

STUDY PROTOCOL

Open Access



# An eHealth intervention (ManGuard) to reduce cardiovascular disease risk in male taxi drivers: protocol for a feasibility randomised controlled trial

James McMahon<sup>1\*</sup> , David R. Thompson<sup>1</sup>, Kevin Brazil<sup>1</sup> and Chantal F. Ski<sup>1,2</sup>

## Abstract

**Background:** Men are at higher risk than women of developing cardiovascular disease (CVD), and male taxi drivers are a particularly high-risk group because of their typically unhealthy behaviours, such as poor eating habits, smoking and sedentary lifestyle. However, only two studies of behavioural interventions targeting taxi drivers have been identified, one of which reported a high attrition rate. Therefore, an eHealth intervention co-designed by taxi drivers may prove more acceptable and effective. The aim of this study is to assess the feasibility of an eHealth intervention (ManGuard) to reduce CVD risk in male taxi drivers.

**Methods:** A randomised wait-list controlled trial will be conducted with a sample of 30 male taxi drivers to establish feasibility, including recruitment, engagement, and retention rates. Program usability and participant satisfaction will be assessed by a survey completed by all participants at 3 months after allocation. Additionally, an in-depth qualitative process evaluation to explore acceptability of the intervention will be conducted with a subset of participants by semi-structured telephone interviews. Preliminary efficacy of ManGuard for improving key CVD-related outcomes will be assessed, including biomarkers (total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, and total/HDL cholesterol ratio), blood pressure, anthropometry (body mass index, body fat percentage, and waist circumference), physical activity (accelerometry, and self-report) and psychosocial status (health-related quality of life, self-efficacy, and social support). Outcomes will be assessed at baseline, 7 weeks, and 3 months after group allocation. The wait-list control group will be offered access to the intervention at the completion of data collection.

**Discussion:** eHealth interventions show potential for promoting behaviour change and reducing CVD risk in men, yet there remains a paucity of robust evidence pertaining to male taxi drivers, classified as a high-risk group. This study uses a randomised controlled trial to assess the feasibility of ManGuard for reducing CVD risk in male taxi drivers. It is envisaged that this study will inform a fully powered trial that will determine the effectiveness of eHealth interventions for this high risk and underserved population.

**Trial registration:** This trial has been registered prospectively on the ISRCTN registry on 5 January 2022, registration number [ISRCTN29693943](https://www.isrctn.com/ISRCTN29693943)

**Keywords:** Cardiovascular diseases, Risk, Telemedicine, Men, Randomised controlled trial as topic

\*Correspondence: [jmcmahon33@qub.ac.uk](mailto:jmcmahon33@qub.ac.uk)

<sup>1</sup> School of Nursing and Midwifery, Queen's University Belfast, 97 Lisburn Road, Belfast BT9 7BL, UK

Full list of author information is available at the end of the article



© The Author(s) 2022. **Open Access** This article is licensed under a Creative Commons Attribution 4.0 International License, which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons licence, and indicate if changes were made. The images or other third party material in this article are included in the article's Creative Commons licence, unless indicated otherwise in a credit line to the material. If material is not included in the article's Creative Commons licence and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder. To view a copy of this licence, visit <http://creativecommons.org/licenses/by/4.0/>. The Creative Commons Public Domain Dedication waiver (<http://creativecommons.org/publicdomain/zero/1.0/>) applies to the data made available in this article, unless otherwise stated in a credit line to the data.

## Background

Cardiovascular disease (CVD), cancer, chronic pulmonary disease, and diabetes account for approximately 80% of non-communicable disease (NCD) related deaths and develop as the result of a combination of genetic, physiological, environmental, and behavioural factors [74]. However, behavioural risk factors such as tobacco use, excessive alcohol consumption, poor dietary choices, and physical inactivity, are most associated with the development of NCDs [31].

CVD remains the leading cause of NCD-related mortality worldwide, accounting for one-third of all deaths in 2019 [75]. Males are at a higher risk of developing CVD than females throughout their lifetime until older age [73]. In the United Kingdom (UK), including Northern Ireland, where 12% of the population are living with CVD and 30% of CVD-related deaths will be premature [8], men have a higher incidence of myocardial infarction and of diabetes.

### Taxi driving and CVD risk

Taxi driving is a male dominated occupation [53] and is associated with an increased risk of CVD [13]. Factors include long working hours and traffic congestion, causing prolonged psychological stress [13, 70], as well as sleep deficiency, irregular work patterns, noise, and regular exposure to air pollution [76]. There is a higher prevalence of modifiable CVD-related risk factors and behaviours among taxi drivers, including having high blood pressure, being overweight or obese, lacking fruit and vegetables, smoking, consuming excessive alcohol and spending long periods sedentary [4, 13, 17, 22, 70, 76].

The long periods of sedentary behaviour and subsequent lack of physical activity directly affect the development of CVD [66], associated with elevated blood pressure, weight gain and poor cholesterol profiles in taxi drivers [3, 12]. Physical activity can mitigate such adverse effects in this population [67], for example, by protecting against hypertension and counter-balancing the negative impact of age, working hours, and weight [69].

Despite the increased risk of CVD and high prevalence of CVD-related risk factors in taxi drivers [3–5, 13, 22, 23, 27, 48, 51, 54, 69], only two studies of behaviour change interventions targeted at this group have been identified [14, 23]. Both interventions were aimed at increasing physical activity through walking, assessing steps [14, 23], days walked, and amount of time walked [14]. Improvements in physical activity were observed for participants receiving either intervention, with significant improvements observed for all walking-related measures in one [14]. However, a major limitation to the study by Gany et al. [23] was the high rate of participant attrition (61%). To improve engagement and reduce

attrition of men in health behaviour change interventions, a gender-sensitised approach to development is recommended [7, 55].

