Author’s response to reviews

Title: The RISAP-study: a complex intervention in risk communication and shared decision-making in general practice

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Abstract

Background
General practitioners (GPs) and patients find it difficult to talk about risk of future disease, especially when patients have asymptomatic conditions, and treatment options are unlikely to cause immediate perceptible improvements in well-being. Further studies in risk communication for disease prevention are needed, as are studies about risk communication training for GPs. **Aim:** 1) to systematically develop, describe and evaluate a complex intervention comprising a training programme for GPs in risk communication and shared decision-making, 2) to evaluate the effect of the training programme on real-life consultations between GPs and patients with high cholesterol levels, and 3) to evaluate patients’ reactions during and after the consultations. The RISAP-study addresses patients with high cholesterol levels and risk of cardiovascular disease.

Objectives: 1) to systematically develop, describe and evaluate a complex intervention comprising a training programme for GPs in risk communication and shared decision-making, 2) to evaluate the effect of the training programme on real-life consultations between GPs and patients with high cholesterol levels, and 3) to evaluate patients’ reactions during and after the consultations.

Methods: The effect of the complex intervention, based around a training programme, will be evaluated in a cluster-randomised controlled trial with an intervention group and an active control group with 40 GPs and 280 patients in each group.

The GPs will receive a questionnaire at baseline and after 6 months about their attitudes towards risk communication and cholesterol-reducing medication. After each consultation with a participating high cholesterol-patient, the GPs will complete a questionnaire about decision satisfaction with questions from the (Provider Decision Process Assessment Instrument). In addition, the GP will be asked to identify which, if any, risk communication tools were used during the consultation.

The patients will receive a questionnaire at baseline and after 3 and 6 months. It includes questions about adherence to chosen treatment (Morisky Compliance Scale), self-rated health (SF-12), patient enablement (Patient Enablement Instrument), and risk communication and decision-making effectiveness (COMRADE Scale). Prescriptions, contacts to the health services, and cholesterol level will be drawn from the register of the National Health Service of Denmark at baseline and at 6 months.

In both intervention group and active control group, 12 consultations will be observed and tape-recorded. The consultations will be divided between 4 GPs with each 3 patients. The patients from these 24 consultations will be interviewed immediately after the consultation and re-interviewed after 6 months.

Eight purposefully selected GPs from the intervention group will be interviewed in a focus group 6 months after participation in the training programme.

The process and context of the RISAP-study will be investigated in detail using an action research approach, in order to describe and analyse research choices, adaptation of the intervention model to the specific context, and GPs’ and patients’ reactions and reflections on trial participation.