

# Evaluation of a Gender-Sensitive Physical Activity Programme for Inactive Men in Ireland: Protocol Paper for a Pragmatic Controlled Trial

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**Abstract** The excess burden of ill-health, mortality and premature death experienced by many men, and poorer men in particular, across the developed world has prompted calls for the development of gender sensitised health related services for men. An emergent body of evidence indicates that successful public health work with men can be accomplished when it utilises elements with which men are familiar and secure. In particular, physical activity (PA) is proven here to be a useful 'hook' to engage men. 'Men on the Move' (MoM) is a community-based PA programme designed to engage inactive men to improve their overall health and well-being. The MoM programme was delivered by practitioner partnerships in diverse communities and among diverse groups of men under 'real world' conditions to assess both its efficacy and replicability with a view to scaling-up the programme nationally for population wide impact. Establishing appropriate protocols is critical when conducting research that translates into practice, is replicable in practice and can be disseminated at a population level. The purpose of this paper is to detail the protocols used in the design, implementation and evaluation of the MoM programme. Specifically, the process of engaging men in a community based PA intervention and sustaining that engagement over the 12 weeks and the protocols used to evaluate the impact of participation in MoM on biopsychosocial health up to 52 weeks will be outlined. If the intervention proves successful, gender-sensitive community based PA interventions for men could be a promising avenue to address their health needs. These findings may be of support to both practitioners endeavouring to engage men and others engaged in translational research to ensure their research translates to meaningful action in practice.

**Keywords:** protocols, men's health, physical activity, gender sensitised, community

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## 1. Introduction

Men's health, particularly the persistence of the gap in life expectancy between men and women, remains an issue of global concern that has not received adequate attention from national governments. [1] Globally this sex-difference in life expectancy is 5yrs [1] and in Ireland it is 4.5yrs. [2] Explanations for this difference vary but, within developed countries, there is general agreement that men's higher rates of smoking, drinking, substance misuse, obesity and similar 'lifestyle' factors, all play some part in men's significantly higher rates of premature mortality. [1,3,4] It is important to note though that men are not a homogenous group and social determinants are also influential. The rates of such lifestyle factors, and related longevity, show a strong social gradient such that, compared to men in the highest occupational classes, men

from the lower occupational classes have poorer health outcomes and experience significantly higher mortality rates. [5,6] Indeed, within an Irish context, the gap between rich and poor (particularly for men) has increased in recent decades. [6]

Men are seen by some as being more reluctant to seek help for health concerns [7] or often described as 'hard to reach'. [8] However, successful public health work with men can be accomplished providing the approach ensures aspects of gender-sensitivity. [9] For example, evaluation of a programme to promote physical activity (PA) and health through sixteen Premier League football clubs in England showed positive results on a range of lifestyle indicators [10] and the Football Fans in Training (FFIT) programme in Scotland provided the first Randomised Controlled Trial of a sporting intervention for weight loss and lifestyle change in men demonstrating positive results. [11] Such programmes show that utilising elements of what men are familiar and secure with aids successful

engagement. [12] In particular, the use of PA in these interventions suggests that PA is a useful ‘hook’ to engage men in public health interventions.

In Ireland, men’s health has been recognised as an issue of policy concern. [13] Indeed, the publication of a National Men’s Health Policy in 2008 [14] marked the first attempt by a national government anywhere in the world to target men as a specific population group for the strategic planning of health. The recent publication of a follow-up National Men’s Health Action Plan [2] is evidence of Ireland’s ongoing policy commitment to men’s health. Underpinning its approach to policy implementation, has been an explicit focus on gender-specific strategies related to community engagement, capacity building, partnership and sustainability. One example of this approach is ‘Men on the Move’ (MoM); a community-based PA programme designed to engage inactive men and to improve their overall health and well-being. The MoM programme was delivered by practitioner partnerships in diverse communities and among diverse groups of men under ‘real world’ conditions to assess both its efficacy and replicability. [15,16,17] If the MoM intervention proves successful, plans for scaling-up the programme nationally for population wide impact may follow. Up-scaling an intervention improves reach (population and geographical access) and equitable access to the intervention and its benefits. [18] Too frequently, however, sound, evidenced-based public health interventions fail to move beyond ‘efficacy testing’. Hence research on large, up-scaled programmes is limited in public health literature and, to the best of the authors’ knowledge, there is no published evidence of such research in Ireland. This represents a significant evidence gap as the implementation of population-based intervention programmes in the ‘real world’ face far greater challenges than the implementation of small efficacy trials that are controllable. [19] Establishing appropriate protocols is critical when conducting research that translates into practice, is replicable in practice and can be disseminated at a population level. The purpose of this paper is to detail the protocols used in the design, implementation and evaluation of the MoM programme. Specifically, the process of engaging men in a community based PA intervention and sustaining that engagement over the 12 weeks and the methods used to evaluate the impact of participation in MoM on biopsychosocial health up to 52 weeks will be outlined. Detailing these protocols may support others engaged in translational research to ensure that their research translates into meaningful outcomes in practice under ‘real world’ conditions.

