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Title: Economic evaluation of 'Men on the Move', a 'real world' community-based physical activity programme for men.

Authors: Liam Kelly[1], Michael Harrison[2], Noel Richardson[1], Paula Carroll[2], Tom Egan[3], Gillian Ormond[3], Steve Robertson[4]

Affiliations: [1] National Centre for Men's Health, Institute of Technology Carlow, Ireland, R93 V960.

[2] Centre for Health Behaviour Research, Waterford Institute of Technology, Ireland.

[3] Department of Business, Accountancy and Economics, Waterford Institute of Technology, Ireland.

[4]University of Sheffield, School of Nursing & Midwifery, Sheffield S10 2LA

Emails: Dr Liam Kelly; Liam.Kelly@itcarlow.ie

Dr Paula Carroll; PCarroll@wit.ie

Dr Noel Richardson; Noel.Richardson@itcarlow.ie

Dr Michael Harrison; MHarrison@wit.ie

Dr Tom Egan; TEGAN@wit.ie

Dr Gillian Ormond; gormond@wit.ie

Prof Steve Robinson; s.robertson@sheffield.ac.uk

Corresponding Author: Dr Paula Carroll; PCarroll@wit.ie

Address: Department of Sport and Exercise Science,

Waterford Institute of Technology, Cork Road, Waterford, Ireland. X91 K0EK

Telephone: +353 (0) 51 834141

Abstract (n = 242)

Background: Physical activity (PA) interventions capable of producing health benefits cost effectively are a public health priority across the Western world. 'Men on the Move' (MOM), a community-based PA intervention for men, demonstrated significant health benefits up to 52-weeks (W) post-baseline. This paper details the economic evaluation of MOM with a view to determining its cost effectiveness as a public health intervention to be rolled out nationally in Ireland.

Methods: Cost-effectiveness was determined by comparing the costs (direct and indirect) of the programme to its benefits which were captured as the impact on quality-adjusted life-years (QALYs). For the benefits, cost utility analysis was conducted by retrospectively adapting various health-related measures of participants to generate health states using Brazier et al.'s (2002) short form-6D (SF-6D) algorithm. This in turn allowed for 'utility measures' to be generated, from which QALYs were derived.

Results: Findings show MOM to be cost-effective in supporting an 'at risk' cohort of men achieve significant improvements in aerobic fitness, weight loss, and waist reduction. The total cost per participant (€125.82 for each of the 501 intervention participants), the QALYs gained (11.98 post 12W intervention, or 5.3% health improvement per participant), and estimated QALYs ratio costs of €3,723 represent cost-effective improvement when compared to known QALY guidelines.

Conclusions: The analysis shows that the cost per QALY achieved by MOM is significantly less than the existing benchmarks of £20,000 and €45,000 in the UK and Ireland respectively, demonstrating MOM to be cost-effective.

Key Words: Cost-effectiveness, Economic Evaluation, Community-based, Physical Activity, QALY

Introduction

Physical inactivity is known to increase chronic disease risk and is a significant global public health concern. Some 9% of premature deaths globally or more than 5.3 million deaths annually are directly linked to low levels of physical activity (PA) (1). Given the prevalence of inactivity and the importance of PA to health, studies have sought to investigate whether increasing PA will reduce costs of care and mortality while enhancing quality of life (2). Within a global context economic analysis estimates the cost of physical inactivity at $67.5 billion (€61.3 billion) a year in health care costs and lost productivity to the world economy (3). Ding et al. (2016) conservatively estimated that physical inactivity costed international health-care systems $53.8 billion in 2013, and noted that physical inactivity related deaths also contributed to $13.7 billion in productivity losses.

Physical inactivity is a significant factor in rising obesity levels. In Ireland 39% of the population are estimated to be overweight, with a further 23% being obese (4). Notably males are more likely to be overweight (43% males; 31% females) and obese (25% males; 22% females) than females (4) with consequent higher associated costs. In 2009 the cost of life years due to overweight and obesity totalled €853 million, of which €576 million (67.6%) accounted for male deaths (5). Efforts to target 'at risk' men with health promotion programmes have typically encountered an 'unwillingness' to engage by this group (6). However, the appeal of such programmes to men is increased when gender-specific strategies linked to community engagement are used (7,8). In times of budgetary restraint, there is a compelling case for looking at sustainable, low-cost, less resource-intensive interventions which can have a significant health impact (9). For policymakers, it is important to know if such programmes are cost-effective when allocating finite public funds. Yet there is a lack of economic evidence for PA interventions delivered in community settings (10,11). Furthermore, there is a need to objectively measure whether meeting PA guidelines translates into better quality of life (12).