### eHealth interventions for behaviour change

eHealth offers a means of tailoring interventions to meet the needs of end-users and has the potential to improve intervention uptake, adherence, and success [65]. Defined as “the use of technology to improve health, well-being and healthcare” [65], eHealth provides participants with an easily accessible and easy to use intervention [45]. The ease of access and use may be of benefit to taxi drivers, presenting as a hard-to-reach group due to the remote nature of the occupation. A recent systematic review and meta-analysis reported the success of eHealth interventions in promoting behaviour change among those living with NCDs [18]. Another recent systematic review and meta-analysis by us found similar findings for the reduction in CVD risk in men, with improvements in body weight, body mass index (BMI), waist circumference and blood pressure observed as a result of eHealth interventions [39].

However, weaknesses of eHealth interventions include poor adherence and high rates of attrition [33, 35]. To counter this, it is important that consideration is given to the needs of the end-users, iteratively developed, grounded in behaviour change theory and rigorously evaluated prior to the dissemination of findings [46, 50, 65].

The IDEAS (Integrate, Design, Assess, and Share) framework has been proposed for the design, development, and evaluation of eHealth interventions [46], and was utilised for the development of ManGuard. This 10-phase framework draws on the strengths of several approaches for eHealth interventions including design thinking, user-centred design, behaviour change theories, evaluation, and dissemination [46]. The framework recommends an intervention be pilot tested to assess preliminary efficacy, providing an opportunity to refine the study protocol prior to progressing to a definitive randomised controlled trial [46].

Due to greater levels of engagement in CVD-related risk behaviours, behaviour change interventions could prove beneficial for this high-risk group. However, little appears to have been done to help reduce the observed risk, with significant participant attrition observed in one of the two trials studying this population. In particular, the provision of an eHealth intervention may prove beneficial due to the ease of access and use for a hard-to-reach population. Guided by the IDEAS framework, a novel eHealth intervention (ManGuard) has been developed alongside end-users through an iterative process, ensuring program acceptability and user satisfaction. This paper describes the study protocol for a feasibility

randomised controlled trial to pilot test ManGuard, an eHealth intervention that aims to reduce CVD risk in male taxi drivers in Northern Ireland.

### Research aims and objectives

This study aims to assess the feasibility of ManGuard. Study objectives are the following:

- Primary—to assess:
  - Acceptability: recruitment, retention, and engagement rates
  - Program usability and participant satisfaction: process evaluation and survey
- Secondary—to assess the preliminary efficacy of ManGuard compared to usual care in improving the following outcomes:
  - Clinical indices: CVD biomarkers (cholesterol, glucose), blood pressure, anthropometry (BMI, waist circumference, body fat percentage)
  - Physical activity
  - Psychosocial status: health related quality of life, self-efficacy, social support

## Methods

### Study design

The study will be a randomised wait-list controlled trial followed by a process evaluation. A wait-list control is employed to increase acceptability of the research protocol to the participants in the control group, and thereby to decrease attrition effects [16]. Both groups will be matched on participant demographics, with those in the wait-list control group receiving the intervention following the final data collection at 3 months after allocation. Semi-structured telephone interviews will be conducted at 3 months as part of a process evaluation.

### Research setting

The research will be conducted in a community setting with male taxi drivers working in Northern Ireland.

### Participants

#### *Eligibility criteria for participants*

- Adult males ( $\geq 18$  years)
- Working part-time or full-time as a taxi driver in Northern Ireland
- Having access to the internet and a smartphone that allows for the downloading of mobile applications.

As this is a feasibility randomised controlled trial, no formal power calculation will be completed to determine sample size. Recommendations on the appropriate sample size for pilot and feasibility studies vary greatly, with sample sizes ranging between 24 and 50 participants [57]. We have chosen a sample size of 30 for this study, as recommended by the National Institute for Health Research (NIHR) in the UK [30].

### Recruitment

As a result of taxi drivers working both independently and for large companies, recruitment will be conducted via the online social media platform 'Facebook' to increase reach. This method of recruitment was employed previously for the recruitment of participants to aid in the co-design of the ManGuard intervention. A Microsoft Forms link, with a brief description of the study, will be posted into two separate Facebook groups dedicated to taxi drivers working across Northern Ireland, estimated as having 4200 members. The link will be posted weekly, with recruitment open for a duration of 17 months, ceasing once the target sample has been achieved. Those who are interested will provide their name and email address, with the lead researcher then sending a participant information sheet with the inclusion/exclusion criteria.

Those that meet the inclusion criteria will be invited to the Northern Ireland Clinical Research Facility (NICRF) to be formally recruited to the study and complete baseline testing. During the participants' final visit to the NICRF, participants in the intervention group will be offered the opportunity to participate in the semi-structured telephone interviews as part of a process evaluation. Verbal consent will be obtained and recorded at the commencement of the telephone interview, with participants made aware of their right to withdraw from the interview at any time.

### Randomisation

Participants will be randomly allocated by blocked randomisation to the intervention and wait-list control group using the Statistical Package for the Social Sciences (SPSS V.24). Due to the small sample size, blocked randomisation is deemed an appropriate technique for reducing the risk of bias and ensuring equal allocation between groups [20]. The wait-list control group will not be provided with any materials relating to the intervention or recommendations on how they can improve on their current lifestyle habits to maintain a 'true control'. Upon the completion of data collection at 3 months, participants in the wait-list control group will be offered access to the intervention. The randomisation procedure will be carried out by a researcher not affiliated with the

study. Participant allocation will be placed in a sealed envelope and opened by the lead researcher upon completion of baseline data collection.