## 2. Methods

A partnership network consisting of thirteen organisations representing PA practitioners (Local Sports Partnership; LSP), men’s health promotion specialists, a national health charity, the national health service and academics oversaw the design and implementation of the programme and research study. All decisions regarding both the study design and the programme design and implementation were focused on what would work feasibly in practice.

### 2.1. Programme Design and Implementation

The MoM programme was originally conceived by one LSP and was adapted for delivery by a second LSP. The evaluation findings from both programmes coupled with those from published literature of similar programmes elsewhere [11,20,21] and considerable reflective practice by practitioners, formed the evidence base for the current MoM programme design (see Table 1 - online supporting information). In brief, the MoM programme is a free, 12-week community based ‘beginners’ PA programme for inactive adult men that aims to improve the overall health and well-being of participants. It consists of structured group exercise twice a week, two facilitated experiential workshops, a 24-page health information booklet, a pedometer for independent PA sessions, weekly phone contact, a customised wallet card to record measures taken and a 5km celebration event at the end. The core components of the structured group exercise are cardiovascular fitness and strength and conditioning training; however, in keeping with good practice, some flexibility is catered for between programmes to ensure that these core components are achieved in a way that best suits the participants’ needs. Social cognitive theory (SCT) is one of the leading behaviour change theories to explain and predict PA in the general population and underpinned the MoM intervention; specifically, components were incorporated to develop self-efficacy (i.e. confidence to perform PA), to focus on outcome expectancies (i.e. positive outcomes weighed against any negative outcomes), to develop skills (e.g. goal setting and problem solving) and to build social support. [20] The programme was gender-sensitised in relation to context (e.g. men only groups, community based settings that appealed to men), content (e.g. information presented in a scientific manner, use of ‘gadgets’) and style of delivery (e.g. participative and peer-supported, use of humour and banter). [11] All staff involved in MoM attended ENGAGE training; ENGAGE, Ireland’s national men’s health training, is a one-day comprehensive training that aims to develop gender competency in the provision of health services for men. [22,23] MoM was delivered by experienced PA Coordinators who were specifically recruited and counselled with respect to the nuances of the programme and of working with male participants. The key qualities sought in recruiting PA Co-ordinators were their capacity to relate to and empathise with the participants as well as their capacity to create a positive group dynamic.

Locally, the delivery of the MoM programme was the responsibility of the LSPs; they oversaw the recruitment strategy, contracted local PA Coordinators and worked closely with them to oversee the day-to-day delivery of the programme. The recruitment strategy was comprehensive. LSP Co-ordinators partnered a variety of existing services in each community that could potentially host the MoM programme e.g. men’s sheds, sports clubs, community development projects. In some instances, local stakeholders from health promotion and primary care services supported the recruitment strategy and programme delivery. Service providers in each community adopted a variety of recruitment strategies including: in-person invitations; invitation via text and

email databases of service users; informing women's groups (as women are often gatekeepers to healthcare for the men in their lives); advertising of branded materials within the service and on the service website and social media. In some counties, GPs were informed of the programme in their locality and were encouraged to refer inactive male patients. These strategies were coupled with a local media campaign (print and radio) and advertisement on the local LSP website and social media sites. Men were invited to contact their local service provider or LSP Co-ordinator for further details of the programme and all men who expressed an interest in becoming more active were invited to register for the programme at a formal registration evening one week before the commencement of the programme. The LSP

Co-ordinator and, on average, six service providers, were present at the registration evenings.

