Ready-made and custom-made eyeglasses in India: a cost-effectiveness analysis of a randomised controlled trial

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ABSTRACT

Objective Ready-made spectacles have been suggested as a less resource-intensive treatment for the millions of people living with uncorrected refractive error (URE) in low-income environments. In spite of this interest, there have been no published economic evaluations examining the cost-effectiveness of ready-made spectacles. This study aims to determine the relative cost-effectiveness of offering ready-made spectacles (RMS) relative to no intervention as well as the relative cost-effectiveness of custom-made spectacles (CS) relative to RMS to treat URE.

Methods and analysis The relative cost-effectiveness of RMS relative to CS and no intervention was tested through a cost-effectiveness analysis from the health service provider perspective conducted alongside a double-masked randomised controlled trial in an urban hospital in Delhi, India. Participants were adults aged 18–45 years with ≥1 dioptre (D) of URE.

Results There was no significant difference between the effectiveness of the CS and RMS interventions in improving visual acuity, but the CS was over four times the price of the RMS per patient (204 INR (US$2.42) and 792 INR (US$11.22)). The cost per unit improvement in logarithm of the minimum angle of resolution (logMAR) relative to baseline with the RMS intervention was 407 INR (US$4.35). Existing estimates of utility resulting from improvements in visual acuity result in incremental cost per quality-adjusted life years gained of between 212 INR and 1137 INR (US$0.44–US$23.74) depending on the source of the utility estimate and assumed expected life of the spectacles.

Conclusion RMS represent a significantly cost-effective option for spectacle provision in low-resource settings. The RMS programme was substantially cheaper than an equivalent CS intervention while being effective in improving visual acuity for the majority of adults with refractive error in this setting. These findings provide further support for including RMS in programmes to address URE.

Trial registration number NCT00657670 , Results.

INTRODUCTION

Uncorrected refractive error (URE) is the leading cause of vision impairment (visual acuity (VA) <6/18) globally and is the second leading cause of blindness behind cataract.[1] URE affects at least 150 million individuals between the ages of 5 and 50 years around the world, almost 31 million of whom live in

Key messages

What is already known about the subject?
► Ready-made spectacles (RMS) have been proposed as a relatively low-cost intervention to deliver spectacles in low-resource settings to treat uncorrected refractive error (URE). Yet, the use of such spectacles is not widespread, and no formal economic evaluations exist comparing RMS to traditional custom-made spectacles.

What are the new findings?
► RMS were found to be a cost-effective intervention to treat URE relative to custom-made spectacles through a cost-effectiveness analysis conducted alongside a randomised controlled trial in an urban hospital setting in New Delhi, India.

How might these results change the focus of research or clinical practice?
► These results strengthen the evidence supporting the use of RMS to treat URE, particularly in low-resource settings.

India.[1] The global economic productivity loss from URE has been estimated as $427 billion.[2] While appropriate spectacles have been shown to reduce the prevalence of refractive error-related blindness in a rural Indian population by 80%,[3] there remains a high level of unmet need across India. In the state of Andhra Pradesh, for example, almost 50% of visual impairment across all age groups can be attributed to URE, where over two-thirds of people with higher degrees of refractive error do not use spectacles.[4,5]

Programmes have been rolled out in low-income settings to provide spectacles to individuals living with URE. For a programme to successfully meet the needs of a population living with URE, spectacles need to be affordable, easily obtained, well tolerated, durable, cosmetically acceptable and improve visual function. A population-based cross-sectional study in Andhra Pradesh found 31% of adults with URE identified economic reasons as the primary barrier to accessing

refractive services.[6] To overcome cost constraints, ready-made spectacles (RMS) have been used for spectacle delivery programmes in some low-resource settings.[7–11] RMS programmes carry an inventory of lower cost new spectacles of commonly required powers, which can be provided to patients on the spot. RMS programmes have been successfully implemented in various settings for both presbyopia and myopia but have never been formally evaluated for cost-effectiveness when compared with custom-made spectacles (CS), which can provide full correction of astigmatism and anisometropia.

