	र 33	Presence of dissociated vertical deviation (DVD) (for certain strabismus types? please specify)	Testing if there is tendency for the eye to move up and out +/- rotates when covered	56	64.3	g, Al training, N/A	://bmjopen.bmj	31	71.0	N/A	N/
S	२ 34	. A or V pattern deviation	Testing if there is a deviation that increases either on looking up or looking down	60	60.0	N/And	<mark>g</mark> N/A	32	81.3	N/A	N/
S	र 35	Fusional vergence at near and distance /fusion amplitudes/prism fusion range	Testing how well the eyes can control a deviation induced with prisms in clinic	60	68.3	similar technologies.	on June 13,	32	81.3	9	55
S	र 36	. Near point of convergence (for any strabismus type)	Testing if the eyes can normally look inwards to see a near object to an acceptable amount	60	31.7	-	2025 at A	32	43.8	9	66
S	र 37	. Near point of convergence (for certain strabismus types? please specify)	Testing if the eyes can normally look inwards to see a near object to an acceptable amount	58	51.7	N/A	Agence Bibliographique de l	32	62.5	N/A	N/

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	FG	38.	Accommodation (for any strabismus type)	Testing if the eyes can change their focus appropriately to see objects at varying distances	60	23.3	nt, including	0-042 403 403	32	18.8	9	44.4
	FG	39.	· · ·	Testing if the eyes can change their focus appropriately to see objects at varying distances	58	60.3	N/Auses	2	31	61.3	N/A	N/A
	SR	40.	AC/A ratio (for any strabismus type)	Testing the ratio between the ability of the eyes to look inwards and their ability to focus	59	30.5	13 13 13	246.2	32	28.1	9	33.3
	SR	41.		Testing the ratio between the ability of the eyes to look inwards and their ability to focus	58	65.5	N/Axt and	nloaded	31	67.7	N/A	N/A
	CLIN PART	42.		000	N/A	N/A	N/Aata mi	fron N/A	31	51.6	N/A	N/A
	PT PART	43.	Immediate result EOst-surgery**		N/A	N/A	N/Ang.	N/A	N/A	N/A	8	12.5
Quality of life	SR	44.	V /	Health related quality of life (all relevant aspects)	53	81.1	13 Al training, 13 13 J	<b>6</b> 9.2	31	93.5	9	66.7
	SR	45.	Psychological impact of the disorder	Negative impact of squint (strabismus) on emotions and/or behaviour	53	88.7	13 ning, a	69.2	30	100.0	9	77.8
	SR	46.		EOsitive impact of treatment on emotions and/or behaviour	53	75.5	and similar	84.6 9	30	80.0	9	77.8
	SR	47.	Social anxiety and social avoidance due to the disorder	Negative impact of squint (strabismus) on social interaction or causing social stigma	53	84.9	ar technol	June 71.4	30	90.0	9	66.7
	FG	48.	Academic/ occupation achievement in relation to the condition or its treatment	Academic/ occupation achievement in relation to the condition or its treatment	52	69.2	13 s.	2025 at Agenc	30	76.7	9	66.7
	FG	49.		Activity of daily living (ADL) such as driving	52	67.3	14	<sup>ត</sup> 78.6 យ	29	86.2	9	77.8
	SR	50.		Patient satisfaction from treatment	53	83.0	14	ce 78.6 Biblio92.9 Graphique de l	29	96.6	9	88.9

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	FG	51.	Future functionality/long- term impact	Future functionality/long-term impact (patient- reEOrted)	52	92.3	in 11 ding 12 fo	÷.	29	96.6	9	88
Compliance	PO	52.	Compliance	How well the treatment is done	52	63.5	12 <b>'g</b>	<sup>9</sup> <u>9</u> 1.7	29	62.1	8	87
Treatment dependency	SR	53.	Successful discontinuation of lens therapy or "special glasses" (for any strabismus type)	Successful discontinuation of lens therapy or "special glasses" such as bifocals or minus lenses	49	40.8	r uses related to text and d 4 2	1 May 2021. D	28	46.4	6	83
	SR	54.		Successful discontinuation of lens therapy or "special glasses" such as bifocals or minus lenses	49	51.0	lata	G	28	64.3	N/A	N
	PO	55.	Successful discontinuation of prism therapy	Successful discontinuation of prism therapy	52	46.2	4 4	100.0	29	51.7	6	83
Adverse events	SR	56.	Adverse effects from treatment (any)	Adverse effects from treatment (any)	53	83.0	10 A tra	<b>6</b> 0.0	29	93.1	9	55
	FG	57.	Adverse effect on vision from patches or prisms used to treat diplopia	Adverse effect on vision from patches or prisms used to treat diplopia such as vision degradation or psychosocial effects	53	67.9	and	.bm 42.9	29	75.9	6	83
	SR	58.	Intolerable diplopia	Intolerable double vision	53	98.1	11 <u>si</u>	<b><u>9</u>81.8</b>	29	96.6	9	77
	SR	59.	Induced ptosis (post toxin injection)	Appearance of transient droopy eye lid as a result of using toxin injection to treat squint	52	51.9	11 11 7 9 9	<b>Մա</b> 57.1 1	29	55.2	8	62
	SR	60.		Appearance of a bleed in the surface of the eye after squint surgery or injection	52	32.7	9 9	<b>3</b> 233.3 25	29	20.7	8	37
	SR	61.	Discomfort or abnormal sensation	Discomfort or pain during/after treatment of squint	53	28.3	9 <mark>%</mark>	at 44.4	29	17.2	8	37
	SR	62.	Overcorrection or under correction of the deviation with surgery or injection	Persistence of the squint at a lesser extent or appearance of deviation in the opEOsite direction	52	71.2	9	gence Bibliographique de l	29	79.3	9	66
	SR	63.	Recurrence of deviation	Reappearance of the squint after treatment	53	66.0	9	grap 77.8	29	75.9	9	88

SR SR SR SR SR Cost SR SR SR SR SR SR SR SR SR SR SR SR	<ul> <li>64. Induced vertical deviation</li> <li>65. Induced A or V pattern</li> <li>66. Development of DVD</li> <li>67. Induced incomitance</li> <li>68. Number of operations/proce dures needed</li> <li>69. Economic data (in general)</li> <li>70. Cost of treatment on services</li> <li>71. Cost of treatment on families/ individuals</li> <li>72. Long-term outcomes</li> <li>73. Long term discomfort from</li> </ul>	Appearance of a vertical squint after treatment of a horizontal deviationAppearance of a deviation that increases either on looking up or looking downAppearance of a tendency for the eye to move up and out when coveredDevelopment of variation of the eye deviation in different EOsitions when looking aroundNumber of operations/procedures neededEconomic data (in general) including services and families/individualsCost of treatment on servicesCost of treatment on families/individualsLong-term outcomes (clinical outcomes)	53 53 50 53 53 45 45 45	69.8 54.7 46.0 56.6 66.0 44.4 46.7 40.0	by copyright, including for uses related to text and data mining, <i>J</i> 8 9 6 7 9 11 11 11 11 <i>N</i> /A	bmjopen-2020-042403 on 11 May 2021. Downloade	29 29 29 29 29 29 27 27	82.8         65.5         34.5         62.1         65.5         37.0	9 8 8 7 8 9	77.8 75.0 37.5 71.4 62.5 33.3
Cost SR SR Cost SR SR SR SR SR SR SR PT	<ul> <li>65. Induced A or V pattern</li> <li>66. Development of DVD</li> <li>67. Induced incomitance</li> <li>68. Number of operations/proce dures needed</li> <li>69. Economic data (in general)</li> <li>70. Cost of treatment on services</li> <li>71. Cost of treatment on families/ individuals</li> <li>72. Long-term outcomes</li> <li>73. Long term</li> </ul>	Appearance of a deviation that increases either on looking up or looking downAppearance of a tendency for the eye to move up and out when coveredDevelopment of variation of the eye deviation in different EOsitions when looking aroundNumber of operations/procedures neededEconomic data (in general) including services and families/individualsCost of treatment on servicesCost of treatment on families/individuals	53 50 53 53 45 45	54.7 46.0 56.6 66.0 44.4 46.7	6 7 srelated to 9	116.7 May 71.4 2021,66.7	29 29 29 29 29 27	65.5 34.5 62.1 65.5	8 7 8	37.5 <b>71.4</b> 62.5
Cost SR SR Cost SR SR SR SR SR SR Dutcomes PT	<ul> <li>66. Development of DVD</li> <li>67. Induced incomitance</li> <li>68. Number of operations/proce dures needed</li> <li>69. Economic data (in general)</li> <li>70. Cost of treatment on services</li> <li>71. Cost of treatment on families/ individuals</li> <li>72. Long-term outcomes</li> <li>73. Long term</li> </ul>	Appearance of a tendency for the eye to move up and out when covered         Development of variation of the eye deviation in different EOsitions when looking around         Number of operations/procedures needed         Economic data (in general) including services and families/individuals         Cost of treatment on services         Cost of treatment on families/individuals	50 53 53 45 45	46.0 56.6 66.0 44.4 46.7	6 7 srelated to 9	116.7 May 71.4 2021,66.7	29 29 29 29 27	34.5 62.1 65.5	7 8	<b>71.4</b> 62.5
Cost SR SR SR SR SR SR SR Dutcomes PT	<ul> <li>67. Induced incomitance</li> <li>68. Number of operations/proce dures needed</li> <li>69. Economic data (in general)</li> <li>70. Cost of treatment on services</li> <li>71. Cost of treatment on families/ individuals</li> <li>72. Long-term outcomes</li> <li>73. Long term</li> </ul>	Development of variation of the eye deviation in different EOsitions when looking aroundNumber of operations/procedures neededEconomic data (in general) including services and families/individualsCost of treatment on servicesCost of treatment on families/individuals	53 53 45 45	56.6 66.0 44.4 46.7	7 related to text and o 11 11 11 11 11	May 71.4 2021.66.7 Downloade	29 27	62.1 65.5	8	62.5
Cost SR SR SR SR outcomes SR PT	<ul> <li>68. Number of operations/proce dures needed</li> <li>69. Economic data (in general)</li> <li>70. Cost of treatment on services</li> <li>71. Cost of treatment on families/ individuals</li> <li>72. Long-term outcomes</li> <li>73. Long term</li> </ul>	Number of operations/procedures needed         Economic data (in general) including services and families/individuals         Cost of treatment on services         Cost of treatment on families/individuals	53 45 45	44.4 46.7	9 11 11 11 11 11 11	202166.7 Down36.4 18.2	27			
ong-term SR butcomes PT	<ul> <li>69. Economic data (in general)</li> <li>70. Cost of treatment on services</li> <li>71. Cost of treatment on families/ individuals</li> <li>72. Long-term outcomes</li> <li>73. Long term</li> </ul>	families/individuals Cost of treatment on services Cost of treatment on families/individuals	45	46.7	11 to text and o 11 11 11 11 11	236.4 2018.2		37.0	9	33.3
Long-term SR Dutcomes PT	<ul> <li>70. Cost of treatment on services</li> <li>71. Cost of treatment on families/ individuals</li> <li>72. Long-term outcomes</li> <li>73. Long term</li> </ul>	Cost of treatment on services Cost of treatment on families/individuals			ext and o	0 ad 0 ad 0 ad	27			
Long-term SR butcomes PT	<ul> <li>71. Cost of treatment on families/ individuals</li> <li>72. Long-term outcomes</li> <li>73. Long term</li> </ul>	$\mathcal{N}_{\mathcal{D}}$	45	40.0		e		44.4	9	33.3
putcomes PT	72. Long-term outcomes 73. Long term	Long-term outcomes (clinical outcomes)				a <del>1</del> 45.5	26	38.5	9	22.2
PT	73. Long term		50	88.0	11 <u>B</u> R	<b>90.9</b>	29	96.6	9	88.9
	scar tissue **		N/A	N/A	ning. A N/Ag. A	http://bmjopen.	N/A	N/A	9	55.6
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## Ocular motility disorders

)cular moti	lity disord	<u>ers</u>					ng for	bmiopen-2020-042403 on 11				
Domain	Source	Out	come	Lay-term summary			Ensei uses r	<b>``</b>	esults			
						Ro	und related	021		Ro	und 2	
						HCPs				HCPs	Pat	tients
			<sup>C</sup>	r	n	% (7-9)	ant Superieur (ABES to text and datamin	wnloader	n	% (7-9)	n	% (7-9)
Symptoms	SR	1.	Patient symptoms	Symptoms or complaints related to vision or eyes	50	92.0	eur ( adat	88.9	29	96.6	5	100.0
	SR	2.	Improvement in diplopia (in general)	Improvement in double vision in general	50	90.0	a BE	100.0	29	100.0	5	100.0
	SR		Improvement of diplopia in primary gaze	Improvement of double vision when looking straight ahead	50	94.0	:(S) 1000 1000	87.5	29	100.0	5	100.0
	SR	4.	Improvement in diplopia in primary and down gaze	Improvement in double vision when looking straight ahead and down (reading position)	50	88.0	Ątra	85.7	29	100.0	5	100.0
	SR	5.	Improvement in diplopia in primary and down gaze with prisms	Improvement in double vision when looking straight ahead and down with prisms	50	86.0	'nįąg,	75.0	29	96.6	5	100.0
	SR		Severity and duration of visual symptoms/eye deviation	Severity and duration of visual symptoms/eye deviation	50	78.0		77.8	29	79.3	5	100.0
	SR	7.	Appearance of the eye deviation	Appearance of the eye deviation	50	74.0	nijar	33.3	29	79.3	5	60.0
	SR		Reduction in pain (for certain types of ocular motility disorders? please specify)	Reduction in pain	49	75.5	ctan ;	ສ ສຸງ ສຸງ	29	89.7	4	100.0
	SR		Improvement in oscillopsia/blur and vertigo in adults (in nystagmus)	Improvement in oscillopsia/blur and vertigo in adults (in nystagmus)	50	92.0		66.7	29	100.0	5	100.0
	FG	10.	Improvement in headaches (for certain types of ocular motility disorders? please specify)	Improvement in headaches	50	80.0	6	42.9	29	79.3	4	40.0
Visual function	SR		Best corrected visual acuity	Vision measured at distance for one eye at a time corrected with glasses	50	60.0	7 4	42.9	29	69.0	5	60.0