### Intervention

The intervention is an eHealth program (ManGuard) that aims to reduce CVD risk in male taxi drivers. ManGuard was developed utilising a co-design approach, involving an ongoing collaboration between the research team, a computer scientist, and end-users (taxi drivers). Utilising co-design with an iterative approach is crucial for the success of an eHealth intervention [64]. First, an online survey was disseminated to gain an insight into life as a taxi driver in Northern Ireland and to guide the initial development of ManGuard. Utilising the iterative process between a Project Advisory Group (PAG) and focus groups with end-users, low-fidelity prototypes for the program and materials that would make up the 'content' were refined. The inclusion of behaviour change theory in the development of health interventions is reported as an essential component for improving their effectiveness [59]. The Behaviour Change Wheel (BCW) was incorporated throughout the development of ManGuard, providing a pragmatic framework and ensuring the incorporation of theory throughout [40]. Guided by the BCW worksheets [42], physical activity was identified as the behaviour anticipated to produce the greatest reduction in CVD risk in male taxi drivers. This was due to the long periods of sedentary time associated with the occupation, the likelihood of male taxi drivers changing the behaviour, the impact that physical inactivity has on other CVD-related behaviours, and the ease of measurement in a clinical trial. Next, it was specified that male taxi drivers should aim to complete greater levels of physical activity daily, in any setting, and with whomever they wish.

The next step in the process was to ensure the intervention was grounded in behaviour change theory, beginning with the conduction of a behavioural analysis. Doing so uncovers what needs modified at the individual level for successful change to occur. Next, the outcomes of the analysis were mapped to intervention functions deemed appropriate for facilitating the necessary change. Lastly, behaviour change techniques (BCTs) that could successfully deliver the intervention functions were identified using the BCT taxonomy [41], and through an assessment of BCTs utilised in previous eHealth interventions targeting male only participants [39]. ManGuard will be delivered as an application (app), accessible through handheld devices including mobile phones and tablets.

ManGuard contains seven modules: (i) introduction and goal setting, (ii) being active (iii) eating well,

(iv) managing stress, (v) smoking, (vi) alcohol, and (vii) keep accelerating, the latter to be used as a re-cap module. Each module was developed through an iterative process between the lead researcher and the PAG, prior to being refined through end-user input gathered during the focus groups. Initially, it was envisioned that participants would access modules in a sequential order, once per week, throughout the intervention period. However, end-user input recommended participants have access to the modules of their choice in any order, dependent on their preference. Therefore, the intervention period will last a total of 7 weeks in line with the number of modules available, with participants having the choice of which modules they wish to access. Each module will take no longer than 10 min to complete, with the content of each module focused on providing participants with brief and motivational information on the CVD-related behaviour or risk factor of interest. Content development was guided by published scientific recommendations, and steered by end-user input, to be delivered in a 'tips and tricks' format, providing short segments of text, and accompanied with images relevant to the taxi driver population. Each module uses positive and motivational language as a means of improving the likelihood of successful behaviour change.

Program features include goal setting and self-monitoring of progress [72], including physical activity, diet, weight, smoking, and alcohol. A group messaging board was envisioned as being embedded into the program, providing an opportunity for enhancing social support, shown to be effective in promoting engagement in an eHealth intervention for men [26]. However, qualitative input from end-users highlighted a social forum as being potentially problematic due to the nature of this population, the language they use, and how they interact with each other. As a result, a Question and Answer (Q&A) page will be utilised during the initial testing of ManGuard. Questions will be sent directly to the lead researcher with the answers posted publicly for all users. The questions and answers will be used as the basis of a Frequently Asked Questions page for future iterations of the program if a definitive trial is deemed feasible. The program will be interactive, with in-app motivational messages displayed as a form of automated feedback. It is envisioned that the messages will provide positive reinforcement when they are progressing well towards their goals, or as messages of encouragement if progress is poor. Participants will be provided with in-app 'awards', badges they collect for achieving milestones such as completing a module or making progress towards a goal. Weekly push notifications will be employed as reminders

to access the program and modules, with twice-weekly notifications delivered to users as a reminder to input and track progress.

### Data collection, management, and analysis

#### Demographic characteristics

A survey will be disseminated during the participants' first visit to the NICRF to gather demographic data. Information will pertain to the participants' age, post-code, education level, employment status, years worked as a taxi driver, working hours, lifestyle factors, knowledge of CVD, and presence of chronic diseases diagnosed by a health professional. The information gathered from the survey will be explored to gain an understanding of factors that may influence a participant's decision to take part in the study.

#### Feasibility measures

As this is a feasibility randomised controlled trial, the primary outcomes of interest are the following:

- Recruitment rates
- Retention rates
- Engagement with the intervention
  - Assessed by program usage via weekly analytics, including the quantity of participant logins, modules accessed, time spent on each module, and frequency of accessing the progress tracking system
- Program usability and participant satisfaction
  - Obtained as part of the process evaluation through semi-structured telephone interviews (Additional file 1) with a subset of participants. Telephone interviews will be conducted by a member of the research team who is trained and experienced in qualitative interviewing. Additionally, a satisfaction survey will be completed by all participants during the 3-month assessment time point.

#### Clinical indices

Though not powered to detect clinically significant change, the following CVD-related outcomes will be assessed to determine preliminary efficacy of ManGuard, and feasibility of each for inclusion in a definitive trial:

#### CVD biomarkers

- CVD biomarkers will be assessed through point-of-care testing with the Alere Cholestech LDX Analyzer, valid for the analysis of cholesterol and glucose measurements [10, 52]. Participants will be required to fast for 8-h prior to testing.

