

Enhancing men's awareness of testicular diseases (E-MAT): a feasibility trial and study within a trial (SWAT)

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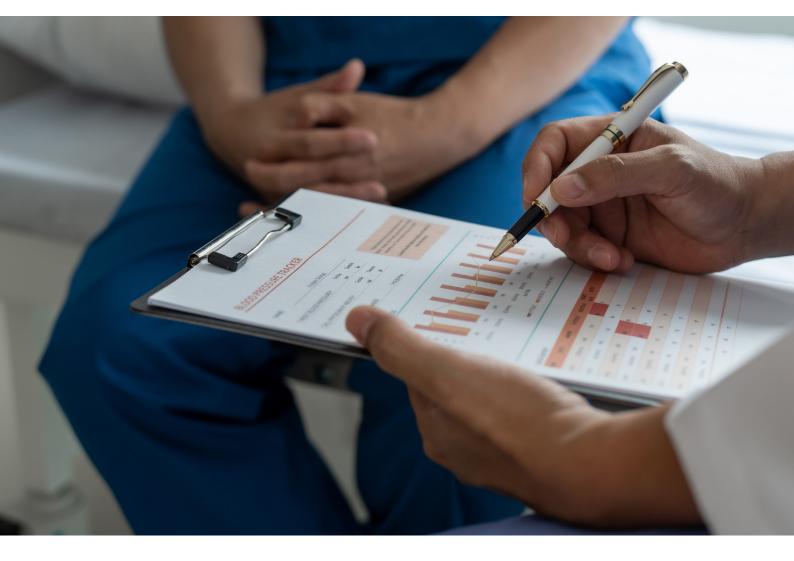




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Facts and Figures about Testicular Diseases

- Testicular cancer is the most common cancer in men aged 15 to 44 years¹.
- The most common symptom of testicular cancer is a painless lump in one of the testicles².
- Benign testicular diseases are more common than testicular cancer and can cause similar symptoms³.
- Epididymo-orchitis is a sexually transmitted infection. It is the most common cause of testicular lumps in men under 50 years³.
- Testicular torsion or twisting of the testicles is another benign disease often affecting men younger than 25 years⁴.
- Men who experience symptoms of testicular disease do not always seek medical help, mainly due to embarrassment, fear of a cancer diagnosis, and lack of awareness⁵.
- Early detection of testicular diseases is associated with lower financial costs and better health outcomes^{6,7}.
- Athletes engaged in games like hurling, the fastest field sport, are particularly at risk for testicular trauma⁸.
- We previously found that virtual reality (VR) gaming may be effective in promoting men's awareness of testicular diseases^{6,9}.

Development of the E-MAT Intervention

We developed the **E**nhancing **M**en's **A**wareness of **T**esticular diseases (or **E-MAT**) intervention as an interactive VR game using the Medical Research Council Framework for complex intervention development and evaluation^{9,10}. The steps that led to the development and initial testing of the E-MAT intervention are summarised in Figure 1.

2014-2015

Three systematic literature reviews of 40 studies on men's awareness of testicular diseases and testicular selfexamination

2015-2016

Qualitative study exploring awareness, help-seeking, and preferred strategies for learning about testicular diseases among 29 men from the community

2016-2017

Development of the Preconscious Awareness of Action theoretical framework to underpin E-MAT

2016-2017

Development of the E-MAT VR game in collaboration with the School of Computer Science and IT at UCC

2017

Testing the feasibility, usability, and acceptability of E-MAT with 15 university students

2017

Pilot testing the effectiveness of E-MAT in raising testicular awareness with 53 university students and staff members

Figure 1. The steps that led to the development and initial testing the E-MAT VR intervention



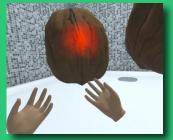










Figure 2. Screenshots from the various levels of the E-MAT intervention

Description of the E-MAT Intervention

We designed E-MAT as a three-level interactive VR game that takes place in a virtual apartment, with each room representing one game level. Various screenshots from E-MAT are presented within Figure 2:

- Level 1 takes place in the shower where two
 walnuts are used to represent the testicles.
 The aim of this level is to familiarise the player
 with the normal look and feel of the testicles
 and the most common testicular symptoms.
- **Level 2** takes place in the bedroom where a 3D model of a testicle is used to explain about different testicular structures and diseases.
- Here, we used a poster of a fingerprint to explain that testicles are unique just like a fingerprint, hence the importance of knowing what is normal for the person. Another poster explained about the technique for testicular self-examination. Finally, we used a representation of a first aid kit to highlight the importance of early help-seeking for testicular symptoms of concern.

