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Protocol for a pilot study of an online (eHealth) intervention to reduce heart disease risk in male taxi drivers

Submission date 16/12/2021	**Recruitment status** Not yet recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 05/01/2022	**Overall study status** Ongoing	
Last Edited 07/09/2026	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims?
Cardiovascular disease (CVD) remains the leading cause of death worldwide, with men at a higher risk of developing the disease compared to their female counterparts. Taxi drivers are at high risk of cardiovascular disease. This increased risk is due to a range of factors, such as their engagement in CVD related risk behaviours including poor nutritional habits, smoking, the overconsumption of alcohol and long periods of sedentary behaviour. However, little has been done to reduce the risk in this population.

To improve engagement and reduce attrition of men in health behaviour change interventions, a gender-specific approach to development is recommended. One such way to tailor an intervention to meet the needs of end-users is through an online platform (eHealth). eHealth interventions targeted at male only participants have proved beneficial in engendering behaviour change and reducing the risk of CVD. However, no eHealth intervention has been developed and tested for this target population. The aim of this study is to pilot test ManGuard, an eHealth intervention for increasing physical activity and reducing CVD risk in male taxi drivers.

Who can participate?
Men aged 18 years or above, working either full-time or part-time as a taxi driver in Northern Ireland.

What does the study involve?
Participants will be randomly allocated into two groups, one that will receive the ManGuard intervention and the other who will no resources relating to the intervention. This will help us to identify whether ManGuard has the potential to improve physical activity and reduce CVD risk in taxi drivers.

ManGuard is an interactive and motivational program will be made up of seven modules, all of which provide information, tips and guidance on the different factors that are increasing the risk of CVD in taxi drivers and how they can make positive changes to reduce their risk. There will be two modules classified as core modules that the participant must complete, with the remaining

classified as voluntary.
Over the 7-week trial period, the participants will have the choice of how many modules they wish to complete, advised to complete those that are going to be of the most benefit to them. Participants will be advised to set goals and monitor their progress, with the program also providing automated feedback.

What are the possible benefits and risks of participating?
We do not anticipate any risks associated with ManGuard. The only possible "risk" is slight bruising on the site where the finger is pricked to take blood for the cholesterol and glucose testing.

Where is the study run from?
Queens University Belfast (UK)

When is the study starting and how long is it expected to run for?
January 2019 to December 2030

Who is funding the study?
Department for the Economy (DfE) (UK)

Who is the main contact?
Mr James McMahon, j.mcmahon@qub.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr James McMahon

Contact details
Medical Biology Centre
97 Lisburn Road
Belfast
United Kingdom
BT9 7BL
+44 (0)28 9097 2233
j.mcmahon@qub.ac.uk

Type(s)
Principal investigator

Contact name
Prof David Thompson

Contact details
Medical Biology Centre
97 Lisburn Road
Belfast
United Kingdom

BT9 7BL
+44 (0)2890972233
David.Thompson@qub.ac.uk

Type(s)
Scientific

Contact name
Prof Chantal Ski

Contact details
University of Suffolk
Integrated Care Academy
Waterfront Building
19 Neptune Quay
Ipswich
United Kingdom
IP4 1QJ
-
c.ski@uos.ac.uk

Additional identifiers

Protocol serial number
JMcMahon.SREC_June19_V2

Study information

Scientific Title
An eHealth intervention (ManGuard) to reduce cardiovascular risk in male taxi drivers: study protocol for a pilot randomised controlled trial

Acronym
ManGuard

Study objectives
The ManGuard program will help to reduce cardiovascular disease (CVD) risk in male taxi drivers

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/07/2019, School of Nursing and Midwifery's Ethics Committee, Queens University Belfast (Medical Biology Centre, 97 Lisburn Road, Belfast BT9 7BL; +44 (0)2890972233; o.perra@qub.ac.uk), ref: JMcMahon.SREC_June19_V2

Primary study design
Interventional

Study design

Pilot unblinded randomized wait-list controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of cardiovascular disease in male taxi drivers

Interventions
Randomisation:
Randomisation will occur following the collection of baseline data using blocked randomisation, using the Statistical Package for the Social Sciences (SPSS V.24) software. Participants will be randomised evenly between the intervention group and the wait-list control group. Due to the nature of the study, it is not possible to blind either the researcher or participant to the treatment allocation