A recent systematic review highlighted both the relative scarcity and the importance of health economic evaluations in India.[12] Similarly, the importance of health economic research has been raised in the ophthalmology setting.[13] Health economic evidence is required to ensure that the scarce resources available to improving the health of Indians are used in the most effective way possible. The relative effectiveness of RMS and CS programmes has been shown through randomised controlled trials in children and adults.[14 15] The acceptability of RMS has been explored in this adult Indian population based on patient-reported planned continued use of RMS, visual performance and quality of life when compared with CS.[14 16] Similarly, previous research has highlighted that RMS can be obtained that are high quality and durable.[17] This paper presents a cost-effectiveness analysis from a health provider perspective of an RMS programme relative to both no intervention as well as against a CS programme. We test the hypothesis that the use of RMS is comparable with CS in visual outcomes and is a relatively cost-effective intervention per unit improvement in VA using a cost-effectiveness analysis from the health provider perspective.

METHODS

A cost-effectiveness analysis from a service provider perspective was conducted alongside a randomised controlled trial in Delhi, India. The trial was a prospective double masked randomised clinical trial of individuals aged 18–45 years recruited from an outpatient eye clinic at the Dr. Shroff's Charity Eye Hospital in Delhi in 2009.[14] Participants had at least 1 dioptre of spherical refractive error and habitual vision of 20/40 or worse in the better-seeing eye. Those recruited to the trial were randomised to receive either RMS or CS. The clinical trial was registered with the US National Institutes of Health Protocol Registration System (https://register.clinicaltrials.gov NCT00657670).

Refraction

All participants were assessed by a hospital optometrist using objective refraction by retinoscopy and subjective refraction using loose trial lenses. The spherocylindrical refractive error was converted into three Fourier coefficients using the method described by Thibos et al.[18] A spherical lens (M) and two cross-cylinders, one at axis 45° (J_{45}) and one at axis 0° (J_0), were used to describe the total refractive error as the length of the power vector ($\sqrt{M^2 + J_0^2 + J_{45}^2}$). Astigmatism was defined as 0.75 dioptres or more and high astigmatism as 2.00 dioptres or more cylindrical refractive error. Anisometropia was defined by between eye difference in refractive error ≥1.00 dioptre but less than 2.00 dioptres and high anisometropia as ≥2.00 dioptres.

The balanced spherocylindrical refraction was recorded, and the equivalent vision sphere (EVS) using the formula EVS = spherical power + cylindrical power/2. There was no cut-off for inclusion in the study. The participant chose a spectacle frame from a choice of popular frames.

An optical technician then manufactured the eyeglasses with either the full spherocylindrical correction (CS) or the EVS (RMS) per the randomisation schedule. The allocation to RMS or CS was concealed to the study participant and the optometrist. The eyeglasses were fitted and dispensed by the optical technician in a subsequent visit by the patient. Further information on the interventions and randomisation process is provided elsewhere.[14]

Costing

Where possible, costing analyses were designed and calculated based on the recommendations of the Panel on Cost-effectiveness in Health and Medicine.[19] Costs were calculated for both interventions using a health provider perspective and based on the following assumptions:

► All fixed and variable costs were estimated based on salaries and equipment costs at the Dr. Shroff's Charity Eye Hospital in Delhi, India.

► Rent costs of the rooms were estimated by attributing a portion of the rent paid for spaces needed for delivery of the intervention. It was assumed that use of the space was divided based on the number of patients seen by optometrists over a month.

► A cost of maintaining an inventory was added to the RMS intervention. This was calculated as an interest cost of 10% applied to the cost of each pair of spectacles indicating the opportunity cost of investing the cost of the spectacles up front and the costs of storing the spectacles before they are issued.

► Labour costs were estimated based on a labour time of 30 min per patient from a 40-hour work week and a 160-hour work month. Equipment costs were based on initial cost and lifespan of each piece of equipment, with a 3% depreciation cost.[19] Cost of equipment routinely involved in refraction was calculated based on an assumption of 1500 uses each year based on advice from local optometrists.

