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 participants 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 152 (88%) 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] for Primrose vs £313 [112]; mean difference –£156, 95% CI –360 to 48; p=0·14) 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=11).

Interpretation Total cholesterol concentration at 12 months did not differ between the Primrose intervention 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.


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Research in context

Evidence before this study
People with severe mental illnesses have an increased risk of morbidity and mortality from cardiovascular disease compared with the general population. We searched for randomised controlled trials of interventions to reduce cardiovascular disease risk in people with severe mental illnesses published in English. On May 19, 2014, we searched the Cochrane Library for existing systematic reviews and the Cochrane Depression, Anxiety and Neurosis, and Cochrane Schizophrenia Group Trial Registers for additional randomised controlled trials from January, 1966, using the search terms: (schizophrenia OR severe mental illness OR bipolar OR mania OR manic OR hypomania OR psychosis OR psychotic OR postpsychotic OR post psychotic OR rapid cycling OR schizoaffective) AND (physical OR cardio OR metabolic OR weight OR tobacco OR smoking OR medical OR alcohol OR nutrition OR diet OR health OR diabetes OR blood pressure OR hypertension OR cholesterol OR statin). 11 026 papers were identified, of which 15 systematic reviews and 28 randomised controlled trials were relevant. Although some evidence existed for effectiveness for pharmacological and behavioural interventions targeting weight (metformin, topiramate, diet, and exercise) and smoking (bupropion, nicotine replacement therapy, and standardised stop smoking services), we found no evidence for interventions targeting cholesterol, hypertension, diabetes, or multiple cardiovascular disease risk factors. Most trials had small sample sizes, short length of follow-up, and were done in secondary care, which limited their generalisability to other settings.

Added value of this study
To our knowledge, this is the first pragmatic cluster randomised controlled trial of a behavioural change intervention targeting multiple cardiovascular disease risk factors in people with severe mental illnesses compared with treatment as usual in primary care in England. The primary outcome of total cholesterol at the 12-month follow-up did not differ between the intervention (Primrose) and treatment-as-usual groups; however, psychiatric inpatient and total health-care costs were lower in the Primrose group and total cholesterol concentrations decreased in both groups at 12 months.

Implications of all the available evidence
The decrease in admissions and costs with the Primrose intervention might be important. General practices should continue to optimise evidence-based treatments for cardiovascular disease prevention in people with severe mental illnesses with the same interventions used in the general population.

Methods

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:HDLD cholesterol ratio of 4·0 mmol/L or more and one or more additional cardiovascular disease risk factors, including hypertension, diabetes, raised glycedated haemoglobin (HbA1c; 42–47 mmol/mol), raised body-mass index (BMI; >30 kg/m²), or current smoker. 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. Ethics approval was obtained from the
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