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SR	12. Near visual acuity	Close up or reading vision	50	44.0	ncluo	<b>62</b> .5	29	48.3	5	6
PO	13. Habitual visual acuity	Vision measured in the usual preferred state for a person	44	50.0		6 /1.4	29	69.0	5	8
PO	14. Uncorrected visual acuity	Vision without glasses or contact lenses	50	6.0	-7°r	11 28.6	29	0.0	5	2
SR	15. Binocular BCVA	Vision measured at distance with both eyes open at the same time corrected with glasses	49	57.1	ses r 55 r	a 80.0	28	71.4	5	10
SR	16. Suppression	Testing if the person has developed "suppression" of one image to improve double vision which usually happens in childhood as a coping mechanism from the brain to improve visual development	50	46.0	Enseignement Superieu g for uses related to text and	021. 33.3	29	48.3	3	6
PO	17. Fixation	Testing "fixation" which is if the person is using the central part of the retina to see with or alternatively using an eccentric part of the retina	50	32.0	Superie ext_and	load 25.0	29	24.1	4	2
PO	18. Contrast sensitivity	Testing "contrast sensitivity" which is objects of varying brightness Contrast sensitivity	49	6.1	eur (AE d gata i	<b>fo</b> 33.3	28	0.0	3	2
PO	<ol> <li>Colour vision test (for any type of ocular motility disorder)</li> </ol>	Colour vision test	50	8.0	ABES) . a mjining,	60.0	29	0.0	5	2
PO	20. Colour vision test (for certain types of ocular motility disorders? please specify)	re.	49	36.7	ng, Ad training, 8,	//bmiope	29	31.0	N/A	1
PO	21. Visual field test (for certain types of ocular motility disorders? please specify)	Visual field test	48	37.5	ining, an	50.0	29	24.1	5	6
SR	22. Broadening of the null region (in nystagmus)	Broadening of the null region (in nystagmus)	48	58.3	d sin	2 100.0 o	29	69.0	4	1
SR	23. Reduce the amplitude of nystagmus (in nystagmus)	Reduce the amplitude of nystagmus (in nystagmus)	48	60.4	and similar technologies	100.0	29	69.0	3	1
SR	24. Stereo acuity	Fine 3D vision or depth appreciation with both eyes or "stereo vision"	50	62.0	otta	ຜູ້ 87.5 N	29	75.9	5	1
SR	25. Field of binocular single vision	Testing the extent of area of vision where there is no double vision while looking around with both eyes open	50	70.0	logies.	025 71.4 at	29	86.2	5	8
PO	26. Post op diplopia test	Testing if a person is likely to get double vision after correcting the eye deviation with surgery	50	68.0	7	A 100.0	29	82.8	5	1
SR	27. Simultaneous perception	Testing lower levels of 3D vision	50	48.0	7	<b>PC</b> 42.9	29	41.4	5	6
SR	28. Retinal correspondence		50	38.0		Bibli	29	24.1	N/A	1
SR	29. Refractive status (for any type of ocular motility disorder)	Testing the amount of prescription of glasses or contact lenses	50	46.0	6	ographique	29	37.9	5	2

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	SR	30.	Refractive status (for certain types of ocular motility disorders? please specify)		47	48.9	including f		29	51.7	N/A	N/
Oculomotor function	SR	31.	Ocular alignment / deviation	Assessing if the eyes are straight or deviated and measuring the amount of eye deviation	47	91.5	n 11 May Ense I for uses	71.4	29	100.0	5	80
	SR	32.	Abnormal head posture	The presence of a compensatory head posture to avoid double vision	47	76.6	Ense Ses r 6	66.7	29	89.7	5	80
	FG	33.	Ocular motor alignment at various positions specially where the deviation is greatest	Assessing if the eyes are straight or deviated and measuring the amount of eye deviation at different positions	47	80.9	seignement related to N	N/A	29	89.7	N/A	N/
	SR	34.	Presence of incomitance (for any type of ocular motility disorder)	Variation of angle of deviation at different positions of gaze	47	63.8	nioadec Superio text and	66.7	29	79.3	3	66
	SR	35.	Presence of incomitance (for certain types of ocular motility disorders? please specify)		44	72.7	i trom http://bn eur (ABES). I data(mining, / Z	N/A	28	75.0	N/A	N/
	PO	36.	Control of deviation (any type)	Measuring how well the person can control the eye turn	47	83.0	· P 🛃		29	89.7	5	10
	PO	37.	Control of deviation (for certain types of ocular motility disorders? please specify)		43	83.7	open.bmj.com I tratning, and Z	N/A	29	96.6	N/A	N/
	SR	38.	• • • • •	How well eyes move as a person is looking	47	85.1	l, and	62.5	29	93.1	5	10
	SR	39.	Forced duction test (for any type of ocular motility disorder)	A test done to check eye muscle action passively using forceps	45	31.1	d sitmilar N∕milar	N/A	29	24.1	N/A	N/
	SR	40.			44	65.9	ne 13, ⊠∕Chn		27	66.7	N/A	N/
	SR	41.	Three step/head tilt test (for any type of ocular motility disorder)	A test to check eye deviation with head tilt and head turn in addition to the straight-ahead EOsition	44	20.5	ologies. N	N/A	29	10.3	N/A	N/
	SR	42.	Three step/head tilt test (for certain types of ocular motility disorders? please specify)		45	66.7	Agence	N/A	28	60.7	N/A	N/
	PO	43.	Presence of dissociated vertical deviation (DVD)	Presence of a tendency for the eye to move up and out when covered	47	46.8	N/A N/A	N/A	29	44.8	N/A	N/
	SR	44.	A or V pattern deviation	Testing if the deviation increases on looking up or looking down	47	55.3	grap	57.1	29	62.1	5	40

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PO	45.	Fusional vergence at near and distance /fusion amplitudes/prism fusion range	Testing how well the eyes can control a deviation induced with prisms in clinic	47	53.2	including fo	042403 on 1	29	62.1	4	7
SR	46.	Reading eye movements (for any type of ocular motility disorders)	Checking if eye movements are normal during reading	45	22.2	_se n.	1 May 71.4	29	20.7	5	6
SR	47.	Reading eye movements (for certain types of ocular motility disorders? please specify)		42	42.9	iseignement Superieu s relatecto text and o Z	21. Downlo	29	48.3	N/A	
SR	48.	Presence of a phoria (for any type of ocular motility disorders)	A test done to check if there is a hidden small eye alignment problem	46	54.3	perieu t and d	aded fr	29	58.6	5	2
SR	49.	Presence of a phoria (for certain types of ocular motility disorders? please specify)	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	41	56.1	eur (ABES). 1 data r⊄ining, ∠	om http://t	28	71.4	N/A	1
SR	50.	Objective extortion (for any type of ocular motility disorders)	Checking if the eye is rotated outwards due to a muscle problem (tested in clinic without the need of patient response)	43	25.6	, Altraining, ∠	42.9	28	25.0	5	2
SR	51.	Objective extortion (for certain types of ocular motility disorders? please specify)		41	58.5	inina, ano N∕a, ano	N/A	27	66.7	N/A	1
SR	52.	Subjective extortion (for any type of ocular motility disorders)	Check if the eye is rotated outward due to a muscle problem (tested in clinic and results depend on patient response)	44	50.0	and similar	42.9	28	60.7	4	2
SR	53.	Subjective extortion (for certain types of ocular motility disorders? please specify)		41	73.2	N/cchno	N/A	27	92.6	N/A	
SR	54.	Near point of convergence (for any type of ocular motility disorders)	Testing if the eyes can normally look inwards to see a near object to an acceptable amount	47	34.0		<b>2025</b> at A	29	34.5	5	4
SR	55.	Near point of convergence (for certain types of ocular motility disorders? please specify)		41	63.4	N/A	gence N/A	28	78.6	N/A	
SR	56.	Accommodation (for any type of ocular motility disorders)	Testing if the eyes can change their focus appropriately to see objects at varying distances	46	15.2	8 4	Bibliographique de	29	13.8	5	(

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	SR	57.	Accommodation (for certain types of ocular motility disorders? please specify)		42	42.9	incluting Z	N/A	28	46.4	N/A
	SR	58.	Dynamic retinoscopy (for certain types of ocular motility disorders? please specify)	Changing refractive power of the eye with varying focus	42	19.0	on 11 May 2021. Downloaded from Enseignement Superieur (A ng for u≶es related to text and data 고	N/A	27	37.0	N/A
	SR	59.	Pursuits (for certain types of ocular motility disorders? please specify)	Testing a specific tracking slow movement of the eye for an object	45	64.4	21. Down inement : lated to t	42.9	28	60.7	5
	SR	60.		Testing a specific rapid tracking eye movement for an object	45	62.2	Superieu Superieu ext and d	57.1	28	67.9	5
	SR	61.	Optokinetic nystagmus (OKN)	Special tracking eye movement using a striped drum	46	34.8		N/A	29	31.0	N/A
Additional clinical signs	SR	62.		Eye movement recordings	40	27.5	.BES) . miniղց, Al trainiրց, and	42.9	28	32.1	5
	SR	63.	Palpebral fissure size/lid position (for certain types of ocular motility disorders? please specify)	Checking eye lid position - whether it is droopy or elevated compared to normal	44	63.6	pen.bmj.com rainiฏg, and	40.0	29	65.5	5
	SR	64.	Facial asymmetry (for 4th n palsy)	Checking if the sides of the face are symmetrical or not to help diagnose some congenital motility disorders	45	33.3	· · · · ·	50.0	29	20.7	4
	SR	65.	Pupil examination (for any type of ocular motility disorders)	To check pupil size; reaction etc	44	45.5	June 13 ar techr	50.0	29	41.4	5
	SR	66.	Pupil examination (for certain types of ocular motility disorders? please specify)		43	74.4	∿ on June 13, 2025 at sijmilar technolo⊈gies ∠		29	79.3	N/A
1	00	07	Duanta ala /awan biba los o o	Observations if the second second sector discussed at the in-							

position

Check eye pressure

Checking if the eyes are protruding out of their

N/A

N/A

40.0

60.0

N/A

40.0

40.0

25.0

20.0

N/A

60.0

100.0

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4

75.0

80.0

Agence

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29

28

86.2

42.9

1 2

67. Proptosis/exophthalmos

(for certain types of

Intraocular pressure (for

certain types of ocular

motility disorders?

please specify)

ocular motility disorders? please

specify)

68.

SR

SR

44

43

79.5

48.8

			BMJ Open			by copyrig					Page
	SR	69. Corneal exposure (for certain types of ocular motility disorders? please specify)	Checking for corneal changes resulting from incomplete eyelid closure	42	76.2	ht, including	<b>75.0</b>	28	96.4	5	80.0
	SR	70. Corneal sensitivity (for certain types of ocular motility disorders? please specify)	Checking if corneal nerve supply is intact	39	66.7	for Uses I	75.0	28	67.9	5	100.0
	SR	71. Canthal displacement (for certain types of ocular motility disorders? please specify)	Change in position of the eye contour	32	28.1	related to to N	N/A	23	21.7	N/A	N/A
	SR	72. Oculocardiac reflex (for certain types of ocular motility disorders? please specify)	Slowing of the heart rate due to entrapped eye muscle	28	32.1	ioaded i Superieu N∕Xnd d	N/A	22	36.4	N/A	N/A
	SR	73. Globe dystopia (for certain types of ocular motility disorders? please specify)	Check the position of the eyeball in relation to the other eye and other parts of the face	33	39.4	r (ABES) ata_minii	60.0	22	36.4	4	50.0
	SR	74. Enophthalmos (for certain types of ocular motility disorders? please specify)	Checking if the eyes are sinking in from their normal position	42	66.7	ng, ДI tra	75.0	29	82.8	5	80.0
linical ivestigations	SR	75. Assessment for fractures and soft-tissue herniation for example inferior rectus muscle; fat; or connective tissue radiographically (for certain types of ocular motility disorders? please specify)	Assessment for fractures and soft-tissue herniation for example inferior rectus muscle; fat; or connective tissue radiographically	41	87.8	שוויסטפרו-ביטבט-ט-ביטס טון אוואס בעבר. בעאוויסטפרע ויטווי (ABES) . א by copyright, including for עַses related to text מַחַל data mining, לא training, and similar technologies. ב	66.7	29	96.6	4	75.0
	SR	76. Assessment for muscle atrophy or absent nerve radiographically (for certain types of ocular motility disorders? please specify)	Assessment for muscle atrophy or absent nerve radiographically	35	65.7	chnologies.	2 2	26	69.2	4	75.0
	SR	77. Histologic examination of excised tissue (for certain types of ocular motility disorders? please specify)	Histologic examination of excised tissue	26	57.7	N/A Constrained of the second	N/A	24	75.0	N/A	N/A
Quality of life	SR	78. Quality of life measures (in general)	Health related quality of life (all relevant aspects)	45	82.2	8 9	87.5	29	93.1	5	100.0

