## Individualised Screening for Diabetic Retinopathy: the ISDR study. A Randomised Controlled Trial of Safety, Efficacy and Cost Effectiveness

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## Background: Varying the intervals in retinopathy screening, informed by personal risk, offers reallocation of resources to better target high risk groups and address the increasing prevalence of diabetes. However safety data especially on extended intervals is minimal.

Aim: To evaluate the safety, efficacy and cost effectiveness (CE) of individualised variable-interval risk-based screening in a population setting compared to usual care.

## Methods: Masked, 2 arm, parallel assignment, equivalence RCT (largest to date in screening) with independent trials unit monitoring in people with diabetes aged ≥12 years attending screening in a single English programme. Randomisation was 1:1 to individualised screening (active group; 6, 12 or 24 months for high, medium and low risk) determined by a risk calculation engine using real-time local demographic, retinal and clinical data, compared with annual screening (control). CE analysis measuring NHS and societal costs took a 2 year time horizon.

## Findings: 4534 participants entered the study - after withdrawals/loss to follow-up: active 2097; control 2224. Attendance rates at first follow up visit (primary outcome, safety) were equivalent (per protocol analysis, 5% margin): active 83.6% control 84.7% (difference 1.0, 90% CI -0.8, 2.9). STDR detection rates were non-inferior (1.5% margin): active 1.43% control 1.71% (difference -0.28, CI -0.93, 0.36). Quality of life (EQ5D5L, HUI3) was not significantly different between the groups. Incremental cost saving per person was £18.75 (NHS cost) rising to £49.96 with societal costs. A 39.3% reduction in number of appointments was seen.

## Conclusions: All parties involved in diabetes care can be reassured that extended and personalised screening intervals can safely be introduced in established screening programmes. Scale-up with further validation outside a research setting is recommended.

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