

A health promotion intervention to improve lifestyle choices and health outcomes in people with psychosis: a research programme including the IMPaCT RCT

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Scientific summary

The IMPaCT RCT

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Scientific summary

Background

Physical health and severe mental illness

The physical health of people with severe mental illness is very poor, resulting in a markedly increased premature mortality rate. Much of the excess mortality is caused by diseases that affect the ageing population (e.g. cardiovascular and respiratory diseases and neoplasms) but affect patients with a diagnosis of severe mental illness earlier. Although intrinsic risk factors, such as age, genetics and ethnicity, may increase vulnerability to physical ill health, people with severe mental illness are more likely to have lifestyles that add to the risk of non-communicable disease, such as tobacco smoking, obesity, poor diet, lack of exercise and poor oral hygiene. Furthermore, amotivation and difficulties in executive function reduce the likelihood of people with severe mental illness engaging in the lifestyle changes needed to avoid diabetic complications, while episodes of acute illness often destabilise glucose control. The development of modifiable cardiovascular risk factors can be prevented and, as the name suggests, reversed; however, there are challenges in achieving this in practice.

Severe mental illness and substance use

Cannabis use is highly prevalent in the UK and results in a vulnerability to severe mental illness, with one-third of new cases of first episode of psychosis in south London now attributable to high-potency cannabis. Regular cannabis use increases the risk of schizophrenia two- to fourfold, and there is a dose-response relationship between the level of use and the risk of psychosis. Ongoing cannabis use by people with severe mental illness leads to increased relapse and hospitalisation, reduced adherence to treatment and longer illness. Early work suggested that cannabis users had higher blood glucose levels than non-cannabis users. A few recent studies note that cannabis use among the general population is not associated with serious physical health problems. A better understanding of the relative effect of cannabis on physical and mental health outcomes in people with severe mental illness is needed to inform the development of focused interventions.

The use of alcohol and other substances adds further complexity. A recent nationwide Danish register study has shown a clear effect on mortality; all types of substances were significantly associated with excess mortality in schizophrenia, especially alcohol and hard drugs. At a practical level, alcohol, itself a high-calorie substance, has well-described properties as an appetite stimulant, quite aside from its disinhibiting effect, which makes choosing the healthy option more difficult. However, the use of any psychoactive substance will affect one's ability to achieve consistency of physical and mental health management.

First episode of psychosis, physical health and substance use

Prior to coming into contact with mental health services, people experiencing their first episode of psychosis have physical health similar to that of the general population. A rapid emergence of cardiometabolic risk is seen on treatment initiation. It is clear that medication has a significant and rapid effect on this risk, but many other factors, including the wider determinants of health, lifestyle choices, substance use and access to preventative interventions, are also relevant. Identifying those most at risk of developing cardiometabolic risk would allow the development and, if appropriate, the targeting of prevention strategies.

Rates of tobacco smoking are very high among people with severe mental illness. This increases the risk of early death. It has long been assumed that people with severe mental illness may take up smoking because of illness-related factors, either to help with symptoms or as a result of custom and practice in inpatient units, such as smoking breaks. However, more recent analyses suggest that tobacco smoking

may predate and itself be a risk factor for schizophrenia, as pre-morbid tobacco use is associated with increased risk of psychosis and an earlier age of psychotic illness onset.

There is, overall, a pressing need to identify the factors most associated with emergent cardiometabolic risk in people with psychosis, as targeting at-risk groups and lifestyle choices may help to reduce the cardiovascular burden responsible for much early mortality.

Established psychosis, physical health and substance use

Effecting behaviour change in the general population is a challenge and likely to be even more so for people with severe mental illness. For those with enduring psychosis, no established and practical treatment programmes target both reducing substance use and improving physical health. Even interventions to improve cardiovascular risk alone encounter hurdles when applied outside selected settings. A recent meta-analysis showed that lifestyle interventions can help prevent and reduce weight gain and cardiometabolic risk in people with psychosis, but most of the interventions trialled were 'added on' to standard care or focused on an individual risk factor, such as weight or body mass index, and had few longer-term follow-ups. Recent European trials have found no effect of a multifactorial lifestyle intervention delivered in the patient's usual health-care setting on cardiovascular risk profiles. A recent trial in UK primary care also failed to show an effect. Furthermore, the patients most at risk of early death may not be those who readily sign up for extra sessions with their health teams. It is, therefore, vital to identify effective and cost-effective ways of reducing cardiovascular risk that are accessible to all people using psychosis services.

Objectives

The overall aims of the improving physical health and reducing substance use in psychosis (IMPACT) programme were to determine the extent of physical health and lifestyle risks for people with psychosis and to develop and evaluate a culturally appropriate, innovative, practical, effective and cost-effective programme for achieving better physical and mental health in people with severe mental illness by improving lifestyle choices and decreasing substance use.