	FG	79.	, , ,	Negative impact of eye motility problem on	45	84.4	d by copyright, including	100.0	29	96.6	5	100.0
	FG	80.	the disorder Psychological impact of	emotions and/or behaviour Positive impact of treatment on emotions and/or	45	77.8	i N/∄ o	N/A	29	93.1	N/A	N/A
	FG	81.	treatment of disorder Social anxiety and social avoidance due to the disorder	behaviour Negative impact of eye motility problem on social interaction or causing social stigma	45	77.8	l forguses	100.0	29	89.7	5	100.0
	FG	82.	Academic/ occupation achievement in relation to the condition or its treatment	Academic/ occupation achievement in relation to the condition or its treatment	44	72.7	s related	87.5	29	79.3	5	80.0
	FG		Activity of daily living (ADL)	Activity of daily living (ADL) such as driving	45	80.0	80 te	100.0	29	93.1	5	100.
	SR		treatment	Patient satisfaction from treatment	45	82.2	oau ‱ar	87.5	29	93.1	5	80.0
	FG	85.	Future functionality/long-term impact	Future functionality/long-term impact (patient- reported)	44	86.4	ieur ( <i>F</i> nd data	100.0	29	96.6	5	100.0
Compliance	SR	86.	Compliance	How well the treatment is done	42	54.8	7 mii	71.4	29	65.5	5	80.0
Treatment dependency	PO	87.	Successful discontinuation of glucocorticoids (in orbital inflammatory conditions such as thyroid eye disease)	Successful discontinuation of lens therapy or glucocorticoids (in orbital inflammatory conditions such as thyroid eye disease)	34	64.7	eignement Superieur (ABES) . ، regated to text and data mining, Al training, and simjjar	66.7	25	76.0	4	50.0
	PO	88.	Successful discontinuation of lens therapy or "special glasses"	Successful discontinuation of lens therapy or "special glasses" such as bifocals or minus lenses	43	51.2	ng, <sub>⊉</sub> nd s	50.0	29	58.6	4	50.0
	PO	89.	Successful discontinuation of prism therapy	Successful discontinuation of prism therapy	44	56.8	simjjar	66.7	29	69.0	3	66.7
Adverse events	SR	90.	Adverse effects from treatment (any)	Adverse effects from treatment (any)	44	79.5	techi teschi		29	82.8	5	100.
	FG	91.	Adverse effect on vision from patches or prisms used to treat diplopia	Adverse effect on vision from patches or prisms used to treat diplopia such as vision degradation or psychosocial effects	44	56.8	ibơlou czoz '	40.0	29	82.8	5	80.0
	PO	92.	Intolerable diplopia	Intolerable double vision	44	97.7	es. 7	100.0	29	100.0	5	100.
	PO	93.	Induced ptosis (Post toxin injection)	Appearance of transient droopy eye lid as a result of using toxin injection to treat squint	43	48.8	5 gen	80.0	29	62.1	5	80.0
	PO	94.	Induced subconjunctival haemorrhage	Appearance of a bleed in the surface of the eye after squint surgery or injection	44	34.1	7 6	57.1	28	32.1	5	80.0
	PO	95.	Discomfort or abnormal sensation	Discomfort or pain during/after treatment of squint	43	39.5	7 bibliographic	85.7	29	48.3	5	100.

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#### A core outcome set for three ophthalmic conditions: a healthcare professional and patient consensus on Core Outcome Sets for Amblyopia, Ocular Motility and Strabismus (COSAMS study)

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# A core outcome set for three ophthalmic conditions: a healthcare professional and patient consensus on Core Outcome Sets for Amblyopia, Ocular Motility and Strabismus (COSAMS study)

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*Transparency statement:* The lead author confirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

**Ethics statement:** Ethical approval was obtained from the University of Liverpool institutional research ethics committee for the focus groups, online survey and the consensus meetings to be undertaken with healthcare professionals and patients (Ref. Nos. 2063 and 2260). Informed consent was obtained from participants.

## Abstract

**Objectives:** Amblyopia, strabismus and ocular motility disorders are common conditions with significant impact on visual function, appearance and quality of life. We aimed to establish a core set of outcomes for each of the three conditions for use in clinical trials and routine clinical practice.

**Design:** A comprehensive databank of outcomes was developed from a systematic review of the literature and a series of focus groups with healthcare professionals, researchers, patients and carers. The databank of outcomes was scored in a two-round Delphi survey completed by two stakeholder groups; healthcare professionals / researchers and patients / carers. Results of the online Delphi were discussed at a face-to-face consensus meeting where the core outcome sets were finalised.

Setting: UK-wide consultation.

Participants: Researchers, clinicians, patients and carers.

Outcome measures: Core Outcome Sets.

**Results:** For amblyopia, strabismus and ocular motility, 40/42/33 participants contributed to both rounds of the Delphi; 6/9/7 members attended consensus meetings, respectively. Consensus was reached on ten core outcomes for both amblyopia and ocular motility and nine for strabismus. All three conditions shared the core outcomes: *adverse events, cost, vision-related quality of life, and ocular alignment*. The strabismus and ocular motility disorder core sets included, in addition, *measuring the deviation, binocular vision, ocular movement, patient satisfaction and symptoms*. The amblyopia set, distinct from the sets for the other two conditions, included *best corrected distance and near visual acuity, spherical and cylindrical refraction, compliance, and treatment-related and functionality / long-term impacts*.

**Conclusions:** The study used robust consensus methods to develop a core outcome set for three ophthalmic conditions. Implementation of these core outcome sets in clinical trials and routine clinical practice will ensure that the outcomes being measured and reported are relevant to all stakeholders. This will enhance the relevance of study findings and enable comparison of results from different studies.

## Keywords:

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Core outcome set; Amblyopia; Strabismus; Ocular motility; Consensus; Delphi

## Article summary:

## Strengths and limitations of this study:

- This study followed robust methodology as guided by the Core Outcome Measures in Effectiveness Trials (COMET) Initiative.
- We targeted amblyopia, strabismus and ocular motility disorders which are common ophthalmic conditions.
- The study included key stakeholders including researchers, clinicians, patients and carers.
- Attrition rates in the Delphi process were moderate but similar to other COS studies.
- Larger response numbers, including international participants, would be preferable for wider generalisability.

#### Introduction

Amblyopia (lazy eye) and strabismus (squint) occur in up to 5% of the general population <sup>1, 2</sup>. It is unknown how prevalent ocular motility disorders (abnormal eye movements) are in the general population. These conditions often present in children and can lead to long-term problems for children and young adults such as blurred vision, double vision, low esteem and even blindness if not treated <sup>3</sup>. There are several approaches to the management of these conditions including occlusion, penalisation, spectacles, prisms, drugs, surgery, botulinum toxin, exercises, watchful waiting, or a combination of two or more of the above <sup>4-20</sup>.

Interventional systematic reviews in this field of research have identified that there is considerable variation in the outcomes being measured and reported in primary research studies, which impacts on the ability to compare and synthesise outcome results across studies. Moreover, it was noted that there is a paucity of outcome data available on important patient outcomes such as quality of life, long-term outcome as well as the cost of treatment <sup>4-20</sup>. To mitigate these issues and to increase the relevance of research, a

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core outcome set (COS) can be developed which represents an agreed standardised set of outcomes that should be measured and reporting in all studies for a specific area of health or healthcare. A search of the COMET (Core Outcome Measures in Effectiveness Trials) database revealed that there are several studies that have investigated important outcomes for eyes and vision disease; examples include cataract <sup>21, 22</sup>, glaucoma <sup>23</sup> and age-related macular degeneration <sup>24</sup> but none have specifically looked at amblyopia, strabismus or ocular motility disorders <sup>25</sup>.

The aim of this study was to develop core outcome sets for use in clinical trials and routine practice for all intervention types for the treatment of amblyopia, strabismus and ocular motility disorders in children and adults that includes input from all stakeholders. While we aim to develop three separate COS for each of the ophthalmic conditions, we anticipate that there could be considerable overlap in the importance of certain outcomes across these conditions. This is due to the fact that the three conditions often overlap and co-exist in patients, are frequently targeted within the same research studies, and are usually managed by the same group of health care professionals.

## Methods

The development of the COS study involved three stages (Figure 1): (1) the generation of a long list of outcomes; (2) a two- round online Delphi survey and (3) face- to- face consensus meetings to discuss the results of the Delphi survey and agree on the COS. The process considered the minimum standards for the design of a COS study (COS-STAD), which included careful consideration of the scope, stakeholders and the consensus process <sup>26</sup>.

## **Outcome list generation**

A databank of outcomes was generated from two sources: a systematic review of outcomes reported by researchers and clinicians in studies for the treatment of the conditions under evaluation, and, secondly using three separate focus groups (one for each condition) containing a mix of healthcare professionals, researchers, patients and carers. The detailed search strategy, methods and results for the systematic review have been published elsewhere <sup>27</sup>. Outcomes from the systematic review and suggested

outcomes from the recorded focus group meetings were extracted verbatim and grouped into suitable domains to facilitate easy classification. The final list was checked by experts in all three clinical conditions (SJ, FR), who also had the opportunity to use their clinical expertise to add additional outcomes to the list. In preparation for the Delphi survey, clinical assessment outcomes used only by healthcare professionals were either separated out (not to be scored by patients) or combined into a simplified outcome for patients to score. Each outcome was written using plain language and feedback sought from four researchers from the Health Service Research department, University of Liverpool and a clinician from a local hospital on the acceptability and their understanding of the wording used. The databank of outcomes can be found in Supplementary Table 1.

#### Online Delphi survey

The databank of outcomes was used to populate an online Delphi survey, which was administered using DelphiManager <sup>28</sup>. Participants were invited from two key stakeholder groups. The first group consisted of healthcare professionals involved in the care for people with one of the three conditions or researchers working within this field. Invitations to participate were sent by email flyers to national professional organisations including the British and Irish Orthoptic Society, Paediatric Ophthalmology networks, and local groups linked with the University of Liverpool. The second group included patients or carers of patients affected by at least one of the three conditions of interest. Patients and carers were invited to participate into the survey using flyers distributed on the University of Liverpool noticeboards, newsletters (via the professional Society), social media (twitter) and in ophthalmology departments in local hospitals including Aintree University Hospital, The Royal Liverpool University Hospital and Southport and Ormskirk hospitals. Through routine clinical practice, the study authors (SJ, FR) and healthcare professionals were also encouraged to distribute the patient survey links to their relevant patients if they showed an interest in the study.

Four surveys were set up, one for the healthcare professionals and researchers that contained the outcomes to be scored for all three conditions, and, three separate surveys containing only the outcomes relevant to patients and carers associated with each individual condition. The Delphi process was completed using two rounds (hereafter referred to R1 and R2). In each round participants were presented with the list of

outcomes and asked to score each outcome on how important it was to include in the COS, using a 9-point Likert scale, with 1-3 labelled 'not important', 4-6 labelled 'important but not critical', and 7-9 labelled as 'critically important' <sup>29</sup>. Participants had the option to indicate 'unable to score' on any outcome they felt unable to score, and at the end of R1, participants were invited to submit additional outcomes they thought were missing from the list. These outcomes were reviewed by the study authors (SJ, FR) and any outcomes that represented a new relevant outcome were added to the list to be scored in R2. Irrespective of participants were shown the distribution of scores for both stakeholder groups for each outcome along with their own score from R1 and asked to score the outcome again, using the same scale, taking this extra information into account.

## Consensus meeting

Separate face-to-face consensus meetings were held at the University of Liverpool, UK for each of the three conditions. Participants who either had an active role in the focus groups and/or completed both rounds of the Delphi survey were invited to attend, although others with an interest in the project were invited to ensure each meeting had a balanced mix of participants from both stakeholder groups. In advance of the meeting, participants received a copy of their scores from the online survey (if appropriate) and a consensus matrix (Supplementary Table 1) detailing the results of R1 and R2 by stakeholder group, and which outcomes had reached a priori definition of consensus in, consensus out or no consensus (Table 1). The consensus definition is similar to that used in other COS development studies.

The meeting for amblyopia was chaired by a non-clinical researcher with expertise in COS development methodology (JJK) while the meeting for strabismus and ocular motility was chaired by a student investigator with a clinical background (SJ).

In order to facilitate the discussion all outcomes that had reached consensus 'in' after R2 for both stakeholder groups were presented first, followed by outcomes that reached consensus 'in' for only one stakeholder group. All outcomes that scored critical for inclusion for 50-69% of the participants for either both or one of the stakeholder groups in

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R2 were presented next followed by all other outcomes that were scored by both stakeholder groups. Outcomes that were only scored by healthcare professionals and researchers were discussed last. Results for each outcome from the Delphi were shown to the participants with more time allocated to discussing outcomes where there was more uncertainty on whether the outcome should be included in the COS or not. Views for and against inclusion in the COS were sought by the meeting chair, who also ensured that participants had equal opportunity to comment prior to voting. Voting was undertaken anonymously using Poll Everywhere <sup>30</sup> software which was linked to mobile and tablet devices. The definition of consensus used in the Delphi survey (Table 1) was applied to the consensus meeting. The final COS was presented at the end of the meetings.

#### Study registration, ethics and reporting guidance

The study was prospectively registered with the COMET Initiative (Core Outcome Measures in Effectiveness Trials)<sup>31</sup>. Ethical approval was obtained from the University of Liverpool institutional research ethics committee for the focus groups, online survey and the consensus meetings to be undertaken with healthcare professionals and patients (Ref. Nos. 2063 and 2260). Informed consent was obtained from participants. The study is reported in line with the Core Outcome Set – Standards for Reporting (COS-STAR) guidance <sup>32</sup> (Supplementary Table 2).

