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Physical health assistance in early recovery of psychosis (PHAstER): study protocol for a randomized controlled trial

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This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/eip.12884

Abstract

Aim: Young people with psychotic disorders have poorer physical health compared to their healthy peers, a state compounded by the metabolic side effects of antipsychotic medications. To address this, Orygen Youth Health has introduced physical health services including exercise physiologists and dietitians. These services are typically coordinated by the case manager and doctor. It is not yet known whether a treating team member dedicated to physical health will improve engagement, adherence and outcomes with these services. Hence, the protocol is presented here for a trial to evaluate the effect of including a physical health nurse in the care of young people with first-episode psychosis.

Methods: This will be a single-blind randomized controlled trial that includes 15- to 24-year-olds with first-episode psychosis who have just commenced (within 30 days) antipsychotic medication. The primary outcome will be the event of clinically significant weight gain (≥7% body weight). Participants will be assigned either a physical health nurse in their treating team (in addition to the case manager and doctor) for a 12-week period, or treatment as usual (case manager and doctor). Research assessments will be conducted at baseline, 12 weeks and 26

weeks. Activity trackers worn by participants for the study's duration will measure sleep and physical activity.

Conclusion: This study will determine whether a physical health nurse will facilitate participants in attending and engaging in physical health interventions and whether this will be associated with physical health improvements or the prevention of worsening physical health.

Keywords: adolescent; mental health; metabolic syndrome; psychotic disorders; weight gain

Introduction

Psychotic disorders typically have peri-adolescent onset and are among the most burdensome and costly disorders (McGorry, Purcell, Goldstone, & Amminger, 2011), negatively affecting young people's development and attainment of vocational and educational goals. Individuals with an enduring psychotic disorder have a life expectancy up to 25 years shorter than the general population (Laursen, Munk-Olsen, & Vestergaard, 2012), and this gap is widening (Saha, Chant, & McGrath, 2007). A major contributor to early mortality are cardiovascular risk factors including a higher rate of smoking (Myles et al., 2012), sedentary lifestyle, poor diet and the adverse metabolic side effects of antipsychotic medication (Curtis, Newall, & Samaras, 2012). However, there are a lack of clinical trials that investigate physical health interventions for people affected by mental health disorders, particularly in first-episode psychosis (FEP).

Physical health complications can occur early and rapidly. Young people with FEP have shown a fourfold increase in weight gain compared to individuals with an enduring psychotic disorder; within 12 weeks, people with FEP can gain between 7.1–9.2 kg with olanzapine, 4.0–5.6 kg with risperidone and 2.6–3.8 kg with haloperidol (Alvarez-Jimenez et al., 2008). Another issue is metabolic syndrome, which refers to the co-occurrence of several cardiovascular risk factors such as insulin resistance, obesity, dyslipidaemia (an abnormal amount of lipids in the blood) and hypertension (Huang, 2009). The presence of these conditions indicates a higher risk of developing cardiovascular disease and type 2 diabetes. In the 2010 Australian National Psychosis Survey, it was found that over 60% of individuals with a psychotic disorder had metabolic syndrome (Morgan et al., 2014)—over three times the rate of the Australian general population (Cameron, Magliano, Zimmet, Welborn, & Shaw, 2007).

Two further issues affecting young people with FEP are sexual health and sleep dysfunction. They are more likely to engage in high risk sexual behaviours, such as not using contraception or having multiple sexual partners; consequently, there can be high rates of unplanned pregnancies and sexually transmitted infections in this population (Adan Sanchez et al., 2018). Moreover, a large number of individuals affected by a psychotic disorder have severe sleep disturbances and shifted sleep–wake rhythms (i.e., circadian abnormalities), which tend to precede and worsen during acute episodes (Cohrs, 2008; Waters & Manoach, 2012). Such sleep dysfunction is of particular relevance in the context of youth people's physical health, given that adolescence and young adulthood is a period associated with profound changes to the sleep–wake system (Colrain & Baker, 2011; Feinberg & Campbell, 2010; Gradisar, Gardner,

& Dohnt, 2011; Roberts, Roberts, & Duong, 2009) and poor sleep is strongly associated with an increase in body weight and adiposity (Chaput, Després, Bouchard, & Tremblay, 2007; Knutson, Spiegel, Penev, & Van Cauter, 2007; Patel & Hu, 2008).

