Plan Overview

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Title: Enhancing Men's Awareness of Testicular Diseases (E-MAT): A Feasibility Study and Study Within A Trial (SWAT)

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Project abstract:

Background: Testicular cancer (TC) is the most common malignancy in men <50yrs. Early detection of TC is cost-effective and yields better clinical outcomes. Most (80%) testicular lumps are benign and detected by men. Gaelic Athletic Association (GAA) players and coaches are at risk for testicular diseases. We developed an immersive experience using virtual reality (VR) to Enhance Men’s Awareness of Testicular diseases (E-MATVR).

Aim: The aim of our study is to examine the feasibility of conducting a definitive trial to test the effect of E-MATVR (intervention) compared to plain Electronic information E-MATE (control) on primary outcomes (testicular knowledge and self-examination behaviours) and secondary outcomes (testicular awareness, frequency of self-examination, recommendation of self-examination to others, help-seeking intentions, implementation intentions, and perceived risk) among GAA players and coaches.

Objectives:

1. Feasibility trial: To determine the processes needed to conduct a definitive trial, identify unforeseen problems, and plan for progression to a definitive trial. Outcomes will be measured at baseline (T0),immediately post-test (T1), and three months post-test (T2) using electronic surveys.

2. Study Within A Trial (SWAT): To determine which recruitment method(s) (Twitter/Facebook/posters with QR code) is/are efficient and cost effective for participant recruitment and retention. Using a cluster cross-over design, GAA clubs will be randomly assigned to either Facebook, Twitter, or QR Code for two weeks. Clubs will be re-randomised to either one of the other recruitment methods for another two weeks. After a further two weeks, the clubs will change to the remaining method.

3. Economic evaluation: To conduct a cost-benefit analysis of E-MATVR compared to E-MATE using a dedicated survey.

4. Mixed-method process evaluation: To explore potential sources of intervention failure (contextual effects, inputs, engagement, activities, and outcomes) and explore participants' experiences of E-MATVR and E-MATE.

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Enhancing Men's Awareness of Testicular Diseases (E-MAT): A Feasibility Study and Study Within A Trial (SWAT)

Data description and collection or re-use of existing data

How will new data be collected or produced and/or how will existing data be re-used?

This feasibility study includes four interlinked work packages as follows (i) a feasibility trial, (ii) Study Within A Trial (SWAT), (iii) economic evaluation, and (iv) process evaluation all aimed to test the feasibility of conducting a future definitive trial to test the effect of a virtual reality based-intervention titled E-MAT (Enhancing Men's Awareness of Testicular Diseases) on GAA players and coaches' knowledge of testicular diseases and testicular self-examination.

The SWAT involves testing three recruitment strategies (Facebook link where players can click and register their interest in participating in the study, Twitter link where players can click and register their interest in participating in the study, and posters with Quick Response [QR] code distributed in target GAA clubs). In the SWAT, data will be collected on the proportion of participants who consent to participate, relative to the number of players and coaches contacted and the number of players and coaches who clicked the link to register their interest. The proportion of participants randomized who remain to the conclusion of the study and the proportion of players and coaches who click the link and register their interest for the primary trial will be collected. The SWAT will also collect data relevant to the cost per strategy including the unit cost per person clicking the link, unit cost per person consented to the primary trial and unit cost per person retained at final end point of primary trial.

In the feasibility trial, data will be collected at pre-test, during testing, immediately post-test, and three months post-test, as described below:

Pre-test (T0): We will administer a pre-test questionnaire to collect data on sociodemographic variables, testicular knowledge, testicular awareness, perceived risk of developing a testicular disease, intentions to seek help, intentions to feel own testes, intentions to advise other men to feel their own testes, and behaviours pertaining to feeling own testes.

During: A fidelity checklist will be used to check if the intervention and control were delivered as intended. This is part of a mixed-method process evaluation. The headset in the E-MATVR intervention will collect data on the time taken to deliver the E-MATVR intervention (dose exposure) and the units of the E-MATVR intervention completed (dose completeness). The same outcomes will be collected for E-MATE (control).