#### **Patient and Public Involvement**

The study was supported by a patient advisory group which provided input to this research study. The patient advisory group met on a regular basis for the duration of the study. Patients contributed to the design of the study and were involved at all stages of the survey and consensus meetings.

#### Results

A summary of the COS development process is shown in Figure 1. The final COS contains ten, nine and ten outcomes across seven, six and seven domains for amblyopia, strabismus and ocular motility respectively (Tables 2-4). Ocular alignment,

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vision-related quality-of-life, adverse events and cost were common to all three conditions.

## Development of the databank of outcomes

The systematic review and focus groups of health care professionals, researchers, patients and carers identified 31, 61, and 78 individual outcomes for amblyopia, strabismus and ocular motility respectively. These were combined with a list of outcomes suggested by professional experts (SJ, FR) resulting in a total of 40, 70 and 106 outcomes for amblyopia, strabismus and ocular motility respectively. The outcomes were classified into 12 domains, (symptoms, visual function, refraction, oculomotor function, quality-of-life, treatment dependency, signs, investigations, long-term outcome, compliance, adverse events, cost) and outcomes that were not considered to be patient relevant were separated out or combined. As an example, 'refractive status', 'spherical and cylindrical refraction' and 'median spherical equivalence' were combined into a single outcome 'refractive status' for patients as they all have a similar meaning, but are often referred to separately by healthcare professionals. Details of all outcomes including domain classification, combined outcomes and plain language descriptions of outcomes is provided in Supplementary Table 1.

## **Online Delphi**

Thirty three healthcare professionals / researchers scored all outcomes for both R1 and R2 of the amblyopia component of the online survey while 29 completed for strabismus and ocular motility. Three patients/carers completed both rounds for amblyopia while nine completed both rounds for strabismus and five for ocular motility (Figure 1). At the end of R1, five outcomes for amblyopia, 12 for strabismus and 23 for ocular motility reached consensus 'in' for both stakeholder groups. After a review of all additional outcomes suggested by participants in R1, three new outcomes were added to the strabismus survey in R2 (improvement in angle by a set amount (suggested by a healthcare professional) and, immediate result post-surgery and long-term discomfort from scar tissue (both suggested by a patient)).

On completion of R2, ten outcomes reached consensus 'in' for amblyopia across both stakeholder groups while 17 and 32 outcomes reached the same criteria for strabismus and ocular motility respectively.

#### Consensus meeting

Six, nine and seven voting participants attended the consensus meeting for amblyopia, strabismus and ocular motility respectively with an even balance of healthcare professional/researchers and patients present (Figure 1).

## Amblyopia

For amblyopia, future functionality/long-term impact and adverse events reached the consensus 'in' criteria for both stakeholder groups in both rounds of the Delphi and remained in the COS. Despite reaching consensus 'in' for both rounds of the Delphi for both stakeholder groups, intolerable diplopia and occlusion amblyopia (both adverse events) were not included in the final COS as it was felt that these could be captured under 'adverse events' and therefore were not critical for separate inclusion in the COS. Long-term outcome was also excluded following discussion as the group felt that there was currently no agreed set time for measuring long-term objective outcomes. Best corrected visual acuity and compliance marginally did not reach consensus 'in' during R2 of the Delphi but made the final COS after discussion. Following a discussion on the other visual function outcomes, near visual acuity was also added because it was noted that it was a good marker of early improvement for the treatment of amblyopia and important for children as it is important to their education. Refractive status reached consensus for both groups in R2 but following discussion this was replaced by spherical and cylindrical refraction (scored only by health care professionals in the Delphi) because it was successfully argued that this was a more precise measurement of refractive status. The list of outcomes within the quality of life domain were discussed simultaneously. While this was not listed specifically as an outcome in the Delphi, participants agreed to include visual-related quality of life in the core set as it was felt that a generic healthrelated quality of life outcome was not sensitive enough. Psychological impact of treatment was scored only by healthcare professionals in the Delphi but reached consensus 'in' during R2. Following discussion led by a parent participant, the panel derived a new outcome to include *treatment-related impact* into the final COS in order to

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capture the effect of treatment, such as patching on children, which could be long lasting. For both Delphi rounds, cost outcomes did not reach consensus 'in' by either stakeholder groups, however, the consensus panellists successfully advocated for its inclusion as a core outcome as *cost* outcome data is vital information for contemporary health systems.

### Strabismus

For strabismus, symptoms and patient satisfaction reached the consensus 'in' criteria for both stakeholder groups in both rounds of the Delphi and remained in the COS. Best corrected visual acuity also reached consensus 'in' for both rounds and groups in the Delphi although the consensus panel argued that any change in vision and/or loss of vision as an adverse event would be very significant and reportable as per standard healthcare safety procedures <sup>33</sup>. At the consensus meeting, participants noted that strabismus interventions aim to change the strabismus angle and visual acuity should not be affected by the intervention unless an adverse event occurred. Thus a change in visual acuity would be captured within adverse events. On this basis a decision was taken to exclude visual acuity from the core set. All remaining visual function outcomes were discussed simultaneously, and while the post-op diplopia test reached consensus 'in' during the Delphi exercise, the consensus panel voted in favour of including *binocular* vision as core, as it was more representative of a group of visual function related outcomes. Oculomotor function outcomes were discussed simultaneously and it was highlighted that ocular movement was critical to be reported in all strabismus types as a change caused by the intervention would be significant. Quantifying both the ocular alignment and deviation were also seen to be critical in the context of any strabismus type and were included as core outcomes. Visual-related quality-of life, adverse events and cost were also included in the COS for reasons discussed for amblyopia.

## Ocular Motility

The discussions for ocular motility closely followed those of strabismus with the addition of clinical signs being added as an extra core outcome. Similar to adverse events, this outcome was a catch all for all clinical signs which were scored individually in the Delphi exercise. This strategy was seen favourably by the meeting participants as many sub-conditions of ocular motility have specific signs associated with them. One example for this is corneal exposure in the ocular motility condition of Thyroid Eye Disease but which is not relevant in other ocular motility disorders.

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# Discussion

This study has developed a set of core outcomes for the treatment of three ophthalmic conditions using a robust consensus process involving healthcare professionals, researchers, patients and carers. Consensus was reached on what should be measured in each of the three COS. They consisted of nine to ten outcomes distributed across six to seven domains to cover all important aspects related to treatment (objective clinical, adverse events, subjective or patient-reported outcomes, and health economics). While these three core outcome sets were developed independently, there are some parallels, and as a consequence, four outcomes (ocular alignment, vision-related quality-of-life, adverse events and cost) were common to all three conditions. The amblyopia COS captures the condition's unique features by reporting additionally on 'best corrected' visual acuity', 'near visual acuity', 'compliance', 'spherical and cylindrical refraction', 'treatment-related impact' and 'future functionality/long-term impact', keeping in mind that children are the predominantly affected population. The COS for strabismus and ocular motility disorders, on the other hand, include 'binocular vision', 'ocular movement', 'measuring the deviation', 'symptoms' and 'patient satisfaction'. The ocular motility disorder COS was unique in additionally reporting 'clinical signs' related to the relevant conditions.

We recommend that, as a minimum, these core outcomes are used in future trials of interventions to treat amblyopia, strabismus and ocular motility disorders. We also advocate that these outcomes are recorded in routine clinical practice to ensure that the outcome data collected is meaningful and important.

A strength of this study is that it was prospectively registered with the COMET Initiative and it was developed using the COS- STAD (Core Outcome Set - STAndards for Development) recommendations <sup>26</sup>. Engagement with patient participants was particularly challenging and we sought to improve patient input by offering paper copies of the Delphi survey with pre-paid return envelopes in orthoptic clinics, although this was later abandoned after a number of sessions when there was no uptake. As a consequence of a relatively low number of patients responding to the Delphi and attrition between the two rounds, there was concern that consensus was not being achieved at

the end of the final round given the number of outcomes reaching consensus for both stakeholder groups had increased dramatically from R1. While measures were taken to ensure survey participation and retention was maximised (including sending reminders and extending deadlines for completion), it was felt that after several months of keeping the survey open, our efforts became futile. In order to compensate for this, we ensured that the consensus meetings where the final COS were ratified, contained a good balance of healthcare professionals and patients. The main limitation of this study was that the consensus process was based using only participants in the UK. However, as a starting point, we have reason to believe that this COS could also be useful in other countries and settings.

Further consensus work is needed to refine and establish the best measurement instruments and time points for when to measure these core outcomes. To assist this process, the systematic review for generating the databank of outcomes also recorded the measurement instruments and timings associated with each outcome <sup>27</sup>.Moreover, for some outcomes, the metric (e.g. change from baseline or inter-ocular difference (IOD) of BCVA), and method of aggregation (e.g. mean or median) <sup>22</sup> would need to be determined. Defining success criteria (e.g. 8 or 10 dioptres from orthophoria for alignment, for distance and/or near) is another aspect of outcome refining and definition to be done by further work. The generalisability of the COS also needs to be reviewed in healthcare settings outside the UK. While the review of outcomes identified studies from around the world (with prominence from the United States, United Kingdom, China and various European countries), the formal consensus process was undertaken using only participants from the UK, and those attending the consensus meeting were mostly localised to the North West of England.

There are few reported COS in the literature that relate to the three conditions in this study. Chiu et al. recommended four outcomes for reporting results of surgery for intermittent exotropia <sup>34</sup>. Their study aimed to explore the extent of standardisation of outcomes reported in surgical studies for the condition. However, the study was limited by the extent of literature review for this specific condition (10-year literature search period) and lack of external consensus. A short narrative review of outcome measurements for size of deviation showed considerable variability across the tests available and the recommendations for their use. They suggested four core outcomes for

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all future studies: alignment, near stereoacuity, control score, and quality of life score. If assigning near stereoacuity and control score to 'binocular vision', their outcomes map to those reported in our COS for strabismus.

Moreover, two recently published studies attempted to define criteria for success in treatment, one for amblyopia and the other for strabismus surgery, which could be considered complementary to the COS and not alternatives because they essentially give more definitions of primary outcomes rather than suggesting a set of specific outcomes to be measured in research.

A report was published by Shoshany et al. <sup>35</sup> stating that the IRIS measures for amblyopia developed by the American Academy of Ophthalmology (IRIS7 <sup>36</sup>, modified in 2019 to IRIS50 <sup>35</sup>) provide uniform criteria for defining amblyopia treatment success. Treatment was defined as 'successful' if corrected IOD was less than 0.23 logMAR 12–18 months after first diagnosis. IRIS50 considers improvement in VA, which may be relevant to patients who had dense amblyopia at baseline but nevertheless improved. Thus, IRIS50 may be a more practical reporting measure than IRIS7. In general, Shoshany et al. propose that these measures will allow more efficient reporting of quality metrics and rapid and objective assessment of new amblyopia treatments <sup>35</sup>.

In addition, a study aiming to define successful outcomes for strabismus surgery was published by Serafino et al. <sup>37</sup>. Although this study did not state an intention to develop a COS, there are a lot of similarities and overlap in the objectives and methodology used. A Delphi process was used to identify areas of consensus and disagreement among experts for the definition of success post strabismus surgery. The panel of experts in their study represented wide international geographic areas and included experts who were chosen based on their peer-reviewed publications, participation at international meetings and their surgical experience. The study concluded the following: they achieved consensus on which strabismus types need their separate set of outcome criteria. They also identified the importance of 'stereopsis' and 'the range of single vision' for inclusion of success definition in some strabismus types, which interestingly could be mapped to 'binocular vision' in our strabismus COS. The study also found that there was no

consensus on the length of time after surgery for determination of success, magnitude of deviation consistent with success, and whether manifest or latent deviation should be considered to define success, which the review of our study <sup>27</sup> has also found, and which we are advocating to define, by future work. Differences from our study is that their survey did not involve scoring of outcomes, there was no systematic search of literature of reported outcomes prior to survey construction, and patients or service users were not consulted in the process.

A search in the COMET initiative database in April 2020 did not reveal registration of any further additions of similar studies in the database. It is advantageous to register COS studies in the database to facilitate collaborative work of similar scope, and to avoid duplication of efforts and waste of research.

## Conclusion

The three COS developed from this study can be applied to future trials and routine data collection for all intervention types to treat the three ophthalmic conditions considered. Their use will allow the comparison of outcome data to be made across studies and to better inform treatment decisions. Future work will include seeking consensus on how these outcomes should be measured and to evaluate the acceptability of the current COS to patients and professionals in other countries, particularly where healthcare systems differ from the UK.

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**Author contributions:** FR and JJK contributed to conceptualising and designing the study. SJ was responsible for the day-to-day running of the project. All authors contributed to the review of the study design and to the review and analysis of study data. JJK drafted the manuscript. FR and SJ made major revisions. Due to the strong involvement of JJK and FR at several different stages of the study, all authors agreed to consider them joint senior. All authors read and approved the final manuscript.