The format of the registration evenings was standardised across sites: men were welcomed by the LSP Co-ordinator and local service providers. This was followed by an input from a local medical professional who spoke about the benefits of PA after which men were invited to have their baseline assessments done. Teas and coffees were provided and service providers sought out opportunities to speak to all men in person. Registration evenings were completed within 2 weeks (4<sup>th</sup> session) across all sites allowing for 88% attendance i.e. 21 out of 24 sessions. The programme was delivered from September – December 2015 and marketing began in earnest in August 2015.

**Table 1. An overview of intervention components, frequencies, behaviour change and gender sensitivity strategies, and targeted constructs (adapted from Andersen et al., 2012 [20])**

Intervention Component	Frequency	Description	Behaviour Change Strategy	Gender Sensitivity Strategy	Targeted Construct
Structured Group Exercise	60 min twice a week	Participants were invited to participate in their local community. Exercise sessions were led by a qualified PA co-ordinator and the programme was designed as an 'entrant programme' for those wishing to become physically active. Each session included approx. 40 mins of cardiovascular fitness and 20 mins of strength and conditioning. Men were encouraged to work at their own pace and to engage in independent sessions outside of the programme with their peers.	<ul style="list-style-type: none"> <li>• Provide opportunities for PA</li> <li>• Increase social support for PA</li> <li>• Promote mastery learning through skill training</li> <li>• Improve knowledge and skill to perform PA</li> <li>• Promote positive outcomes for PA</li> </ul>	<ul style="list-style-type: none"> <li>• Training in gender competency for PA co-ordinator</li> <li>• All male groups</li> <li>• Participative programme</li> <li>• Peer-supported (encourage male banter)</li> <li>• Accessible venue</li> <li>• Accessible time</li> <li>• Relating programme content to men's lives</li> <li>• Use of appropriate language</li> </ul>	<ul style="list-style-type: none"> <li>• Environment</li> <li>• Expectancies</li> <li>• Self-efficacy</li> </ul>
Experiential Workshops	2*1 hour	Two experiential workshops were delivered and were entitled: <ul style="list-style-type: none"> <li>• 'Diet'. This was developed and delivered by National Health Service dietician.</li> <li>• 'Well-being' with a focus on mental fitness and stress. Developed by National Health Service by a suicide resource officer and delivered by suicide resource officers, community mental health office or ENGAGE trainers.</li> </ul>	<ul style="list-style-type: none"> <li>• Improve knowledge of a 'heathy diet' for health and well-being and capacity to do PA and manage weight</li> <li>• Improve knowledge of healthy alcohol consumption and relation to capacity to do PA and manage weight</li> <li>• Improve knowledge of how to improve mental fitness and relationship of same with PA</li> <li>• Increase social support</li> </ul>	<ul style="list-style-type: none"> <li>• Training in gender competency for workshop facilitators</li> <li>• Use of experiential methodologies whereby men were supported to reflect on the context of their own lives as a basis from which to set and achieve goals</li> <li>• Use of tangible examples for demonstrations</li> </ul>	<ul style="list-style-type: none"> <li>• Social support</li> <li>• Self-efficacy</li> <li>• Expectancies</li> </ul>
Information Booklet	Given to all participants week 1	Provides information on PA, diet, stress management, a PA log book and useful numbers for referral	<ul style="list-style-type: none"> <li>• Improve knowledge and skill to perform PA</li> <li>• Provide tracking mechanism for PA behaviour</li> </ul>	<ul style="list-style-type: none"> <li>• Imagery and language of booklet</li> <li>• Log book provided tangible feedback that was both informative and appealed to their competitive nature to try to better their score</li> </ul>	<ul style="list-style-type: none"> <li>• Expectancies</li> <li>• Self-efficacy</li> </ul>
Pedometer	Given to all participants week 1	Pedometers given to all men to support them to do PA independently twice weekly. These 'gadgets' can be used to set weekly targets and also give feedback to men as an educational component to the programme.	<ul style="list-style-type: none"> <li>• Improve knowledge and skill to perform PA</li> <li>• Promote positive outcomes for PA</li> </ul>	<ul style="list-style-type: none"> <li>• Reflecting men's preferences for 'gadgets' seeing how things work and acting as a motivational tool for men to engage in PA (goal setting and feedback on behaviour)</li> <li>• Competition re trying to better their score (self-monitoring)</li> </ul>	<ul style="list-style-type: none"> <li>• Expectancies</li> <li>• Self-efficacy</li> </ul>
Phone Call/ Text Message	Weekly	Men received a personalised contact weekly from the PA Co-ordinator or the LSP Co-ordinator. These contacts encouraged men to attend the sessions, praised their achievement to date and on occasion were a support for some men who wanted to talk.	<ul style="list-style-type: none"> <li>• Provide feedback on PA behaviour</li> <li>• Reinforce problem solving for PA</li> <li>• Provide encouragement and help</li> <li>• Provide social support</li> </ul>	<ul style="list-style-type: none"> <li>• Regular human interaction can be important to support men to sustain engagement.</li> <li>• Social isolation is a reality for many men and the contact offered a connection for them to their community.</li> </ul>	<ul style="list-style-type: none"> <li>• Social support</li> <li>• Self-efficacy</li> </ul>
Measurements & Wallet Card	Start and end of programme	Objectives measures [time to complete one mile, BMI, weight and waist circumference] were measured and results were given to the men in a personalised wallet card.	<ul style="list-style-type: none"> <li>• Improve knowledge of health and wellbeing and impact of PA on measures</li> <li>• Promote positive outcomes for PA</li> <li>• Increase social support as measures taken collectively</li> </ul>	<ul style="list-style-type: none"> <li>• Training in taking measures for all service providers</li> <li>• Relating the results given to men's health, wellbeing and their lives</li> <li>• Use of appropriate language (science of PA and weight management)</li> </ul>	<ul style="list-style-type: none"> <li>• Expectancies</li> <li>• Social support</li> </ul>
Celebration Event	Once off	A 5Km fun walk/run event in each county for participants and their families. The three MoM groups in each county come together for this event.	<ul style="list-style-type: none"> <li>• Provide opportunities for PA</li> <li>• Increase social support for PA</li> <li>• Promote positive outcomes for PA</li> </ul>	<ul style="list-style-type: none"> <li>• Provided motivation by having something to strive towards (goal setting and feedback on behaviour)</li> <li>• Competition between MoM groups</li> <li>• Self-monitoring</li> </ul>	<ul style="list-style-type: none"> <li>• Expectancies</li> <li>• Self-efficacy</li> </ul>