Waitlist-control group:
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'. Following the completion of data collection at 3 months, the wait-list control group will be offered access to the intervention

Intervention group: ManGuard
ManGuard will be provided to participants allocated to the intervention group upon the collection of baseline data. ManGuard is a theory driven eHealth intervention, co-designed with end-users, with the aim to reduce CVD risk in male taxi drivers. Following the co-design process, it was identified that the program would need to address a range of lifestyle factors impacting the risk of CVD in male taxi drivers as well as psychological issues. These include physical activity, nutritional habits, smoking, alcohol and stress. The program will be delivered as an application, downloaded to the participants smartphone or tablet, accessible to the user at any time.

The program is comprised of seven modules, two classified as essential to complete (core modules) and the remaining five being voluntary, providing the user with the opportunity to access the modules most appropriate for their personal circumstances. Delivery of these modules will be dependent on the order and time in which the user wishes to access them across the 7-week trial period. Each module will take no longer than 10 minutes to complete, with the content focused on providing participants with brief, but motivational, information on CVD-related behaviour or risk factor of interest in the module, and tips on how they can successfully make changes to these as a taxi driver. Each module uses positive and motivational language as a means of improving the likelihood of promoting behaviour change. Alongside the modules, the program will provide participants with the opportunity to set goals and self-monitor their progress. ManGuard will be interactive, with in-app motivational messages being displayed as a form of automated feedback to provide positive reinforcement when they are progressing well towards their goals, or as messages of encouragement if progress is not occurring as they had anticipated. Participants will also be provided with in-app 'awards', badges that they can collect for completing milestones such as completing a module or making progress towards a goal.

Intervention Type
Behavioural

Primary outcome(s)

Feasibility related outcomes:
1. Recruitment and retention rates
Measured by identifying the number of participants taking part in the study (from start to end) and number of participants who withdraw from the study at any point.
2. Engagement with the intervention
Engagement rates will be assessed by program usage. Analytics will be retrieved weekly, including the amount of times a participant logs into the program, how many modules they access, how long they spend on each module and how frequently they access the progress tracking page
3. Usability and participant satisfaction
Obtained as part of a process evaluation through telephone interviews with a subset of participants following the 7-week assessment time point, as well as a satisfaction survey completed by all participants during the 3-month assessment time point.

Key secondary outcome(s)
Assessed at baseline, 7 weeks, and 3 months
1. Clinical indices
1.1 CVD biomarkers (cholesterol and glucose) measured using the Alere Cholestech LDX Analyzer
1.2 Blood pressure (sphygmomanometer)
1.3 BMI (kg/m^2)
1.4 Body fat percentage (bioelectrical impedance analysis)
1.5 Waist circumference (cm) (measuring tape)
2. Physical activity (Actigraph GT3X+ accelerometer and the International Physical Activity Questionnaire (IPAQ-SF))
3. Psychosocial measures
3.1 Health related quality of life (12-item Short Form Health Survey (SF-12))
3.2 Self-efficacy (General Self-Efficacy Scale (GSE))
3.3 Social support Multidimensional Scale of Perceived Social Support (MSPSS))

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. Adult males (18 years or older)
2. Working either part-time or full-time as a taxi driver in Northern Ireland
3. Must have access to the internet and have a smartphone that allows for the downloading of mobile applications
4. Able to consent to participate
5. Able to understand and comprehend English

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
Male

Total final enrolment
0

Key exclusion criteria
1. Children and young adults (younger than 18 years old)
2. Female gender
3. No access to the internet or a smartphone that would allow for the downloading of a mobile applications
4. Unable to consent to participate
5. Unable to understand and comprehend English

Date of first enrolment
04/09/2028

Date of final enrolment
01/06/2029

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Queen's University Belfast
Medical Biology Centre
97 Lisburn Rd
Belfast
Northern Ireland
BT9 7BL

Sponsor information

Organisation
Queen's University Belfast

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Government

Funder Name
Department for the Economy

Alternative Name(s)
An Roinn Geilleagair, Department for the Economy NI, Department for the Economy (Northern Ireland), Department for the Economy, Northern Ireland, Northern Ireland, Department for the Economy, DfE

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		14/09/2022	15/09/2022	Yes	No