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# Figure 1 Study flowchart

## Table 1 Definition of consensus

Consensus classification	Description	Definition of consensus
Consensus in	Consensus that the outcome	≥70% of participants scoring
	should be included in the core	the outcome as '7–9' (critically
	set	important)
Consensus out	Consensus that the outcome	≥70% of participants scoring
	should not be included in the	the outcome as '1–3' (not
	core set	important)
No consensus	Uncertainty about the	Anything else
	importance of the outcomes	

## Table 2 Final COS for amblyopia

Domain	Outcome
Visual function	1. Best corrected visual acuity
	2. Near visual acuity
Refractive status	3. Spherical and cylindrical refraction
Oculomotor function	4. Ocular alignment (is there an ocular deviation?)
Quality of life	5. Vision-related quality of life (for example, activities o
	daily living)
	6. Treatment-related impact (for example, negative
	effects of patching on children during treatment)
	7. Future functionality / long-term impact
Compliance	8. Compliance
<b>A</b> de la marca de	9. Any adverse events (for example, intolerable diplopia
Adverse events	
Adverse events	occlusion amblyopia)
Cost	occlusion amblyopia) 10. Cost (for example, cost to services, families, and

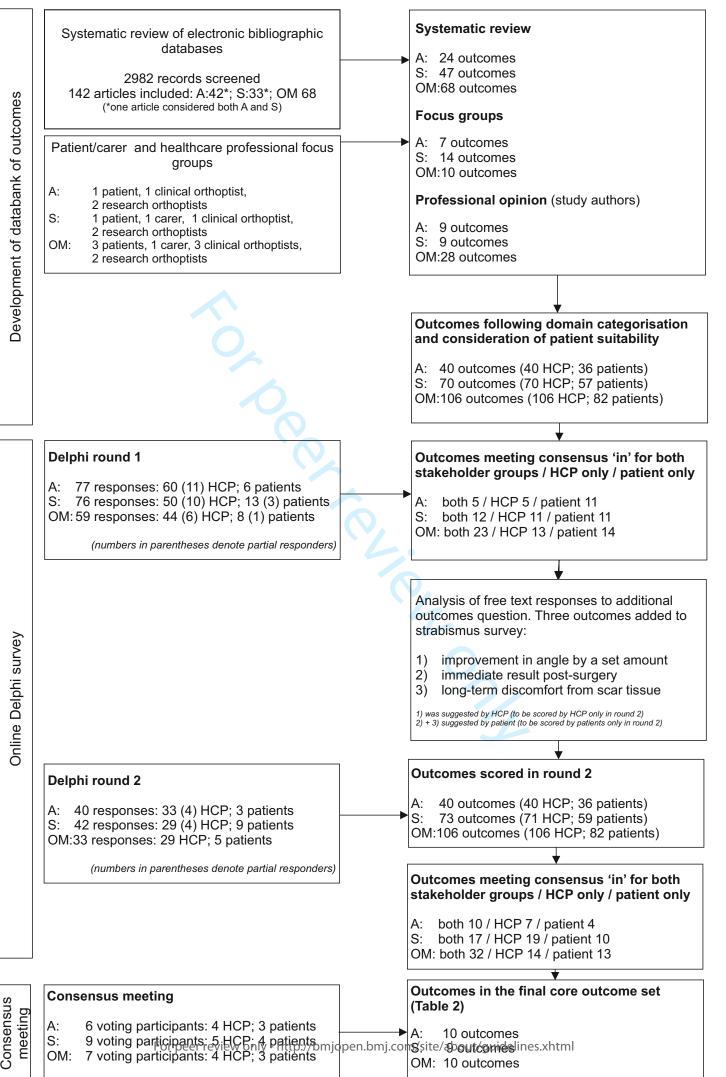
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#### Table 3 Final COS for strabismus

Domain	Outcome
Symptoms	1. Symptoms (for example, diplopia and appearance of the strabismus)
Visual function	2. Binocular vision (for example, stereoacuity and binocular single vision)
Oculomotor function	3. Ocular alignment (are the eyes straight?)
	<ol> <li>Measurement of deviation (what is the amount of deviation?)</li> </ol>
	5. Ocular movement (specifically incomitance, latent nystagmus, DVD and A&V pattern)
Quality of life	6. Vision-related quality of life; psychosocial aspects (such as self-esteem, confidence, behaviour, social interaction) and functional aspects (such as activities of daily living)
	7. Patient satisfaction
Adverse events	8. Any adverse events (for example, intolerable diplopia, recurrence of the deviation, overcorrection or under-correction of the deviation)
Cost	9. Cost (for example, cost to services, families, and individuals)

## Table 4 Final COS for ocular motility disorders

Domain	Outcome
Symptoms	1. Symptoms (for example, diplopia and appearance o
	the eye deviation)
Visual function	2. Binocular vision (for example, stereoacuity, field o
	binocular single vision, and post-op diplopia test)
Oculomotor function	3. Ocular alignment (are the eyes straight?)
	4. Measurement of deviation (what is the amount o
	deviation?)
	5. Ocular movement (specifically incomitance, later
	nystagmus, DVD and A&V pattern)
Quality of life	6. Vision-related quality of life; psychosocial aspects (suc
	as self-esteem, confidence, behaviour, social interaction) an
	functional aspects (such as activities of daily living)
	7. Patient satisfaction
Adverse events	8. Any adverse events (for example, intolerable diplopia
	recurrence of the deviation, and adverse effects from patche
	or prisms)
Cost	9. Cost (for example, cost to services, families, an
	individuals)
Clinical signs	10. Clinical signs (for example, corneal exposure, proptosis
	exophthalmos, enophthalmos)



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	Supplementar	y Table 1:	Long list of outcomes	used in the Delphi survey and critical sco	ring in bo	oth rounds	of the D	5	ey by sta	keholder g	roup	
				SR), focus groups (FG) and professional op			= •	ω				
	-					/].	for	n 11				
	Percentages h	ighlighted	in red denote outcome	es that reached the consensus 'in' criteria.			Ens	Mav				
	N/A: not score	ed by stake	holder group (HCPs or	patients)			seigr	202				
	<u>Amblyopia</u>						ited					
							ont S	own				
	Domain	Source	Outcome	Lay-term summary	Delphi	results	xt al	oado				
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				2	n	% (7-9)		% (7-9)	n	% (7-9)	n	% (7-9
	Symptoms	FG	1. Patient symptoms	Symptoms or complaints related to vision or eyes	67	34.3	annod sincolar de	<b>5</b> 0.0	37	37.8	3	66.
	Visual function	SR	2. Best corrected visual acuity		70	98.6	arte	50.0 66.7	37	100.0	3	66.
		SR	3. Near visual acuity	Close up or reading vision	70	65.7	<u> </u>	ຜີ 50.0	37	78.4	3	66.
		PO	4. Habitual visual acuity	Vision measured in the usual preferred state for a person	62	58.1	tmologies.	80.0	37	67.6	3	100
		SR	5. Uncorrected visual acuity	Vision without glasses or contact lenses	70	4.3	ies.	at 40.0	37	5.4	3	0.0
		FG	6. Suppression	Testing if the person has developed "suppression" of one image to improve double vision which usually happens in childhood as a coping mechanism from the brain to improve visual development	70	42.9	4	Agence Bit	36	47.2	2	100
		FG	7. Fixation	Testing if the person is using the central part of the retina to see with or alternatively using an eccentric part of the retina	70	52.9	3 4	Bibliographique de	36	50.0	3	33.

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	FG	8.	Contrast sensitivity	Objects of varying brightness	66	12.1	0-042403 It, inœhudii	60.0	34	5.9	3	0.0
	SR	9.	Visual evoked potentials	Testing vision signals from the eyes to the brain with electrodiagnostics (visual evoked potentials/VEP)	56	8.9	403 on uding f	33.3	33	3.0	2	0.0
	SR	10.	Binocularity	to check if the eyes are working together to give any level of 3D vision or depth appreciation	70	47.1	07-01-1 1-1 N	80.0	36	63.9	2	50.0
	SR	11.	Stereoacuity	Fine 3D vision or depth appreciation with both eyes or "stereo vision"	70	37.1	11 May 20 Ensei onvoisesore	80.0	35	34.3	2	100.0
	PO	12.	Simultaneous perception	Testing lower levels of 3D vision	70	30.0	2021. Dow Pignement related b	60.0	35	25.7	2	0.0
	PO	13.	Retinal correspondence		70	31.4	d n D N¢Agi M	N/A	35	11.4	N/A	N/A
Refraction	SR	14.	Refractive status		69	84.1	text text	66.7	35	94.3	3	100.0
	SR	15.	Spherical & cylindrical refraction	Testing the amount of prescription of glasses or	69	79.7	nloaded Superie text And	N/A	35	91.4	N/A	N/A
	SR	16.	Median spherical equivalent	contact lenses	64	26.6	detro	N/A	33	21.2	N/A	N/A
Dculomotor unction	SR	17.	Ocular alignment /deviation	Assessing if the eyes are straight or deviated and measuring the amount of eye deviation	68	63.2	a oni	66.7	35	71.4	3	100.0
	PO	18.	Abnormal head posture	The presence of a compensatory head posture to avoid double vision	68	33.8	l from http://bu eur(ABES). Ispatacminicog,	66.7	34	32.4	3	66.7
Quality of life	SR	19.	Quality of life measures (in general)	Health related quality of life (all relevant aspects)	69	53.6	, Aldrainiong,	100.0	35	62.9	3	100.0
	FG	20.	Psychological impact of the disorder	Negative impact of lazy eye (amblyopia) on emotions and/or behaviour	69	55.1	n.brr indong	83.3	34	67.6	3	100.0
	SR	21.	Psychological impact of treatment of disorder	The psychological impact of treatment of lazy eye (amblyopia) on emotions and/or behaviour	69	62.3		N/A	34	73.5	N/A	N/A
	PO	22.	Self-esteem	Negative impact of lazy eye (amblyopia) on self- esteem & confidence	69	59.4	sippil	100.0	34	70.6	3	100.0
	SR	23.	Social anxiety and social avoidance due to the disorder	Negative impact of lazy eye (amblyopia) on social interaction or causing social stigma	69	55.1	June 13, Iar techn	83.3	34	67.6	3	100.0
	SR	24.	Academic/ occupation achievement in relation to the condition or its treatment	Academic/ occupation achievement in relation to the condition or its treatment	69	60.9	2025 at <i>F</i> ologies.		34	76.5	3	66.7
	SR	25.	Activity of daily living (ADL)	Negative impact of lazy eye (amblyopia) on normal daily activities	68	52.9	Agence 6	100.0	33	72.7	3	100.0
	SR	26.	Patient satisfaction from treatment	Patient satisfaction from treatment	68	61.8	6 <b>Bib</b>	83.3	34	76.5	3	100.0
	FG	27.	Future functionality/long- term impact	Future functionality/long-term impact (patient- reEOrted)	69	78.3	iographique 6	100	34	91.2	3	100.0

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SRComplianceSRAdverse eventsSRSRSRSRSRPOSRPOSRCostSRPOSRPOSRPOSRPOSRFOFG	SR 2 SR 3 SR 3 SR 3 SR 3 PO 3 SR 3 PO 3 SR 3	<ol> <li>Fear of losing better eye</li> <li>Compliance</li> <li>Adverse effects from treatment (any)</li> <li>Intolerable diplopia</li> <li>Occlusion amblyopia</li> <li>Visual disorientation</li> <li>Disturbed distance estimation</li> <li>Skin irritation or allergy to patches</li> <li>Atropine eye drops side effects</li> </ol>	How well the treatment is doneAdverse effects from treatment (any)Intolerable double vision as a side effect from treatmentDevelopment of lazy eye (amblyopia) in the better eye as a result of patching/penalisation treatmentVisual disorientation due to treatment with occlusion of better eyeDisturbed distance estimation due to treatment with occlusion of better eyeSkin irritation or allergy from eye patches used	69 69 69 69 69 69 64	71.0 95.7 73.9 89.9 76.8 45.3	brownio aded Enseignement Superie by copyright, including foor usses rectated too text and	66.7 66.7 80.0 83.3 100.0	33 33 33 33 33	84.8 97.0 87.9 100.0	3 3 2 3	
Adverse events SR SR SR PO SR PO Cost SR PO PO PO	SR : SR : SR : SR : PO : SR : SR : SR :	<ol> <li>29. Compliance</li> <li>30. Adverse effects from treatment (any)</li> <li>31. Intolerable diplopia</li> <li>32. Occlusion amblyopia</li> <li>33. Visual disorientation</li> <li>34. Disturbed distance estimation</li> <li>35. Skin irritation or allergy to patches</li> <li>36. Atropine eye drops</li> </ol>	Adverse effects from treatment (any)Intolerable double vision as a side effect from treatmentDevelopment of lazy eye (amblyopia) in the better eye as a result of patching/penalisation treatmentVisual disorientation due to treatment with occlusion of better eyeDisturbed distance estimation due to treatment with occlusion of better eye	69 69 69 64	73.9 89.9 76.8	on 11 nag foor	80.0 83.3	33 33	87.9	2	
Adverse events SR SR SR PO SR PO Cost SR PO PO PO	SR : SR : SR : SR : PO : SR : SR : SR :	<ol> <li>Adverse effects from treatment (any)</li> <li>Intolerable diplopia</li> <li>Occlusion amblyopia</li> <li>Visual disorientation</li> <li>Disturbed distance estimation</li> <li>Skin irritation or allergy to patches</li> <li>Atropine eye drops</li> </ol>	Intolerable double vision as a side effect from treatment Development of lazy eye (amblyopia) in the better eye as a result of patching/penalisation treatment Visual disorientation due to treatment with occlusion of better eye Disturbed distance estimation due to treatment with occlusion of better eye	69 69 69 64	73.9 89.9 76.8	Ē 1	80.0 83.3	33 33	87.9	2	1
SR SR PO SR PO Cost SR PO PO PO	SR : SR : PO : SR : PO : SR :	<ol> <li>Intolerable diplopia</li> <li>Occlusion amblyopia</li> <li>Visual disorientation</li> <li>Disturbed distance estimation</li> <li>Skin irritation or allergy to patches</li> <li>Atropine eye drops</li> </ol>	treatmentDevelopment of lazy eye (amblyopia) in the better eye as a result of patching/penalisation treatmentVisual disorientation due to treatment with occlusion of better eyeDisturbed distance estimation due to treatment with occlusion of better eye	69 64	76.8	May 2021. D Enseignem usces redated			100.0	3	
SR PO SR PO Cost SR PO PO PO	SR : PO : SR : PO : SR :	<ol> <li>Visual disorientation</li> <li>Disturbed distance estimation</li> <li>Skin irritation or allergy to patches</li> <li>Atropine eye drops</li> </ol>	better eye as a result of patching/penalisation treatment Visual disorientation due to treatment with occlusion of better eye Disturbed distance estimation due to treatment with occlusion of better eye	64		2021. D seignem s redated	100.0				
PO SR PO Cost SR PO PO PO	PO : SR : PO : SR :	<ol> <li>34. Disturbed distance estimation</li> <li>35. Skin irritation or allergy to patches</li> <li>36. Atropine eye drops</li> </ol>	occlusion of better eye Disturbed distance estimation due to treatment with occlusion of better eye		45.3	<u>2</u> 20		33	87.9	3	
Cost SR PO PO PO PO	SR : PO : SR :	estimation 35. Skin irritation or allergy to patches 36. Atropine eye drops	with occlusion of better eye				66.7	32	56.3	3	
Cost SR PO PO PO	PO :	allergy to patches 36. Atropine eye drops	Skin irritation or allergy from eve patches used	64	39.1	nloa Sup teort	66.7	32	46.9	3	
Cost SR PO PO	SR :		to occlude the eye	69	50.7	ded t erieu ancol	33.3	33	51.5	3	
PO PO			Side effects of the eye drops used regularly at home for treatment of lazy eye (amblyopia)	69	65.2	from 9ur (Al Idadaa	33.3	33	69.7	3	
PO		<ol> <li>Economic data (in general)</li> </ol>	Economic data (in general) including services and families/individuals	54	24.1	http://br \BES). Invianingg	16.7	30	20.0	3	
		<ol> <li>Cost of treatment on services</li> </ol>	Cost of treatment on services	55	25.5	ng /	16.7	31	32.3	3	
Long-term FG	PO :	39. Cost of treatment on families/individuals	Cost of treatment on families/individuals	54	37.0	Victa	33.3	30	50.0	3	
	FG 4	40. Long-term outcomes	Long-term outcomes (clinical outcomes)	59	84.7		100.0	33	93.9	3	Τ
				59		njopen.bmj.com/ on June 13, 2025 at Agence Bibliographique de I Aktraitiong, and similar technologies.					