- Full cholesterol breakdown (total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, and total/HDL cholesterol ratio)

#### Blood pressure

- Systolic and diastolic blood pressure will be measured using a calibrated sphygmomanometer three times during each visit, with one-minute intervals between each. An average of the three measures will be calculated and used as the final reading [62]. Measurements will be taken from a seated position by a trained member of the research team, with the cuff placed in line with the midpoint of the sternum. Participants will be asked to sit upright, feet flat on the floor, for 3–5 min prior to the first measurement being taken [47].

#### Anthropometry

- BMI
- Body fat percentage will be analysed through Bioelectrical Impedance Analysis (BIA). BIA is a valid, precise, and cost-effective method of assessing body fat percentage and lean mass, both having strong correlations with mortality and morbidity [6]
- Waist circumference will be measured midway between the lowest rib and the iliac crest, proven to be the most reliable for defining central obesity [36].

#### Physical activity

Physical activity will be measured both objectively and subjectively using accelerometer data and the short-form version of the International Physical Activity Questionnaire (IPAQ-SF), respectively.

- Accelerometer data will be collected using the Actigraph GT3X+ accelerometer, deemed a reliable tool for measuring physical activity in adults living in 'free conditions' [1]. Participants will be required to wear the accelerometer for 3–5 days to ensure the most reliable estimates of physical activity [61]
- The International Physical Activity Questionnaire (IPAQ-SF), a 7-item self-report survey of physical activity completed in the last 7 days, is a valid and reliable tool [15]. Items include frequency and intensity of physical activity, as well as time spent sedentary [15]. The IPAQ-SF has previously shown significant associations with accelerometer derived physical activity data (Murphy et al. 2017).

**Psychosocial status**

Psychosocial status will be assessed through health-related quality of life (HRQoL), self-efficacy, and social support measures.

- HRQoL will be assessed using the ‘generic’ 12-item Short Form Health Survey (SF-12) to measure physical and mental health components across the last 4 weeks [71]. The SF-12 has adequate scale reliability (Cronbach’s alpha = 0.89) and has been validated in the ‘general’ UK population [9].
- Self-efficacy will be assessed using the General Self-Efficacy Scale (GSE), a 10-item self-report measure of an individual’s self-belief in coping with a variety of difficult and demanding life tasks [34]. The GSE has demonstrated validity and reliability across 25 countries consisting of a variety of cultures and genders, with a Cronbach’s alpha of 0.88 in participants from Great Britain [56].
- Social support will be assessed using the Multidimensional Scale of Perceived Social Support (MSPSS). The MSPSS is a reliable, brief, and easy to complete [2] 12-item self-report measure of support from an individual’s family, friends and their significant other [77]. The MSPSS has strong internal reliability (Cronbach’s alpha of 0.93–0.98) in both clinical and non-clinical subjects, of different ages and gender [28].

The schedule for the enrolment of participants, administration of the intervention, and the outcomes with assessment time points is shown in Fig. 1.

**Data management**

Hard copies of data will be kept confidential and stored securely in a locked cabinet within the School of Nursing and Midwifery, Queen’s University Belfast. Soft copies of data obtained throughout the study will be stored on the Queen’s University Belfast Cloud Storage (Q) Drive.

**Statistics and data analysis****Quantitative analysis**

Quantitative data analysis will be conducted using SPSS V.24. Descriptive statistics will be used to report on baseline demographic, clinical data, and program usability. Categorical data will be presented as frequencies and percentages, whilst continuous data is presented as means and standard deviations. Numerical data will be analysed using SPSS V.24. Repeated measures ANOVA will be used to assess the preliminary efficacy between groups across three time points for physical activity, clinical indices, and psychosocial status.

As a feasibility randomised controlled trial, and therefore not statistically powered, results will be interpreted with caution. Recruitment and retention rates will be reported on and presented using the CONSORT flow diagram [21].

**Qualitative analysis**

Semi-structured telephone interviews for collecting data on participant satisfaction, experience, and program usability will be audio recorded and transcribed verbatim. Transcripts will be analysed using conventional content analysis using an inductive approach for the coding and categorising of data. Content analysis involves a systematic approach for exploring large amounts of textual information [63], suitable for intervention refinement [49]. All participants in the intervention group will be invited to complete the telephone interviews, with interviews ceasing once data saturation is achieved [37]. Members of the research team will be involved in the qualitative analysis of data and will assess data saturation throughout the telephone interview process.

**Progression criteria**

Progression to a definitive trial will be determined by the following progression criteria for participant recruitment, utilised previously in pilot and feasibility studies [11, 38].

- 75-100% of the target sample size (30) recruited to the study will warrant progression to a definitive trial
- 50-74% of the sample size (30) recruited to the study will warrant progression to a definitive trial following necessary adjustments to barriers of recruitment outlined during the process evaluation
- 25-49% sample size (30) recruited to the study will only warrant progression to a definitive trial if changes to the protocol are made by both the research team and the potential future co-applicants
- Less than 25% of the sample size (30) recruited to the study will indicate that the trial is unlikely to progress.