Aim of the Current Study

The Gaelic Athletic Association (GAA) is Ireland's largest sporting and cultural organisation, focused on promoting indigenous Gaelic games including hurling, Gaelic football, handball, rounders, camogie and ladies' football. More GAA clubs are adopting "The Healthy Club" project to promote the health of their members.

In the current study, we examined the feasibility of conducting a larger study to test the effect of the E-MAT intervention among male GAA players and coaches aged 18 to 50 years. To achieve this, we compared the effect of E-MAT delivered as an interactive VR game to E-MAT delivered as a non-interactive portable document format (PDF) on a Tablet. The PDF contained plain text and screenshots from the VR game, similar to those in Figure 2.

The current study had four interlinked sub-studies:

- Study Within A Trial (SWAT) to help determine which recruitment method(s) (Facebook™, X™ [formerly Twitter™], and poster with Quick Response [QR] code) is/are more efficient for recruiting participants to the E-MAT study.
- Feasibility trial to determine the processes needed to conduct a future definitive/ larger trial.
- **Mixed-method process evaluation** to explore participant satisfaction and the processes surrounding the delivery and testing of E-MAT.
- **Economic evaluation** to conduct a cost-benefit analysis of E-MAT delivered using VR compared to E-MAT delivered using a Tablet.



Methods for Delivering and Testing the E-MAT Intervention

A Study Within A Trial (SWAT) was conducted. This involved posting about the study on each club's Facebook™ and X™ pages and using posters with a QR code in each club.

Each of the three strategies (Facebook™, X™, and QR code) contained a link that GAA players could click on in order to register their interest in participating in the study.

Data collection date and time were agreed with participants who registered their interest in participating during the SWAT.

An information leaflet was read and an informed consent form was signed by 74 participants from 9 GAA clubs in Cork.

All 74 participants were individually randomised to receive either the interactive VR game or the non-interactive PDF on the Tablet.

All 74 participants completed a baseline questionnaire.

A checklist was completed by researchers to ensure that the VR intervention was delivered as intended and to note the time it took participants to complete the study.

The VR intervention was administered to 37 participants.

The Tablet-based intervention was administered to 37 participants.

A checklist was completed by researchers to ensure that the Tablet-based intervention was delivered as intended and to note the time it took participants to complete the study.

All 37 participants completed a questionnaire immediately after the VR intervention.

All 37 participants completed a questionnaire immediately after the Tablet-based intervention.

Of the 37 participants, 34 completed a questionnaire three months after the VR intervention and received a €50 voucher.

Of the 37 participants, 32 completed a questionnaire three months after the Tablet-based intervention and received a €50 voucher.

Figure 3. The process followed while testing the E-MAT intervention.

Key Findings

Below is a summary of key findings from each of the four sub-studies.

Study Within A Trial (SWAT)

- A total of 50 participants from 7 GAA clubs participated in the SWAT. Of those, 47 were retained until the end of the study.
- There were 234 clicks on X[™], 177 on Facebook[™], and 13 on the poster with QR code. Of those, 16 participants consented to participate in the study. The remaining participants were either referred by a friend, saw posts about the study on more than one social media platform, or received a text/ WhatsApp[™] message about the study.
- A single link was used for all 7 GAA clubs. This made it impossible for us to determine which clicks came from which club.
- In terms of cost, the QR code was the most expensive at €4,121, while X[™] and Facebook[™] had an equal total cost of €3,740 each.
- While X[™] was cheaper than Facebook[™] in terms of the number of clicks, the engagement was better with Facebook[™] resulting in more participants consenting and being retained through Facebook[™], thereby reducing costs per participant.