► All costs were collected in 2009 Indian rupees (INR) and have been inflated to 2016 costs using the World Bank GDP deflator index.[20] The exchange rate from June 30 2009 of 47.89 INR per American dollar (US$) was used to convert prices into US$.[21]

The cost of the CS intervention was based on provision of CS from the hospital optical shop and laboratory following spherocylindrical refraction. The costs included the labour

cost of an optometrist and an optical shop technician, with equipment costs of spectacles (including frame, lenses, manufacturing costs and delivery), retinoscope, trial lens set, trial frame, standardised logarithm of the minimum angle of resolution (logMAR) letter chart occluder and ruler.

For the RMS intervention, the costs of refractive services and spectacle provision by a trained vision technician offering RMS were estimated. A vision technician was used in the modelled costs for RMS, as this is the planned staffing for vision centres in rural locations. For the RMS intervention, costs included the labour cost of a trained vision technician, with equipment costs of one pair of ready-made spectacles, retinoscope, trial lens set, trial frame, standardised logMAR letter chart, ruler and occluder.

Visual acuity

VA measurements were taken using tumbling E-charts (Precision Vision, Villa Park, Illinois, USA) with retroillumination.[14] VA was letter scored with 0.02 logMAR assigned to each letter.

Cost-effectiveness

Incremental cost-effectiveness ratios (ICERs) were calculated for the RMS intervention relative to no intervention and for moving to a CS programme from RMS. Calculated costs were measured against improvement in VA (logMAR) at 1 month following dispensing of spectacles as a measure of relative cost per unit improvement in VA. Trial participants who required the spectacles to be remade as they could not wear them were allocated their presenting uncorrected acuity.

Incremental cost per quality-adjusted life year gained was estimated using utility estimates gained from the literature associated with improvements in VA.[22-25] Clients were also asked their willingness to pay for the spectacles, providing an estimate of the measure of benefit as assessed by the patients and potential cost recovery.

Sensitivity analysis

To test the robustness of the results, sensitivity tests were performed to examine the impact of variation of input variables on the cost-effectiveness results. Labour costs, device costs and equipment costs in each respective delivery scheme were varied at feasible ranges from the literature. The following additional scenarios were also tested:

► For spectacle costs, the costs of remakes were added to the RMS sensitivity range. Based on previous work, this was estimated as 11% of those that were originally designated to receive RMS.[14]

RESULTS
General characteristics

One hundred and eighty-three participants received the RMS intervention and 180 received the CS intervention. The two randomisation groups did not differ by age,

Table 1 General characteristics of participants in a study comparing ready-made spectacles (RMS) with custom-made spectacles (CS) in India

	RMS (n=193)	CS (n=197)
Age, mean (±SD)	30.4 (±9.3)	30.4 (±9.3)
Gender, n (% male)	82 (42.5)	83 (42.1)
Household annual income in INR, n (%)		
<60 000 (US$1500)	151 (80.3)	151 (77.8)
60 000–120 000 (US$1500–US$3000)	23 (12.2)	31 (16.0)
>120 000 (>US$3000)	14 (7.5)	12 (6.2)
Own following items, n (%)		
Television	140 (72.5)	141 (71.6)
Telephone	151 (78.2)	155 (78.7)
Bicycle	55 (28.5)	50 (25.4)
Scooter, motorcycle or moped	47 (24.4)	44 (22.3)
Car, jeep or van	12 (6.2)	4 (2.0)
None of the above	20 (10.4)	19 (9.6)
People in household		
Adults, median (IQR)	3 (2–5)	3 (2–5)
Children, median (IQR)	2 (1–4)	2 (1–3)
Married, n (%)	107 (55.4)	113 (57.4)
Education, n (%)		
Illiterate	30 (15.5)	25 (12.7)
Primary school	45 (23.3)	48 (24.4)
Secondary school	37 (19.2)	31 (15.7)
Higher secondary school	33 (17.1)	37 (18.8)
Graduate, postgraduate or professional	48 (24.9)	56 (28.4)
Occupation, n (%)		
Labourer	23 (11.9)	24 (12.2)
Office	27 (14.0)	32 (16.2)
Professional	6 (3.1)	4 (2.0)
None	91 (47.2)	101 (51.3)
Other	46 (23.8)	36 (18.3)