The specific objectives were to:

- Determine the prevalence of cardiovascular risk factors and substance use in people with psychosis, both at first presentation [work package 1: physical health and substance use in first episode of psychosis (PUMP)] and in those with established psychosis (work package 3: IMPACT randomised controlled trial).
- Develop a better understanding of the roles cannabis plays in the pathophysiology and health outcomes of psychosis (see work package 1: PUMP).
- Define the development of cardiovascular risk after first presentation with psychosis (work package 1: PUMP).
- Develop guidelines for screening for the emergence of cardiometabolic risk.
- Use this information for training and screening guidelines for cardiovascular risk factors in early psychosis.
- Develop a manualised modular health promotion programme to improve health choices of people with psychosis (work package 2).
- Evaluate the effectiveness of this manualised health promotion programme on the quality of life of people with psychosis (work package 3: IMPACT randomised controlled trial).
- Examine the costs associated with these patient groups and evaluate the cost-effectiveness of the health promotion intervention from health/social care and societal perspectives (work package 3: IMPACT randomised controlled trial).

Methods

We divided the study into three phases, which took place between 2008 and 2014.

Work package 1: PUMP

We conducted a prospective cohort study examining physical health and substance use in people with a first episode of psychosis, aged 16–65 years. Patients were assessed at first presentation with psychosis and again 12 months later. A proportion was also assessed at 3 months. Cardiometabolic markers (including vitamin D and inflammatory markers), substance use, lifestyle choices and psychiatric symptomatology were recorded at each time point. Psychotropic medications and resource utilisation were recorded, with permission, from the electronic health records and a full economic evaluation performed.

Work package 2: development of the health promotion intervention (IMPACT therapy)

We used the emerging knowledge base to design a manualised, modular health promotion intervention. The health promotion intervention principles and techniques were based on an adapted version of the physical health intervention used in the 'Well-being Support Programme' and a substance use intervention model, 'Managing Mental Health and Drug Use'. The intervention was integrated to cover physical health, mental health and substance use, using motivational interviewing and cognitive-behavioural therapy approaches, and aimed to be pragmatic enough to be deliverable within the NHS. We employed a Delphi technique to refine and co-produce the intervention with people with lived experience. To support the intervention, we published in book form a manual, reference guide and *Better Health Handbook* for service users.

We also developed a 4-day training programme for practitioners, encompassing skills and knowledge about physical health, substance use, cognitive-behavioural therapy and motivational interviewing.

Work package 3: IMPACT randomised controlled trial

We undertook a Phase III randomised controlled trial comparing the clinical effectiveness and cost-effectiveness of combining treatment as usual with a 1-year IMPACT health promotion intervention with that of treatment-as-usual alone for improving health at 1-year follow-up. The randomised controlled trial had a multicentre, two-arm, parallel-cluster design and was conducted across five mental health NHS trusts in the south of England. Eligible participants were aged 18–65 years and had a diagnosis of a psychotic disorder. The cluster was at the level of the community care co-ordinators who were randomly assigned to deliver the health promotion intervention IMPACT therapy or treatment as usual to their own patients. The primary outcome was the physical and mental health component scores of the quality-of-life measure, the Short Form-36 questionnaire. A mixed-effects model was used to analyse the data. The trial included a comprehensive economic evaluation from two perspectives: (1) health and social care and (2) societal. Resource use data were collected by self-report using a specifically adapted interview schedule at baseline and at 12 months and 15 months; the data from 12 and 15 months were the focus for the economic evaluation. Costs estimated for each perspective were linked with outcome measures at 15 months.

Results

Work package 1: PUMP

Overall, 293 people experiencing their first episode of psychosis consented to the study [mean age 30.6 years (standard deviation 10.5 years), 65% male, 22% antipsychotic naive]. At baseline, half of the participants were overweight and 18% were obese. There were higher rates of central obesity among women (62.7%) than among men [35.3%, $\chi^2(1) = 11.34$; $p = 0.001$]. Tobacco was smoked by 76.8% of participants, and a similar proportion (77.0%) did < 150 minutes of moderate or vigorous exercise per week. One-quarter of participants had a high-fat diet and nearly half had hazardous patterns of alcohol consumption. Almost half (102/206) of the participants were current users of cannabis and

12.6% used other recreational drugs. Dietary fat scores, sedentary behaviour, alcohol use and pre-baseline olanzapine use were not significantly associated with any of the baseline cardiometabolic outcomes or change in cardiometabolic outcomes over the year, taking into account potential confounders. Patients from black and minority ethnic groups were more likely to develop glucose dysregulation over the first year, with a mean rise in HbA_{1c} levels of 3.3 mmol/mol over the year, than patients of white ethnicity, whose HbA_{1c} levels showed no change, suggesting a differential pattern of emergence of glucose dysregulation. By contrast, white men showed a marked increase in waist circumference, gaining a mean of 4.9 cm over the year, whereas men from black and minority ethnic groups gained 1.6 cm.