Crucially, all these physical health issues involve modifiable or preventable risk factors. Hence, the physical health comorbidity in FEP is a prime candidate for early intervention—a paradigm that emphasizes that the best outcome for psychotic disorders will be achieved if intervention occurs early in the course of the disorder (Jackson, 2009). Recently, it was shown that a 12-week intervention for FEP led to a much lower proportion of young people (13% vs 75%) who experienced clinically significant weight gain, compared to a different early intervention service that did not offer this intervention (Curtis et al., 2015). The intervention consisted of a clinical nurse consultant who provided motivational interviewing to promote attendance and participation in the intervention program; weekly dietetic consultations including educational modules focused on weight management, food quality, nutrition and cooking skills (see also Teasdale, Ward, Rosenbaum, Samaras, & Stubbs, 2017); and finally, individually tailored exercise physiology programs (Lederman et al., 2016), of particular value because exercise interventions can both benefit physical fitness and also reduce symptoms in individuals diagnosed with a psychotic disorder (Firth, Cotter, Elliott, French, & Yung, 2015).

At Orygen Youth Health (OYH), a public mental health service for young people aged 15 to 24 years, several physical health interventions have been introduced, including exercise physiologists, dieticians, yoga and gym groups and tobacco-use reduction programs. However,

a review of the attendance of the services for physical health revealed that only a minority of young people are offered and referred to these services, and once referred, the attendance rate is low. The treating team (a case manager and doctor) have responsibilities that include regular metabolic screening and supporting young people's engagement in the above interventions, but they have high caseloads and psychiatric emergencies can often supersede scheduled work. These competing demands can forestall addressing the physical health of young people affected by psychosis, even if the clinicians acknowledge the importance of this aim. Therefore, this trial will evaluate the effect on physical health, primarily in terms of weight gain, of including a physical health nurse (who can coordinate the physical health services) in the treating team of young people receiving treatment for first-episode psychosis.

The primary aim of this trial is to determine whether the proposed inclusion of a physical health nurse in the care of young people receiving treatment for first-episode psychosis will result in a lower proportion of clients who gain weight compared to treatment as usual. Secondary aims at the 12-week and 26-week follow-ups include whether the intervention will result in (i) a lower incidence of the development of components of the metabolic syndrome; (ii) a mean difference in weight between the intervention and control group; (iii) a higher proportion of young people attempting to cease smoking tobacco; (iv) a higher rate of contraception use; (v) greater compliance to screening guidelines; and (vi) differences in sleep.

Methods

Design

This will be a single-blind randomised controlled trial. Participants receive either the physical health nurse as part of their treating team or treatment as usual. While it will not be possible to blind participants, the assessors will be blinded to treatment allocation. Participants will be asked to refrain from discussing their allocation with the assessors and whether they have a physical health nurse involved in their care. Figure 1 contains a schedule of enrolment, interventions, and assessments according to Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines.

Setting

This study will be conducted at the Early Psychosis Prevention and Intervention Centre (EPPIC), an OYH service in Melbourne, Australia. The EPPIC service provides care for approximately 400 young people with a psychotic disorder at any one time and accepts over 200 new referrals each year. A young person referred to EPPIC is allocated a case manager from an allied health discipline and a medical doctor (as well as a consultant psychiatrist, if the allocated doctor is a registrar). This treating team has a range of responsibilities, including conducting assessments for diagnosis and formulation, delivery of effective treatments including medication, psychotherapy, and facilitating group-based activities. The treating team meet with the young person's family or caregivers, deliver psychoeducation, and manage any acute crisis or emergencies. EPPIC provides 18 to 24 months of specialised care, after which clients are referred to a service appropriate to their needs, such as a private psychiatrist or psychologist or adult mental health service.

Participants

Inclusion criteria. To be eligible for the study, participants must be eligible for EPPIC: that is, reside within the geographically defined catchment area, be aged between 15 and 24, and be experiencing a first episode of psychosis (at least one positive psychotic symptom daily for at least one week). They must also be able to provide informed consent and have at least 12 weeks of care remaining in EPPIC.