INR, Indian rupees.

gender or socioeconomic parameters (table 1). Vision without refractive correction was significantly impaired (~6/24), and the majority of study participants were myopic (381/390, 72%). Table 2 shows the refractive characteristics of the study population.

Vision without refractive correction was significantly impaired (~6/24), and the majority of study participants were myopic (381/390, 72%). Table 2 shows the refractive characteristics of the RMS and CS groups. Around one-third had astigmatism (125/390, 32%), mostly between 1 and 2 dioptres. Less than 10% had anisometropia (31/390, 8.9%).

Table 2 Refractive status of participants in a study comparing ready-made spectacles (RMS) to custom-made spectacles (CS) in India

	RMS (n=193)	CS (n=1937)
Uncorrected visual acuity (logMAR)	0.56 (±0.21)	0.57 (±0.21)
Equivalent vision sphere (EVS) (dioptres, power vector length)	2.22 (±1.31)	2.34 (±1.40)
Myopia EVS*, n (%)	133 (68.9)	148 (75.1)
Degree of myopia (dioptres), mean (±SD)	−2.07 (±1.27)	−2.19 (±1.44)
Maximum myopia (dioptres)	−7.50	−8.50
Hyperopia EVS*, n (%)	60 (31.1)	49 (24.9)
Degree of hyperopia (dioptres), mean (±SD)	1.68 (±1.33)	1.77 (±1.17)
Maximum hyperopia (dioptres)	8.50	5.50
Astigmatism* ≥0.75 and <2.00 dioptres, n (%)	45 (23.3)	57 (28.9)
Degree of astigmatism (dioptres), mean (±SD)	−1.16 (±0.32)	−1.07 (±0.35)
Astigmatism* ≥2.00 dioptres, n (%)	13 (6.7)	12 (6.1)
Degree of astigmatism (dioptres), mean (±SD)	−2.44 (±0.66)	−2.25 (±0.38)
Anisometropia, ≥1 and <2 dioptres difference, n (%)	10 (5.2)	12 (6.1)
Difference (dioptres), mean (±SD)	1.24 (±0.25)	1.28 (±0.25)
Anisometropia, ≥2 dioptres difference, n (%)	5 (2.6)	4 (2.0)
Difference (dioptres), mean (± SD)	2.60 (±0.41)	2.72 (±0.56)

*For the eye with lower refractive error.

Cost-effectiveness

The cost per pair of CS, including frame, lenses, manufacturing and delivery, was estimated at 700 INR (US$14.62) (table 3). Labour costs (78 INR) summed with equipment costs for CS provision resulted in a total cost of 792 INR (US$16.53) per pair of spectacles made. The cost per pair of spectacles in an inventory of RMS, including the costs of maintaining an inventory is estimated at 162 INR (US$3.38). Labour costs (28 INR) summed with equipment costs for RMS spectacle provision resulted in a total cost of 204 INR (US$4.25) per pair of spectacles.