Progression criteria for retention rates will follow the criteria below [29]:

- >80% retention rate will warrant progression to a definitive trial
- 60-80% retention rate will warrant progression to definitive trial following necessary adjustments to counter attrition
- <60% retention rate will indicate progression to a definitive trial is unlikely

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		Close-out
	- <i>t</i> <sub>1</sub>	0	7 weeks <i>t</i> <sub>1</sub>	3 months <i>t</i> <sub>2</sub>	<i>t</i> <sub>x</sub>
<b>TIMEPOINT**</b>	- <i>t</i> <sub>1</sub>	0	7 weeks <i>t</i> <sub>1</sub>	3 months <i>t</i> <sub>2</sub>	<i>t</i> <sub>x</sub>
<b>ENROLMENT:</b>					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
<b>INTERVENTIONS:</b>					
<i>ManGuard</i>		↔			
<i>Waitlist control</i>					
<b>ASSESSMENTS:</b>					
<i>Baseline: Age, postcode, country of birth, education, employment status, average hours working per week, medication, medical history, lifestyle (smoking, alcohol, physical activity, diet)</i>		X			
<b>Feasibility measures</b>					
<i>Recruitment</i>	X				
<i>Retention</i>		X	X	X	X
<i>Usability and satisfaction</i>				X	X
<b>Clinical indices</b>					
<b>CVD biomarkers</b>		X	X	X	
<b>Blood pressure</b>		X	X	X	
<b>Anthropometric measures (BMI, waist circumference, BIA)</b>		X	X	X	
<b>Physical activity</b>		X	X	X	
<b>Psychosocial measures</b>					
<i>HRQoL</i>		X	X	X	
<i>GSE</i>		X	X	X	
<i>MSPSS</i>		X	X	X	

**Fig. 1** SPIRIT figure of the schedule for enrolment, intervention implementation, and assessment time points

Participant satisfaction will be assessed through the process evaluation and will provide information on whether the intervention was feasible, including the process of randomisation. Progression to a definitive trial will be dependent on acceptability, with necessary modifications indicated by the participants being made prior to progressing.

## Discussion

Whilst male taxi drivers have been identified as a high-risk group of developing CVD due to their engagement in CVD-related risk behaviours, there is a dearth of literature concerning health interventions for this population. eHealth interventions may prove beneficial for the reduction in CVD risk in this population due to the ease of access and use from any location. Yet, in the absence of published research, it is unknown whether delivering such an intervention is feasible.

Previous research has identified that men benefit from their own behaviour change interventions, taking into consideration the method of engagement, the way information is presented and the mode of delivery [24]. Considering such preferences has been identified as positively influencing intervention uptake and reducing the risk of participant attrition in interventions targeting men [24]. Reducing risk of attrition is of the upmost importance in interventions with male only subjects, presenting as a common limitation in previous trials [19, 32, 58].

One such way to tailor an intervention towards men is using eHealth, providing the end-user with the ability to take an active role in their own health care [65]. Previous eHealth interventions have shown potential for promoting behaviour change and reducing CVD risk in male only participants [39]. However, trials often involve the use of an 'active control' [19, 25, 44, 60], which may obscure the 'true' perceived benefits of the eHealth intervention. This was evident whilst comparing results from these studies to those that included a 'true control' [43, 68], who reported greater impact from eHealth interventions on behaviour change.

Whilst research has shown male taxi drivers are at an increased risk of CVD, few studies of interventions to reduce this risk have been conducted. We aim to fill this gap by describing a protocol for a feasibility randomised controlled trial of an eHealth intervention (ManGuard) designed to reduce CVD risk in male taxi drivers. In addition, we aim to assess preliminary efficacy of ManGuard for improving clinical indices, physical activity, and psychosocial status in this high-risk group. We envisage that this study will add to the literature on the choices and preferences of men for behaviour change interventions using eHealth, whilst providing the basis for a definitive trial to assess the effectiveness of an eHealth intervention for reducing CVD risk in this high-risk and underserved population.

## Abbreviations

BCTs: Behaviour Change Techniques; BIA: Bioelectrical Impedance Analysis; CVD: Cardiovascular disease; GSE: General Self-Efficacy Scale; HRQoL: Health-related quality of life; IPAQ-SF: International Physical Activity Questionnaire Short Form; MSPSS: Multidimensional Scale of Perceived Social Support; NCD: Non-communicable disease; NICRF: Northern Ireland Clinical Research Facility; NIHR: National Institute for Health Research; SF-12: 12-Item Short Form Health Survey; SPSS V.24: Statistical Package for the Social Sciences; UK: United Kingdom.

## Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s40814-022-01163-4>.

**Additional file 1.** Process evaluation interview guide.

## Acknowledgements

Not applicable

## Authors' contributions

JM, DRT, CFS, and KB were involved in the development of the trial design and in the drafting and refining of the protocol manuscript. All authors read and approved the final manuscript for submission.

## Funding

This research protocol is funded by the Department for the Economy for the completion of a PhD studentship at Queen's University Belfast. The funding body has had no input into the design of the study, the collection, analysis, or interpretation of data, or in the writing of the manuscript.

## Availability of data and materials

Data sharing is not applicable to this article as no datasets have been generated or analysed. It is intended that data generated during the study described in this protocol will be disseminated in peer-review journals and at relevant scientific conferences.

## Declarations

### Ethics approval and consent to participate

This study protocol and necessary ethics forms have been submitted and approved by the School of Nursing and Midwifery's Ethics Committee at Queen's University Belfast. Ethical consideration has been given to (i) data protection, (ii) informed consent, (iii) voluntary participation, and (iv) protecting the wellbeing and safety of the research participants. A signed consent form will be gathered from participants during their first visit to the NICRF. In addition, participants taking part in the telephone interviews will be asked to provide verbal consent prior to the interview commencing.

### Consent for publication

Not applicable.

### Competing interests

The authors declare that they have no competing interests.

### Author details

<sup>1</sup>School of Nursing and Midwifery, Queen's University Belfast, 97 Lisburn Road, Belfast BT9 7BL, UK. <sup>2</sup>Integrated Care Academy, University of Suffolk, 19 Neptune Quay, Ipswich, IP4 1QJ Ipswich, UK.