Economic evaluations typically compare the incremental costs associated with a new intervention with the additional outcomes achieved. They can inform resource allocation decisions by assessing an

intervention's value for money (13). Some cost-effectiveness studies, such as Shaw et al. (2011), compare the additional costs associated with an intervention per additional unit of outcome generated by the intervention (e.g. reaching a target weight reduction); however, this does not enable comparison of interventions across different programmes and as a result, an outcome measure common to all interventions is required. One such outcome measure is 'Quality Adjusted Life Years' (QALYs) which amalgamates the impacts of interventions on both quality and quantity of life in a single, common metric thus facilitating comparisons between different health programmes as it is universally applicable (14). The QALY has been designed to capture these outcomes, and is a measure of an individual's length of life that has been adjusted for the health-related quality of that life (14). Despite being the subject of debate, QALY is still considered a cornerstone of economic analysis and aids decision making in healthcare in order to prioritise limited resources (15). The incremental benefits from programmes are assessed using measures of health related quality of life (HRQoL) which is recognised as a key indicator of treatment outcomes (15). The cost-effectiveness threshold for Ireland is currently €45,000 per QALY, but has historically varied between €20,000 and €45,000 per QALY (16). This is broadly similar to the UK threshold where the National Institute of Health and Care Excellence (NICE) set the threshold at £20,000 (17).

The aim of this paper is to conduct an economic evaluation on Men on the Move (MOM), a community-based, gender specific PA programme for adult men in Ireland. The programme was delivered amongst diverse groups of men in diverse communities aimed at improving their overall health and well-being (18).

Methods

'Men on the Move' (MOM) was the subject of a pragmatic controlled trial from September 2015 – August 2016. A total of 927 inactive men were recruited across eight Irish counties, [Intervention Group (IG), n=501; Comparison-in-waiting Group (CG), n-426]. Inclusion criteria comprised being male,

aged at least 18 years, having completed the physical activity readiness questionnaire, and having provided written consent. The comparative demographic group means were as follows; IG: age = 52.0 ± 10.7 yr, height = 174.6 ± 6.5 cm, weight = 94.2 ± 16.0 kg; CG: age = 49.3 ± 11.4 yr, height = 176.0 ± 6.6 cm, weight = 91.0 ± 15.9 kg. Local Sports Partnership's (LSPs – recreational sport providers) co-ordinated and delivered the programme which comprised of a combination of structured group exercise sessions twice weekly over a 12W period, health-related workshops (diet and well-being), a health information booklet, a 5k celebration event and a pedometer for independent PA sessions. Self-administered questionnaires combined with recorded outcome measures (weight, BMI, waist circumference and time-to-complete one mile) were used to gather data on participants at baseline, 12W, 26W and 52W post-baseline (Refer to (18) for the full protocol). The intervention targeted PA improvements (a 1 MET increase in aerobic fitness, a 5% weight reduction and a 5 cm waist reduction; refer to (12) for details on outcomes in all three of these metrics). At baseline the majority of participants were inactive (59.2%), overweight/obese (89.7%) and had at least two cardiovascular disease (CVD) risk factors (53.1%).

Incremental Costs

In line with previous research (13), the economic evaluation compared additional costs to additional benefits achieved, with an assessment of incremental costs restricted to the resources associated with providing the intervention. Direct and indirect costs incurred in the implementation of the programme for the IG over the initial 12W period, along with the additional costs relating to the maintenance of the programme from 12W to 52W are presented (Table 1). Direct costs included the marketing, recruitment, co-ordination, management and delivery of the programme. All resources required to deliver the intervention were costed according to the price paid at the start of the MOM programme (September 2015). Indirect costs are those that occurred despite not being directly assigned to the MOM programme. This included staff who although not directly employed to work on the programme or who work with LSP, did give a substantial amount of time in helping with the co-ordination and

implementation of the programme generally in the form of meetings, training, support and material development. This time data has been costed based on the proxy good method, also known as the replacement cost approach which values the time for different activities and tasks at a shadow price of a market substitute (19). In the case of the MOM programme, the market substitute price is taken as the hourly rate of a €21.44. The salary grade of €41,800 is chosen based on mid-salary entry grade for Post-Doc position in Ireland (20). These final costs are acknowledged to estimations applied after the assessment phase of the study, and thus represent a limitation to this study.

