

PB-PG-0107-10647 – NIHR Research for Patient Benefit Programme – Final report

Project title: Pilot Study to Enhance Recovery Through Physical Activity and Healthy Lifestyles in an Acute Psychiatric Day Hospital Setting

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Plain language summary

Serious mental illnesses, such as schizophrenia and depression, affect 5-10% of adults in the UK at any time. People who experience these conditions may die 20-30 years earlier than the general population, most often from heart disease. The most likely explanations are obesity, diabetes, high blood pressure, smoking, poor diet and sedentary lifestyle. Diabetes trials show that increasing physical activity can be effective and sustainable, but it requires motivational support. There are promising lifestyle change interventions among people with serious mental illness, but none has been fully evaluated and services remain rare.

We aimed to extend a healthy living initiative for improving the physical health of people with serious mental illness, to prepare for a definitive clinical trial. The intervention had 3 components: physical health and lifestyle assessment; formulation of individual care plans based on risk profile and personal preference; and lifestyle interventions including physical activity, group education and individual review. We assessed uptake and acceptability, participation and lifestyle change over 6 months following recruitment in a busy acute psychiatric day hospital. Participants underwent cardiovascular and metabolic assessment at baseline and after 3 and 6 months, when we collected data on physical activity, smoking and diet. Using a before and after design, we explored outcomes with reference to different types of physical activity, and interventions delivered in group versus individual settings. Qualitative interviews were used to explore strengths and limitations of the programme, and study methods.

Despite the exploratory nature of the trial, the potential feasibility and impact of the healthy lifestyle programme for individuals with severe mental illness within an acute psychiatric day hospital setting has been demonstrated, serving to validate the intervention developed thus far. However, engagement in both the intervention and the trial were modest, highlighting the challenges of this type of research in people suffering from acute mental illness. Further development of intervention and trial methodology is needed before advancing to full RCT.

Keywords

Mental illness

Lifestyle

Behaviour change

Physical activity

Recovery

Summary of research findings

Background

Individuals with serious mental disorders are at increased risk of premature mortality, mostly due to cardiovascular causes. It has been estimated that these individuals may lose up to 30 years of life compared with the general population. Explanations include obesity, diabetes (exacerbated by medication), hypertension, smoking, poor diet and sedentary lifestyle. These risks extend beyond schizophrenia. Diabetes is three times more common in schizophrenia than in the general population, and twice as common in depression. Central abdominal (visceral) adiposity occurs in depressed patients and this rather than weight gain probably mediates metabolic dysfunction through release of fatty acids and adipocytokines. In fact, depression - ten times more common than schizophrenia - is associated with a risk of death from cardiovascular causes similar to that of smoking. The need for action is widely recognised, yet despite these calls for urgent action services are rare and without thorough evaluation.

Aims and objectives

The aims of the study were to pilot, refine and explore the potential impact of a complex, evidence based lifestyle and physical activity intervention designed to improve the physical health of individuals with serious mental illness within an acute psychiatric day hospital setting, and to define the optimal trial protocol and intervention implementation with a view to informing a large, controlled Phase III trial.

The objectives of the study were thus to assess uptake of and participation in the research and intervention, including evaluating the acceptability of the intervention.

Methods

The study was an uncontrolled, unblinded pilot trial of a complex intervention with assessment at baseline and follow up at three months and six months. The study was set in an acute psychiatric day hospital, and participants were adults with an acute episode of serious mental illness.

A multi-method process and preliminary outcome evaluation was undertaken. Data relating to the feasibility, acceptability and effectiveness of the trial protocol and intervention delivery were collected at interviews with participants (including staff) and via observation. These data were analysed quantitatively and qualitatively. The preliminary outcome evaluation employed a before and after design, with participants acting as their own controls and the data analysed quantitatively.

Key findings

Recruitment to the study was satisfactory but retention with respect to follow up assessments and participation in the intervention was relatively poor. Willow View provided an optimum setting for the trial; all service users are under the care of SW, minimal effort was required in attending the gym and group education sessions, numerous prompts were received, satisfaction with the service was good and the programme was perceived to have a positive subjective impact upon health behaviours and mental health and recovery (i.e. beyond standard the impact of psychiatric treatment at Willow View), which should have encouraged uptake and participation. As such, this finding is critical in that it underscores the difficulty in engaging individuals with serious mental illness in lifestyle interventions and health behaviour change. Encouragingly, though, the process evaluation additionally identified the shortcomings that prohibited engagement with the study and intervention. As such, it seems that there is scope for refinement of the intervention and trial protocol in accordance with the invaluable feedback received from participants and the observations made, which could promote acceptability and participation in future endeavours (discussed below).

Of further interest was the potential impact of the intervention, particularly on behavioural outcomes including physical activity, and with a focus upon whether sustained change beyond discharge from the acute day hospital setting could reasonably be expected. The preliminary outcome evaluation identified, as anticipated, substantial improvements in psychological well-being and quality of life outcomes over time, consistent with the psychiatric treatment received during admission to Willow View. There was less evidence of change in the behavioural, clinical and readiness to change behaviour outcomes, yet some identified trends suggested potentially important findings. There was some indication of a slight improvement in physical activity whilst admitted at Willow View (i.e. average additional expenditure of circa 500 kcal/week), yet this was not upheld post-discharge from Willow View and in fact reduced to a level below that present at baseline (i.e. average reduction of circa 600 kcal and 2 hours moderate activities less per week). There was additionally a slight reduction in consumption of fat over the study period, yet also a reduction in the consumption of fibre over time, which was mostly attributable to a reduction post-discharge. This underscores again the challenges faced in achieving sustained health behaviour changes amongst individuals with severe mental illness.