Received: 7 January 2022 Accepted: 25 August 2022

Published online: 14 September 2022

## References

- Aadland E, Ylvisäker E. Reliability of the Actigraph GT3X+ accelerometer in adults under free-living conditions. *PLoS ONE*. 2015;10(8):e0134606.
- Adamczyk K. Development and validation of the Polish-language version of the Multidimensional Scale of Perceived Social Support (MSPSS). *RevInt Psychol Soc*. 2013;26:25–48.

3. Alves De Sena JE, Meireles De Pontes L, Magno U, Ferreira G, Mendonça Da Silva J. Body composition and relationship with the level of physical activity of taxi drivers and postmen of João Pessoa-PB. *Fitness Perform J*. 2008;7(1):20–5.
4. Apantaku-Onayemi F, Baldyga W, Amuwo S, Adefuye A, Mason T, Mitchell R, Blumenthal DS. Driving to better health: cancer and cardiovascular risk assessment among taxi cab operators in Chicago. *J Health Care Poor Underserved*. 2012;23:768–80.
5. Bigert C, Gustavsson P, Hallqvist J, Hogstedt C, Lewné M, Plato N, Reuterwall C, Schéele P. Myocardial infarction among professional drivers. *Epidemiology*. 2003;14(3):333–9.
6. Böhm A, Heitmann BL. The use of bioelectrical impedance analysis for body composition in epidemiological studies. *Eur J Clin Nutr*. 2013;67:S79–85.
7. Böttorff JL, Seaton CL, Johnson ST, Caperchione CM, Olliffe JL, More K, Jaffer-Hirji H, Tillotson SM. An updated review of interventions that include promotion of physical activity for adult men. *Sports Med*. 2015;45:775–800.
8. British Heart Foundation. Northern Ireland Factsheet. 2022. Retrieved from: <https://www.bhf.org.uk/-/media/files/research/heart-statistics/bhf-cvd-statistics-northern-ireland-factsheet.pdf?rev=8c960ebccb384e48a264e6911e4deab8&hash=DA89D1B824947D3D46B4FB851951FE4D>. (5 September 2022).
9. Busija L, Pausenberger E, Haines TP, Haymes S, Buchbinder R, Osborne RH. Adult measures of general health and health-related quality of life: Medical Outcomes Study Short Form 36-Item (SF-36) and Short Form 12-Item (SF-12) Health Surveys, Nottingham Health Profile (NHP), Sickness Impact Profile (SIP), Medical Outcomes Study Sh. *Arthritis Care Res*. 2011;63:S383–412.
10. Carey M, Markham C, Gaffney P, Boran G, Maher V. Validation of a point of care lipid analyser using a hospital based reference laboratory. *Ir J Med Sci*. 2006;175:3–35.
11. Carswell C, Reid J, Walsh I, Mcaneney H, Noble H. Implementing an arts-based intervention for patients with end-stage kidney disease whilst receiving haemodialysis: a feasibility study protocol. *Pilot Feasibility Stud*. 2019;5:1–11.
12. Carter S, Hartman Y, Holder S, Thijssen DH, Hopkins ND. Sedentary behavior and cardiovascular disease risk. *Exerc Sport Sci Rev*. 2017;45(2):80–6.
13. Chen J-C, Chen Y-J, Chang WP, Christiani DD. Long driving time is associated with haematological markers of increased cardiovascular risk in taxi drivers. *Occup Environ Med*. 2005;62(12):890–4.
14. Choi YH, Chae M-J. Development and effects of smartphone app-based walking exercise program for taxi drivers: based on Bandura's self efficacy theory. *J Korean Acad Nurs*. 2020;50(2):242–54.
15. Craig CL, Marshall AL, Sjoström M, Bauman AE, Booth ML, Ainsworth BE, Pratt M, Ekelund U, Yngve A, Sallis JF, Oja P. International physical activity questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc*. 2003;35:1381–95.
16. Darker CD, French D, Eves FF, Sniehotta FF. An intervention to promote walking amongst the general population based on an "extended" theory of planned behavior: a waiting list randomized controlled trial. *Psychol Health*. 2009;25(1):71–88.
17. de Oliveira BG, Ribeiro IJS, Bomfim ES, Casottie CA, de Oliveira Boery RNS, Boery EN. Cardiovascular risk factors and quality of life of taxi drivers. *J Nurs*. 2015;9(5):7797–803.
18. Duan Y, Shang B, Liang W, Du G, Yang M, Rhodes RE. Effects of eHealth-based multiple health behavior change interventions on physical activity, healthy diet, and weight in people with noncommunicable diseases: systematic review and meta-analysis. *J Med Internet Res*. 2021;23:e23786.
19. Duncan M, Vandelanotte C, Kolt GS, Rosenkranz RR, Caperchione CM, George ES, Ding H, Hooker C, Karunanithi M, Maeder AJ, Noakes M, Tague R, Taylor P, Viljoen P, Mummery WK. Effectiveness of a web- and mobile phone-based intervention to promote physical activity and healthy eating in middle-aged males: randomized controlled trial of the manup study. *J Med Internet Res*. 2014;16(6):e136.