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<u>Strabismu</u>	<u>s</u>						ncluding	042403 o				
Domain	Source	Outcome		Lay-term summary	by copyright, including for uses reign     Page       Delphi results     ruses reign       Round 1     relation							
					Round 1			2021	Round 2			
					HCPs		PatientsO	.≤	HCPs		Patients	
				Or	n	% (7-9)	text and	nloade(7-9)	n	% (7-9)	n	% (7-9)
Symptoms	FG	sym	ient nptoms	Symptoms or complaints related to vision or eyes	60	91.7		<b>075.0</b>	33	100.0	9	77.8
	FG	2. Dip	lopia	Improvement in double vision in general	60	95.0		<b>285.7</b>	33	100.0	8	62.5
	FG		bearance of abismus	Appearance of the squint	60	85.0	<sup>15</sup> .	<b>\$</b> 46.7	33	87.9	9	33.3
	FG	the	e aesthetics as patient ceives	Appearance of the squint as the patient perceives	60	80.0	15 training,	<b>9</b> 40.0	33	84.8	9	44.4
	FG	rela	e aesthetics as atives and nds perceive	Appearance of the squint as the relatives and friends perceive	60	58.3	ning, a	46.7	33	63.6	9	33.3
Visual function	SR	6. Bes	st corrected ual acuity	Vision measured at distance corrected with glasses	60	71.7	and si	<b>2</b> 72.7	33	90.9	7	100.0
	PO		ar visual acuity	Close up or reading vision	60	45.0	12 3	<sup>9</sup> 75.0	33	63.6	7	71.4
	PO	8. Hat	bitual visual litv	Vision measured in the usual preferred state for a person	53	41.5	12 imilar tech	un <mark>70.0</mark>	32	59.4	7	100.0
	PO	9. Uno	corrected ual acuity	Vision without glasses or contact lenses	60	8.3	12 chnc	<u>.</u> 	33	3.0	7	71.4
	FG		opression	Testing if the person has developed "suppression" of one image to improve double vision which usually happens in childhood as a coping mechanism from the brain to improve visual development	60	65.0	12 nologies.	2025 at A	32	75.0	8	75.0
	PO	11. Fixa	ation	Testing if the person is using the central part of the retina to see with or alternatively using an eccentric part of the retina	60	46.7	9	gence 33.3	32	46.9	7	42.9
	PO	12. Cor sen	ntrast sitivity	Objects of varying brightness	59	6.8	8	<b>Bi</b> 37.5	32	0.0	8	37.5
	SR	13. Bin		Testing "binocularity" which is to check if the eyes are working together to give any level of 3D vision or depth appreciation	60	76.7	12	ogr <sub>58.3</sub>	32	75.0	8	87.5

of 40			BMJ Open			by copyright,	bmjopen-2020				
						=.	<b>4</b>				
	SR	14. Stereoacuity at near	Fine 3D vision or depth appreciation with both eyes measured for near	60	60.0	12 ud	<b>42</b> 58.3 <b>03</b>	32	62.5	8	
	SR	15. Stereoacuity at near and distance (any strabismus type)	Fine 3D vision or depth appreciation with both eyes measured for both near and distance	59	44.1	12 uding for us	958.3	32	46.9	8	
	SR	16. Stereoacuity at near and distance (for certain strabismus types? please specify)	Fine 3D vision or depth appreciation with both eyes measured for both near and distance for certain types of squint	54	53.7	es related to N/A	ay 2021. Dov	30	56.7	N/A	
	SR	17. Field of binocular single vision	Testing the extent of area of vision where there is no double vision while looking around with both eyes open	60	46.7	12 and	vnloaded f	32	53.1	8	
	FG	18. Post op diplopia test	Testing if a person is likely to get double vision after correcting the eye deviation with surgery	59	81.4	<u> </u>	<u>7</u> 781.8	32	93.8	9	
	SR	19. Simultaneous perception	Testing lower levels of 3D vision	59	37.3	10 <u>m</u>		32	25.0	8	
	PO	20. Retinal correspondence	Testing lower levels of 3D vision	60	43.3	N/Ang	N/A	32	37.5	N/A	
	PO	21. Refractive status	Testing the amount of prescription of glasses or contact lenses	60	61.7	11 <b>≥</b>	<b>5</b> 4.5	32	75.0	8	
Oculomotor function	SR	22. Ocular alignment /deviation	Assessing if the eyes are straight or deviated and measuring the amount of eye deviation	60	86.7	12 nin	<b>9</b> 91.7	32	100.0	8	
	SR	23. Abnormal head posture	The presence of a compensatory head EOsture to avoid double vision	60	66.7	11 🤤	<b>2</b> 63.6	32	84.4	9	
	FG	24. Ocular motor alignment at various positions especially where the deviation is greatest	Assessing if the eyes are straight or deviated and measuring the amount of eye deviation at different EOsitions	60	75.0	and similar tec	om/ on June	32	87.5	N/A	
	SR	25. Presence of incomitance (any strabismus type)	Testing if there is variation of the eye deviation in different EOsitions when looking around	59	71.2	N/Anologie	13, 2025	32	78.1	N/A	
	SR	26. Presence of incomitance (for certain strabismus types? please specify)	Testing if there is variation of the eye deviation in different EOsitions when looking around	58	75.9	gies. N/A	at Agence	31	80.6	N/A	
	SR	27. Control of deviation (any strabismus type)	Measuring how well the person can control the eye turn	59	79.7	12	B. 5 <mark>83.3</mark>	32	96.9	9	
	SR	28. Control of deviation (for	Measuring how well the person can control the eye turn	58	81.0	N/A	graphique	31	93.5	N/A	

		certain				inclu	bmjopen-2020-042403				
		strabismus types? please specify)				by copyright, including f	on				
SR	29.	Ocular movement	How well eyes move as a person is looking around	60	66.7	13 <b>ද</b>	<b>二</b> 61.5	32	71.9	9	7
SR	30.	Presence of latent nystagmus (any strabismus type)	Checking if there are involuntary rapid movements of the eyes when one eye is covered	58	46.6	11 11	Enseigne	32	53.1	9	4
SR	31.	Presence of latent nystagmus (for certain strabismus types? please specify)	Checking if there are involuntary rapid movements of the eyes when one eye is covered	57	54.4	ed to text and N/Aext and	T61.5 May 63.6 Enseignement Superieur	32	71.9	N/A	Ν
SR	32.	Presence of dissociated vertical deviation (DVD) (any strabismus type)	Testing if there is tendency for the eye to move up and out +/- rotates when covered	58	51.7	11 8	ABES	32	53.1	8	3
SR	33.	Presence of dissociated vertical deviation (DVD) (for certain strabismus types? please specify)	Testing if there is tendency for the eye to move up and out +/- rotates when covered	56	64.3	Al training, N/A	njopen.bmj	31	71.0	N/A	N
SR	34.	A or V pattern deviation	Testing if there is a deviation that increases either on looking up or looking down	60	60.0	N/And	₿N/A	32	81.3	N/A	Ν
SR	35.	Fusional vergence at near and distance /fusion amplitudes/prism fusion range	Testing how well the eyes can control a deviation induced with prisms in clinic	60	68.3	similar technologies.	on June 13,	32	81.3	9	5
SR	36.	Near point of convergence (for any strabismus type)	Testing if the eyes can normally look inwards to see a near object to an acceptable amount	60	31.7	13 13 13	2025 at A	32	43.8	9	6
SR	37.	Near point of convergence (for certain strabismus types? please specify)	Testing if the eyes can normally look inwards to see a near object to an acceptable amount	58	51.7	N/A	Agence Bibliographique de l	32	62.5	N/A	Ν

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	FG	38.	Accommodation (for any strabismus type)	Testing if the eyes can change their focus appropriately to see objects at varying distances	60	23.3	includin	<b>042</b> <b>0</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b>	32	18.8	9	44.4
	FG	39.	Accommodation (for certain strabismus types? please specify)	Testing if the eyes can change their focus appropriately to see objects at varying distances	58	60.3	g for uses i N/A N	on 11 May 20246.2	31	61.3	N/A	N/A
	SR	40.	AC/A ratio (for any strabismus type)	Testing the ratio between the ability of the eyes to look inwards and their ability to focus	59	30.5	13 13 13	<b>N</b> 46.2	32	28.1	9	33.3
	SR	41.	AC/A ratio (for certain strabismus types? please specify)	Testing the ratio between the ability of the eyes to look inwards and their ability to focus	58	65.5	I to text and N/At and	Š	31	67.7	N/A	N/A
	CLIN PART	42.	Improvement in angle by a set amount e.g. >10^	D <sub>C</sub>	N/A	N/A	dat ⊂		31	51.6	N/A	N/A
	PT PART	43.	Immediate result EOst-surgery**		N/A	N/A	N/Ages) · N/Ages 13	N/A	N/A	N/A	8	12.5
uality of life	SR	44.	Quality of life measures (in general)	Health related quality of life (all relevant aspects)	53	81.1	13 Iraining,	<b>6</b> 9.2	31	93.5	9	66.7
	SR	45.	Psychological impact of the disorder	Negative impact of squint (strabismus) on emotions and/or behaviour	53	88.7	13 g, a	<b>1.</b> 69.2	30	100.0	9	77.8
	SR	46.	Psychological impact of treatment of disorder	EOsitive impact of treatment on emotions and/or behaviour	53	75.5	and simil	984.6	30	80.0	9	77.8
	SR	47.	Social anxiety and social avoidance due to the disorder	Negative impact of squint (strabismus) on social interaction or causing social stigma	53	84.9	and similar technologies.	June 13, 2	30	90.0	9	66.7
	FG	48.	Academic/ occupation achievement in relation to the condition or its treatment	Academic/ occupation achievement in relation to the condition or its treatment	52	69.2	13 <b>1</b> 3	2025 at Agenc	30	76.7	9	66.7
	FG	49.	Activity of daily living (ADL)	Activity of daily living (ADL) such as driving	52	67.3	14	មិ <mark>ភិ8.6</mark>	29	86.2	9	77.8
	SR	50.	Patient satisfaction from treatment	Patient satisfaction from treatment	53	83.0	14	ce 78.6 Bibliographique de l	29	96.6	9	88.9