Incremental Benefits

Quality-Adjusted-Life-Years were calculated by assigning a value or weight (utility) to identified health states. Utilities are measured on a scale that ranges in value from 0 (death) to 1 (perfect health). The use of QALYs allows a measure of value for different health states to be computed and also facilitates comparisons between different health programmes as it is universally applicable (14).

Brazier et al. (2002) conducted a preference scoring study in order to generate the health state utility values needed to construct QALYs and hence conduct cost–utility analyses. In this study, a range of health related data was gathered from MOM participants to assess the programme and this data was retrospectively best-matched to the six-dimensions identified in Brazier et al.'s (2002) SF-6D study. Wong et al., (2013) has previously shown a high degree of agreement between directly measured SF-6D and SF-6D measures derived from the SF36. While this justifies the use of SF-6D in the current study, limitations exist given the fact that we retrospectively had to match MOM survey data to SF-6D. The SF-6D has a total of six-dimensions; Physical Functioning, Role Limitations, Social Functioning, Pain, Mental Health and Vitality, each one having between four and six levels, allowing for a potential 18,000 varying health states to be defined. Descriptive statistics initially collated and relevant to the six-dimensions of the SF-6D are presented in Table 2. Categories for the Physical Functioning dimension were defined based on time-to-complete 1-mile, and matched to Brazier et al.'s (2002) Physical Functioning utility weights. Role Limitations were calculated based on a composite score

average achieved for both the Physical Functioning and Mental Health categories. The Social Functioning dimension was assessed using the Berkman-Syme social network index (23) and scored according to criteria defined by Loucks *et al.* (24). Pain was categorised using self-reported health data while Mental Health was calculated based on a composite score average achieved for specific well-being questions. Mental well-being was assessed via the Warwick-Edinburgh Mental Well-being Scale (WEMWBS), which comprises 14 positively worded statements describing thoughts and feelings which are scored on a 5-point scale (25)**.** Finally, Vitality was assessed using a question relating to the spare energy levels of the participants.

The final values generated for the MOM participants from the matching of MOM data to the Short Form-6D (SF-6D) dimensions were used to create a six-digit 'health state' code that were converted into 'utility weights' using the SF-6D algorithm at each time-point (baseline, 12W, 26W and 52W). The analysis of this data commenced with a collation of these scores from both groups across the six-dimensions. It should be noted that the usable sample sizes for this analysis declined at each time-point for both groups due to non-completion of certain dimensions by some participants, and thus imputation occurred for missing data at a specific time-point. The incremental cost-effectiveness ratio (ICER) was then derived to show the additional cost for one additional QALY gained by the IG compared to the CG. This ICER ratio would be a basis for assessing the net benefit of the MOM project and could be compared to similar studies to see which represents the best resource allocation. In this case, the incremental cost ratio was calculated by dividing the incremental costs (Table 1) by QALYs (Table 3).

To account for uncertainty in the input values for cost per QALY, sensitivity analysis was conducted on the estimated cost per person and the estimated change in QALY per person using exponential and normal distributions respectively with randomly generated samples of 1,000. This probability sensitivity analysis (PSA) led to the generation of a cost-effectiveness acceptability curve which

captures this uncertainty by plotting the probability of cost-effectiveness against different threshold values (Figure 1).

Results

The estimated total incremental cost of the intervention (Table 1) was €63,035 which works out at €125.82 for each of the 501 participants in the IG. The majority of these costs were incurred during the initial 12W intervention, with relatively minor amounts at subsequent time intervals.

Results presented (Table 2), and previously published (18), show that MOM led to considerable improvements within the 12W intervention period for the IG relative to the CG. For example, there was a reduction of greater than 20% in time-to-complete one mile for the IG at 12W, compared to an insignificant reduction for the CG. Equally, there was a considerable improvement in mental health (7% increase in those reporting above average after 12W), and vitality (15% rise in those reporting that they have energy to spare). The improvements made following the initial 12W were maintained at subsequent time-points.