20. Efrid J. Blocked randomization with randomly selected block sizes. *Int J Environ Res Public Health*. 2011;8(1):15–20.
21. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *Pilot Feasibility Stud*. 2016;2:64.
22. Elshatarat RA, Burgel BJ. Cardiovascular risk factors of taxi drivers. *J Urban Health*. 2016;93(3):589–606.
23. Gany F, Gill P, Baser R, Leng J. Supporting South Asian Taxi drivers to Exercise through Pedometers (SSTEP) to decrease cardiovascular disease risk. *J Urban Health*. 2014;91(3):463–76.
24. Gavarkovs AG, Burke SM, Petrella RJ. Engaging men in chronic disease prevention and management programs: a scoping review. *Am J Mens Health*. 2016;10:N145–54.
25. George ES. Increasing physical activity and reducing sedentary time in middle-aged males. (PhD thesis). Australia: University of Western Sydney, Australia; 2013.
26. George ES, Kolt GS, Duncan MJ, Caperchione CM, Mummery WK, Vandelanotte C, Taylor P, Noakes M. A review of the effectiveness of physical activity interventions for adult males. *Sports Med*. 2012;42(4):281–300.
27. Hachesu RR, Sh NF, Sakhvidi Z, Hachesu MRR. Prevalence of cardiovascular risk factors among taxi drivers in Yazd Iran. *J Commun Health Res*. 2017;6(4):200–6.
28. Harden-Khalil K, Mayo AM. Psychometric properties of the multidimensional scale of perceived social support within Hispanic college students. *Clin Nurse Spec*. 2015;29(5):258–61.
29. Hawkins J, Edwards M, Charles J, Jago R, Kelson M, Morgan K, Murphy S, Oliver E, Simpson S, Edwards RT, Moore G. Protocol for a feasibility randomised controlled trial of the use of Physical Activity monitors in an Exercise Referral Setting: the PACERS study. *Pilot Feasibility Stud*. 2017;3:51.
30. Hooper R. Justifying sample size for a feasibility study. 2019. Retrieved from: <https://www.rds-london.nihr.ac.uk/resources/justify-sample-size-for-a-feasibility-study>. (18 March 2020).
31. Hunter DJ, Reddy KS. Noncommunicable diseases. *N Engl J Med*. 2013;369:1336–43.
32. Johnson ST, Stolp S, Seaton C, Sharp P, Caperchione CM, Böttorff JL, Olliffe JL, Jones-Bricker M, Lamont S, Medhurst K, Errey S, Healy T. A men's workplace health intervention: results of the POWERPLAY program pilot study. *J Occup Environ Med*. 2016;58(8):765–9.
33. Kelders SM, Kok RN, Ossebaard HC, Van Gemert-Pijnen JE. Persuasive system design does matter: a systematic review of adherence to web-based interventions. *J Med Internet Res*. 2012;14(6):e152.
34. Kvarme LG, Haraldstad K, Helseth S, Sørum R, Natvig GK. Associations between general self-efficacy and health-related quality of life among 12–13-year-old school children: a cross-sectional survey. *Health Qual Life Outcomes*. 2009;7:85.
35. Ludden GD, van Rompay TJ, Kelders SM, van Gemert-Pijnen JE. How to increase reach and adherence of web-based interventions: a design research viewpoint. *J Med Internet Res*. 2015;17(7):e172.
36. Ma W-Y, Yang C-Y, Shih S-R, Hsieh H-J, Hung CS, Chiu F-C, Lin M-S, Liu P-H, Hua C-H, Hsein Y-C, Chuang L-M, Lin J-W, Wei J-N, Li H-Y. Measurement of waist circumference: midabdominal or iliac crest? *Diabetes Care*. 2013;36:1660–6.
37. Mason M. Sample size and saturation in PhD studies using qualitative interviews. *Qual Soc Res*. 2010;11(3):1–19.
38. McConnell T, Graham-Wisener L, Regan J, McKeown M, Kirkwood J, Hughes N, Clarke M, Leitch J, McGrillen K, Porter S. Evaluation of the effectiveness of music therapy in improving the quality of life of palliative care patients: a randomised controlled pilot and feasibility study. *Pilot Feasibility Stud*. 2016;2:70.
39. McMahon J, Thompson DR, Pascoe MC, Brazil K, Ski CF. eHealth interventions for reducing cardiovascular disease risk in men: a systematic review and meta-analysis. *Prev Med*. 2021;145:106402.
40. Michie S, Van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci*. 2011;6:42.
41. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, Eccles MP, Cane J, Wood CE. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. *Ann Behav Med*. 2013;46(1):81–95.
42. Michie S, Atkins L, West R. The behaviour change wheel: a guide to designing interventions. London: Silverback Publishing; 2014.
43. Morgan PJ, Collins CE, Plotnikoff RC, Cook AT, Berthon B, Mitchell S, Callister R. Efficacy of a workplace-based weight loss program for overweight male shift workers: the Workplace POWER (Preventing Obesity Without Eating like a Rabbit) randomized controlled trial. *Prev Med*. 2011;52(5):317–25.