## 2.2. Research Design and Participants

Both the research design and the protocols used to evaluate the impact of the MoM programme on biopsychosocial health up to 52 weeks were developed by the partnership network to ensure their feasibility in practice.

## 2.3. Research Design

The research design used to evaluate the impact of the MoM programme was a pragmatic controlled trial. This design was chosen over the preferred randomised controlled trial for a number of reasons. Notably, a number of LSPs were involved in the study's conception and funding award and therefore were automatically included in the study. Thereafter, LSPs were selected for the study on the basis of a) having sufficient staff numbers to meet the commitment of the study, b) being committed and enthusiastic about MoM and c) conducting research on their practice. Group randomisation did not occur between LSPs; group allocation was determined by the point at which the LSP committed to the project i.e. the first in were assigned the intervention group. In total eight LSPs were included in the study; 4 in the intervention group and 4 in the 'comparison in waiting group' that acted as a control. Each LSP was set a target of recruiting 104 men across 3 community settings in their county. Randomisation at an individual level was not conducted within community settings because contamination was a major risk, especially in rural Ireland. We recognise the limitation of non-randomisation but also assert that the decision regarding LSP group assignment may be a natural occurrence in action-based research with multiple 'practitioner partners' involved. The group dynamic within the network of partners was critical to the success of the study. The research team therefore decided to accept the limitation of non-randomisation to safeguard against the potentially more negative impact that randomisation would likely have on the group dynamic within the network of partners and consequently the integrity of programme delivery.