Exclusion criteria. Grounds for exclusion from the study are the inability to provide informed consent, or more than 30 days total exposure to the minimum effective dose for a psychotic disorder according to the Maudsley Prescribing Guidelines. Young people who become pregnant during the study can remain involved in the study and can complete the study intervention and follow-up assessments. However, they will be excluded from the primary outcome analysis, as any weight gain due to the pregnancy would confound the primary outcome. However, the data collected from any participant who becomes pregnant will contribute towards analysis of the secondary aims.

Ethical approval and consent procedure

This trial was approved by the Melbourne Health Human Research Ethics Committee on 24 May 2018 (HREC/18/MH/77). Informed consent will be obtained from all study participants. Young people referred to OYH will be screened for eligibility by a research assistant with the intent of recruiting young people at their point of entry into EPPIC, as most EPPIC clients commence antipsychotic medication immediately. Clinicians in EPPIC will inform eligible

clients of the study and ask whether they wish to meet a member of the research team to learn more. Young people may also learn about the study from brochures available at the study sites. Information will be provided in both verbal and written forms. Informed consent will be sought from participants (or their parents or guardians, for participants aged between 15 and 17). Participants will undergo three research assessments (each taking 2 to 3 hours) in addition to their standard care, and will be reimbursed $50 for each assessment. Participants will also be provided with an activity tracker (a Fitbit Alta) to be worn throughout the study period, which they are permitted to keep following the study's completion.

Randomization and treatment allocation

Following informed consent, participants will be randomized on a 1:1 ratio to the intervention and control arms. Randomization will be performed by a statistician independent of the study using a custom online clinical trials management system. Participants will be stratified according to sex and baseline body mass index (BMI).

Intervention

The physical health nurse will have weekly contact with participants via a combination of face-to-face and telephone contact, typically separate to the treating team appointments. Their role will include performing physical health screening (metabolic monitoring) and facilitating clients to attend the services at OYH that have been established to address the physical health of young people, including but not limited to exercise physiologists and dieticians who provide individual consultations and group programs, gym and yoga groups, and programs aimed at

reducing and/or ceasing alcohol, tobacco or substance use (if indicated). If a participant is sexually active or in a relationship, the physical health nurse will provide information on contraception and refer them to a sexual health service. It will be recorded when individuals are referred to the above services and the number of appointments that they attend during the 12-week intervention period and further 14-week follow-up period. Figure 2 illustrates the referral pathways for participants.

Control group

The control group will receive treatment as usual, and their treating team will consist of a case manager and doctor. All people in this group will still have access to the physical health services available at OYH, except that it will not be coordinated by a physical health nurse. The responsibility for screening and co-ordinating the physical health services will be with the case-manager and doctor. It would be unethical to deny participants in the control group access to these physical health services, and attendance at these services will be recorded.

Instruments

Components of metabolic syndrome will be evaluated in line with the International Diabetes Federation criteria for metabolic syndrome (International-Diabetes-Federation, 2006) using BMI (using a stadiometer and digital scale to measure height and weight), waist circumference (tape measure), blood pressure (digital sphygmomanometer), and haematological investigations of fasting glucose, total cholesterol, low- and high-density lipoprotein, triglycerides, and HbA1c.

Physical activity will be determined using the Simple Physical Activity Questionnaire (SIMPAQ) (Rosenbaum, Ward, & International Working, 2016), as well as an objective basis using measurement data from the activity tracker worn by participants (e.g. number of steps). There will also be a Bailey Diet screening instrument to assess whether clients are at risk of nutritional deficits, possibly at risk or not at risk (Bailey et al., 2009).

Diagnosis will be determined using the Structured Clinical Interview for DSM-5 Disorders (SCID-5) (First & Spitzer R.L, 1995). Modules A to E will be undertaken. General psychopathology will be measured using the Brief Psychiatric Rating Scale (BPRS) (Rhoades & Overall, 1988). Positive psychotic symptoms will be assessed by using the sum of four BPRS items (hallucinations, unusual thought content, conceptual disorganisation and suspiciousness). Negative symptoms will be measured using the Schedule for Assessment of Negative Symptoms (SANS), a widely used scale for the assessment of negative symptomatology in psychotic disorders (Andreasen, 1984). In addition, the Social and Occupational Functioning Assessment Scale (SOFAS) will be used to subjectively rate the client's social, occupational, and psychological functioning.