44. Morgan PJ, Lubans DR, Collins CE, Warren JM, Callister R. The SHED-IT randomized controlled trial: evaluation of an internet-based weight-loss program for men. *Obesity*. 2009;17:2025–32.
45. Muellmann S, Forberger S, Möllers T, Zeeb H, Pischke CR. Effectiveness of eHealth interventions for the promotion of physical activity in older adults: a systematic review protocol. *Syst Rev*. 2016;5:47.
46. Mummah SA, Robinson TN, King AC, Gardner CD, Sutton S. IDEAS (Integrate, Design, Assess, and Share): a framework and toolkit of strategies for the development of more effective digital interventions to change health behavior. *J Med Internet Res*. 2016;18(12):e317.
47. Muntner P, Shimbo D, Carey RM, Charleston JB, Gaillard T, Misra S, Myers MG, Ogedegbe G, Schwartz JE, Townsend RR, Urbina EM, Viera AJ, White WB, Wright JT. Measurement of blood pressure in humans: a scientific statement from the American Heart Association. *Hypertension*. 2019;73(5):e35–66.
48. Murray KE, Buul A, Aden R, Cavanaugh AM, Kidane L, Hussein M, Eastman A, Checkoway H. Occupational health risks and intervention strategies for US taxi drivers. *Health Promot Int*. 2019;34(2):323–32.
49. Neergaard MA, Olesen F, Andersen RS, Sondergaard J. Qualitative description - the poor cousin of health research? *BMC Med Res Methodol*. 2009;9:52.
50. Ossebaard HC, Van Gemert-Pijnen L. eHealth and quality in health care: implementation time. *Int J Qual Health Care*. 2016;28(3):415–9.
51. Persu A, Andries A, Demedts S, Van Der Niepen P, Van De Borne P. Elevated prevalence of arterial hypertension amongst Belgian taxi drivers during the World Hypertension Day campaign 2006. *J Hypertens*. 2006;24(11):2311–2.
52. Plüddemann A, Thompson M, Price CP, Wolstenholme J, Heneghan C. Point-of-care testing for the analysis of lipid panels: primary care diagnostic technology update. *Br J Gen Pract*. 2012;62:e224–6.
53. Poó FM, Ledesma RD, López SS. The taxi industry: working conditions and health of drivers, a literature review. *Transp Rev*. 2018;38(3):394–411.
54. Ramukumba TS, Mathikhi MS. Health assessment of taxi drivers in the city of Tshwane. *Curationis*. 2016;39(1):a1671.
55. Robertson S, Witty K, Zwolinsky S, Day R. Men's health promotion interventions: what have we learned from previous programmes. *Community Pract*. 2013;86:38–41.
56. Scholz U, Doña BG, Sud S, Schwarzer R. Is general self-efficacy a universal construct? Psychometric findings from 25 countries. *Eur J Psychol Assess*. 2002;18(3):242–51.
57. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol*. 2012;65:301–8.
58. Siren R, Eriksson JG, Vanhanen H. Observed changes in cardiovascular risk factors among high-risk middle-aged men who received lifestyle counselling: a 5-year follow-up. *Scand J Prim Health Care*. 2016;34(4):336–42.
59. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, Boyd KA, Craig N, French DP, McIntosh E, Petticrew M, Rycroft-Malone J, White M, Moore L. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ*. 2021;374:n2061.
60. Tanaka M, Adachi Y, Adachi K, Sato C. Effects of a non-face-to-face behavioral weight-control program among Japanese overweight males: a randomized controlled trial. *Int J Behav Med*. 2010;17:17–24.
61. Trost SG, Mclver KL, Pate RR. Conducting accelerometer-based activity assessments in field-based research. *Med Sci Sports Exerc*. 2005;37(Supplement):S531–43.
62. TRUE Consortium. Recommended standards for assessing blood pressure in human research where blood pressure or hypertension is a major focus. *Kidney Int Rep*. 2017;2:733–8.
63. Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nurs Health Sci*. 2013;15(3):398–405.
64. van Gemert-Pijnen JE, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, Seydel ER. A holistic framework to improve the uptake and impact of eHealth technologies. *J Med Internet Res*. 2011;13(4):e111.
65. van Gemert-Pijnen L, Kelders SM, Kip H, Sanderma R. eHealth research, theory and development: a multidisciplinary approach. London: Routledge; 2018.
66. Varela-Mato V, Yates T, Stensel DJ, Biddle SJH, Clemes SA. Time spent sitting during and outside working hours in bus drivers: a pilot study. *Prev Med Rep*. 2016;3:36–9.
67. Varghese T, Schultz WM, McCue AA, Lambert CT, Sandesara PB, Eapen DJ, Gordon NF, Franklin BA, Sperling LS. Physical activity in the prevention of coronary heart disease: implications for the clinician. *Heart*. 2016;102(12):904–9.
68. Veverka DV, Anderson J, Auld GW, Coulter GR, Kennedy C, Chapman PL. Use of the stages of change model in improving nutrition and exercise habits in enlisted air force men. *Mil Med*. 2003;168(5):373–9.
69. Vieira MC, Sperandei S, Reis AC. Physical activity overcomes the effects of cumulative work time on hypertension prevalence among Brazilian taxi drivers. *J Sports Med Phys Fitness*. 2016;56(5):631–8.
70. Wang PC, Delp L. Health status, job stress and work-related injury among Los Angeles taxi drivers. *Work*. 2014;49:705–12.
71. Ware JE, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care*. 1996;34(3):220–33.
72. Wijsman CA, Westendorp RG, Verhagen EA, Catt M, Eline Slagboom P, de Craen AJ, Broekhuizen K, van Mechelen W, van Heemst D, van der Ouderaa F, Mooijaart SP. Effects of a web-based intervention on physical activity and metabolism in older adults: randomized controlled trial. *J Med Internet Res*. 2013;15:e233.
73. Woodward M. Cardiovascular disease and the female disadvantage. *Int J Environ Res Public Health*. 2019;16(7):1165.
74. World Health Organisation. Noncommunicable diseases. 2021a. Retrieved from: <https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases>. (17 May 2022).
75. World Health Organisation. Cardiovascular diseases (CVDs). 2021b. Retrieved from: <https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-cvds>. (3 November 2021).
76. Wu W-T, Tsai S-S, Wang C-C, Lin Y-J, Wu T-N, Shih T-S, Liou S-H. Professional driver's job stress and 8-year risk of cardiovascular disease. *Epidemiology*. 2019;30:539–47.
77. Zimet GD, Dahlem NW, Zimet SG, Farley GK. The Multidimensional scale of perceived social support. *J Pers Assess*. 1988;52:30–41.

## Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

**Ready to submit your research? Choose BMC and benefit from:**

- fast, convenient online submission
- thorough peer review by experienced researchers in your field
- rapid publication on acceptance
- support for research data, including large and complex data types
- gold Open Access which fosters wider collaboration and increased citations
- maximum visibility for your research: over 100M website views per year

**At BMC, research is always in progress.**

Learn more [biomedcentral.com/submissions](https://biomedcentral.com/submissions)

