

5th CHRC Annual Summit

September 23rd & 24th, 2024

Preventing type 2 diabetes in Portugal: Type 1 hybrid effectivenessimplementation trial of a person-centered digital intervention – Study Protocol

Lucia Domingues¹, Marta M. Marques², Joana Alves2, Isa B. Félix3, Nuno Pimenta,4,5,6 Mara Pereira Guerreiro3, on behalf of the VA | PREVENTION consortium

¹ Comprehensive Health Research Centre, NOVA Medical School, NOVA University ²NOVA National School of Public Health, Public Health Research Centre, Comprehensive Health Research Center, CHRC, NOVA University Lisbon, Lisbon, Portugal ³ Egas Moniz Center for Interdisciplinary Research (CiiEM); Egas Moniz School of Health & Science, Caparica, Almada, Portugal; ⁴ Sport Sciences School of Rio Maior – Polytechnic Institute of Santarém, Rio Maior, Portugal; ⁵Centro Interdisciplinar de Estudo da Performance Humana (CIPER), Faculdade de Motricidade Humana, Universidade de Lisboa, Lisboa, Portugal; ⁶ SPRINT – Sport Physical activity and health Research and INnovation CenTer, Polytechnic University of Santarém, Portugal.

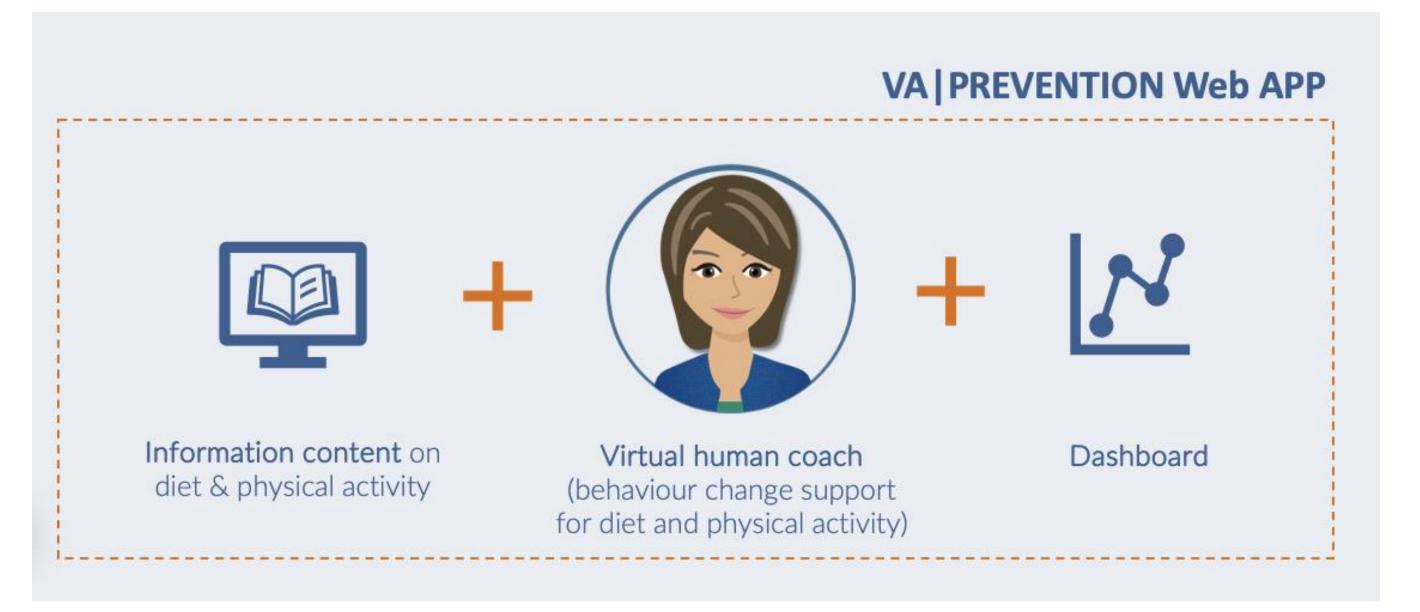
BACKGROUND

- In-person interventions focused on diet and physical activity can halt the progression to Type 2 Diabetes (T2D) in high-risk individuals. However, implementation at scale is challenging (e.g. intensive resources, low uptake).
- T2D prevention interventions using automated virtual coaches are needed, tested through well-powered RCTs.

OBJECTIVES

Evaluate the effectiveness, implementation and cost-effectiveness of a novel person-centred digital intervention to prevent T2D in highrisk adults, the first in Portugal, through a **type 1 multi-centric hybrid** effectiveness-implementation study (HEI), supplemented by

METHODS (CONT.)



- 280 participants will be recruited, eligibility criteria include >18 years old and high risk of T2D (FINDRISC Score >= 15)
- This digital intervention is intended to be qualified as a medical device in accordance with the Medical Device Regulation (EU) 745/2017.

qualitative and economic studies.

VA PREVENTION



METHODS

Type 1 hybrid effectiveness-implementation trial



Semi-structured interviews

Fundação

para a Ciência

Tecnologia

- Participants (Experimental Group)
- Health Professionals (Experimental Group)
- Healthcare managers from Community and Health Units

Recruitment centres: Primary care units and Community

pharmacies, within the Ezfy network will recruit participants and

collect data, supported by the VA|PREVENTION team.

RESULTS



Submission to Competent Authority and independent ethics committee (CEIC).

CONCLUSION

The main expected result of VA|PREVENTION is a TRL7 web app prototype.



REFERENCES

- Griauzde, D., Kullgren, J. T., Liestenfeltz, B., Ansari, T., Johnson, E. H., Fedewa, A., Saslow, L. R., Richardson, C., & Heisler, M. (2023). A mobile phone-based program to promote healthy behaviors among adults with prediabetes who declined participation in free diabetes prevention programs: Mixed-methods pilot randomized controlled trial. *JMIR Formative Research, 7*(3), e29907. <u>https://doi.org/10.2196/29907</u>
- Ross, J. A. D., Barron, E., McGough, B., Valabhji, J., Daff, K., Irwin, J., Henley, W. E., & Murray, E. (2022). Uptake and impact of the English National Health Service digital diabetes prevention programme: Observational study. *BMJ Open Diabetes Research & Care, 10*(1), e002736. <u>https://doi.org/10.1136/bmjdrc-2021-002736</u>
- Wilson, K. E., Michaud, T. L., Almeida, F. A., Schwab, R. J., Porter, G. C., Aquilina, K. H., Brito, F. A., Golden, C. A., Dressler, E. V., Kittel, C. A., Harvin, L. N., Boggs, A. E., Katula, J. A., & Estabrooks, P. A. (2021). Using a population health management approach to enroll participants in a diabetes prevention trial: Reach outcomes from the PREDICTS randomized clinical trial. *Translational Behavioral Medicine*, *11*(5), 1066–1077. <u>https://doi.org/10.1093/tbm/ibab010</u>

FUNDING

This work was funded by FCT – Fundação para a Ciência e a Tecnologia, I.P., by means of national funds

(grant reference 2022.02969.PTDC; <u>https://doi.org/10.54499/2022.02969.PTDC</u>)