Findings presented show (Table 3) an average utility improvement of 0.053 (5.3% health improvement) for the IG at 12W; which translates to 11.98 additional QALYs gained (226 participants x average of 5.3% improvement in utility per person). The changes in utility values at subsequent time-points are insignificant in comparison to initial benefit achieved at 12W suggesting that the health levels achieved after 12W are subsequently maintained. The results show insignificant changes in QALYs (-0.004 utility decrease) for the CG suggesting that the utility benefits are largely confined to the IG. Quality Adjusted Life Years ratio costs were estimated at €3,723 (€44,600 ÷ 11.98) for the IG at 12W which represents a cost-effective improvement when compared to known QALY guidelines. The cost-effectiveness curve presented (Figure 1) shows that if one is willing to pay at least €4,000 per

QALY (a figure close to the estimated cost per QALY in this programme), there is a 90% chance that this programme is more effective compared to no intervention.

Discussion

Previously published results have shown MOM to improve health outcomes (26) and this study extends the assessment of the programme to demonstrate that those health outcomes are cost-effective in supporting an 'at risk' cohort of men achieve significant improvements in aerobic fitness, weight loss, and waist reduction, with improvements maintained 52W post-baseline.

The within-trial cost-effectiveness analysis demonstrated that the MOM intervention was inexpensive to deliver; the estimated total incremental cost of the intervention was €63,035 (€125.82 per participant) which is comparable to that reported by club based PA interventions for men (FFIT study (27); £205 per participant: EuroFiT (28,29) £189.50 - £267.50 per participant depending upon country). The differences in costs may be accounted for by a) club running and/or football federation costs (MOM used outdoor spaces only) and b) the inclusion of costs in the club based studies related to health service and medication use (these were £40/participant in FFIT). This analysis also indicated that MOM is more effective than no active intervention in terms of QALYs (Δ0.050 in IG v Δ 0.006 in CG up to 52W) which is keeping with that reported elsewhere (27). Estimated incremental cost effectiveness was €3,723 per QALY gained. This represents a cost-effective improvement when compared to known guidelines of €20,000 per QALY gained (16,17) and echoes that reported elsewhere (27; £13,847/QALY gained) i.e. group based PA programmes for men are a cost effective way to improve health. Sensitivity analysis (PSA) confirms that this cost-effective outcome is robust to changes in the input parameters. The change in utility scores post 12W for both groups was insignificant; i.e. the 5% in utility values rise were maintained by the IG while the average utility of those in the CG remained largely unaltered. This reinforces the findings (26) which suggest that the MOM programme delivers an immediate benefit following the 12W intervention, which is maintained

up to 52W. Findings reflected in the cost-effectiveness curve (Figure 1) can be of use to decision makers as it provides a measure of the uncertainly surrounding a resource allocation decision, and show MOM to have very high probabilities of being successful if one is willing to pay up to €10,000 per QALY which is well below costs effectiveness thresholds of €20,000 in Ireland and the UK (11).

Limitations

Due to the 'real world' nature and application of this community-based PA programme of this scale there are a number of limitations to be considered in the context of the economic evaluation presented. Firstly, indirect cost analysis did not account for healthcare utilisation, medication use, and absenteeism from work; however it did account for hours attributed by the partnership network to the design, delivery and implementation of the programme. In addition, it is also acknowledged that the incremental costs in this paper are estimations applied after the assessment phase of the study, and therefore potentially contain some degree of error.

Secondly, this study has retrospectively best matched data gathered from the MOM survey to the six dimensions in Brazier *et al.'s* SF-6D study in order to derive utility weights which enabled QALYs to be calculated. Details of this matching have been outlined in the incremental benefits section and while it is felt that the MOM data fits the 6d study very well for most of the dimensions, some dimensions such as Role Limitations do require assumptions to be made. In hindsight, further consideration at the design stage of the programme, in particular to the choice of questions included in the questionnaire used, would allow for a more thorough economic evaluation to be performed by; 1) actually use the SF-6D questionnaire and 2) incorporating healthcare utilisation, medication use, and absenteeism from work into the indirect cost analysis. While these limitations may cause some inaccuracies in the economic evaluation presented, and are acknowledged, the estimations presented are still well within cost effectiveness thresholds.

The authors would also like to acknowledge that three of the authors were involved in the development of the programme in conjunction with service providers. To mitigate against unconscious bias, two independent authors (who are not listed on any other MOM publications) with expertise in economic evaluation came on board after the completion of the study to oversee the economic analysis.

Conclusion

With due regard to the limitations highlighted, it is evident from this study that resources allocated to gender specific 'at risk' groups such as the inactive men who were targeted in this study can be very effective in terms of resource allocation. The findings from this study along with those from the health outcomes study has informed the decision of the National Health Service in Ireland to scale up the roll out of MOM nationally.

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Conflict of Interest: The authors have no conflicts of interest.