The trial found no significant difference between the effectiveness of the two interventions. Specifically, the average improvement in VA was measured at 0.56 logMAR for CS (95% CI 0.48 to 0.64) and 0.5 logMAR for RMS (95% CI 0.38 to 0.62) relative to baseline. ICERs

Table 3 Costs of delivering either RMS or CS (2016 INR)

	RMS	CS
Labour cost		
Optometrist, 25 048 INR/month,		78.28
Vision technician, 8841 INR/month,	27.63	
Device cost		
Spectacles (includes frame, lenses, manufacture and delivery)		699.88
Ready-made spectacles and cost of maintaining inventory	147.34	
Cost of maintaining an inventory	14.73	
Equipment for eye testing		
Retinoscope, 28 732 INR, 6-year life	3.20	3.20
Trial set, 22 544 INR	1.00	1.00
Trial frame, 1915 INR	0.09	0.09
Letter chart, 21 129 INR, 10-year life	0.03	0.03
Indirect costs for infrastructure (room required to deliver the intervention)	9.21	9.21
Occluder	0.01	0.01
PD ruler	0.01	0.01
Frame warmer	0.29	0.29
Total	203.54	791.98

CS, custom-made spectacles; INR, Indian rupee; PD, pupillary distance ; RMS, ready-made spectacles.

were calculated as a ratio of cost to logMAR unit improvement in VA. The cost-effectiveness of RMS was calculated to be 364 INR (US$7.89) per logMAR unit improvement in vision relative to baseline (table 4). This equates to a cost per additional line on the chart (0.1 logMAR) of 36 INR (US$0.76) for the RMS intervention. While we set out to measure the relative cost-effectiveness of CS relative to RMS, no ICER was calculated as the CS intervention was dominated by the RMS, in that there was no significant difference in their effectiveness and the RMS was less costly to implement. The median price the participants were willing to pay for the spectacles they received was 295 INR (US$6.16), and this did not differ between the RMS and CS groups.

Sensitivity analyses confirmed the robustness of the cost-effectiveness estimates (table 5). The estimates were most sensitive to changes in the equipment cost of the spectacles provided. Allowing for CS remakes for 11% of RMS recipients resulted in an ICER of 479 INR (US$10.00) per unit of logMAR gained relative to no intervention.

Existing estimates of utility gains associated with improvements in VA[22] suggest the utility gain associated with a single pair of RMS spectacles ranged between 0.179 and 0.32 (table 6). The cost of gaining an additional

Table 4 Cost-effectiveness of RMS intervention relative to no intervention

	2016 INR
Incremental cost	203.54
Improvement in visual acuity (logMAR)	0.50
Incremental cost-effectiveness ratio	407.08

INR, Indian rupee; RMS, ready-made spectacles.

quality adjusted life year (QALY) through the interventions depended on the assumed life of the glasses. For the RMS intervention, the cost per QALY ranged from 212 INR if the glasses lasted 3 years with the highest utility calculation to 1137 INR if the spectacles only lasted 1 year and had the most conservative utility estimate.

DISCUSSION

The use of RMS is a highly cost-effective means to overcome vision loss due to URE in this population in the Indian setting. Given the magnitude of the problem across India and the relative ease of implementation of this intervention, these findings suggest that implementation of programmes using RMS could have significant benefits for the Indian population. Estimates of cost-per-QALY measures compare favourably with other interventions such as telescreening for diabetic retinopathy[26] and universal immunisation for hepatitis B[27 28] among others. The results are also consistent with other comparable studies both in India as well as other low-resource settings of interventions looking at addressing URE.[29] The sensitivity analysis demonstrated that the findings were robust across a wide range of input costs improving the potential generalisability of the results to other parts of India and perhaps even other low-resource settings with comparable input costs to India.

Our findings support investments by donors and governments to develop interventions to provide spectacles to underserved populations. In areas where costs are limiting the reach of these programmes, RMS are a clear

Table 5 Sensitivity analysis of cost-effectiveness of RMS

	Range tested	ICER result (INR 2016) – cost per unit increase in logMAR relative to no intervention
Effectiveness	±0.12	265–583
Production and equipment costs	±20%	291–437
Cost of maintaining inventory	Interest rate varied 0.05–0.15	321–373
Including the cost of CS remakes for those who find RMS unacceptable	11% of RMS recipients	479

CS, custom-made spectacles; ICER, incremental cost-effectiveness ratio; RMS, ready-made spectacles .