Post-test (immediately; T1): We will administer a post-test questionnaire to collect data on testicular knowledge, testicular awareness, perceived risk of developing a testicular disease, intentions to seek help, intentions to feel own testes, and intentions to advise other men to feel their own testes. Interviews/focus groups will also be conducted to explore participants' experiences of E-MATVR and E-MATE and key stakeholders' (e.g., researchers') experiences of delivering the interventions. This is part of a mixed-method process evaluation.

Post-test (3 months; T2): We will administer a questionnaire three-month post-test to collect data on testicular knowledge, testicular awareness, perceived risk of developing a testicular disease, intentions to seek help, intentions to feel own testes, intentions to advise other men to feel their own testes, and behaviours pertaining to feeling own testes.

Within the feasibility trial, a mixed-method process evaluation will be conducted to explore participants' experiences of E-MATVR and E-MATE and potential sources of intervention failure. Data for the process evaluation will be collected within the outcome measures for the feasibility trial at T0 and T1.

An economic evaluation will also be conducted to compare incremental costs and benefits of E-MATVR with E-MATE. Data for the economic evaluation will be collected within the outcome measures for the

feasibility trial at T0, T1 and T2.

The feasibility trial will be conducted with approximately 74 participants, who are aged between 18 and 50 years, residing in Ireland and players and coaches in the target GAA clubs. All data will be fully anonymized without any identifiers.

What data (for example the kind, formats, and volumes), will be collected or produced?

At T0, we will collect data on sociodemographic variables, testicular knowledge, testicular awareness, perceived risk of developing a testicular disease, intentions to seek help, intentions to feel own testes and behavior:

- The sociodemographic questionnaire will collect data on sociodemographic variables including age, gender, GAA club, role within GAA club, nationality, marital status, occupation, level of education, history of testicular diseases (if any) and experience of using virtual reality (if any).
- The testicular knowledge questionnaire consists of 8 multiple choice questions and 4 ‘true’ and ‘false ‘type questions which will assess men’s knowledge of the normal testes, symptoms of testicular disease, testicular self-examination, and the most common testicular diseases.
- The testicular awareness scale, perceived risk item and implementation intentions scale will be assessed on a 5-point Likert scale with answers ranging between “Strongly Disagree=1; Disagree=2; Neutral=3”; “Agree=4”; and “Strongly Agree=5”. The testicular awareness scale will assess men’s familiarity with their own testes, what is normal and what is not normal, and ability to differentiate between what is normal and what is not normal. The perceived risk item will assess men’s perceived risk of developing a testicular disease. The implementation intentions scale will assess men’s intentions to purposefully feel their own testes and advise at least one man to feel his own testes at least once over a one-month period.
- The behavior questionnaire consists of ‘Yes’ and ‘No’ type questions which will assess men’s past behaviors pertaining to feeling their testes and having their testes examined by a healthcare professional.
- The general help seeking questionnaire will be assessed on a 7-point Likert Scale with answers ranging between “Extremely Unlikely=1”; “Unlikely=3”; “Likely= 5”; “Extremely Likely=7” and will assess men’s intentions to seek help for testicular symptoms.

During the intervention, we will use intervention fidelity checks to check if the interventions were delivered as intended. The intervention fidelity checklist will consist of 6 items (E-MATVR) and 3 items (E-MATE). The headset in the E-MATVR intervention will collect data on the time taken to deliver the E-MATVR intervention (dose exposure) and the units of the E-MATVR intervention completed (dose completeness). The same data will be capture for E-MATE (control arm) which involves administering the same information contained in E-MATVR Electronically using a tablet (e.g., iPad).

At T1, we will collect data on testicular knowledge, testicular awareness, perceived risk of developing a testicular disease, intentions to seek help and intentions to purposefully feel their own testes. Details above.

Interviews and focus groups will also be conducted at T1 to explore participants’ experiences of E-MATVR and E-MATE (topic guide with 6 questions) and key stakeholders’ experiences of delivering the interventions (topic guide with 10 questions).