The number of cigarettes smoked by current smokers reduced over time, which was mostly attributable to a reduction whilst admitted to Willow View yet was maintained at long-term follow up (average reduction of at least 10 cigarettes per week). Trends for improved HbA1c and cholesterol were also evident and typically attributable to changes post-discharge (i.e. these outcomes are less immediately influenced). The change in HbA1c was on average around 0.6%, which is encouraging in that a change of 0.5% is considered clinically important in terms of reduced risk for cardiovascular complications among individuals with diabetes.

We assessed the acceptability and feasibility of the data collection methods, in particular the use of accelerometers as a means of measuring physical activity. We identified that self-report questionnaires, when administered by a researcher, provide more complete and valid responses. Furthermore, whilst the accelerometers seem to provide conflicting data to that derived from self-report questionnaires, they do not, apparently, offer a more valid means of measuring energy expenditure as would initially be anticipated. The conflicting

data more likely reflects the fact that the accelerometers were worn for 3 days following each assessment interval whereas the CHAMPS questionnaire reflects energy expenditure for a typical week in the past 4 weeks; the CHAMPS data better represents the physical activity undertaken whilst admitted to Willow View. Indeed, at least initially, 3 month assessment was often post discharge from Willow View and the integrity of the accelerometer assessment intervals was particularly questionable. This likely also explains the less notable improvement in physical activity between baseline and 3 months for the PWA compared to the CHAMPS, as the former reflects activity in the past 7 days. In fact, the accelerometers were additionally demonstrated not to be acceptable to some service users and were associated with a number of pragmatic and logistical issues, which may necessitate further financial investment in them. Consequently, it seems that there is no real advantage associated with the use of accelerometers as opposed to administering questionnaires, which would suggest they should not be used in future studies of this nature.

Expected impact

The intervention warrants revision in terms of a) implementing sustained behaviour change (e.g. extending the duration of the intervention, introducing booster sessions and or promoting inclusion gym sessions post-discharge), b) increasing the repertoire of physical activity options to ensure variety but also include those that are less formal, demanding and difficult for those with self-confidence/esteem issues and are more consistent with daily living (e.g. facilitated walks), c) eliminating stigma when attending external services, d) emphasising the importance of not merely reducing unhealthy food consumption but actively improving consumption of healthier foods, e) improving the structure of the education sessions and inclusion of external, expert speakers, f) addressing intervention delivery (i.e. attention to aspects that are perceived to be patronising), g) ensuring collaboration in, attention to lifestyle issues and frequent revisiting of care plans, and h) placing an emphasis on the role of the former service users volunteers and their ability to educate owing to shared mastery experiences.

With respect to study design, we suggest that a) providing comprehensive information and addressing misconceptions about the programme, b) recruitment as soon as possible post-admission, c) assessment post-discharge, d) persistence in contacting service users post-discharge (ie regular prompts), e) promotion of group cohesion, f) staff cooperation and engagement with the programme, g) personally salient incentives, h) emphasis on the importance and non-judgemental and confidential nature of the study assessments, and i) researcher familiarity and flexibility with service users, are important for maximising recruitment and retention rates. A focus on obtaining more complete anthropometric, metabolic and cardiovascular data is also required –in particular the implementation of a more efficient means of obtaining this data at long-term follow up.

Conclusions

Despite the exploratory nature of the trial, the potential feasibility and impact of the healthy lifestyle programme for individuals with severe mental illness within an acute psychiatric day hospital setting has been demonstrated, serving to validate the intervention developed thus far. However, engagement in both the intervention and the trial were modest at best, highlighting the challenges of this type of research in people suffering from acute mental illness. Further development of intervention and trial methodology is needed before advancing to full RCT.

Patient and public involvement

Willow View Acute Day Service (where this research was undertaken) has a longstanding policy of recruiting former service users to work as volunteers in the unit. We formally involved three service user volunteers in the study. We initially recruited three service user volunteers at Willow View to work on the project for up to 3 hours per week each (at a rate of £10 per hour). All three had other regular weekly commitments at Willow View, typically supporting staff in delivering group-based sessions. These individuals reviewed the study procedure and commented on implications for participation, liaised informally with participants (and potential participants) and fed back responses (for instances about general barriers to participation) and met with the research team monthly where they reported problems or suggestions for improvement.

These service users were involved in dissemination and frequently spoke to other service users (locally and regionally) of their positive experiences of working on this project.

It is with enormous sadness that we note the death of one of our service user colleagues (KD) after the end of this study. We will remain grateful to him for his outstanding contribution.

Data sharing statement

See link

[\[https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253\]](https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253) for the NIHR position of the sharing of research data. The NIHR strongly supports the sharing of data in the most appropriate way, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic growth in the UK. All requests for data should be directed to the award holder and managed by the award holder.

Disclaimer

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This project was carried out between September 2008 and June 2011. This final report has not been peer-reviewed. The report was examined by the Programme Director at the time of submission to assess completeness against the stated aims.