Table 6 Utility gains and cost per QALY results based on published evidence (INR 2016)

Utility calculation	Sharma et al[22]	Brown et al[23]		Brown et al[24]	Sharma et al[25]	
		Using time trade off method	Using standard gamble		Using time trade off method	Using standard gamble
Utility improvement based on improvements in VA (utility of improved state less initial utility)	=0.84−0.62=0.22	=0.89−0.57=0.32	=0.96−0.69=0.27	=0.97−0.76=0.21	=0.908−0.708=0.2	=0.948−0.769=0.179
Incremental cost per QALY of RMS versus no intervention (INR 2016)						
If spectacles lasted 1 year	925	754	636	969	1018	1137
If spectacles lasted 2 years*	463	377	318	485	509	569
If spectacles lasted 3 years*	308	251	212	323	339	379

*Future benefits discounted at a rate of 3% per year as recommended.[18]
INR, Indian rupee; RMS, ready-made spectacles; VA, visual acuity.

alternative and a cheaper alternative to effectively address URE. Using estimates of the prevalence of URE in India[1] and the costs of spectacle provision in this trial, it would cost approximately 6.3 billion INR (US$131.6 million) to treat the entire affected Indian population with RMS and just under 24.6 billion INR (US$513.7 million) with CS. RMS programmes could also theoretically improve the reach of programmes as patients will only have to attend the service a single time; no return visit is required to pick up the spectacles as is the case with CS. Furthermore, with the increased availability of new RMS with changeable lenses, even smaller inventories can be maintained, and each eye can receive the best sphere that would improve on the results reported here.

One important limitation of the RMS approach, however, is the need to provide CS to about 10% of the wearers. Astigmatism and anisometropia play a role in this, so intelligent prescribing guidelines could likely reduce this failure rate and CS could be used in refractions at high risk of failing with RMS. The International Agency for the Prevention of Blindness position statement on RMS recommends that RMS are suitable when there is less than 1.00 dioptres of anisometropia, astigmatism less than or equal to 0.75 dioptres and less than 0.5Δ prism.[30] In previously published analysis of this trial,[14] we found a relationship between increasing degrees of astigmatism and anisometropia and dissatisfaction with RMS; however, no clear cut-off was defined on who cannot benefit from RMS. It may be possible to use RMS as a triage process, with all patients provided with RMS in the first instance and then those who are not appropriately treated or satisfied with those spectacles then be provided with CS. Using the costs identified above, such a two-stage process would likely still be considered very cost-effective.

The willingness-to-pay of participants of 295 INR per pair of spectacles both provide an alternative measure of value of the programmes and also information about potential cost recovery for any future programmes. Given the low-resource setting in which this analysis took place, any potential cost recovery will serve to make delivering the intervention more sustainable and further highlights the case for RMS. Depending on the model of service delivery used, there are potential economic impacts for local manufacturers and entrepreneurs. Training vision technicians to deliver this intervention represents a significant area for capacity building to improve the skills and economic opportunities for local communities.

There were several limitations to this analysis. The trial was conducted in a large urban hospital very different in nature to smaller regional or rural settings. This could impact the generalisability of the results. The relative cost-effectiveness of the intervention may vary in different populations, for example, if the range of refractive errors is different across the population or where astigmatism or anisometropia are more prevalent. The main analysis of this trial did not define a cut-point for prescribing RMS in these patients, which could be investigated further in future implementation studies. Finally, there are some concerns over the acceptability of RMS among practitioners prescribing glasses that will need to be addressed for any RMS intervention to be successfully implemented. Nonetheless the findings provide, important insights on the implementation process for these interventions.

CONCLUSION

RMS were shown to be a cost-effective intervention to address URE in an urban Indian setting. The RMS intervention was similarly effective to CS, while the spectacles under this intervention were cheaper to produce and distribute, such that the RMS intervention was a significantly more cost-effective intervention to improve the vision of the population. Given the huge burden of URE across India and many lower income nations across the world, these findings suggest that RMS can be an important and cost-effective intervention to significantly improve the quality of life of millions of people around the world.

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