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	FG	51.	Future functionality/long- term impact	Future functionality/long-term impact (patient- reEOrted)	52	92.3	, includin	-042 <sup>4</sup> 00.0	29	96.6	9	88.9
Compliance	PO	52.	· · · · · · · · · · · · · · · · · · ·	How well the treatment is done	52	63.5	12 <b>'g</b>	<sup>9</sup> <u>91.7</u>	29	62.1	8	87.5
Treatment dependency	SR	53.	Successful discontinuation of lens therapy or "special glasses" (for any strabismus type)	Successful discontinuation of lens therapy or "special glasses" such as bifocals or minus lenses	49	40.8	uses relat 4	1 May 2021. Do	28	46.4	6	8       87.5         6       83.3         I/A       N/A         6       83.3         9       55.6         6       83.3         9       77.8         8       62.5         8       37.5         9       66.7
	SR	54.	Successful discontinuation of lens therapy or "special glasses" (for certain strabismus types? please specify)	Successful discontinuation of lens therapy or "special glasses" such as bifocals or minus lenses	49	51.0	to text and data A X	N/A N/A	28	64.3	N/A	N/A
	PO	55.	Successful discontinuation of prism therapy	Successful discontinuation of prism therapy	52	46.2	mining 4		29	51.7	6	83.3
dverse events	SR	56.	Adverse effects from treatment (any)	Adverse effects from treatment (any)	53	83.0		<b>1</b> 60.0	29	93.1	9	55.6
	FG	57.	Adverse effect on vision from patches or prisms used to treat diplopia	Adverse effect on vision from patches or prisms used to treat diplopia such as vision degradation or psychosocial effects	invation of prism therapy       52       46.2       4       5       6       83.3         om treatment (any)       53       83.0       10       10       10       29       51.7       6       83.3         vision from patches or prisms bia such as vision degradation or ts       53       67.9       7       9       29       75.9       6       83.3							
	SR	58.	Intolerable diplopia	Intolerable double vision	53	98.1	11 <b>Si</b>		29	96.6	9	77.8
	SR	59.	Induced ptosis (post toxin injection)	Appearance of transient droopy eye lid as a result of using toxin injection to treat squint	52	51.9	lar tech	<b>J</b> une 1	29	55.2	8	62.5
	SR	60.	Induced subconjunctival haemorrhage	Appearance of a bleed in the surface of the eye after squint surgery or injection	52	32.7	9 9	<b>.3</b> 233.3 2025	29	20.7	8	37.5
	SR	61.		Discomfort or pain during/after treatment of squint	53	28.3	9 <b>es</b> .	<sup>a</sup> 44.4	29	17.2	8	37.5
SR	62.	Overcorrection or under correction of the deviation with surgery or injection	Persistence of the squint at a lesser extent or appearance of deviation in the opEOsite direction	52	71.2	9	vgence Biblio	29	79.3	9	66.7	
	SR	63.	Recurrence of deviation	Reappearance of the squint after treatment	53	66.0	9	gr <mark>77.8</mark> Phique	29	75.9	9	88.9

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	SR	64.	Induced vertical deviation	Appearance of a vertical squint after treatment of a horizontal deviation	53	69.8	8 u	04275.0 4275.0	29	82.8	9	77.8
	SR	65.	Induced A or V pattern	Appearance of a deviation that increases either on looking up or looking down	53	54.7	9 g	<b>o</b> <b>o</b> <b>6</b> 6.7	29	65.5	8	75.0
	SR	66.	Development of DVD	Appearance of a tendency for the eye to move up and out when covered	50	46.0	6 <b>f</b>	<b>⊥</b> 16.7	29	34.5	8	37.5
	SR	67.	Induced incomitance	Development of variation of the eye deviation in different EOsitions when looking around	53	56.6	7 8	¶≦ 271.4	29	62.1	7	71.4
	SR	68.	Number of operations/proce dures needed	Number of operations/procedures needed	53	66.0	related 9	on 116.7 116.7 1170 1170 116.7 116.7 1170 116.7 1170 116.7 1170 116.7 1170 116.7 1170 116.7 1170 116.7 1170	29	65.5	8	62.5
Cost	SR	69.	Economic data (in general)	Economic data (in general) including services and families/individuals	45	44.4	11 6	36.4	27	37.0	9	33.3
	SR	70.	Cost of treatment on services	Cost of treatment on services	45	46.7		2018.2	27	44.4	9	33.3
	SR	71.	Cost of treatment on families/ individuals	Cost of treatment on families/individuals	45	40.0	11 dat	led trop	26	38.5	9	22.2
_ong-term	SR	72.	Long-term outcomes	Long-term outcomes (clinical outcomes)	50	88.0	11 3		29	96.6	9	88.9
alcomes	PT PART	73.	Long term discomfort from scar tissue **	L. L.	N/A	N/A	ni.€ N/A@, ·	N/A	N/A	N/A	9	55.6
				EV.			Al training, and similar technologies.	mjopen.bmj.com/ on June 13, 2025				

## **Ocular motility disorders**

Ocular moti	ility disord	<u>ers</u>	BMJ Open			Ense by copyright, including for uses i	bmjopen-2020-042403 on 11				Page :
Domain	Source	Outcome	Lay-term summary			Ense Jses I	≤ ≥ Delphi r	esults			
					Ro	und 🖉	021		Ro	und 2	
					HCPs	s related to	Patients		HCPs	Pa	tients
		C C	r.	n	% (7-9)	nt Superieur (ABES) . o texِt and data mining, o texِt and data mining,	wnloadeo	n	% (7-9)	n	% (7-9)
Symptoms	SR	1. Patient symptoms	Symptoms or complaints related to vision or eyes	50	92.0	d da	5 88.9	29	96.6	5	100.0
	SR	2. Improvement in diplopia (in general)	Improvement in double vision in general	50	90.0	(ABE	<sup>B</sup> 100.0	29	100.0	5	100.0
	SR	3. Improvement of diplopia in primary gaze	Improvement of double vision when looking straight ahead	50	94.0	ining 8000	87.5	29	100.0	5	100.0
	SR	<ol> <li>Improvement in diplopia in primary and down gaze</li> </ol>	Improvement in double vision when looking straight ahead and down (reading position)	50	88.0	), A_l tra	6700 85.7	29	100.0	5	100.0
	SR	5. Improvement in diplopia in primary and down gaze with prisms	Improvement in double vision when looking straight ahead and down with prisms	50	86.0	ining,	75.0	29	96.6	5	100.0
	SR	6. Severity and duration of visual symptoms/eye deviation	Severity and duration of visual symptoms/eye deviation	50	78.0	ng s	77.8	29	79.3	5	100.0
	SR	7. Appearance of the eye deviation	Appearance of the eye deviation	50	74.0	nijar Ogr	<del>م</del> 33.3 <del>ک</del>	29	79.3	5	60.0
	SR	<ol> <li>Reduction in pain (for certain types of ocular motility disorders? please specify)</li> </ol>	Reduction in pain	49	75.5	techn	Ine 13, 50.0	29	89.7	4	100.0
	SR	9. Improvement in oscillopsia/blur and vertigo in adults (in nystagmus)	Improvement in oscillopsia/blur and vertigo in adults (in nystagmus)	50	92.0	-	2025 at Age	29	100.0	5	100.0
	FG	10. Improvement in headaches (for certain types of ocular motility disorders? please specify)	Improvement in headaches	50	80.0		gence Bibliographique	29	79.3	4	40.0
Visual	SR	11. Best corrected visual acuity	Vision measured at distance for one eye at a time corrected with glasses	50	60.0	7	42.9	29	69.0	5	60.0

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SR	12. Near visual acuity	Close up or reading vision	50	44.0	ոշլկս	62.5	29	48.3	5	
PO	13. Habitual visual acuity	Vision measured in the usual preferred state for a person	44	50.0	0 <u>0</u>	71.4	29	69.0	5	
PO	14. Uncorrected visual acuity	Vision without glasses or contact lenses	50	6.0	79 1	28.6	29	0.0	5	
SR	15. Binocular BCVA	Vision measured at distance with both eyes open at the same time corrected with glasses	49	57.1	May 2 Ense uses	80.0	28	71.4	5	
SR	16. Suppression	Testing if the person has developed "suppression" of one image to improve double vision which usually happens in childhood as a coping mechanism from the brain to improve visual development	50	46.0	y 2021. Downloaded f seignement Superieu s related to text_and ر المحالية	33.3	29	48.3	3	
PO	17. Fixation	Testing "fixation" which is if the person is using the central part of the retina to see with or alternatively using an eccentric part of the retina	50	32.0	loadec Superio ext₁anc	25.0	29	24.1	4	
PO	18. Contrast sensitivity	Testing "contrast sensitivity" which is objects of varying brightness Contrast sensitivity	49	6.1	l from data	33.3	28	0.0	3	
PO	19. Colour vision test (for any type of ocular motility disorder)	Colour vision test	50	8.0	n http: ABES) a minir	60.0	29	0.0	5	
PO	20. Colour vision test (for certain types of ocular motility disorders? please specify)	re.	49	36.7	1. http://bmjoper NBES) 1. mjining, Al trail	N/A	29	31.0	N/A	
PO	21. Visual field test (for certain types of ocular motility disorders? please specify)	Visual field test	48	37.5	njopen.bmj.com/ on June 13, 2025 at ≰1 training, and similar technologies ⊠	50.0	29	24.1	5	
SR	22. Broadening of the null region (in nystagmus)	Broadening of the null region (in nystagmus)	48	58.3	d sin ∂⊰in	100.0	29	69.0	4	
SR	23. Reduce the amplitude of nystagmus (in nystagmus)	Reduce the amplitude of nystagmus (in nystagmus)	48	60.4	n June nilar te	100.0	29	69.0	3	
SR	24. Stereo acuity	Fine 3D vision or depth appreciation with both eyes or "stereo vision"	50	62.0	13, 2 ¢8no		29	75.9	5	
SR	25. Field of binocular single vision	Testing the extent of area of vision where there is no double vision while looking around with both eyes open	50	70.0	2025 at ologies.	71.4	29	86.2	5	
PO	26. Post op diplopia test	Testing if a person is likely to get double vision after correcting the eye deviation with surgery	50	68.0	7 >	100.0	29	82.8	5	
SR	27. Simultaneous perception	Testing lower levels of 3D vision	50	48.0	7 Agence	42.9	29	41.4	5	
SR	28. Retinal correspondence		50	38.0	N/A Bibli		29	24.1	N/A	
SR	29. Refractive status (for any type of ocular motility disorder)	Testing the amount of prescription of glasses or contact lenses	50	46.0	6 6 6	50.0	29	37.9	5	

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	SR	30. Refractive status (for certain types of ocular motility disorders? please specify)		47	48.9	00	2	29	51.7	N/A	N/A
Culomotor Inction	SR	31. Ocular alignment / deviation	Assessing if the eyes are straight or deviated and measuring the amount of eye deviation	47	91.5	ו לקד uses	71.4	29	100.0	5	80.0
	SR	32. Abnormal head posture		47	76.6	ses i	66.7	29	89.7	5	80.0
	FG	<ol> <li>Ocular motor alignment at various positions specially where the deviation is greatest</li> </ol>	Assessing if the eyes are straight or deviated and measuring the amount of eye deviation at different positions	47	80.9	s related to	N/A	29	89.7	N/A	N/A
	SR	34. Presence of incomitance (for any type of ocular motility disorder)	Variation of angle of deviation at different positions of gaze	47	63.8	t Superie text and	66.7	29	79.3	3	66.7
	SR	35. Presence of incomitance (for certain types of ocular motility disorders? please specify)	Deer	44	72.7	eur (ABES) I data(minin N	N/A	28	75.0	N/A	N/A
	PO	36. Control of deviation (any type)	Measuring how well the person can control the eye turn	47	83.0	g A	83.3	29	89.7	5	100.0
	PO	37. Control of deviation (for certain types of ocular motility disorders? please specify)		43	83.7	I tratining, and	N/A	29	96.6	N/A	N/A
	SR	38. Ocular movement	How well eyes move as a person is looking around	47	85.1	, an	62.5	29	93.1	5	100.0
	SR	<ol> <li>Forced duction test (for any type of ocular motility disorder)</li> </ol>	A test done to check eye muscle action passively using forceps	45	31.1	d sitmilar	g N/A	29	24.1	N/A	N/A
	SR	40. Forced duction test (for certain types of ocular motility disorders? please specify)		44	65.9	N/Chn	N/A	27	66.7	N/A	N/A
	SR	41. Three step/head tilt test (for any type of ocular motility disorder)	A test to check eye deviation with head tilt and head turn in addition to the straight-ahead EOsition	44	20.5	N⁄des	005 N/A	29	10.3	N/A	N/A
	SR	42. Three step/head tilt test (for certain types of ocular motility disorders? please specify)		45	66.7	N/A	>	28	60.7	N/A	N/A
	PO	43. Presence of dissociated vertical deviation (DVD)		47	46.8	N/A	N/A	29	44.8	N/A	N/A
	SR	44. A or V pattern deviation		47	55.3	7 4	57.1	29	62.1	5	40.0