An experimental mixed methods approach was used to ascertain the following:

- a) The impact of the programme on the biopsychosocial health of the participants up to 52 weeks.
- b) The broader impact of the programme on the health and well-being of the participants and their significant others.
- c) The process of designing and implementing a community based PA intervention for inactive men.

## 2.4. Ethics, Consent and Inclusion

Ethical approval for the study was sought and obtained from the ethics committees at Waterford Institute of Technology [15/Dept-HSES/13]. This study has been registered with the 'International Standard Randomised Controlled Trial Number' registry [ISRCTN55654777]. Written informed consent was provided by all study participants. It was agreed that men were eligible for inclusion in the study if they were aged at least 18 years,

did not meet the recommended physical activity guidelines, completed the physical activity readiness questionnaire (PAR-Q) and provided written consent. Answering 'yes' to any item on the PAR-Q did not warrant inevitable exclusion from the programme or study; as per the FFIT trial [11], men were advised to discuss any issues arising from PAR-Qs either with their own GP or with a medical professional who was present at registration evenings. In keeping with good practice, all PAR-Qs were given to PA Co-ordinators so that they could adapt the programme to meet the particular needs of men. The partnership network felt it was unethical to exclude any man who attended at registration and who fitted the criteria for inclusion but did not provide consent for the study. It was believed that their attendance was indicative of a health need and that to prioritise the research (i.e. sample size number) over the health needs of a man was unethical; 2 men did not provide consent and were not included in the analysis.

## 2.5. Sample Size Estimates and Study Participant Numbers

Sample size calculations were undertaken to power for a 1 MET (aerobic fitness), 5% bodyweight and 5 cm waist circumference between group difference in the baseline to 52-week change scores. The sample size requirement estimate was greatest for weight loss. Using similar assumptions to the FFIT trial [11], the 5% between group difference in percentage weight loss at 12 months was estimated to require 250 participants in each group (80% power, two-sided test,  $p=0.05$ ). The minimum sample size was increased to 830 to allow for 40% attrition. A greater attrition rate at 12 months was predicted compared to the FFIT study, as all testing was conducted in community settings at specified times. A total of 906 men entered the study at baseline [ $n=489$ , intervention group;  $n=417$ , comparison group in waiting].

## 2.6. Data Collection Instruments

All data collection instrumentation and processes for data collection were the subject of considerable discussion at partnership network meetings; data collection instruments were reviewed by LSP staff and the research team and revised, as in other community based evaluations [24,25], with a view to optimising acceptability to clients engaged in the MoM programme and service providers involved in data collection.

The protocols used for the data collection completed to date along with the data analysis to be completed will be presented here for all quantitative and qualitative data.

## 2.7. Quantitative Outcomes

Quantitative measures were obtained at baseline, 12 weeks (12W), 26 weeks (26W) and 52 weeks (52W) to investigate the impact of the programme on the health and well-being of participants. All frontline staff involved in the MoM programme were trained in data collection procedures to ensure standardised measurement and questionnaire administration across sites. All LSP Co-ordinators were provided with a comprehensive

'procedures manual' for managing the registration evening, data collection and submission for analysis as well as a custom made video detailing the correct procedure for measuring weight, height and waist circumference. In order to safeguard against inter-tester errors, the same personnel conducted weight, height and waist circumference measures across sites. To maximise retention at 12W, 26W and 52W, men were telephoned by the LSP Co-ordinator, sent an email (if available) and/or a text reminder in the days before data collection. Members of the research team supported the data collection across all sites and independently analysed all data.

Self-reported outcomes were recorded via self-administered questionnaires. At baseline, participant demographics (date of birth, ethnic origin, educational attainment, relationship, housing and employment status) and how participants had heard about the programme was recorded. At all-time points, self-reported measures addressed adapted versions of lifestyle behaviours including PA, consumption of fruit and vegetables, smoking, consumption of alcohol, use of primary care services and prescription medicine, perception of health and workplace capacity. Service providers were on hand to assist any man who needed help to complete the questionnaire due to literacy issues and to check questionnaires before participant left registration to minimise missing data.