Key Points:

- To the best of this author's knowledge, this is the first study to attempt to capture the costs associated with a delivering community-based PA intervention in Ireland.
- 'Men on the Move' was shown to be cost-effective in supporting an 'at risk' cohort of men achieve significant improvements in aerobic fitness, weight loss, and waist reduction, with improvements maintained 52W post-baseline.
- Future research in this area should ensure economic analysis is integrated into the research design at the outset.

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Table 1 Costs per MOM Programme for the Intervention Group

	Item	Cost		
		Baseline - 12W	**12W-26W**	**26W-52W**
Direct Costs	LSP Co-ordinator	€3,264		
	Branding (posters, flyers, wallet cards, health information booklet)	€610		
	PA Programme (PA Coordinator)	€4,800		
	In-door venue hire	€1,280		
	Workshop Delivery	€800		
	Hosting Celebration Event	€1,600		
	Group Maintenance (Supporting existing groups of vulnerable men who cannot contribute to sustaining the programme)		€800	€915
	Equipment		€2,000	€2,285
Indirect Costs	Estimation of hours associated with planning, co-ordination, training, implementation, data collection, reflection and learning.	€32,245.76	€4,245.12	€8,190.08
Total Costs		**€44,600**	**€7,045**	**€11,390**

Key: W= week; LSP = Local Sport Partnership; PA = Physical Activity.
Note: Indirect Costs were based on Post-Doc Mid-Scale Salary for Ireland pprox €41,800 (Jan 2019) = Approx €21.44 per hour (i.e. 52 weeks / 37.5 hours per week)

Table 2 Descriptive Data for the SF-6D for participants who attended baseline and at least one other data collection time-point

	Baseline	12W	26W	52W
OUTCOME MEASURES				
Physical Measure; Time to complete 1 Mile (m:dm)				
IG (Mean ± SD)	13.58 ± 3.1	10.29 ± 2.8	10.99 ± 8.2	11.43 ± 3.0
CG Mean ± SD)	12.48 ± 3.9	12.04 ± 3.5	11.76 ± 3.8	11.78 ± 3.9
Physical Measure; 1 Mile Categories (8:00 – 12:00 minutes)				
IG (%)	29.3	44.4	45.8	51.0
CG (%)	39.1	40.6	42.9	37.3
Mental Well-being; WEMWBS – Above Average				
IG (%)	15.5	22.2	21.6	21.5
CG (%)	15.2	19.2	18.0	18.4
Social Functioning Measure; Socially Integrated				
IG (%)	38.8	39.1	42.5	41.3
CG (%)	40.8	38.9	37.3	34.8
Pain Measure; Self-Reported Health – Excellent				
IG (%)	6.1	10.1	9.9	11.1
CG (%)	4.2	6.7	6.5	8.0
Vitality; I've had energy to spare – All of the Time				
IG (%)	3.9	14.1	2.0	5.9
CG (%)	4.6	6.7	3.5	6.8

Key: W = week; SD = Standard Deviation; N = number; IG = Intervention Group; CG = Comparison-in-waiting Group; m:dm = minutes:deci-minutes; WEMWBS = Warwick-Edinburgh Mental Well-being Scale.

Table 3 Utility analysis and QALYs by group and across all time-points

Group	Time-point	N	Utility Scores			
			Baseline	**12W**	**26W**	**52W**
IG	**Baseline**	403	0.630	-	-	-
	12W	226	0.648	0.701	-	-
	26W	120	0.649	0.702	0.704	-
	52W	81	0.656	0.700	0.707	0.700
	Utility Change			0.053	0.002	-0.003
	(denotes change from BL)				(0.055)	(0.044)
	QALYs Gained			11.98	0.24	-0.57
CG	**Baseline**	322	0.664	-	-	-
	12W	211	0.666	0.662	-	-
	26W	140	0.670	0.668	0.675	-
	52W	107	0.670	0.668	0.668	0.674
	Utility Change			-0.004	0.007	0.006
	(denotes change from BL)				(0.005)	(0.004)
	QALYs Gained			-0.84	0.98	0.64
	Programme Costs			€44,600		
	Costs per QALY for IG			€3,723		

Key: N = number; BL = baseline; W = week; IG = Intervention Group; CG = Comparison-in-waiting Group; QALYs = Quality Adjusted Life Years; QALYs gained = N x Utility Change.

Figure 1 Cost-effectiveness Acceptability Curve for MOM (Threshold up to €10,000)