Feasibility Study

- We met our recruitment target with 74 participants recruited from 9 GAA clubs. This number is inclusive of the 50 participants recruited from the SWAT.
- Across all participants (i.e., both VR and Tablet), with a maximum score of 1, mean knowledge scores increased from 0.41 (Standard Deviation [SD] 0.15) at baseline, to 0.77 (SD 0.16) immediately after the intervention indicating greater knowledge of testicular symptoms and diseases.
- Three months later, the overall mean knowledge score for all participants was still higher than baseline at 0.65 (SD 0.15).
- The mean knowledge scores for E-MAT delivered using VR versus E-MAT delivered using a Tablet did not differ significantly at any timepoint.
- At baseline, 54% (n=20) of participants in the VR intervention versus 24% (n=9) in the Tablet-based intervention reported purposefully feeling or examining their testicles within the past month. Three months after the study, all participants in the VR intervention (n=34, 100%) and most participants in the Tablet-based intervention (n=29, 91%) reported purposefully feeling or examining their testicles within the past three months.







Mixed-Method Process Evaluation

- Satisfaction with the study was overwhelmingly high, particularly among participants who engaged with the VR intervention.
- Both VR and Tablet-based interventions were perceived as user friendly and applicable to men from different backgrounds.
- Participants used words like "engaging", "quick", "visual", "interactive", "clear", "realistic", "informative", "fun", and "enjoyable" to describe the VR intervention.
- The Tablet-based intervention was described as "simple", "easy", "user friendly", and "visual" yet "not interactive".
- It took participants around 10 minutes to complete the VR intervention and around 4 minutes to complete the Tablet-based intervention.
- Only 2 participants ended the VR intervention early. One due to mild nausea and one due to a technical problem.

Economic Evaluation

- On average, participants were willing to pay €22 for E-MAT delivered using VR and €11 for E-MAT delivered using the Tablet.
- The mean cost of the VR intervention was €104 and the mean cost of the Tablet-based intervention was lower at €23.
- The mean benefit of the VR intervention was €22 and the mean benefit of the Tablet-based intervention was lower at €11. The higher costs were attributable to the capital costs associated with developing and delivering the VR intervention.
- Three participants who received the VR intervention and one participant who received the Tabletbased intervention visited a doctor for testicular pain or testicular injury within the three months following their participation in the study.



Lessons Learned

Below is the list of lessons learned from the various sub-studies. While this list is not exhaustive, it is valuable for the scaling up of the VR and Tablet-based interventions and the conduct of a larger study in the future. The below lessons are also of relevance to researchers who are planning on testing the feasibility of complex technology-based health promoting interventions and/or using social media to recruit participants into a clinical trial:

- 1. VR has the potential to engage hard to reach populations (i.e., younger men) as evident by the high satisfaction with the study and the high retention rate since around 90% of the 74 participants who were recruited stayed until the conclusion of the study (three months).
- 2. Providing an incentive at the conclusion of the study was one of the key contributors to the high retention rate.
- 3. The contribution of public and patient representatives was instrumental in ensuring that study documents were clear, and that the study was relevant to younger men. In addition, public and patient representatives played a key role in recruiting participants from various clubs.
- 4. Recruitment using posters with a QR code was ineffective, expensive, and led to minimal engagement.
- 5. Both, club members and non-members can follow a GAA club on social media. Therefore, relying on club membership to determine the denominator within the SWAT was not meaningful.
- 6. Creating different sets of links for Facebook™, X™, and QR code for each of the participating clubs would allow for a more granular analysis of the recruitment process.
- 7. Peak hours for X[™] and Facebook[™] should be considered while advertising the study. X[™] peaked in use at 12pm, 6pm, and 9pm. Facebook[™] peaked in use at 8am, 9am, 10am, 5pm, and 8pm. X[™] peaked on Tuesday and Thursday while Facebook[™] peaked on Friday.
- 8. We did not have direct access to clubs' X[™] and Facebook[™] accounts. Therefore, in order to be able to evaluate recruitment, researchers would need to be given user/ administrator