The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) was developed for the World Health Organization to detect and manage substance use and related problems in primary and general medical care settings. The ASSIST has undergone significant testing to ensure its reliability, validity, cross-cultural relevance, and feasibility in brief interventions. In

addition, attempts to reduce smoking and referrals to a smoking cessation service will be recorded.

Data pertaining to objective sleep (i.e. sleep onset latency; total sleep time; wake after sleep onset; sleep efficiency) will be retrieved from the commercial actigraphs provided to participants. Data pertaining to subjective sleep will be assessed by the Pittsburgh Sleep Quality Index (PSQI) (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989) and Insomnia Severity Index (ISI) (Bastien, Vallieres, & Morin, 2001); chronotype will be established using the Morningness-Eveningness Questionnaire (MEQ) (Horne & Ostberg, 1976).

A questionnaire on sexual health was devised for a previous study undertaken at OYH (McMillan et al., 2017), in which over 100 young people completed the questionnaire. The items were adapted from an instrument developed by the Australian Research Centre in Sex, Health & Society (Smith, Agius, Mitchell, Barrett, & Pitts, 2009), and include questions relating to current sexual partners, sex, condom and contraceptive use, history of sexually transmitted infections, and history of pregnancy.

The Youth (Mental Health) Service Satisfaction Scale (YSSS) is a purpose-designed 14-item scale for use with adolescents and young adults attending youth mental health services to measure their satisfaction with the centre (three items), staff (four items), outcomes (five items) and general satisfaction (two items) (Rickwood et al., 2017).

Youth participation

Members of the Youth Research Council were consulted with during the design phase of this study and a member of the Youth Research Council is a member of the research team and has been involved throughout all phases of the study design.

Statistical analysis

The primary outcome will be determined using chi-square analysis, comparing the proportion of individuals who gained ≥7% of body weight in the two groups. To control for potential confounds that may not have been addressed by randomization, a further binary logistic regression analysis will be performed, with all of the potential confounders (such as age and medication prescribed) in the first block and the treatment allocation in the second block.

Chi-square analysis will also be conducted for selected secondary aims (i.e. development of components of the metabolic syndrome; proportion of young people attempting to cease smoking tobacco; rate of contraception use). Descriptive statistics will be calculated for all measures.

Power and sample size

A total of 88 participants will be recruited, which will allow for attrition of just over 10%. It has been demonstrated that at least 50% of young people with a first episode of psychosis will gain ≥7% of their body weight in the first 12 weeks of treatment. The Healthy Active Lives (HeAL) Declaration sets out a target of no more than 25% of young people with a first episode

of psychosis gaining ≥7% of their body weight following treatment for a first episode of psychosis. Therefore, with an estimated proportion of 50% in the non-intervention group and 20% in the intervention group who experience clinically significant weight gain (≥7% body weight), with 80% power at 95% significance level would require a total sample size of 78 with 39 in each group. Therefore, this study will aim to recruit a total of 88 participants with a first episode of psychosis from EPPIC to allow for approximately 10% attrition. Disengagement rates can be as high as 30% in those with a first episode of psychosis (Doyle et al., 2014); however, this tends to occur in the periods six months after initial presentation. Furthermore, the primary outcome of weight gain is measured routinely by the treating team and therefore it will be possible to obtain information on individuals for the intention to treat analysis.

Safety assessment

Adverse events will be recorded and reported throughout the study period. Protocols have also been devised to support research staff in the circumstances in which a participant becomes distressed or presents with risks to self or others.

Data collection and management

Participants can withdraw at any time if they wish and this is clearly stated in the information sheet and consent form. Participants who withdraw will not be replaced, as a certain level of attrition has been accounted for within the sample size calculation. All paper records will be stored locally and will be kept in a locked filing cabinet in a locked office. Data from the study

will be stored locally in a re-identifiable manner, with the ID code stored separated to the data. All computer files will be password protected. Records will be kept for a total of 15 years.

Conclusions

The findings of this study will inform clinical services as to whether the physical health complications observed in psychotic disorders can be prevented by the addition of a physical health nurse in the treating team. Should the findings of this study be positive, it would be indicated to replicate the findings across multiple sites and to incorporate a cost-effectiveness component into a large study.

Trial status

Registered on 20 July 2018 in the Australian New Zealand Clinical Trials Registry (ACTRN12618001222235). Participant recruitment began on 31 July 2018.

