# Individualised variable-interval risk-based screening in diabetic retinopathy: the ISDR research programme including RCT

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Primary conflicts of interest: Philip Burgess reports positions as Director of National Institute for Health and Care Research (NIHR) Applied Research Collaboration NWC (2019 to present); Director of NIHR Collaborations for Leadership in Health Research and Care (CLAHRC) North West Coast (NWC) (2014–19); Programme Grants for Applied Research ISDR Co-Applicant (2012–19); RfPB COPES Trial (2019–22); member of Health Technology Assessment (HTA) IP Panel (2016–18); Member HTA Prioritisation Committee (2016–20); Associate Director NIHR Research Design Service North West (2008 to present). Mark Gabbay reports positions as Director of NIHR Applied Research Collaboration North West Coast (NWC) (2019 to present), Associate Director NIHR Research Design Service North West (2013–22), Director NIHR Collaborations for Leadership in Health Research and Care NWC (2014–19), NIHR Research for Patient Benefit COPESS Trial Co-Investigator (2019–22) and membership of the HTA IP Prioritisation Committee (2016–2020). Christopher Sampson reports employment from The Office of Health Economics outside the submitted work. Irene Stratton reports fees paid to their employer, Gloucester NHS Foundation Trust, from Public Health England outside the submitted work. Paula Williamson reports Directorship of Liverpool Clinical Trials Centre (formerly Clinical Trials Research Centre) (2005–18), which received funding from NIHR (end date 31 August 2021).

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## Plain language summary

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## **Plain language summary**

Diabetic retinopathy remains a leading cause of vision loss for people with diabetes. Annual photographic screening allows early detection and prompt treatment in many countries. A new approach is to vary how often this is undertaken at each visit, after calculating each person's risk of progression; we have called this 'individualised' screening.

We tested this variable-interval risk-based approach against annual screening in a randomised controlled trial of 4534 people in Liverpool. Six-, 12- or 24-month intervals represented high, medium and low risks, respectively, of becoming screen-positive by the next appointment. With our patient and public involvement group, we designed a computer-based risk-calculation system using personal information from screening, general practitioners and hospitals.

Attendance rates at the next screening appointment were similar in the individualised (84%) and annual (control) (85%) groups. Similar amounts of sight-threatening diabetic retinopathy were detected in the two arms (1.4% individualised, 1.7% control), with 43% fewer visits. In this study in a single geographical region, savings estimated to accrue to the NHS per person over 2 years were £17.34 and £23.11 for wider society, but estimates did not include treatment costs.

During interviews, 60 people with diabetes and 21 healthcare professionals said that individualised screening would be acceptable because of increasing rates of diabetes and the chance to target high-risk people. Patients had anxieties about the reliability of the risk-calculation and restricting access, requesting opportunities for earlier screening if risks changed.

Varying screening intervals based on a person's own risk of progression appears feasible and safe. Lowrisk people would be spared unnecessary appointments. Introducing an individualised approach could now move to wider testing and validation in other UK and international settings. The trial only ran for 2 years and was in a long-established programme with low rates of disease, so monitoring of attendance and retinopathy rates should be included as part of wider testing.

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