- rights to the club's FacebookTM and X^{TM} accounts.
- Some participants accessed the Facebook[™] and X[™] links via text message or WhatsApp[™], making it difficult to track the effect of the recruitment methods.
- 10. There were no major differences in testicular knowledge or testicular self-examination scores between the VR and Tablet groups since the sample size was not large enough to detect a difference.
- 11. The conduct of an economic evaluation as part of a feasibility study was valuable and will help define and refine methods for data collection and explore the validity and sensitivity of alternative economic outcomes within a future larger trial.
- 12. Alternative intervention delivery strategies should be considered to reduce the cost of VR intervention delivery.
- 13. Information overload and repetition within the surveys were identified as problematic by some participants and researchers. To this end, there is value from revisiting and scrutinising the instruments.
- 14. Qualitative research, particularly in the process evaluation, was a strength in this study as it provided in-depth recommendations from participants as well as researchers who collected data in the 9 GAA clubs.
- 15. There is scope to increase the interactivity and visual content of the VR and Tablet-based interventions within future iterations of the E-MAT intervention.

Conclusion

VR as a health promotion intervention is feasible and acceptable. Study results suggest VR may be effective in enhancing men's awareness of testicular diseases and testicular self-examination behaviours by providing more engaging and effective learning experiences for younger men. A future definitive trial is warranted to test the effect of E-MAT, considering lessons learned from the various sub-studies within this feasibility study.

Impact

Conference Presentations and Invited Talks

- 12th to 15th November 2023: "Is Dismissing Intervention Development Costs a Fallacy? A Case Study of a Digital Health Intervention" at ISPOR Europe, Copenhagen, Denmark.
- 11th to 15th November 2023: Enhancing Men's Awareness of Testicular Diseases using Virtual Reality: The E-MAT Trial£ at the Sigma Nursing 47th Biennial Convention, San Antonio, Texas, USA.
- **9th November 2023:** "Enhancing Men's Awareness of Testicular Diseases (E-MAT): A Feasibility Trial and Process Evaluation" at the European Public Health Conference, Dublin, Ireland.
- **10th October 2022:** "Cancers of Young and Older Men: A Focus on Testicular and Lung Cancers" at the Global Action on Men's Health webinar, Brussels, Belgium.
- **6th October 2023:** "Conducting Economic Evaluations Alongside Feasibility Trials: A Case Study with the Enhancing Men's Awareness of Testicular Diseases (E-MAT) Feasibility Trial" at the University College Cork (UCC) Department of Economics, Cork, Ireland.
- **21st September 2023:** "Enhancing Men's Awareness of Testicular Diseases (E-MAT) Using Virtual Reality: A Feasibility Randomized Controlled Trial" at the UCC College of Medicine and Health Futures Research Conference, Cork, Ireland (best oral presentation award).
- **15th May 2023:** "Enhancing Men's Awareness of Testicular Diseases using Virtual Reality: The E-MAT Trial" at the UCC Cancer Seminar Series, Cork, Ireland.
- 23rd and 24th September 2022: "Enhancing Men's Awareness of Testicular Diseases (E-MAT): A Feasibility Study and Study Within A Trial (SWAT)" at the 2nd Milan Cancer Meeting: Innovations in Prevention, Research and Care, Milan, Italy.
- 17th February 2022: "Enhancing Men's Awareness of Testicular Diseases (E-MAT) using Virtual Reality" at the Hariri School of Nursing virtual research seminar, Beirut, Lebanon.

Public Engagement

- **25**th **April 2023:** RTE Radio One interview: https://podcasts.apple.com/ie/podcast/could-vr-play-a-role-in-raising-awareness-about/id203094311?i=1000610607254
- **28**th **March 2023:** RTE Brainstorm: https://www.rte.ie/brainstorm/2023/0328/1366716-testicular-health-men-gaa-emat-vr-game/
- January 2023: Cork LGBT+ Pride Festival https://online.flippingbook.com/view/850487848/100-101/
- July 2022: Feature in the Southern Star Newspaper

Protocols and Data Management Plan

- **Feasibility trial protocol:** https://www.clinicaltrials.gov/ct2/show/NCT05146466?term=testicular+diseases&recr=b&draw=2&rank=1
- **SWAT protocol:** Filetoupload,1358622,en.pdf (qub.ac.uk).
- Process evaluation protocol: https://doi.org/10.12688/hrbopenres.13515.1
- Data management plan: https://dmponline.dcc.ac.uk/plans/79922/export.pdf?export%5Bquestion_headings%5D=true





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