The three key outcome measures for this study were changes in aerobic fitness, percentage bodyweight and waist circumference. Aerobic fitness was computed using the time to do 1-mile [mins: decimal mins] as per Daniel and Gilbert (see below). [26]

$$VO_{2\max} = \frac{0.000104v^2 + 0.182258v - 4.6}{\left( \begin{array}{l} 0.2989558e - 0.1932605t \\ +0.1894393e - 0.012778t + 0.8 \end{array} \right)}$$

v = velocity in meters per minute; t = time in minutes

The 1 mile route was measured using a Trumeter 5500E trundle wheel, with times recorded using a digital timer. Weight (kg) was measured using a Seca 813 electronic weighting scales with participants wearing light clothing, no shoes and with empty pockets. Waist circumference was measured using a standard Irish Heart Foundation tape measure. Body mass index ( $\text{kg}/\text{m}^2$ ) was measured using weight and height measurements. Height (cm) was measured without shoes using a portable Seca 213 stadiometer. All equipment was calibrated prior to commencing fieldwork.

Mental well-being was assessed at all time points via the Warwick-Edinburgh Mental Well-being Scale (WEMWBS). WEMWBS provides a psychometrically sound tool for measuring mental wellbeing at a population level and comprises 14 positively worded statements describing thoughts and feelings relating to aspects of mental wellbeing that are scored on a 5-point scale. The minimum score possible from the scale is 14 while the maximum is 70. The higher a person's score is, the better their mental wellbeing. Inferential statistical analysis will be undertaken on the between group change scores from baseline across all timepoints whereby meaningful change will be interpreted as per Putz et al., [27] i.e.  $\geq +3$  above equates to a meaningful improvement and  $\geq -3$  equates to a meaningful dis-improvement in mental well-being respectfully.

Social well-being was assessed via the Berkman-Syme social network index [28] and scored according to Loucks et al. [29] The index was scored as follows: Married (no=0; yes=1); close friends and relatives (0–2 friends and 0–2 relatives=0; all other scores=1); group participation (no=0; yes=1); participation in religious meetings or services (less than or equal to every few months=0; greater than or equal to once or twice a month=1). Scores were summed: 0 or 1 being the most isolated category (socially isolated; SI); and 2 (moderately isolated; MI), 3 (moderately integrated; MIn) or 4 or 5 (Socially Integrated; SIn) formed the other three categories of increasing social connectedness.

## 2.8. Qualitative Data: Impact Measures

Qualitative data were collected from both participants and their significant others (SOs) to ascertain the men's experience of the programme, its broader impact on their health and well-being and any ripple effects of the programme on the lives of their SOs. In order to be considered eligible for inclusion, participants were required to have had attended  $\geq 50\%$  of programme (n=340), had the ability to participate in an English language interview, and been identified by LSP or PA Co-ordinators as having actively engaged with the programme. Eligible participants identified by LSP or PA Co-ordinators as having actively engaged with the programme were contacted by their respective PA Co-ordinators who sought their consent to participate in this aspect of the study. Those who consented to be interviewed were then contacted by the researcher. Men were asked to identify SOs (spouses, partners or close family members) to take part in an interview. These were typically individuals who would have been well placed to observe (i) changes in the men attributable to the programme, and/or (ii) an impact on themselves through their acquaintance with a programme participant.

The approach was broadly interpretivist in nature and supported by a thematic analysis of the data. Thirty two interviews (7-60 mins) and one focus group (27 mins) were conducted with MoM participants (n=39). Thirty interviews and the focus group were in-person (n=37) and two interviews were conducted via telephone. The men in the focus group asked to be interviewed together on the basis that they had experienced the MoM journey together and wanted to contribute to the research process as a collective unit. Fourteen interviews were conducted with SOs (8-50 mins); 3 in-person and the majority (n=11) via telephone. All data were recorded on a Sony ICD-SX733D Dictaphone and transcribed verbatim.

## 2.9. Qualitative Data: Process Measures

A qualitative, process evaluation was conducted between weeks 6 and 9 of the programme to investigate the factors that contributed to men's a) engagement in the registration evening for the MoM programme (intervention group) and the initial health check (comparison in waiting group) and b) sustained engagement over the 12 weeks of the MoM programme. LSP coordinators and their team of community practitioners involved in the study in all eight counties

(n = 49) participated either in a focus group (n=12; 11-96 mins) or a semi-structured interview (n=1; 24 mins). The topic guide was based upon a conceptual framework for sustaining community-based health promotion interventions [30] and investigated: project design and implementation factors; factors within the organisational setting; factors within the broader community environment. All data were recorded on a Sony ICD-SX733D Dictaphone and transcribed verbatim.