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PO	45. Fusional vergence at near and distance /fusion amplitudes/prism fusion range	Testing how well the eyes can control a deviation induced with prisms in clinic	47	53.2	ncluding for		29	62.1	4	7
SR	46. Reading eye movements (for any type of ocular motility disorders)	Checking if eye movements are normal during reading	45	22.2	T May 2021. Down Enseignement S r uses related to to Z	71.4	29	20.7	5	6
SR	47. Reading eye movements (for certain types of ocular motility disorders? please specify)		42	42.9	nement Su ated⊄o text Z	N/A	29	48.3	N/A	1
SR	48. Presence of a phoria (for any type of ocular motility disorders)	A test done to check if there is a hidden small eye alignment problem	46	54.3	aded fr perieu t and d	42.9	29	58.6	5	2
SR	49. Presence of a phoria (for certain types of ocular motility disorders? please specify)	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	41	56.1	nownloaded from http://omjopen.bmj.com/ on-June 13, 2023 at ment Superieur (ABES) . مطرة text and data reaning, ALtraining, and similar technologies. Z	N/A	28	71.4	N/A	1
SR	50. Objective extortion (for any type of ocular motility disorders)	Checking if the eye is rotated outwards due to a muscle problem (tested in clinic without the need of patient response)	43	25.6	mjope A_tra	42.9	28	25.0	5	2
SR	51. Objective extortion (for certain types of ocular motility disorders? please specify)		41	58.5	ining, an	N/A	27	66.7	N/A	
SR	52. Subjective extortion (for any type of ocular motility disorders)	Check if the eye is rotated outward due to a muscle problem (tested in clinic and results depend on patient response)	44	50.0	d șimili	42.9	28	60.7	4	2
SR	53. Subjective extortion (for certain types of ocular motility disorders? please specify)		41	73.2	ar te¢chno N	N/A	27	92.6	N/A	
SR	54. Near point of convergence (for any type of ocular motility disorders)	Testing if the eyes can normally look inwards to see a near object to an acceptable amount	47	34.0	>	•	29	34.5	5	4
SR	55. Near point of convergence (for certain types of ocular motility disorders? please specify)		41	63.4	N/A Sibil	N/A	28	78.6	N/A	ſ
SR	56. Accommodation (for any type of ocular motility disorders)	Testing if the eyes can change their focus appropriately to see objects at varying distances	46	15.2	8 8 8	62.5	29	13.8	5	6

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	SR	57.	Accommodation (for certain types of ocular motility disorders? please specify)		42	42.9	, including f		28	46.4	N/A	N/A
	SR	58.	(for certain types of ocular motility disorders? please specify)	Changing refractive power of the eye with varying focus	42	19.0	N/S E	N/A	27	37.0	N/A	N/A
	SR	59.		Testing a specific tracking slow movement of the eye for an object	45	64.4	ر 2021. Downloaded f seignement Superieu s related to text عِnd ر	42.9	28	60.7	5	40.0
	SR	60.	Saccades (for certain types of ocular motility disorders? please specify)	Testing a specific rapid tracking eye movement for an object	45	62.2	loaded fr Superieu ext And d	57.1	28	67.9	5	60.0
	SR	61.	Optokinetic nystagmus (OKN)	Special tracking eye movement using a striped drum	46	34.8	data r N/ta r	N/A	29	31.0	N/A	N/A
Additional clinical signs	SR	62.	Eye movement recordings (for certain types of ocular motility disorders? please specify)	Eye movement recordings	40	27.5	a http://bmjop ABES) . a mining, Al tra	42.9	28	32.1	5	40.0
	SR	63.	Palpebral fissure size/lid position (for certain types of ocular motility disorders? please specify)	Checking eye lid position - whether it is droopy or elevated compared to normal	44	63.6	ainiŋg, a	40.0	29	65.5	5	40.0
	SR	64.	Facial asymmetry (for 4th n palsy)	Checking if the sides of the face are symmetrical or not to help diagnose some congenital motility disorders	45	33.3	nd simili	50.0	29	20.7	4	25.0
	SR	65.	Pupil examination (for any type of ocular motility disorders)	To check pupil size; reaction etc	44	45.5	June 13 ar tech	50.0	29	41.4	5	20.0
	SR	66.	Pupil examination (for certain types of ocular motility disorders? please specify)		43	74.4	nokogies Z	N/A	29	79.3	N/A	N/A
	SR	67.	Proptosis/exophthalmos (for certain types of ocular motility disorders? please specify)	Checking if the eyes are protruding out of their position	44	79.5	Agence	75.0	29	86.2	5	60.0
	SR	68.	Intraocular pressure (for certain types of ocular motility disorders? please specify)	Check eye pressure	43	48.8	5 5 5 S S S S S S S S S S S S S S S S S	80.0	28	42.9	4	100.0

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	SR	69.	Corneal exposure (for certain types of ocular motility disorders? please specify)	Checking for corneal changes resulting from incomplete eyelid closure	42	76.2	including	<b>75.0</b>	28	96.4	5	8
	SR	70.	Corneal sensitivity (for certain types of ocular motility disorders? please specify)	Checking if corneal nerve supply is intact	39	66.7	for Uses I	75.0	28	67.9	5	1
	SR	71.	Canthal displacement (for certain types of ocular motility disorders? please specify)	Change in position of the eye contour	32	28.1	by copyright, including for uses related to text and Enseignement Superie by copyright, including for uses related to text and Z	N/A	23	21.7	N/A	
	SR	72.	Oculocardiac reflex (for certain types of ocular motility disorders? please specify)	Slowing of the heart rate due to entrapped eye muscle	28	32.1	Superieu Stand d ⊠	N/A	22	36.4	N/A	
	SR	73.	Globe dystopia (for certain types of ocular motility disorders? please specify)	Check the position of the eyeball in relation to the other eye and other parts of the face	33	39.4	r (ABES) ata_minii	60.0	22	36.4	4	
	SR	74.	Enophthalmos (for certain types of ocular motility disorders? please specify)	Checking if the eyes are sinking in from their normal position	42	66.7	ng, ⊉l tra	75.0	29	82.8	5	1
Clinical investigations	SR	75.	Assessment for fractures and soft-tissue herniation for example inferior rectus muscle; fat; or connective tissue radiographically (for certain types of ocular motility disorders? please specify)	Assessment for fractures and soft-tissue herniation for example inferior rectus muscle; fat; or connective tissue radiographically	41	87.8	ur (ABES) . data mining, Al training, and similar technologies.		29	96.6	4	
	SR	76.	Assessment for muscle atrophy or absent nerve radiographically (for certain types of ocular motility disorders? please specify)	Assessment for muscle atrophy or absent nerve radiographically	35	65.7		60.0	26	69.2	4	
	SR	77.	Histologic examination of excised tissue (for certain types of ocular motility disorders? please specify)	Histologic examination of excised tissue	26	57.7	N/A	N/A	24	75.0	N/A	
Quality of life	SR	78.	Quality of life measures (in general)	Health related quality of life (all relevant aspects)	45	82.2	8 cg	87.5	29	93.1	5	1

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	FG	79. Psychological im the disorder	pact of Negative impact of eye motility problem on emotions and/or behaviour	45	84.4	ıt, includi <b>n</b> g	100.0	29	96.6	5	100.0
	FG	80. Psychological im treatment of disc	pact of Positive impact of treatment on emotions an	nd/or 45	77.8	N/A g	N/A	29	93.1	N/A	N/A
	FG	81. Social anxiety ar social avoidance the disorder	nd Negative impact of eye motility problem on	45	77.8	forwses	100.0	29	89.7	5	100.0
	FG	82. Academic/ occup achievement in r to the condition of treatment	elation to the condition or its treatment	ion 44	72.7	s related	87.5	29	79.3	5	80.0
	FG	83. Activity of daily li (ADL)	ving Activity of daily living (ADL) such as driving	45	80.0	ents 80 te	100.0	29	93.1	5	100.0
	SR	84. Patient satisfacti treatment	on from Patient satisfaction from treatment	45	82.2	Supe	87.5	29	93.1	5	80.0
	FG	85. Future functionality/long impact	-term Future functionality/long-term impact (patient reported)	nt- 44	86.4	rieur (/ nd <sub>o</sub> data	100.0	29	96.6	5	100.0
Compliance	SR	86. Compliance	How well the treatment is done	42	54.8		71.4	29	65.5	5	80.0
Treatment dependency	PO	87. Successful discontinuation of glucocorticoids ( orbital inflammat conditions such thyroid eye disea	in conditions such as thyroid eye disease) ory as	or 34	64.7	eignement Superieur (ABES) . regated to text and data mining, AJ training, and s	66.7	25	76.0	4	50.0
	PO	88. Successful discontinuation of therapy or "spec glasses"	Successful discontinuation of lens therapy o of lens "special glasses" such as bifocals or minus		51.2	ng, <sub>4</sub> nd s	50.0	29	58.6	4	50.0
	PO	89. Successful discontinuation of therapy	Successful discontinuation of prism therapy	44	56.8	simjjar	66.7	29	69.0	3	66.7
Adverse events	SR	90. Adverse effects treatment (any)	from Adverse effects from treatment (any)	44	79.5	tech	100.0	29	82.8	5	100.0
	FG	91. Adverse effect o from patches or used to treat dip	prisms used to treat diplopia such as vision	isms 44	56.8		40.0	29	82.8	5	80.0
	PO	92. Intolerable diplor	ia Intolerable double vision	44	97.7	7: 7:	± 100.0	29	100.0	5	100.0
	PO	93. Induced ptosis (F toxin injection)	Post Appearance of transient droopy eye lid as a result of using toxin injection to treat squint		48.8	5	80.0	29	62.1	5	80.0
	PO	94. Induced subconj haemorrhage			34.1	7	<b>5</b> 7.1	28	32.1	5	80.0
	PO	95. Discomfort or ab sensation		43	39.5	7	85.7 85.7	29	48.3	5	100.0

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				4	0	9
Long-term	SR	106. Long-term outcomes	Long-term outcomes (clinical outcomes)	44	88.6	8
	FG	105. Cost of treatment on families/individuals	Cost of treatment on families/individuals	39	41.0	8
	PO	104. Cost of treatment on services	Cost of treatment on services	39	46.2	8 8 8
Cost	PO	103. Economic data (in general)	Economic data (in general) including services and families/individuals	39	48.7	
	PO	102. Number of operations needed	Number of operations/procedures needed	44	68.2	8
	PO	101. Induced incomitance	Development of variation of the eye deviation in different positions when looking around	44	56.8	6
	PO	100. Development of DVD	Appearance of a tendency for the eye to move up and out when covered	44	31.8	5
	PO	99. Induced A or V pattern	Appearance of a deviation that increases either on looking up or looking down	44	59.1	6 5
	PO	98. Induced vertical deviation	Appearance of a vertical squint after treatment of a horizontal deviation	44	63.6	5
	PO	97. Recurrence of deviation	Reappearance of the squint after treatment	44	70.5	8
	PO	96. Overcorrection or under correction of the deviation with surgery or injection	Persistence of the squint at a lesser extent or appearance of deviation in the opposite direction	44	72.7	6 6 8 5

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open.bmj.com/ on June .	87.5	50.0 <b>75.0</b>	75.0	87.5	66.7	<b>D</b> 60.0	<b>8</b> 33.3	40.0	<b>3</b> 75.0	open-2020-042403 o
29	27 29	27	27	29	29	29	29	29	29	29
30.0	48.1 <b>96.6</b>	51.9	59.3	75.9	58.6	27.6	48.3	65.5	79.3	75.9
	5	5 5	5	5	5	5	5	5	5	5
	100.0	60.0 <b>80.0</b>	100.0	80.0	60.0	40.0	40.0	40.0	100.0	60.0

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SECTION/TOPIC	ITEM	BMJ Open BMJ Open CHECKLIST ITEM	<b>REPORTED ON PAGE #</b>
	No.	ing 3 or	
TITLE/ABSTRACT			
Title	1a	Identify in the title that the paper reports the development of a COS	1
Abstract	1b	Provide a structured summary	2-3
INTRODUCTION		aner ate	
Background and	2a	Provide a structured summary       The structured summary         Describe the background and explain the rationale for developing the COS       The structured summary	3-4
objectives	2b	Describe the specific objectives with reference to developing a COS       Image: Cost of the specific objectives with reference to developing a COS         Describe the health condition(s) and population(s) covered by the COS       Image: Cost of the specific objectives with reference to developing a COS	4
Scope	3a	Describe the health condition(s) and population(s) covered by the COS	4
-	3b	Describe the intervention(s) covered by the COS	4
	3c	Describe the setting(s) in which the COS is to be applied $\overrightarrow{A}$	4
METHODS		Describe the setting(s) in which the COS is to be applied	
Protocol/Registry	4	Indicate where the COS development protocol can be accessed, if available and/og the	7
Entry		study registration details	
Participants	5	Describe the rationale for stakeholder groups involved in the COS developmest process,	5
		eligibility criteria for participants from each group and a description of how the	
		eligibility criteria for participants from each group and a description of how the individuals involved were identified	
Information sources	ба	Describe the information sources used to identify an initial list of outcomes	4-5
	6b	Describe how outcomes were dropped/combined, with reasons (if applicable)	5-6
Consensus process	7	Describe how the consensus process was undertaken	5-7
Outcome scoring	8	Describe how outcomes were scored and scores summarised	6-7
Consensus definition	9a	Describe the consensus definition	Table 1
	9b	Describe the procedure for determining how outcomes were included or excluded from	7
		consideration during the consensus process	
Ethics and consent	10	Provide a statement regarding the ethics and consent issues for the study	7
RESULTS		0 0 00	
Protocol deviations	11	Describe any changes from the protocol (if applicable), with reasons, and a describe	N/A
		what impact these changes have on the results     Og       Sector provide and the sector of th	

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Participants	12	Present data on the number and relevant characteristics of the people involved at all stages of COS development	8-9
Outcomes	13a	List all outcomes considered at the start of the consensus process $\vec{\sigma}$	Supplementary Table 1
	13b	Describe any new outcomes introduced and any outcomes dropped, with reasons during the consensus process	8-9
Core outcome set	14	List the outcomes in the final core outcome set	11 & Table 2
DISCUSSION			
Limitations	15	Discuss any limitations in the COS development process	11
Conclusions	16	Provide an interpretation of the final COS in the context of other evidence, and go of the implications for future research	12-13
OTHER INFORMATION		data n	
Funding	17	Describe sources of funding, role of funders	1
Conflicts of interest	18	Describe any conflicts of interest within the study team and how these were rearinged	1

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