Obesity at baseline was associated with higher subsequent admission costs, low levels of high-density lipoprotein cholesterol at baseline were associated with lower subsequent admission costs and higher levels of high-density lipoprotein cholesterol at baseline was associated with a greater subsequent quality-of-life gain.

Together with our colleagues in the Biomedical Research Council-funded Genetics and Psychosis study, we demonstrated that one-quarter of first presentations of psychosis to the South London and Maudsley NHS Foundation Trust are attributable to the use of high-potency cannabis. This has since risen to one-third.

Substance use also had an effect on medication adherence over the first year of psychosis, thereby affecting outcomes.

Work package 2: development of the health promotion intervention (IMPACT therapy)

Five expert therapists took part in two rounds of Delphi consultation on the therapy manual, reference book, and service user handbook, informing the redrafting after each round and providing additional qualitative feedback. Two clinicians provided quantitative feedback when they each used the therapy manual with a service user, and all four provided qualitative feedback, which informed the final version. The mean ratings for user-friendliness, spirit of motivational interviewing, integration with cognitive-behavioural therapy, usability in the NHS, length and complexity increased with development.

Work package 3: IMPACT randomised controlled trial

We recruited 104 care co-ordinators in random order; 52 (with 213 patients overall, mean age 43.8 years, 54.9% male) were randomised to receive training and supervision in IMPACT therapy, and the other 52 (with 193 patients, mean age 44.7 years, 60.6% male) were randomised to administer treatment as usual. Of the 406 patients randomised, 318 (78%) attended 12-month and 301 (74%) attended the 15-month follow-up assessments. There was no significant effect of IMPACT therapy on the physical or mental health component Short Form questionnaire-36 items scores versus treatment as usual at either 12 or 15 months [physical health score ('d'): -0.17 at 12 months and - 0.09 at 15 months; mental health score ('d'): 0.03 at 12 months and -0.05 at 15 months]. No statistical difference was observed for the secondary outcomes, including cardiometabolic risk, substance use or mental health measures, compared with treatment as usual alone, except for high-density lipoprotein cholesterol, which improved more with IMPACT therapy than with treatment as usual (treatment effect 0.085, 95% confidence interval 0.007 to -0.16; $p = 0.034$). There were challenges in delivering additional time for the intervention with just 19 (9%) out of 219 IMPACT patients receiving six or more sessions of ≥ 30 minutes from their care co-ordinator in addition to their routine care. When participants received > 180 minutes of IMPACT therapy in addition to usual care, they achieved a greater reduction in waist circumference than those in the treatment-as-usual group, and this was clinically significant.

The economic evaluation suggested no difference between the trial arms in costs from either perspective or for any of the four outcomes. Data suggested that the health promotion intervention was unlikely to be cost-effective from a health and social care perspective, with probabilities of cost-effectiveness ranging between 29% and 38% at willingness-to-pay thresholds of £0–50,000 per quality-of-life gain. Probabilities of cost-effectiveness were even lower from a societal perspective.

Conclusions

Work package 1: PUMP

Even within the first month of treatment, people experiencing their first episode of psychosis have high levels of cardiometabolic risk factors, which worsen over the following year, with a differential effect of ethnicity on glucose dysregulation. In addition, the use of tobacco and high-potency cannabis is common in this population, and this reduced medication adherence and the likelihood of remission in the first year.

Work package 2: development of the health promotion intervention (IMPACT therapy)

Three books (a reference guide, a manual and a *Better Health Handbook*) to support IMPACT therapy were written and a Delphi process was used to co-produce IMPACT therapy with patients, staff and carers. IMPACT therapy training significantly improved knowledge of physical health and substance use.

Work package 3: IMPACT randomised controlled trial

Training and supervision in IMPACT therapy was insufficient to produce significant improvements in physical or mental health quality of life or to meaningfully improve cardiovascular risk. Only a minority of patients received the intervention in six or more sessions of ≥ 30 minutes in addition to routine care. There was some dose effect, with patients who received the intervention for > 180 minutes having greater reductions in waist circumference.

Recommendations for future research

People with psychosis in the UK have extremely high levels of cardiovascular risk, which are compounded by high tobacco use; and this is evident soon after first presentation. We have demonstrated that simply enhancing care provided by the local care team is insufficient to reverse cardiovascular risks in people with established psychosis. Identifying effective, affordable interventions to improve health outcomes in psychosis remains a priority of health services internationally. Evidence-based approaches to prevent emergent cardiometabolic risk in people first presenting with psychosis are also needed.

Trial registration

The IMPACT randomised controlled trial is registered as ISRCTN58667926.

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