## 2.10. Approach to Data Analysis

With respect to aerobic fitness, bodyweight, waist circumference and mental well-being and social integration, the intervention effect will be determined by comparing the between group change scores from baseline at 12W, 26W and 52W. A non-parametric analysis will be undertaken on social integration. Non-normal values for the other variables will be log-transformed prior to analysis. Significance will be set at  $p=0.05$ .

Imputation for missing data will not be applied during data analysis due to the attrition rate predicted and the likelihood that missing data will not be at random. Rather, two analysis methods will be applied in the calculation of

percentage success rates for the key outcome variables. The intervention effects will be assessed at 12W, 26W and 52W (a) based only on those who presented for retesting at these timepoints but separately (b) assuming a worst-case scenario for absentees i.e. that absentees failed to achieve the aerobic fitness, bodyweight reduction or waist reduction target. These worst-case scenario analyses will reflect the intention to treat principle. Specifically, the intervention targeted a 1 MET increase in aerobic fitness, 5% reduction in bodyweight and 5 cm reduction in waist circumference. The numbers who achieved those targets at 12W, 26W and 52W will be presented as a percentage of those who were tested at these timepoints. For the initial intervention effect worst-case scenario, the numbers who achieved the specified targets at 12W will be presented as a percentage of those who were tested at baseline. The worst-case scenario for maintenance of this initial intervention effect will present the numbers who achieved the specified targets at 26W and 52W as a percentage of those who completed stage 1 of the study and were tested at the 12W timepoint. Observed success rates will be compared between the intervention and comparison group in waiting using Chi-Square analysis.

Table 2. A framework for conceptualising program sustainability (adapted from Ammerman (2002) [39])

Sustainability Planning Guide	Elements of the MoM Intervention Designed to Foster Sustainability
<b>PROGRAMME DESIGN AND IMPLEMENTATION FACTORS</b>	
Negotiation process for developing the MoM model	The MoM model of delivery was designed via extensive input from Local Sports Partnerships (LSP) with practical experience of delivering such programs to men. Flexibility was also accommodated to meet the specific needs of local communities. Furthermore, the workshops were designed collaboratively between a Health Service Executive (HSE) Senior Dietician (Diet) a Resource Officer for Suicide Prevention (Well-being) and a men's health practitioner researcher.
Evidence of effective practice underpinning the MoM model	The program model was developed via negotiation with service providers and based upon practical experience as well as lessons from RCTs and practice elsewhere. Therefore, all partners shared ownership of the program and were invested in its success. The model was underpinned by both a behaviour change strategy as well as a gender sensitive strategy (see Table 1). The development of the MoM brand i.e. the title, strapline, use of imagery and language for all branded and promotional materials, as well as the marketing strategy was also evidence based. The selection of PA Co-ordinators was also given a lot of consideration given their central role in facilitating the group dynamic.
MoM model type	The focus of the program was preventative v curative, which necessitates a long-term approach to foster sustainability. Essentially, the program has a holistic focus that went beyond the promotion of PA and increasing the level of PA among the participants
Cost of Delivery	The model was designed to require minimal funding by integrating services and using local facilities. Research related study costs were clearly separated from operational costs.
Training	All front line staff were trained in both ENGAGE, the national men's health training program and in data collection. Data collection by practitioners was a key part of forming relationships with men that supported their engagement in the program.
<b>FACTORS WITHIN THE ORGANISATIONAL SETTING</b>	
Institutionalization strength:	Key local organisations, linked via a national structure were selected based upon their experience of the program or their desire to become involved.
Integration with existing services	The program was co-ordinated locally via Local Sports Partnerships, an existing service provider with considerable links and networks in their localities. The delivery of the workshops was integrated into business plans of HSE staff which represents joined up service provision.
Programme Champion/Leader	Locally, leadership of the program came from the LSP Co-ordinators who had a remit to meet the objectives of the program and research project.
<b>FACTORS WITHIN THE BROADER COMMUNITY ENVIRONMENT</b>	
Social and political considerations	While LSPs have a remit for increasing PA levels, few had experience of working with men as a priority population. Given their critical role, LSPs are well positioned to engage men via PA and all embraced this role.
Community participation	LSP Co-ordinators partnered a variety of existing services in each community that could potentially host the MoM program and community champions were identified. All programs were located in existing community organisations/services/facilities. Many local organisations/services had previously struggled to work with men and were looking for something that they could bring to their organization to stimulate engagement. MoM also acted as a mechanism to link men with other services/facilities in their community.

