The impact of individualised cardiovascular disease (CVD) risk estimates and lifestyle advice on physical activity in individuals at high risk of CVD: a pilot 2 × 2 factorial understanding risk trial

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Background
There is currently much interest in encouraging individuals to increase physical activity in order to reduce CVD risk. This study has been designed to determine if personalised CVD risk appreciation can increase physical activity in adults at high risk of CVD.
Methods/Design
In a 2 × 2 factorial design participants are allocated at random to a personalised 10-year CVD risk estimate or numerical CVD risk factor values (systolic blood pressure, LDL cholesterol and fasting glucose) and, simultaneously, to receive a brief lifestyle advice intervention targeting physical activity, diet and smoking cessation or not. We aim to recruit 200 participants from Oxfordshire primary care practices. Eligibility criteria include adults age 40–70 years, estimated 10-year CVD risk ≥20%, ability to read and write English, no known CVD and no physical disability or other condition reducing the ability to walk. Primary outcome is physical activity measured by ActiGraph accelerometer with biochemical, anthropometrical and psychological measures as additional outcomes. Primary analysis is between group physical activity differences at one month powered to detect a difference of 30,000 total counts per day of physical activity between the groups. Additional analyses will seek to further elucidate the relationship between the provision of risk information, and intention to change behaviour and to determine the impact of both interventions on clinical and anthropometrical measures including fasting and 2 hour plasma glucose, fructosamine, serum cotinine, plasma vitamin C, body fat percentage and blood pressure.
Discussion
This is a pilot trial seeking to demonstrate in a real world setting, proof of principal that provision of personalised risk information can contribute to behaviour changes aimed at reducing CVD risk. This study will increase our understanding of the links between the provision of risk information and behaviour change and if successful, could be used in clinical practice with little or no modification.