At T2, we will collect data on testicular knowledge, testicular awareness, testicular problems, perceived risk of developing a testicular disease, intentions to seek help, intentions to purposefully feel their own testes and behavior. Details above.

A more detailed description of the feasibility trial data collection instruments is summarized in Table 1. As mentioned previously, the data for the process evaluation will be collected within the outcome measures for the feasibility trial. A summary of the process evaluation data collection instruments is summarised in Table 2.

the entire data collection is expected to comprise of less than 500 GB of digital storage.

Documentation and data quality

What metadata and documentation (for example the methodology of data collection and way of organising data) will accompany data?

Data collection will be conducted by members of the research team using questionnaires, interviews, focus groups and fidelity checklists.

Data on dose exposure, dose completeness and dose satisfaction will be collected within the VR headset in EMATVR (intervention arm). This data will be recorded in the headset for each participant and will be extracted following the intervention for data analysis. Each participant will be given a unique record number which will enable us to correlate the data from the headset with the data recorded on the Tablet (e.g., iPad) within E-MATE (control arm)

All variables will be recorded within Comma Separated Value (.csv) data tables. Data files will include metadata in line with the Dublin Core Metadata Initiative (http://dublincore.org/) alongside accompanying data dictionaries which will be developed in parallel. The Castor Electronic Data Capture (EDC) platform to be used will also contain an in-built audit trail to document data entry and quality. This tool will host all the collected data mentioned above. Throughout the study, routine data visualization and exploration approaches using the R statistical computing and graphics language will be performed. This will allow for the development of standardized documentation of both data review and reporting processes, in collaboration with the Statistics and Data Analysis (SDAU) of the HRB Clinical Research Facility-Cork (CRF-C) that is both reproducible and linked to version control strategies.

What data quality control measures will be used?

FAIR data principles will be followed at all times. The Castor EDC platform enables data validation checks and contains an in-built audit trail to document data quality. This platform can also assign roles to users and can hide parts of the study for certain users based on their particular role. As mentioned above, routine data visualization and exploration approaches using the R statistical computing and graphics language will be performed which will allow for the development of standardized documentation of both data review and reporting processes, in collaboration with the SDAU, that is both reproducible and linked to version control strategies. Study participants will be assigned a persistent digital object identifier (DOI). All data will be anonymized.

Storage and backup during the research process

How will data and metadata be stored and backed up during the research process?

The data will be securely stored on University College Cork (UCC) cloud storage facilities (UCC NAS and UCC One Drive). UCC cloud storage is protected by Multi-Factor Authentication (MFA). The data will be retained securely for at least 10 years.

How will data security and protection of sensitive data be taken care of during the research?

The data will be securely stored on UCC cloud storage facilities which is protected my MFA as mentioned above. Only research team members who are involved in the data analysis will have access to the relevant data. Dr Mohamad Saab (PI), Megan McCarthy (Research Support Officer), Dr Darren Dahly (Co-Applicant and Lead Statistician) and Brendan Palmer (HRB CRF-C Associate Statistician will control the data during active research. All data are stored and used in accordance with the Irish Data Protection Amendment Act of 2003 and General Data Protection Regulation (GDPR, 2018).

Legal and ethical requirements, codes of conduct

If personal data are processed, how will compliance with legislation on personal data and on security be ensured?

All personally identifiable data will be subject to General Data Protection Regulation (GDPR) (https://eurlex.europa.eu/eli/reg/2016/679/oj) and the Irish Health Research Regulations (https://www.hrb.ie/funding/gdprguidance-for-researchers/health-research-regulations-2018/). All staff with data access permissions will be required to undergo training in GDPR to ensure that all data which is collected for the purposes of this project will be treated with the highest standards of security and confidentiality. Participation in the study and participant identifiers will be treated as confidential and no participant identifiable records or results relating to the study will be disclosed to any third party other than the authorized investigators. Personal identifiers will undergo pseudonymization. An encryption key, held securely away from the data, will be accessible to the project Principal Investigator at site only.