In relation to the qualitative interviews (impact measures), initially, 10 participants' transcripts will be independently coded by the interviewer and two other research team members to develop a list of codes and emerging key concepts. These codes will be further developed (expanded and collapsed) using constant comparative analysis resulting in a 'master' code list. All codes will then be unified around relevant core categories. These categories will then be built into a thematic framework that will be used for the analysis of all further transcripts (n=22) to ensure consistent analysis. Any data not fitting the framework will be accounted for and existing categories, and/or the overall framework, amended to incorporate this data. Throughout this process the emphasis will be on both semantic (surface) and latent (interpretive) level analysis. [31] The analysis of SO interviews will follow the same format.

The qualitative process evaluation is underpinned by a process of abductive reasoning which will also be adopted for the analysis of this stage. Deductive elements involve the application of predetermined codes that will test the model developed for the implementation of MoM (see Table 2 – online supporting information). This model was based upon the conceptual framework defined by Shediac-Rizkallah and Bone (1998) [30]. Initial coding will therefore be done into the framework derived from this conceptual model. Inductive elements will then be applied by undertaking further analysis within each area of the framework. This aspect, as with the analysis outlined above, will follow the process outlined by Braun & Clarke (2006) [31] and will focus on both the semantic and latent levels. Analysis will be conducted primarily by two researchers; two other researchers will independently analyse a selection of data to provide a degree of inter-rater reliability.

### 3. Discussion

The excess burden of ill-health, mortality and premature death experienced by many men, and poorer men in particular, across the developed world [3,32], has prompted calls for the development of gender sensitised health related services for men [3,14,33]. In recent years, a body of evidence has emerged that identifies effective gender sensitive strategies to engage men in public health interventions that include; a) the use of community settings [8] or sports clubs [10,11] as opposed to healthcare settings (Robertson et al., 2014), b) including family and friends [36], c) adopting strengths-based approaches that revolve around creating safety, trust, rapport, and meaningful relationships with men [35] d) using strong, positive messages that encourage men to engage with services without amplifying shame or blame, e) connecting positive masculine identities with being healthy and productive, f) reflecting the wishes of men to maintain control and to engage with services on their own terms and in their 'own way', g) sharing men's stories to show common challenges, to foster peer-support and to create a community of mutual help. [9,37,38] The use of PA has also been proved to be a useful 'hook' to engage many men in public health interventions. [11,12] These strategies have been integrated into the MoM programme

to maximise the engagement of, and consequently benefit to, the men who participated.

This paper details the protocols used in the design, implementation and evaluation of the MoM programme. Notably, the programme was delivered by practitioners under 'real world' conditions and both the efficacy and replicability of the programme was evaluated with a view to national scale-up for population wide impact should the MoM intervention prove successful. [15,16,17] In general, however, the implementation of population-based intervention programmes in the 'real world' face far greater challenges than the implementation of small efficacy trials that are controllable. [19] Consequently, too often, sound, evidenced-based public health interventions fail to move beyond 'efficacy testing' and are not translated into practice. And yet, the wide scale dissemination of effective public health interventions is necessary to improve population health outcomes. Therefore, it is critical that appropriate protocols are established when conducting practitioner based research in the 'real world' so that effective research can be translated into practice to produce meaningful public health outcomes at a population level. By detailing the protocols established for the MoM programme in this paper, if the intervention proves successful, gender-sensitive community based PA interventions for men could be a promising avenue to address their health needs. These findings may be of support to both practitioners endeavouring to engage men and others engaged in translational research to ensure their research translates to meaningful action in practice.

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### Statement of Competing Interests

The authors have no competing interests.

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