Clinical and cost-effectiveness of an intervention for reducing cholesterol and cardiovascular risk for people with severe mental illness in English primary care: a cluster randomised controlled trial


Summary

Background People with severe mental illnesses, including psychosis, have an increased risk of cardiovascular disease. We aimed to evaluate the effects of a primary care intervention on decreasing total cholesterol concentrations and cardiovascular disease risk in people with severe mental illnesses.

Methods We did this cluster randomised trial in general practices across England, with general practices as the cluster unit. We randomly assigned general practices (1:1) with 40 or more patients with severe mental illnesses using a computer-generated random sequence with a block size of four. Researchers were masked to allocation, but patients and general practice staff were not. We included participants aged 30–75 years with severe mental illnesses (schizophrenia, bipolar disorder, or psychosis), who had raised cholesterol concentrations (5.0 mmol/L) or a total:HDL cholesterol ratio of 4.0 mmol/L or more and one or more modifiable cardiovascular disease risk factors. Eligible participants were recruited within each practice before randomisation. The Primrose intervention consisted of appointments (≤12) with a trained primary care professional involving manualised interventions for cardiovascular disease prevention (ie, adhering to statins, improving diet or physical activity levels, reducing alcohol, or quitting smoking). Treatment as usual involved feedback of screening results only. The primary outcome was total cholesterol at 12 months and the primary economic analysis outcome was health-care costs. We used intention-to-treat analysis. The trial is registered with Current Controlled Trials, number ISRCTN13762819.

Findings Between Dec 10, 2013, and Sept 30, 2015, we recruited general practices and between May 9, 2014, and Feb 10, 2016, we recruited participants and randomly assigned 76 general practices with 327 participants to the Primrose intervention (n=38 with 155 patients) or treatment as usual (n=38 with 172 patients). Total cholesterol concentration data were available at 12 months for 137 (88%) participants in the Primrose intervention group and 125 (79%) participants in the treatment-as-usual group. The mean total cholesterol concentration did not differ at 12 months between the two groups (5.4 mmol/L [SD 1.1] for Primrose vs 5.5 mmol/L [1.1] for treatment as usual; mean difference estimate 0.03, 95% CI –0.22 to 0.29; p=0.788). This result was unchanged by pre-agreed supportive analyses. Mean cholesterol decreased over 12 months (–0.22 mmol/L [1.1] for Primrose vs –0.36 mmol/L [1.1] for treatment as usual). Total health-care costs (£1286 [SE 178] in the Primrose intervention group vs £2182 [328] in the treatment-as-usual group; mean difference –£895, 95% CI –1631 to –160; p=0.012) and psychiatric inpatient costs (£157 [135] vs £956 [313]; –£799, –1480 to –117; p=0.018) were lower in the Primrose intervention group than the treatment-as-usual group. Six serious adverse events of hospital admission and one death occurred in the Primrose group (n=7) and 23, including three deaths, occurred in the treatment-as-usual group (n=17).

Interpretation Total cholesterol concentration at 12 months did not differ between the Primrose and treatment-as-usual groups, possibly because of the cluster design, good care in the treatment-as-usual group, short duration of the intervention, or suboptimal focus on statin prescribing. The association between the Primrose intervention and fewer psychiatric admissions, with potential cost-effectiveness, might be important.

population have not been observed to the same degree in people with severe mental illnesses. \textsuperscript{2,3} Less evidence exists regarding which interventions effectively decrease the cardiovascular risk in people with severe mental illnesses, and few studies have taken a pragmatic or multi-risk factor approach to decreasing the cardiovascular disease risk in real-life settings. Interventions focused on single risk factors have shown some promise, including smoking cessation\textsuperscript{4} and weight reduction,\textsuperscript{5} and statins have been shown to decrease cholesterol concentrations effectively in large studies\textsuperscript{6} of people with severe mental illnesses. Based on economic modelling, screening for cardiovascular disease risk in people with severe mental illnesses (with risk algorithms) and prescribing statins for those individuals with a 10-year risk of more than 10\%, might be cost-effective in UK primary care.\textsuperscript{7}

We developed a pragmatic intervention aimed at reducing cardiovascular disease risk factors among people with severe mental illnesses in primary care in England, using published evidence and evidence from focus groups,\textsuperscript{8} and incorporating scientific behaviour change theory.\textsuperscript{9} Nurses and health-care assistants were trained to deliver the intervention and to target relevant cardiovascular disease risk factors in a collaborative way, with recommended risk reduction strategies for the participant risk profile. We selected the cluster trial design to minimise the risk of contamination of the intervention between the trial groups. Our aims were to compare the clinical effectiveness and cost-effectiveness of the intervention versus treatment as usual for people with severe mental illnesses.

\textbf{Methods}

\textbf{Study design and participants}

We did this cluster randomised trial with general practices from across England as the unit of cluster. We included people aged 30–75 years on the Quality and Outcomes Framework register for severe mental illnesses, including schizophrenia, bipolar affective disorder, or other non-organic psychoses, with a mean total cholesterol concentration of 5·0 mmol/L or a total:HDLC cholesterol ratio of 4·0 mmol/L or more and one or more additional cardiovascular disease risk factors, including hypertension, diabetes, raised glycated haemoglobin (HbA\(_1\)c: 42–47 mmol/mol), raised body-mass index (BMI: >30 kg/m\(^2\)), or current smoker.\textsuperscript{10} We excluded people currently under the care of acute psychiatric services, with organic psychoses or personality disorder diagnoses, with less than 6 months life expectancy, pre-existing cardiovascular disease, or who were pregnant. General practices in England were eligible to participate in the study if they had an available nurse or health-care assistant who could deliver the intervention and at least 40 patients on their practice register with severe mental illness. Data from screening, baseline assessments, and follow-up were collected in the general practices from patient questionnaires and medical records by research nurses.

The trial was delivered according to the published protocol.\textsuperscript{11} Ethics approval was obtained from the...
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