How will other legal issues, such as intellectual property rights and ownership, be managed? What legislation is applicable?

The role of the Office of Technology Transfer (TTO) within UCC is to capture, protect, and explore the commercial potential of UCC research. The TTO achieves this through adherence to the National Intellectual Property Protocol and continued guidance from internal as well as external stakeholders (for example, Knowledge Transfer Ireland). The background Intellectual Property (IP) to be introduced to the project was developed within UCC and captured in the invention disclosure form entitled "E-MAT (Enhancing Men’s Awareness of Testicular Disorders)” (IDF_UCC-17-62) registered with the TTO in December 2017. We are not aware of any restrictions in using the E-MAT software in the proposed study. It is envisioned that the E-MAT software will be released as open-source for non-commercial research and education purposes in the future. Given our previous engagement with the TTO, any IP generated during the study will be captured and submitted to the TTO via the invention disclosure form. Dissemination of study results will not take place until the TTO has reviewed and considered whether protection should be sought for such resulting IP.

What ethical issues and codes of conduct are there, and how will they be taken into account?

Ethical approval for the study was received from the Clinical Research Ethics Committee of the Cork

Teaching Hospitals (CREC) in UCC [CREC Review Reference Number: ECM 4 (e) 01/12/21]. All data will be collected, managed and processed in line with the recommendations of CREC. All research will be conducted in line with the UCC Code of Research Conduct.

Data sharing and long-term preservation

How and when will data be shared? Are there possible restrictions to data sharing or embargo reasons?

Identification of data dissemination repositories and construction of Open Science Framework (OSF) projects will dictate data sharing outputs that will be returned from this project. This will allow for links to these resources to appear within associated publications. The Situation, Task, Action and Result (STAR) of this work will form part of the final DMP deliverable.

How will data for preservation be selected, and where data will be preserved long-term (for example a data repository or archive)?

Data sharing repositories will be formerly identified via careful alignment of the expected data object outputs and evaluated using the re3data resource (https://www.re3data.org/). This is to ensure maximum utility and interoperability of the final data package(s) and assignment of a persistent digital object identifier (DOI). Additional post-study data provenance will be enacted through sharing of analysis scripts and study protocols via OSF and/or the HRB Open Research platform projects with accompanying DOI(s).

What methods or software tools are needed to access and use data?

R and RStudio software will be used to reproduce the results of the analyses. RStudio is an Integrated Development Environment for R, a programming language for statistical computing and graphics. All data and metadata will be shared in open and accessible file formats such as csv or txt. Qualitative data (e.g., interviews and focus groups conducted as part of the process evaluation) will be analysed in Nvivo.

How will the application of a unique and persistent identifier (such as a Digital Object Identifier (DOI)) to each data set be ensured?

The infrastructure of the re3data.org repository will be leveraged to assign a unique and persistent DOI to the dataset. This will ensure maximum utility and interoperability of the final data package(s) and assignment of a persistent DOI. This will be included in the data availability statement of all publications, linking all research outputs from this project. DOI from previously published outputs such as protocols will be included in the metadata of the shared datasets.

Data management responsibilities and resources

Who (for example role, position, and institution) will be responsible for data management (i.e. the data steward)?

Day-to-day data management will be the responsibility of the Principal Investigator (Dr Mohamad Saab) and the Research Support Officer (Ms Megan McCarthy). Dr Brendan Palmer (HRB CRF-C Associate Statistician) is the FAIR Data Steward and will provide the necessary data management expertise and guidance alongside Dr Darren Dahly (Co-Applicant and Principal Statistician for the HRB CRF-C).

What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?

Pre-study budgeting factored FAIR data costs into consideration and as such funds are in place to enact all aspects outlined in the DMP. The research team will work closely with the SDAU to ensure that the study data is FAIR. Prior to study initiation, study staff will be instructed by members of the SDAU on data collection, organization, and spreadsheet entry techniques that adhere to the FAIR data principles and will guide development of the study data management plan.