Conflict of interest statement

The authors declare that they have no competing interests.

Funding

This trial is funded by a philanthropic donation from the Morris Family Foundation and an Early Career Researcher Grant awarded to BO'D by the University of Melbourne. BO'D is supported by an Early Career Fellowship (1142045) from the National Health and Medical Research Council in Australia.

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Figure 1: Schedule of enrolment, interventions, and assessments.

Figure 2: Referral pathways for participants.

	STUDY PERIOD						
	Enrolment	Allocation	Post-allocation				
TIMEPOINT	0	0	0	4 w	8 w	12 w	26 w
ENROLMENT							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS							
Physical health nurse included in treating team			—	—	—	—	
Treatment as usual							
ASSESSMENTS							
Demographic details			X				
Axis I diagnosis (SCID-5)			X				
Physical health (weight, waist blood pressure)			X	X	X	X	X
Height			X			X	X
Pathology test (HbA1c, fasting glucose & fasting cholesterol)			X			X	X
Physical activity (SIMPAQ)			X			X	X
Substance use (ASSIST)			X			X	X
Symptomatology (BPRS SANS)			X			X	X
Functioning (SOFAS)			X			X	X
Sleep (PSQ-I, ISI, MEQ)			X			X	X
Sexual health			X			X	X
Satisfaction with services (YSSS)			X			X	X

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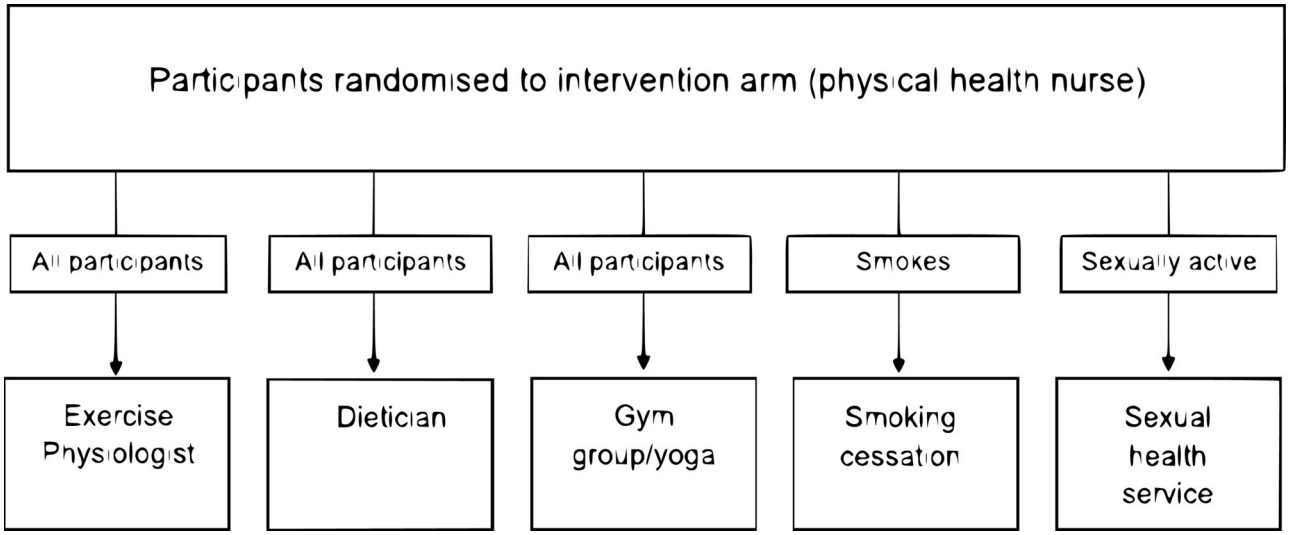

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Title:
Physical health assistance in early recovery of psychosis: Study protocol for a randomized controlled trial

Date:
2020-10

Citation:
O'Donoghue, B., Mifsud, N. G., Tindall, R. M., Foote, L., Hartmann, J. A., Obst, K., Simmons, M. B., McGorry, P. D. & Killackey, E. (2020). Physical health assistance in early recovery of psychosis: Study protocol for a randomized controlled trial. EARLY INTERVENTION IN PSYCHIATRY, 14 (5), pp.587-593. https://doi.org/10.1111/eip.12884.